A public law approach to health research in South Africa

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SUMMARY OF THE THESIS

The resolution of health research problems has over the years generally been guided by private law approaches, mainly under the laws of contract and delict. The dominance of private law approaches has mainly been evident in the context of health research litigation. This study is therefore about the plausibility or otherwise of a public law approach (PLA) to the resolution of health research problems. The study argues that the PLA is more plausible, and in particular better enhances the protection of health research participants.

In doing so the study, after examining the historical evolution of the thinking and frameworks relevant to bioethics, examines the existing legal and ethical theories, and their adequacy in the resolution of health research problems. The theories, on the whole, have been found not to be adequate in this regard, more particularly when used in isolation. The study further examines existing SA law, including some ethical instruments. The possible adequacy of this framework in the resolution of health research problems, as well as its consistency with a PLA, is also examined. The study further examines the comparability of the SA law with the UK and US laws, as well as the consistency of the three jurisdictions' frameworks with the PLA. The study has however found that though there is some, though incoherent, presence of some public law elements in the three jurisdictions, these have not yet found application in the context of health research litigation in these jurisdictions. The study further had to examine the international legal position (including the African, European and Inter-American regional frameworks) and its consistency with the PLA. Despite that, on the whole, the international legal framework does tend towards the PLA, the framework has yet to be used in the context of health research litigation. A paradigm shift is therefore required, both theoretically and pragmatically. A 'Public Law Approach' is therefore proposed. Such a proposed framework shall therefore ensure that public law approaches are also used alongside, as a supplement to or, where applicable, as an alternative to, private law approaches, further enhancing protection for research participants.

KEY WORDS

Public Law Approach; Private Law Approaches; Bioethics; Health Research; Research oversight; SA law; research participants; International law; American law; English law; Inter-American; European law; African Union; Children; UK law.

NKOMISO WA THESISI (NDZAVISISO)

Malembe yo tala lama hundzeke ku ahluriwa ka swiphiko swa ndzavisiso wa swa rihanyo wu ve ngopfu ehansi ka milawu ya ta (vuxaka bya) vanhu ntsena (private law), ngopfu-ngopfu milawu ya tikontiraka na ya dilikti. Tirhelo ra swa milawu ya ta vanhu ntsena ri tikombisile ngopfu eka swa milandzu ya swa ndzavisiso ya swa rihanyo. Hikokwalaho ka sweswo ndzavisiso lowu wu langutanaka na ku amukeleka ka matirhelo ya swa milawu ya ta vanhu na mfumo (Public law approach) (PLA) eku ololoxeni ka swiphiko swa ndzavisiso wa swa rihanyo. Ndzavisiso lowu wu koxa leswaku tirhelo ra PLA ra amukeleka swinene, no tlhela ri antswisa ku sirheleriwa ka vanhu lava va nghenelaka eka ndzavisiso wa swa rihanyo (health research participants).

Ku fikelela sweswo ndzavisiso lowu, endzaku ka loko wu xopaxopile matimu ya maendlelo yo karhi lama fambisanaka na bayo-ethiki, wu tlhela wu lavisisa tithiyori leti ti nga kona ta xinawu na xiethiki, leti ti fambelanaka na ku ahluriwa ka swiphiko swa ndzavisiso wa swa rihanyo. Ku eneteleka ka matirhelo lama ku thlela ku langutisisiwa. Tithiyori leti ti kumekile, hi ku angarhela, leswaku a ti enelanga, ngopfu ngopfu loko ti tirhisiwa ti ri toxe ku ololoxa swiphiko swa ndzavisiso wa swa rihanyo. Ndzavisiso wu tlhlela wu langutisisa nawu wa Afrika-Dzonga, ku katsa na tiethiki ta rona. Ku enetelaka ka tirhelo leri eku ololoxeni ka swiphiko swa ndzavisiso wa swa rihanyo na ku fambisana ka rona na PLA na swona swa langutisisiwa. Ndzavisiso lowu wu tlhela wu fananisa tirhelo ra nawu wa Afrika-Dzonga na tirhelo ra milawu ya UK na US, no tlhlela wu langutisisa ku fambelana ka matirhelo lama (ya matiko manarhu) na PLA. Ndzavisiso lowu wu tlhela wu kuma leswaku hambiloko ku ri na vukona byo karhi bya PLA, hambi byi tsekatseka, eka milawu ya matiko lamanharhu, PLA a yi se tirhisiwa eka matiko lama, etikhoto, hi mayelana na swa ndzavisiso wa swa rihanyu. Ndzavisiso a wu fanele ku tlhela wu langutisisa tirhelo ra milawu ya matiko ya misava (international law), ku katsa na matirhelo ya tikontinente ta Afrika; Yuropa na Americas, na ku fambisana ka matirhelo lama na tirhelo ra PLA. Hambileswi nawu wa matiko ya misava wu voyamelaka ngopfu eka tirhelo ra PLA, tirhelo leri a ri se tirhisiwa etikhoto, hi mayelana na ndzavisiso wa swa rihanyo. Ku cinca ka matirhelo, hi mavonelo na hi ku tirhisiwa ka wona, swa laveka. Hikokwalaho, tirhelo ra PLA ra laveka. Tirhelo rero ri ta vona leswaku matirhelo lama ya voyamelaka eka nawu wa ta vanhu na mfumo (public law approaches) ya tirhisiwa swin'we, kumbe ku tlhandlekela

eka, kumbe ku tirhisiwa handle ka, matirhelo ya nawu wa ta vanhu ntsena (private law approaches). Leswi swi ta antsiwa ku sirheleriwa ka lava va nghenelaka eka swa ndzavisiso wa swa rihanyo.

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CHAPTER ONE: INTRODUCTION AND BACKGROUND

1.1 Introduction

All sciences and fields of study are vulnerable to working within specific, and sometimes restricted, paradigms in resolving problems within their spheres. The fields of bioethics and law are not fool proof to such risks. The fields of bioethics and law, more especially as they relate to the protection of relevant stakeholders in health research, have tended to work mainly within the private law paradigm. The law of obligations, in particular the laws of delict and contract, which have traditionally been part of private law, has played a central role in this regard.

Although the post-World War II era also saw researchers drawing some guidance from human rights law (which is part of the field of constitutional law or even part of international humanitarian law), these have often served as sources of ethical principles, rather than legal principles. In other words, even though researchers and research protocol reviewers sometimes appeal to some human rights principles to guide their decisions, these principles hardly dominate legal thinking.

Where any appeal to these principles has existed, it has mainly been from bioethicists from the fields of medicine and philosophy, whose interests have been in the ethical value of these principles, rather than their legal significance. Jurists and other legal theorists have apparently been less than interested. A preliminary study of notable cases focusing on the conduct of stakeholders in health research in South Africa, the United Kingdom (UK) and the United States of America (USA) few though such health research review cases are, shows that private law, particularly the law of contract, has been the main field relied on in the legal sphere to regulate the conduct of stakeholders to health research. Public law has generally been absent. Of the branches of public law identified above, administrative law and public interest law have been the most absent.

This research investigates the role public law, more in particular constitutional law, including administrative law and public interest law, can play in the field of health research, from a South African perspective. In the context of ethical theory, the public law approach might include *Ubuntu*-based principles. The researcher argues that the public law approach to research protection will enhance protection of all the relevant

stakeholders in health research. The research does not, however, call for the replacement of existing private law approaches, except where this becomes necessary, but for their enhancement through appeal to public law approaches.

1.2 Background

In the 1600s John Locke, a British philosopher whose political philosophy has influenced most modern democracies[1] was, despite not having qualifications in medicine, appointed as a personal physician to Lord Ashley, a British political leader at the time. When Lord Ashley became sick, "suffering from a suppurating abscess of the liver'', Locke decided to operate on him and "inserted a silver tube to drain the abscess''.[2] In France, he also examined the British Ambassador's wife, diagnosed her with trigeminal neuralgia and prescribed some medication.[3]

When Locke himself had continued medical problems, *"*drawing from extensive medical researches he eventually diagnosed himself as suffering from phthisis - which causes wasting of the body, especially the lungs''.[4] At the time, these series of acts happened without causing ethical alarms. If these were to occur today, irrespective of whether the acts were medical treatment issues, health research issues or both, they would certainly raise biomedical questions.

Although problems of research atrocities have existed for many years, it is only in the 20th century that the problems became more explicit.[5] Just after the Second World War (World War II), the nations of the world had to deal with research atrocities committed by the Nazi adherents during the War. The experiments were conducted in ways that violated human rights. This resulted in the Nuremberg Trial, where those involved were prosecuted in terms of the framework created under the Charter of the International Military Tribunal (1945) (IMT).[6] The outcome of the trial resulted in some ethical

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1 Stratherrn P *Locke in 90 Minutes* (Constable London 2003) 36.
2 Stratherrn *Locke* 33.
3 Stratherrn *Locke* 40.
4 Stratherrn *Locke* 39.
5 In the earlier part of the 20th century, there was also generally no outrage, nor any culture of following ethical protocols when conducting research. A good example is the 'Yellow-fever experiment', conducted by Walter Reed, an army doctor who conducted the experiment on army volunteers and then recent immigrants, by exposing themselves to mosquitos that had fed themselves on fever-infected persons. This led to the death of some of the participants. See Cheney LA *Time for Freedom* (Simon & Schutter New York 2005) 133.
6 There was another similar tribunal, the International Military Tribunal for the Far East (1946)

guidelines, which came to be known as the Nuremberg Code. In 1966 a researcher, Henry Beecher, revealed in a publication a number of ethically controversial experiments, which were conducted some years earlier.[7] In the period spanning 1932 and 1972 the USA Public Health Service funded what later came to be known as the Tuskegee experiments, whose ethics was also questionable.[8] The Tuskegee study was aimed at evaluating "the natural history of untreated syphilis in human beings".[9] The ethical concerns the study raised were around the exploitation of vulnerable research participants, namely the socially disadvantaged African-American sharecroppers.[10]

The discovery of research scandals in the USA led to the development of some legislative and ethical frameworks, through the National Research Act of 1974 (the National Research Act).[11] The National Research Act provided for the National Commission for Protection of Human Subjects of Biomedical and Behavioural Research (the US National Commission).[12] The US National Commission then

(IMTFE), established under the Charter of the International Military Tribunal for the Far East, which had to deal with the war-related atrocities during the World War II in the Far East, more in particular in Tokyo, Japan (The researcher sometimes refers to the tribunal as the Tokyo Tribunal, while the one under the IMT is sometimes referred to as the Nuremberg Tribunal, so it should be understood in this context). Although the Charter establishing the IMTFE had almost the same mandate as the Charter establishing the IMT, not much is known about the handling of research-related atrocities by the Tokyo Tribunal, whose work was governed by the IMTFE Charter. The Tokyo Tribunal is therefore not the point of focus in this study, except where a specific context requires otherwise. It is however important to point out that neither the Charter of the IMT nor the IMTFE has a specific reference to biological experiments. The research atrocities, which for certain were dealt with under the Nuremberg Tribunal were therefore here dealt with in terms of the more generic provisions dealing with war crimes and the crimes against humanity in art 6 of the IMT Charter. The IMTFE Charter has equivalent, though not identical, provisions in art 5. Article 147 of the Fourth Geneva Convention Relative to the Protection of Civilian Persons in Time of War of 12 August 1949, however, does make specific provision for biological experiments, to which art 2(b) of the Statute of the International Tribunal for the Prosecution of Persons Responsible for Serious Violations of International Humanitarian Law Committed in the Territory of the Former Yugoslavia since 1991 (the Yugoslavia Tribunal) refers (Also see United Nations Basic Documents: International Tribunal for the Prosecution of Persons Responsible for Serious Violations of International Humanitarian Law Committed in the Territory of the Former Yugoslavia since 1991(United Nations1998). The most recent international humanitarian legal framework, the Rome Statute of the International Criminal Court (2002) makes specific mention of biological experiments, in art 8(2)(a)(ii) thereof. The trend towards specific mention of biological instruments in the Nuremberg Trial suggests that what transpired during the trial could have conscientised societies to start taking the issue seriously.

7 Boleyn-Fitzgerald P "Experimentation on Human Subjects" in Frey RG and Wellman CH (eds) *A Companion to Applied Ethics* (Blackwell Publishing Oxford 2005) 411.

8 Boleyn-Fitzgerald *Experimentation* 411. Also see Amdur R *Institutional Review Board: Member Handbook* (Jones and Bartlett Publishers Sudbury 2003) 17.

9 Amdur, *Institutional Review Board* 17.

10 Amdur, *Institutional Review Board* 18.

11 Amdur, *Institutional Review Board* 21.

12 Amdur, *Institutional Review Board* 21.

produced a report, which came to be known as the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (1979) (the Belmont Report). In terms of the National Research Act, the USA Department of Health and Human Services (HHS) promulgated regulations called the Code of Federal Regulations (CFR).[13] Most federal agencies have adopted the CFR; hence the CFR has come to be known as the Common Rule.[14]

At international level guidelines were also developed, including the Helsinki Declaration,[15] which was developed a few years earlier than the regulations in the USA. In the South African context, the Department of Health also developed its own research ethics guidelines.[16] The National Health Act 61 of 2003 (NHA) also touches on some research ethics issues. S 12 of the Constitution of the Republic of South Africa, 1996 (the Constitution), also requires that research participants give informed consent before participating in health research experiments.

Despite that these and other related instruments to some extent do provide for the obligations of the researcher, the instruments have not found application in legal circles or case law. As indicated earlier, the starting point has always been private law, in particular the laws of contract and delict. The fact that there is also insufficient clarity, even when using the private law approach, about the nature of the legal relationship between relevant stakeholders in research, compounds the problem. This has made

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13 Amdur, *Institutional Review Board* 20. One should take note of the latest version of these regulations (the Common Rule), which the USA Department of Health and Human Services announced in January 2017. See https://www.research.psu.ed/irb/commonrulechanges. (Accessed 29 March 2019).

14 Amdur *Institutional Review Board* 20. However, it is possible for agencies not to adopt the Common Rule but use their own regulations. The Food and Drug Administration (FDA), despite being an organ of the HHS, is one such agency that uses its own regulations. The differences between the Common Rule and the FDA regulations (regarding IRB regulations) are insignificant.

15 The document is formally known as the World Medical Association Declaration of Helsinki (1964). The document has come to be informally referred to as the 'Helsinki Declaration', because of the place where the conference adopting it was held, namely, Helsinki in Finland. The Helsinki Declaration has since been amended many times, including the 64th WMA Assembly Amendment in 2013. Reference to the Helsinki Declaration in this study therefore includes these latest amendments.

16 The Department developed the following guidelines: The Department of Health Ethics in Health Research: Principles, Structures and Processes (2004) (which has, as appears below, since been replaced by the Ethics in Health Research: Principles, Processes and Structures (2015) and the Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa (2006) (as appears below, the latter have also been replaced by new guidelines in 2020, namely the South African Good Clinical Practice: Clinical Trial Guidelines (2020) (the 2020 Clinical Trial Guidelines).

it difficult for the nature and content of the obligations by the researchers to be clearly defined. This silence, for example, has made it difficult to clearly define the nature and content of the obligations of the various stakeholders towards the weakest of the stakeholders, namely the research participants.

Although this research looks at research obligations towards vulnerable research participants in general, it places more emphasis on children, including displaced children. Children, particularly *displaced* children, are some of the most vulnerable in society in general, and are even more vulnerable in the context of research, when used as research participants. Their diminished maturity makes it difficult for them to make an informed decision on issues related to participation in research. It could, for example, be difficult for them to take informed decisions concerning payments for participation in research.

Children therefore must rely on the decisions of someone else, being parents or guardians. Even those who might give assent might not be sufficiently mature to understand the implications of assent. Those parents or guardians who give consent might themselves be drawn from other categories of vulnerable research participants, or at worst be exploiters of children. This makes children vulnerable to exploitation. Displaced persons face similar problems. With no stable place to live in, it is difficult for them to make informed choices about their lives. It will therefore be difficult for them to say no if promised payments in exchange for participation in research. A mere opportunity for them to have access to the medicine still on trial, could itself be an incentive to participate in a research project. When these displaced persons are also still young, this compounds the situation.

The problem for investigation can therefore be summarised as the absence, or little application, of a public law approach in the resolution of health research issues. This has resulted in a narrow approach to the determination of the relationship between relevant stakeholders in health research, and their attendant obligations. The research seeks to explore the plausibility of using a public law approach to the resolution of health research issues. This approach entails drawing on established constitutional principles, particularly principles of human rights and interrelated principles of administrative justice and public interest, while also drawing on communitarian principles like *Ubuntu*, more especially in the shaping of an appropriate ethical

framework. These principles are, in the main, briefly reflected on in chapter 3. Because there is a close interface between law and ethics, especially in the context of health research, the public law approach may also help shape the ethical framework required for the conduct of health research.

1.3 Problem statement and research questions

In health research vulnerable research participants often feel, whether rightly or wrongly, that justice has not been done to them. This problem can best be resolved by looking at the regulatory framework that governs the conduct of the various stakeholders in health research, and the way this framework is used. If the regulatory framework and its usage are faulty, problems are bound to arise. There has been little usage of the public law framework in dealing with health research problems. The research thus deals with this problem under the following research questions:

- What is the current approach to the resolution of health research problems in South Africa?
- Does the existing legal and ethical framework adequately resolve health research problems?
- What is the most plausible legal and ethical approach for adequately dealing with health research problems, and what is the nature of the obligations such an approach creates?
- What is the plausibility of using a public law approach in adequately resolving health research problems?
- What are the implications of a public law approach for the development of an ethical theory and theory of law as well as principles for the adequate resolution of health research problems?
- How does the South African legal position fare when compared to the position in other countries and at international level?

1.4 Hypothesis

A public law approach is the most plausible approach for the adequate resolution of health research problems. A public law approach is also likely to positively influence the development of an appropriate ethical and legal approach to health research.

1.5 Definitions

To place the study in proper context, the researcher works within the following defined framework:

Children

Unless the context otherwise indicates, the word refers to persons below the age of 18. This is the definition of a child in terms of s 1 of the Children's Act 38 of 2005, read with s 28 of the Constitution.

Continental

Unless the context otherwise provides, the word refers to Africa as a continent, or to another continent, with the necessary qualification to differentiate one continent from another. Unless the context indicates otherwise, the concept is used interchangeably with the word 'regional'.

Displaced persons

Unless the context indicates otherwise, the phrase shall include both externally displaced persons and internally displaced persons. Unless the context otherwise suggests, the phrase 'displaced children' shall bear a corresponding meaning. The concept, unless the context indicates otherwise and except for the fact that the research also covers externally displaced persons, also assumes the meaning as understood in terms of the African Union Convention on the Protection and Assistance of Internally Displaced Persons in Africa (2009).[17]

Ethical Consideration

The concept, unless the context indicates otherwise, only refers to ethical issues that the researcher has considered when conducting this research. It should therefore be differentiated from the 'ethical framework', 'ethical theories' or related concepts that

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17 Maswanganyi JV "An examination of legal and ethical frameworks for protecting displaced persons participating in health research in Africa" in Delener NJ Fuxman L, Lu FV and Rodrigues S (eds) *Exploring the possibilities for sustainable future growth in business and technology management. Seventeenth Annual Conference Readings Book Peniche/Lisbon, Portugal July 7th – 11th, 2015* (Global Business and Technology Association New York 2015) 425.

this study often refers to in the rest of the study, which refer to what other researchers consider.

Externally displaced persons

Unless the context otherwise indicates, the phrase shall mean persons who have crossed the borders from one country and become displaced in another country. The phrase shall therefore include migrants who are displaced, whether refugees or not.

Health research

The South African Department of Health defines health research as research that

> Contributes to the knowledge of biological, clinical and psychological, or social welfare matters concerning processes; causes and effects of and responses to diseases; effects of environment on humans; methods to improve health care delivery; new pharmaceuticals, medicines, interventions and devices; new technologies to improve health and health care.[18]

This definition should be read together with the definition of health research in s 1 of the NHA. Unless the context indicates otherwise, this study approaches the question of health research as understood in these two definitions.

Health research problems

Unless the context indicates otherwise, the concept is used here to also include health research disputes.

Human participants

Unless the context indicates otherwise, the concept refers to human beings who are the subject of research. Also note the definition in the Regulations Relating to Research with Human Participants, 2014, which confines the protection to living human beings. The usage of the word in this study however, though mainly having living human beings in mind does not, unless the context indicates otherwise, exclude possibilities where a non-living human being might need some protection. Unless the context indicates otherwise, the concept is used interchangeably with the concept of "research participants".

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[18] Department of Health's Ethics in Health Research: Principles, Structures and Processes (2015) (2015 Ethics in Research). Also see Department of Health's Ethics in Health Research: Principles, Structures and Processes (2004) (the 2004 Ethics in Research), which was replaced by the 2015 Ethics in Research. Further see Maswanganyi *Health research in Africa* 425.

Internally displaced persons

Unless the context suggests otherwise, the meaning shall be as per the African Union's Convention for the Protection and Assistance of Internally Displaced Persons, which defines the phrase as:

> Persons or groups of persons who have been forced or obliged to flee or to leave their homes or places of habitual residence, in particular as a result of or in order to avoid the effects of armed conflict, situations of generalized violence, violations of human rights or natural or human-made disasters, and who have not crossed an internationally recognised state border.

The concept as used in this research does not, however, exclude children who might have left home for reasons not covered in the definition, as what are commonly referred to as street children sometimes do.

Regional and sub-regional

When used in relation to instruments, unless the context otherwise suggests, the word 'regional' means continental. The concept sub-regional means the sub-continental, i.e. within a continent, with the necessary qualifications to distinguish one sub-continent from another.

Public law approach

Unless the context indicates otherwise, and when used mainly in a legal sense, the 'public law approach' (PLA) means using constitutional law principles, particularly human rights, administrative justice[19] and public interest[20] law principles to the resolution of biomedical problems. Under certain circumstances it may include approaches wherein a legislation, regulation or related public instrument regulates the conduct of the relevant research stakeholders. At international level it may include some principles of public international law. It, overall, means resolving health research issues from a public law perspective, as opposed to a private law-centred perspective. When used mainly in an ethical sense, the concept shall mean drawing from some

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19 The intention here is not to cover the whole of administrative law, but only principles dealing with judicial review, mainly in an administrative law sense, where a litigant challenges administrative decisions based on specific grounds of review as provided for in the Constitution, the Promotion of Administrative Justice Act 3 of 2000 (PAJA), the common law, and related grounds. For a discussion of the concept of judicial review in an administrative law sense, see Hoexter *Administrative law* (Cape Town 2012) 113.

20 Although its meaning is very fluid, one's conception of public interest in this study is one that promotes general or common interests, rather than private or individual interests. Also see https://definitions.uslegal.com/p/public- interest/ (Accessed 31 March 2019).

ethical principles supporting justice and fairness to stakeholders in health research, and these shall include *Ubuntu* principles. The PLA's central claim is that actions are right, and actors good, if they are motivated by public interest considerations supporting public interest, common interest, general interest, human rights, Ubuntu and justice, while actions are wrong and actors bad if they are motivated by individualist and other non-public considerations. The PLA is therefore, as used in this study, largely a normative rather than merely a descriptive concept, reflecting on the need for a reorientation, including the approaches to interpretation, around the way health research issues are dealt with.

Research participants

Unless the context indicates otherwise, this refers to those persons subjected to, or targeted for subjection to, research. Unless the context indicates otherwise, the concept is used interchangeably with the concept of human participants.

Research-related harms

Unless the context indicates otherwise, this refers to all sorts of disadvantages associated with the conduct of the research, including research-related injuries.

Relevant stakeholders

Unless the context indicates otherwise, the study uses the concept of relevant stakeholders to mean the following persons or bodies: researchers and their employers, Research Ethics Committees (RECs), research participants and the sponsors of research.

Research Ethics Committees (RECs)

These are oversight committees or bodies used to assess the compliance of research protocols with existing ethical guidelines and norms. Depending on the preferred usage in a particular country, these types of committees are sometimes referred to as Institutional Review Boards (IRBs) or Ethical Review Boards (ERBs).[21]

USA

[21] See Amdur *Institutional Review Board* 8.

Unless the context indicates otherwise, it refers to the United States of America. Unless the context indicates otherwise, the concept is used interchangeably with the concept ‘US’.

UK law

Unless the context indicates otherwise, ’UK law’ shall mean the law of the United Kingdom i.e. the laws applying to the whole of the United Kingdom. Though England is merely part of the UK, because of England’s historical dominance, unless the context indicates otherwise, the concept of ‘English law’ shall be used interchangeably with the concept of UK law.

Vulnerable persons or research participants

It means persons or research participants whose conditions make them more exposed to risk of exploitation or some other harm than persons with other conditions.

Vulnerability

This means greater risk of exposure to manipulation and exploitation, usually where there is a power imbalance between the two parties interacting. In the context of research this exists where the research participant’s decision-making capacity is absent, or present but weakened (limited) by circumstances like young age, low education level, gender, displacement from one’s home or country, and other related factors. The word ‘vulnerable’ has, unless the context suggests otherwise, a corresponding meaning.[22]

A researcher

Unless the context otherwise indicates, the research uses the concept ‘a researcher’ to refer to an investigator or any person conducting health research, other than the person conducting the research in this thesis. The research, however, unless the context indicates otherwise, uses the concept ‘the researcher’ to refer to the person conducting the research in this thesis.

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[22] Maswanganyi *Health research in Africa* 425. Further see the 2015 Ethics in Research for the definition of vulnerability. For a detailed exposition of the concept of vulnerability, see Dhai A “A study of vulnerability in health research” (PHD Thesis University of the Witwatersrand 2014).

1.6 Aims of the study

- To investigate the current approach about the resolution of health research problems in South Africa.
- To investigate whether the current ethical and legal framework adequately deals with the resolution of health research problems.
- To investigate the most plausible approach to the adequate resolution of health research problems.
- To investigate the plausibility of the public law approach to the adequate resolution of health research problems and its implications for the nature of obligations and the development of an appropriate ethical theory, theory of law and relevant principles.
- To investigate the comparative position between South Africa and other jurisdictions as well with the international legal position.

1.7 Significance of the study

The alternative approach proposed could play an important role in redefining the nature of the relations between various stakeholders in health research, and the rest of the field of bioethics, which is largely defined as a private law relationship.[23] The research could therefore play an important role in transforming the narrow, private law-centred law of obligations, as traditionally understood into a broader, public law-centred conception of obligations. The nature of obligations as amongst the different stakeholders in health research is therefore redefined. This has far reaching implications for the benefits, more especially the remedies that stakeholders may claim against one another.

1.8 Methodology

This is a qualitative study using a conceptual analysis, literature review and a comparative method. The comparative method in the main enables the researcher to compare the South African position, both in terms of legal and ethical frameworks, with the position in other jurisdictions, namely the USA and the UK.[24]

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[23] For the private law-orientation of this relationship, see Dhai A and Mcquoid-Mason D *Bioethics, Human Rights and Health Law* (Juta Cape Town 2003) 62.

[24] Although the countries mentioned here are the focal point for comparative purposes, where the

The researcher has chosen the countries of comparison for their special influence in research matters. The USA is one of the main sources of research funding in the world, but whose research does not necessarily take place within that country. Most of the pharmaceutical companies sponsoring research work also originate from the USA. Several research incidents that triggered some regulatory frameworks also originated from that country. The USA's research framework has been a reference point for many countries. The researcher therefore considers the USA framework a good point of comparison.

The UK, although it left the European Union (EU), has been an influential player in Western Europe, with some of the pharmaceutical companies involved in research located there. The three countries are also part of the Common Law family, while also sharing some other related historical experiences. For example, both South Africa and the USA were partly colonised by the UK,[25] but both later developed legal frameworks that are substantially different from the British legal framework.[26] These related shared experiences will ensure that the researcher compares likes with likes, and therefore avoid the problem of dis-analogy. The latter might affect the reliability of the research.

Regional instruments developed by continental bodies to which the three countries belong are also looked at. The continental bodies to which these countries belong include the African Union (AU), the Council of Europe (COE) and the Organisation of American States (OAS). Although the study covers the regional instruments under international law, the regional instruments themselves are compared where necessary. In some instances, the regional instruments are contrasted with the intercontinental instruments. Such a comparison is very useful in gaining insight into the various instruments.

1.9 The ethical framework

The various ethical theories, principles and guidelines discussed in this research are:

researcher finds other useful points of comparison from jurisdictions other than those mentioned here, the researcher does look at that, without going into detail.

25 For US legal origin, see http://study.com/academy/lesson/american-law-history-origins-from-/english-common-law.html (Accessed 31 March 2019).

26 For example, both South Africa and the US have legal frameworks underpinned by the principle of constitutional supremacy, while the British legal framework is substantially underpinned by the principle of parliamentary sovereignty.

- The Hippocratic ethics

One important set of principles of ethics, which has been influential in shaping modern biomedical ethics, including health research ethics, is the Hippocratic Oath, named after the person to whom its origin is attributed, an ancient Greek doctor and philosopher, Hippocrates.[27] Although the Hippocratic Oath lists a number of principles covering different angles to ethics, the research looks at those principles that have some relevance to modern health research ethics.

- Beauchamp & Childress' principles

Beauchamp & Childress[28] recognise four biomedical principles, namely justice, beneficence, respect for autonomy and non-maleficence.[29]

- The biomedical principles under the Belmont Report

The Belmont Report structures the principles under three categories as follows: the principle of respect for persons, the principle of beneficence and the principle of justice.

While the principles, as developed by Beauchamp & Childress and the Belmont Report, could be considered very helpful in most areas of public health, they might not necessarily adequately address ethical issues in the area of research. These principles are, for example, silent on questions of the scientific validity of research, the social value of research, the sharing of research benefits as well as (independent) research oversight. The researcher therefore argues that the public law approach could assist in closing this gap. For example, from a public law perspective, the socio-economic rights in the Constitution,[30] including the right of access to healthcare services, could be important in the resolution of the problem relating to access to benefits of the research.

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27 Agard WR "Hippocrates investigates the nature of disease" in Schaefer L.F, Resnick DP and Netterville GL, III (eds) *The Traditional World: The Shaping of Western Civilization Vol. 1* (Holt, Rinehart and Winston, Inc New York 1970) 98.

28 Beauchamp TL and Childress JF *Principles of Biomedical Ethics* 4th ed (Oxford University Press New York 1994) 38.

29 One could, for example, argue that to promote the avoidance of harm is also another way of promoting beneficence.

30 S 27 of the Constitution.

- Emanuel's principles

Emanuel, Wendler and Grady[31] identify eight principles of research ethics (Emanuel's Principles). Though some are a reformulation of Beauchamp & Childress's biomedical principles, others go beyond these principles. The principles of fair participant selection, informed consent; respect for participants and favourable risk-benefit ratio are closely related to those of Beauchamp & Childress, except for some specificity and formulation. The remaining Emanuel's Principles, which are not directly related to Beauchamp & Childress' principles, are the need for an independent review of research, community partnership (for benefit sharing), scientific value of research and the social value of the research.

Although the Emanuel's principles are broader than those of Beauchamp & Childress, and are more suited for research review contexts, there are aspects that they do not adequately address. For example, they do not adequately address questions of conflict of interest. The public law approach could arguably cure the defect. For example, the constitutional principle of accountability[32] discourage any unjustified presence of a conflict of interests.

- Kant's Deontology

The theory of deontology provides that an act is right or wrong if the act complies with some existing duties or principles.[33] The theory therefore does not consider the goodness or badness of a consequence as the main determining factor for assessing the rightness or wrongness of the act.[34] Kantianism, so named after Immanuel Kant, is arguably the most well-known of the deontological versions. Kant argues for two broad principles namely, the categorical imperative and respect for persons.[35] Kant, in

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31 Emanuel EJ, Wendler D and Grady C "An ethical framework for biomedical research" in Emanuel EJ et al. (eds) *The Oxford Textbook of Clinical Research Ethics* (Oxford University Press New York 2008) 123 -135.

32 S 1 of the Constitution includes accountability, responsiveness and transparency as some of its constitutional values (the researcher here, unless the context indicates otherwise, uses the concepts 'values' and 'principles' interchangeably, although the concepts might not mean the same thing in some other contexts). Section 195, more in particular s 195(1)(f) could also be applicable in instances where the decision under review has been taken by an organ of state or another public institution.

33 For the discussion of deontology, see Davis N (Ann) "Contemporary deontology'' in Singer P (ed) *A companion to ethics* (Blackwell Publishing Oxford 1991) 205 - 218.

34 Further see Davis N (Ann) *Contemporary deontology* 205 – 218.

35 As indicated below, these could also be understood as just two versions of categorical

his work, Foundations of the Metaphysics of Morals, 1785,[36] describes the categorical imperative as follows:

> Act only according to that maxim by which you can at the same time will that it should become a universal law.[37]

This principle states that if one person prescribes that a rule should be followed, the person so declaring must be prepared that the rule be also applied to him or her (this principle could be said be to the principle of universalisability, and therefore one of categorical imperative's versions).[38] This also means that the rule must be capable of being followed under all circumstances, which suggests that the rule be absolute.[39] The principle therefore demands that there be consistency in our assessment of right and wrong. Kant expressed the other principle,[40] namely respect for persons, as requiring that persons treat other persons as ends in themselves, rather than only as a means to an end. He said in this regard:

> Act so that you treat humanity, whether in your own person or in that of another, always as an end and never as a means only.[41]

The principle of respect for persons has been widely adopted as part of bioethical principles by both scholars and policy makers.[42] A notable objection to Kantianism arises from the absolutist nature of the theory. This makes the theory inflexible and therefore not adaptable to different situations. The theory might not be able to resolve moral dilemmas, in instances where two rules or principles are in conflict.[43] The public law approach, through one of its components' constitutionalism,[44] has provision for

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imperative namely the principle of universal law (universalisability) and the principle of respect for persons. The first could be considered the stricter version (and therefore the categorical imperative proper) while the second could be considered comparatively less stricter (and the second – order version of the categorical imperative) (also see O'Neill O "Kantian Ethics" in Singer P (ed) *A companion to ethics* (Blackwell Publishing Oxford 1991) 176.

36 See Rachels J & Rachels S *The Elements of Moral Philosophy* 7th ed (New York McGraw-Hill 2012) 128.

37 As quoted in Rachels & Rachels *Elements of philosophy* 128.

38 Also see Rachels & Rachels *Elements of philosophy* 129.

39 Rachels & Rachels *Elements of philosophy* 129.

40 As earlier indicated this principle is sometimes expressed as just an extension of the categorical imperative, rather than a separate principle (also see Rachels & Rachels *Elements of philosophy* 137 and O'Neill O *Kantian Ethics* 176). If viewed in that sense, we could then say that the categorical imperative has two principles, one being the principle of universalisability (as stated above) and the other being one of respect for persons.

41 As quoted in Rachels & Rachels *Elements of philosophy* 137.

42 For example, Beauchamp & Childress, *Principles of Biomedical Ethics*, discusses this principle in detail, as part of respect for autonomy. The Belmont Report also covers the principle.

43 On Kantiniasm's shortcomings also see Moodley K (ed) *Medical ethics, law and human rights: a South African perspective* 2nd ed (Van Schaik Pretoria 2017) 28 – 29.

44 Some of the principles proposed in Chapter 9 as part of the PLA theory are closely linked to

limitations of rights and other exceptions where it is in the public interest to do so. Constitutionalism, human rights theory and the public interest theory, which are closely associated with the public law approach will therefore assist in curing the shortcomings of deontology.

- Utilitarianism

This theory is one version of consequentialism. Consequentialism considers an act to be right or wrong based on the assessment of its consequences.[45] According to the theory, an act is right if its consequences are good and wrong if its consequences are bad.[46] Utilitarianism, therefore, taking the same line, considers an act right if it maximizes utility, and wrong if it maximizes disutility.[47] The theory's approach could therefore be interpreted as a cost and benefit analysis. The principle has been criticized for giving room for the justification of immoral actions, so long as the immoral actions maximize utility.[48] This could therefore place research participants at risk of harm and potentially undermining their rights. The researcher is of the view that the public law approach, which implicitly covers the human rights approach, could therefore also mitigate against unchecked utilitarian thinking in the ethical review of health research protocols.

- Virtue ethics

It must be observed that both the deontological ethics and utilitarianism, as discussed above, focus on the assessment of the rightness and wrongness of actions, as opposed to the character of the actors. Virtue ethics, however, takes a different direction and uses character as its starting point.[49] The virtues (qualities) required of a person could be honesty, wisdom, courage, fairness, compassion, etc.[50] Instead of

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constitutionalism, even if they are not so named.

45 See Rachels & Rachels *Elements of philosophy* 109. Further see Pettit P "Consequentialism'' in Singer P (ed) *A companion to ethics* (Blackwell Publishing Oxford 1991) 230 – 240. Further see Goodin RE "Utility and the Good" in Singer P (ed) *A companion to ethics* (Blackwell Publishing Oxford 1991) 241 – 248.

46 See Rachels & Rachels *Elements of philosophy* 109.

47 This conception is more consistent with John Stuart Mill's approach to utilitarianism (see Curd M (ed) *Argument and analysis: an introduction to philosophy* (West Publishing Company New York 1992) 114. Further see Rachels J and Rachels S (eds) *The right thing to do: basic readings in moral philosophy* 5th ed (McGraw Hill New York 2010) 30).

48 Beauchamp and Childress *Principles of Biomedical ethics* 53.

49 Rachels & Rachels *Elements of philosophy* 169.

50 Rachels & Rachels *Elements of philosophy* 161.

asking whether certain actions are right or wrong, it asks whether the character of the actors is good or bad.[51]

In the context of bioethics, virtue ethics asks whether a researcher who conducted a particular study could be said to be a fair person. This implies that the conduct of the researcher, in relation to the research participants, could be said to be fair solely on the basis that the researcher is a fair person. It therefore does not tell us anything about whether the actions of the researcher were themselves right or wrong. Virtue ethics has therefore been criticized for not being a good action guide.[52] It is the researcher's view that a public law approach argued for in this research could influence the ethical review of protocols, and therefore providing clear action guides in instances where these are lacking.

- *Ubuntu*[53]

Ubuntu theory originates from the African[54] proverb saying a person is a person through or because of other people.[55] The theory provides for the mutuality or interdependence of humanity.[56] Other properties associated with *Ubuntu* are compassion, community-centeredness, harmonious relations and sharing spirit.[57] While it may not be precise as to where this theory falls within the broader schemes of ethical theories, the theory shares a lot of characteristics with virtue ethics, communitarianism[58] and the social contract theory.[59] For the purposes of this study

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51 Rachels & Rachels *Elements of philosophy* 158.

52 Van Niekerk AA "Ethics theories and the principalist approach in bioethics" in Moodley K (ed) *Medical Ethics, Law and Human Rights: A South African Perspective* (Van Schaik Publishers Pretoria 2010) 32.

53 Though the theory is here discussed as an ethical theory, the theory has also been used in legal contexts. Also note Benett TW's discussion of Ubuntu in Benett TW "Ubuntu: African equity" 2011 *PER/PELJ* 30 – 61.

54 Ubuntu is the Nguni version of the proverb, but there are equivalent versions in other languages. It is called Vumunhu in Tsonga and Botho in Tswana, Pedi and South Sotho. Other equivalents exist in various other languages.

55 Also see Jolley DR "A person is a person through other persons'' (LLM Thesis Southern Utah University 2011) 6. Further see Oosthuizen S "The normative value system underpinning the Companies Act 71 of 2008 with specific reference to the protection of creditors and employees" (LLD Thesis University of Pretoria 2017) 134.

56 Also note Benett TW's discussion of Ubuntu in Benett 2011 *PER/PELJ* 30 – 61. *Potchefstroom Electronic Law Journal* 30 – 61.

57 Benett 2011 *PER/PELJ* 30 - 61. Further see Rautenbach IM and Venter R *Rautenbach – Malherbe Constitutional law* 2nd ed (LexisNexis Durban 2018) 11.

58 Communitarianism places community above an individual.

59 The whole idea of mutuality, which is part of Ubuntu, could also be said to be contractualist in nature. In other words, doing to others what you also expect to be done to you could be said to be grounded on social contractual principles.

however, the researcher uses *Ubuntu* as a version of communitarianism, and therefore sometimes uses '*Ubuntu*' and *Ubuntu*-based communitarianism interchangeably.

In the context of research, a researcher could be expected to be compassionate. *Ubuntu's* principle of interdependence could also mean that the decisions of certain categories of research participants to partake in the research could be a result of the fact that even though the participants might have nothing to benefit personally, they might see the participation as part of promoting interdependence. *Ubuntu's* potential to provide for the moral motivation for partaking in research could therefore make it distinct from the other theories discussed. But an *Ubuntu* approach does not provide a good action guide to deal with specific situations and is therefore not sufficient if used alone. The public law approach as proposed in the study could therefore arguably assist in providing the needed action guides.

- Ethical principles covered in specific instruments

One of the most important instruments is, as alluded to earlier, the South African Good Clinical Practice: Clinical Trial Guidelines (2020) (the 2020 Clinical Trials Guidelines),[60] which replaced the Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa (2006) (the 2006 Clinical Trials Guidelines), whose main purpose is to provide guidance on the conduct of stakeholders when conducting, or intending to conduct, clinical trials.[61] The 2020 Clinical Trials Guidelines reaffirm the principles under the Belmont Report and those by Beauchamp & Childress, as discussed earlier, namely respect for (autonomy and dignity of) persons, beneficence, justice and non-maleficence.[62]

The 2020 Clinical Trials Guidelines also require researchers to follow other established ethical guidelines, namely the Declaration of Helsinki and the International Council for

60 Unless the context indicates otherwise, whenever the concept 'Clinical Trial Guidelines' is used without being qualified by the year of publication, it refers to any of the editions of the South African Good Clinical Practice Guidelines.

61 See Preamble to the (2020) Clinical Trials Guidelines. It should be noted that the 2006 Clinical Trials Guidelines had themselves replaced the similar guidelines published in 2000 (see the Preamble to the 2006 Clinical Trials Guidelines).

62 Para 2.1 of the 2020 Clinical Trials Guidelines.

Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH): Guidelines for Good Clinical Practice,[63] amongst other guidelines mentioned.[64]

The 2020 Clinical Trials Guidelines also provide for the review of research protocols by independent Research Ethics Committees (RECs).[65] The 2020 Clinical Trials Guidelines require researchers to pay special attention to certain types of research, more in particular research involving vulnerable participants like children.[66] The 2020 Clinical Trials Guidelines do not only provide an ethical framework but also have the force of law.[67] Unfortunately, despite the 2006 Clinical Trial Guidelines having being referred to in *Venter v Roche Products (Pty) Ltd* (A11/2014) [2014] ZAWCHC 157 (22 October 2014), the approach to the guidelines was very narrow.[68]

Another important instrument is the Ethics in Health Research: Principles, Processes and Structures (2015) (2015 Ethics in Research), which provides guidelines for the conduct of health research in South Africa. The 2015 Ethics in Research replaced the 2004 version[69] of the guidelines. The 2015 Ethics in Research restates some of the biomedical principles covered by other guidelines like the Belmont Report and the Clinical Trials' Guidelines, namely beneficence, respect for persons, justice and non-maleficence.[70] The 2015 Ethics in Research makes provision for the review of research protocols by the RECs.[71] The RECs must be registered with the National Health Research Ethics Council (NHREC).[72]

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63 The latest version of which is ICH Guideline for Good Clinical Practice (2016).

64 Para 2.1, read with para 1.2.2, of the 2020 Clinical Trials Guidelines.

65 Para 2.6 of the 2020 Clinical Trials Guidelines.

66 Para 3 of the 2020 Clinical Trials Guidelines. The 2020 Clinical Trial Guidelines are however less detailed on vulnerable persons than the 2006 Clinical Trial Guidelines (for example, they make no specific provision for women as a vulnerable group). It could be that the former already, generally, emphasizes its linkage to the 2015 Ethics in Research, which already provides for such details, including the protection of women (see para 3.2.3 of the 2015 Ethics in Research, read with para 2.3.2 of the 2006 Clinical Trials Guidelines).

67 Para 1.3 of the 2020 Clinical Trials Guidelines.

68 In that case the respondent was considered to be not a sponsor, and therefore not liable to pay compensation as per the 2006 Clinical Trial Guidelines. The 2020 version of the Clinical Trial Guidelines does not appear to make provision for payment of research-related injuries beyond the provision for insurance against same, and provision for indemnity against the investigator or institution against claims likely to arise from the trial, other than claims arising from professional negligence or malpractice (See Clinical Trial Guidelines para 6.2.6).

69 Department of Health Ethics in Health Research: Principles, Structures and Processes. (Department of Health Pretoria 2004)

70 Para 2.1 of the 2015 Ethics in Research.

71 Para 1.6.

72 Para 1.4.

The 2015 Ethics in Research restates the point that its guidelines must be read together with other frameworks like the Belmont Report, the Clinical Trials Guidelines, the Helsinki Declaration (2013), Singapore Statement on Research Integrity, etc.[73] Of importance, the 2015 Ethics in Research clarifies its difference from the Clinical Trials Guidelines and the latter's predecessor. The 2015 Ethics in Research does not deal with clinical trials, which the Clinical Trials Guidelines deal with.[74] Because the 2015 Ethics in Research is still relatively recent, its impact is yet unknown. The trend, as observed regarding other guidelines, appears to be that these types of instruments do not appear to influence what happens in the courtroom. Its predecessor, the 2004 edition,[75] did not appear to have such influence.

Another ethical instrument important at international level is the Nuremberg Code (1947) (the Code), a product of the American Military Tribunal, which was set up in trial of the German (Nazi) Doctors who were involved in human research scandals conducted during the World War II.[76] The experiments were conducted without informed consent.

The Code, in response to these atrocities, provides for voluntary consent for any research on human subjects.[77] The Code then outlines what voluntary consent means in the context of research. It describes it as meaning having the legal capacity to give consent.[78] It further means having the freedom to give the consent, without any fear from any other person or situation.[79] It also means not being manipulated through fraud, deceit, over-reaching or any other form of unjust influence.[80] It also means having the necessary understanding and knowledge of the subject matter of research.[81] This, the Code provides, will enable the research participant to take an informed decision.[82]

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73 Para 1.8.
74 Para 1.1.14.
75 Department of Health Ethics in Health Research: Principles, Structures and Processes (Department of Health Pretoria 2004).
76 Also see Dugard J *International law: A South African Perspective* 2nd ed (Juta Cape Town 2000) 236.
77 Para 1.
78 Para 1.
79 Para 1.
80 Para 1.
81 Para 1.
82 Para 1.

So as to enable the research participant to take such an informed decision, the participants should be supplied with sufficient information regarding the research, including information relating to the nature, the duration, the purpose of the study, the method by which the study is to be conducted, all side effects and hazards reasonably anticipated to come from the study and the effects upon his or her health reasonably anticipated to come from the study.[83]

The Code, however, has a few shortcomings. It says very little about the payments of research participants. The Code does not make any distinction between research on vulnerable participants and research on non-vulnerable participants. In particular, it does not make any distinction between research on adults and research on children, despite that some children were already victims of unethical research practices at the time of the Code. The Code also appears to make the requirement of voluntary consent absolute,[84] creating a perception that it does not accommodate exceptions to the rule, in so far as voluntary consent is concerned.

The Code also says very little about the nature of the relationship between a researcher and research participants, e.g. whether it is one of contract or otherwise. It further says very little about the nature of the relationship between different stakeholders and the research participant. Nor does it say anything about the nature of obligations between the stakeholders and the research participants. This creates a situation where the sponsors of research and other stakeholders are nowhere to be found when something injurious to research participants occurs. Though the Code does not have any legal force, its provisions could augment a public law approach, as its provisions are more oriented towards public law obligations.

Another relevant instrument, also operating at international level, is the Ethical Principles for Medical Research involving Human Subjects (1964) (the Helsinki Declaration), adopted by the World Medical Association (WMA) in 1964 in Helsinki, Finland.[85] The Helsinki Declaration has been amended from time to time since then.[86]

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83 Para 1.

84 This is implied partly from the assertion that 'the voluntary consent of the human subject is absolutely essential' (para 1), while not providing for any instances of justified deviations in the rest of the Code.

85 See https://www.wma.net/wp-content /uploads/2016/11/DoH-Oct2013-JAMA.pdf (Accessed 29 March 2019).

86 See https://www.wma.net/wp-content /uploads/2016/11/DoH-Oct2013-JAMA.pdf (Accessed 29 March 2019).

The Helsinki Declaration requires the researchers to respect the dignity, life, health and integrity of the research participants.[87] The Helsinki Declaration requires that the research conducted be based on 'generally accepted scientific principles'.[88] Though the Helsinki Declaration is not intended to be a legal document, it is an important source of ethical obligations whose provisions are consistent with public law obligations.

Yet, another critical instrument is the Proposed Guidelines for Biomedical Research involving Human Subjects,[89] developed in 1982 by the Council for International Organisation of Medical Sciences (CIOMS), in cooperation with the World Health Organisation (WHO). In 1993 a revised version of the CIOMS Guidelines was introduced.[90] In 2002 a further revised version, the International Ethical Guidelines for Biomedical Research involving Human Participants (the 2002 CIOMS Guidelines), was introduced, followed by the current version, the 2016 CIOMS Guidelines. The CIOMS Guidelines[91] in the main seek to assist in shaping national policies on the question of the ethics of biomedical research,[92] adapting ethical standards to local circumstances of states, etc.[93] The CIOMS Guidelines also focus on the adaptability of the Helsinki Declaration to the local circumstances of states, more in particular the developing states.[94]

The Guidelines further provide for the role and responsibilities of RECs, which they refer to as Ethical Review Committees. In particular the Guidelines provide for RECs to be resourced, for RECs to be independent, for RECs to withdraw approvals where

87 Para 11. Also see Moodley K (ed) *Medical Ethics, Law and Human Rights: A South African Perspective* (Van Schaik Publishers Pretoria 2010) 359.

88 Para 12. Moodley *Medical Ethics, Law and Human Rights: A South African Perspective* 359.

89 Idanpaan-Heikkila JE and Fluss SE "International ethical guidance from the Council for International Organisation of Medical Sciences*"* in Emanuel EJ *et al*. (eds) *The Oxford Textbook of Clinical Research Ethics* (Oxford University Press New York 2008 168 - 173).

90 Idanpaan-Heikkila and Fluss *"*International ethical guidance from the Council for International Organisation of Medical Sciences*"* 168.

91 Although the latest version is the 2016 CIOMS Guidelines this Chapter, being only introductory, mainly focuses on the 2002 CIOMS Guidelines. The 2016 CIOMS Guidelines shall in the main be the focal point in Chapter Eight, alongside other international instruments.

92 It should be noted that the concept of health-related research, as the tittle itself suggests, is now mainly preferred in the 2016 CIOMS Guidelines, rather than that of biomedical research (see the Preface to the 2016 CIOMS Guidelines).

93 Idanpaan-Heikkila and Fluss *"*International ethical guidance from the Council for International Organisation of Medical Sciences*"* 169.

94 Idanpaan-Heikkila and Fluss *"*International ethical guidance from the Council for International Organisation of Medical Sciences*"* 169.

necessary, etc.[95] Though the Guidelines do make room for payment for REC members, such payment must not, however, be directed at influencing the outcome of the protocol review.[96] The Guidelines also do make provision for continued reviews and monitoring of the research.[97]

The Guidelines make provision for the protection of vulnerable populations in research. They provide for the protection of children, by amongst other things providing for conditions under which they can partake in research.[98] The Guidelines only mention displaced persons and homeless persons, as part of vulnerable groups, but only in passing.[99] It is expected though that most of the principles applying to other vulnerable persons also apply to them. The Guidelines also make provision for informed consent, where they outline the different aspects on which information should be supplied to the research participants, for them to decide whether or not to give informed consent thereon.[100]

One of the leading ethical instruments is the WCRI's Singapore Statement on Research Integrity (2010) (The Singapore Statement).[101] The Singapore Statement provides for certain responsibilities that researchers and other relevant stakeholders have to respect. These responsibilities include the reporting of research-related misconduct;[102] the avoidance of conflict of interest;[103] the taking of responsibility by researchers for their work's trustworthiness and integrity;[104] compliance with research-related regulations and policies;[105] the keeping of accurate research records for purposes of enabling verification or replication by others;[106] the prompt and open sharing of data;[107] the responsible handing of complaints about research misconduct,

95 Idanpaan-Heikkila and Fluss "International ethical guidance from the Council for International Organisation of Medical Sciences*"* 169*.*

96 Idanpaan-Heikkila and Fluss *"*International ethical guidance from the Council for International Organisation of Medical Sciences*"* 169*.*

97 Idanpaan-Heikkila and Fluss "International ethical guidance from the Council for International Organisation of Medical Sciences" 169*.*

98 Idanpaan-Heikkila and Fluss "International ethical guidance from the Council for International Organisation of Medical Sciences" 170.

99 See Guideline 13 of the 2002 CIOMS Guidelines. Further see Guideline 15 of the 2016 CIOMS Guidelines.

100 Idanpaan-Heikkila and Fluss *"*International ethical guidance from the Council for International Organisation of Medical Sciences*"* 170.

101 WCRI Singapore Statement on Research Integrity (2010). Also see a related and more expanded statement by the WCR's Montreal Statement on Research Integrity in Cross-boundary Research Collaborations (2013) (the Montreal Statement).

102 Para 11 of the Singapore Statement.

103 Para 9.

104 Para 1.

105 Para 2.

106 Para 4.

107 Para 5.

including the protection of those reporting the misconduct, by research institutions, agencies, journals and organizations[108] and the balancing of social benefits against the risks associated with research.[109]

An overall observation about the Singapore Statement is that it promotes accountability and transparency, and therefore substantially tending more towards the PLA contemplated in this thesis. Its principles have however not been the reference point in the context of health research litigation.

Apart from the above ethical instruments, other ethical instruments providing guidelines specific to certain environments are also looked at as and when it becomes necessary in a specific context. These ethical instruments include those by the South African Medical Research Council (SAMRC)[110] and the guidelines by the Health Professions Council of South Africa (HPCSA).[111]

1.10 The legal framework

1.10.1 The national legal framework

Various national laws exist regulating the rights of research participants, which indirectly place obligations on other stakeholders. These range from the Constitution, common law, legislations and case law.

- The Constitution of the Republic of South Africa,1996

The Constitution, which is the highest law of the land, provides a variety of rights that different categories of persons can enjoy. These include the right to equality,[112] the

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108 Para 12.

109 Para 14.

110 Which has, amongst other guidelines, the South African Medical Research Guidelines on the Responsible Conduct of Research.

111 The HPCSA has several ethical guidelines, including the general guidelines and the specific guidelines dealing with specific aspects of the health profession. Though the other HPCSA guidelines may also receive attention where required by the context, the guidelines to receive more attention in this study are: Health Professions Council of South Africa Confidentiality: Protecting and Providing Information (Booklet 5) (HPCSA's Booklet 5) and Health Professions Council of South Africa General Ethical Guidelines for Health Researchers (Booklet 13) (HPCSA's Booklet 13). Though also touching on other ethical principles the HPCSA's Guidelines do in substance embrace the four biomedical principles by Beauchamp & Childress, as discussed above (see para 2 of the Health Professions Council of South Africa Guidelines for Good Practice in the Health Care Professions: General Ethical Guidelines for the Health care professions (Booklet 1) (HPCSA's Booklet 1). A further instrument of note is the Human Sciences Research Council Ethics Guideline (which is also referred to in para 1.8.3 of the 2015 Ethics in Research).

112 S 9 of the Constitution.

right to human dignity,[113] the right to freedom of association,[114] the right to privacy,[115] etc.

These rights are also relevant to the protection of research participants. These rights intersect with other ethical principles. For example, the right to human dignity is also consistent with the ethics of respect for persons. The right to equality is consistent with the principle of justice. The right to freedom of association, which allows a person to choose who he or she wants to associate with, which in the context of research participation can include the right not to partake in the research, is consistent with the ethics of respect for autonomy. The constitutional right to privacy is also consistent with the respect for autonomy, including respect for confidentiality. Even more directly relevant to questions of research is the right to bodily and psychological integrity, which embraces rights including the right "not to be subjected to medical or scientific experiments without their informed consent*".*[116]

In the context of research participation by children, s 28 could also be relevant. Despite that s 28 does not specifically deal with research contexts, the principles it makes provision for can be adapted for research situations. S 28 specifically protects children against neglect, abuse, exploitation, etc. Relying on this provision, parents or guardians will need to be careful in agreeing to have their children participate in exploitative research, with a view to getting payment. S 28 further provides for the consideration of the best interests of the child when dealing with matters concerning a child. This generic principle will assist in protecting children against a variety of research harms. As to when it can, or cannot, apply will be a matter of fact.

The Constitution also makes provision for an 'administrative action that is lawful, reasonable and procedurally fair'.[117] This provides the basis for the judicial review of administrative decisions that fall short of the set standard. In the context of research, this could be the basis for challenging research decisions that fall short of this standard.[118]

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113 S 10.
114 S 18.
115 S 14 read with s 12.
116 S 12(2)(c).
117 S 33.
118 See further discussion of this aspect under the common law and legislation below.

The Constitution further creates space for the pursuit of decisions on a public interest ground. S 38, for example, broadens the issue of legal standing,[119] therefore making it possible for persons other than the affected litigants to initiate proceedings of behalf of those affected. This could be very important for affected research participants who might not have the resources or the knowledge to pursue cases against big pharmaceutical companies that may have wronged them.

The constitutional framework has not been relied on in case law dealing with health research in South Africa. Equivalent constitutional principles in other countries have also not been used by the courts in those countries when dealing with health research problems.

- The South African common law

It is fitting to start off by stating the importance and place of common law as a source of South African law within the post-94 constitutional jurisprudence. S 8(3) of the Constitution grants the courts the powers to apply, and if applicable develop, the common law, to the extent that a particular 'legislation does not give effect to' a right in the Bill of Rights.[120] S 8(3)(b) further grants the courts the powers to develop the rules of common law so as to limit a particular right, if the limitation complies with the limitation clause in terms of s 36(1) of the Constitution.[121]

Various principles derived from the South African common law are of relevance to questions of protection of research participants. The most important of these principles derive from the law of delict, law of contract and other fields of private law. Both the law of delict and the law of contract form an important source of the law of obligation, both within the field of private law. The two fields, namely the law of delict and the law of contract, creating delictual and contractual obligations respectively, therefore play

119 It should be noted in particular that even in those instances where persons are entitled to act in their own interest, this does not necessarily mean that the persons must themselves be the right holders (see Hoexter C and Penfold G *Administrative law in South Africa* 3rd ed (Juta Cape Town 2021) 693, where the authors critic what appears to be the opposite approach by the Constitutional Court in *State Information Technology Agency Soc Limited v Gijima Holdings (Pty) Limited* 2018 (2) SA 23 (CC).

120 S 8(3)(a) of the Constitution.

121 Also see s 39(2) of the Constitution which also touches on what the courts and other forums must do when developing the common law or customary law.

an important role in defining the content of obligations expected of stakeholders in research.

Apart from the delictual and contractual obligations, which the researcher for convenience refers to as private law obligations,[122] there are also common law public law obligations arising from criminal law, administrative law, and other legal principles. A violation of privacy by a researcher not only gives rise to a private law form of delictual action, but also gives rise to an action under criminal law. This equally applies to instances where a researcher violates a person's dignity. These public law approaches are, however, rarely used in the context of health research.

Even more rarely used are the common law administrative law obligations, which existed even before the new constitutional era. Under the common law a person is entitled to challenge an administrative action on various grounds, including the ground that an action is *ultra vires.*[123] The common law-based administrative law is now augmented by s 33 of the Constitution, the Promotion of Administrative Justice Act 3 of 2000 (PAJA), the principle of legality and judicial review mechanisms provided for under specific statutes.[124] An administrative law angle to health research could be of assistance in a variety of contexts, including a challenge to faulty REC's decisions, decisions of sponsors not to compensate research participants, etc.

As indicated already in the background to the study above, the private law common law obligations, which dominate the research ethics discourse, are inadequate in resolving health research problems. These shortcomings can be augmented by the public law approach.

- South African legislation

The main legislation dealing with general health matters is the NHA, which also regulates issues relating to participation in research. Of particular importance is s 71 of the NHA, which requires that research be conducted in a prescribed manner, and after securing the informed written consent of the person participating.[125] It further

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122 Though in other contexts one could use the concept of private law obligations to include other obligations within the fields of private law, beyond these two categories.

123 Hoexter C *Administrative law in South Africa* 2nd ed (Juta Cape Town 2012) 14 & 115.

124 Hoexter *Administrative law* 118 – 125.

125 S 71(1)(a) and (b) of the NHA.

requires that the participating person be informed of the objects of the experiments and any positive or negative effects on the person's health.[126] In the case of minors, the NHA makes a distinction and sets different conditions as between non-therapeutic research and therapeutic research.[127] In the case of therapeutic research, the conditions are that it be conducted only if it is in the minor's best interests;[128] within certain prescribed conditions;[129] if the parent or guardian of the child consents[130] and with the consent of the minor if the minor is capable of understanding.[131]

In the case of non-therapeutic research on minors, the NHA sets a far more onerous combination of conditions. Research may only be done in such manner as may be prescribed;[132] after consent from the Minister;[133] with parental or guardian consent[134] and with the consent of the minor where the minor is capable of consenting.[135] The NHA further prescribes the conditions under which the Minister may not give consent.[136] Despite the usefulness of the provisions of the NHA, not much is known about the courts' application of its provisions when dealing with health research problems.

Another relevant regulatory legal instrument is the Regulations Relating to Research with Human Participants, 2014 (Health Research Regulations), which seek to provide for additional measures to protect human participants in research. Regulation 2 of the Health Research Regulations outlines certain principles that should guide the conduct of health research. The principles include fair and just recruitment and selection processes for research participants; informed consent of the research participants; respect for the rights of human participants; technical competence (including relevant experience) by those conducting the research; use of valid[137] research methodologies; a risk and benefit analysis favouring the research participants; compliance with the

126 S 71(1)(b).
127 S 71(2).
128 S 71(2)(a).
129 S 71(2)(b).
130 S 71(2)(c).
131 S 71(2)(d).
132 S 71(3)(a)(i).
133 S 71(3)(a)(ii).
134 S 71(3)(a)(iii).
135 S 71(3)(a)(iv).
136 S 71(3)(b).
137 The word 'valid' (instead of the word 'right') may have been more carefully chosen to avoid instances where the review committee must enquire into the rightness or wrongness of the decision of the researcher, i.e.to avoid going into the merits of the decision, rather the process.

research guidelines of the National Department of Health (South Africa); responsiveness to the country's health needs or priorities (this may however risk going into the merits, rather than the process of the decision), subjecting the process to a review by an independent review body, etc. Most of these legal principles are already established as ethical principles in health research review circles.

Regulation 3 of the Health Research Regulations provides for further protection mechanisms to research participants, before, during and even after the completion of the research process. It provides for the correct procedures to be followed before the start of the research; the protection of research participants for whatever happens during the conduct of the research (e.g. research-related injuries) and it provides for post-research benefits, like the publication of the research results.

The Health Research Regulations also provide for the registration of clinical trials, if so classified, in the South African National Clinical Trials Register.[138] These provisions could be very useful in the protection of research participants. Though not much of their application in case law is known (though the Health Research Regulations are still very new to expect that they could have been applied widely in the courtroom), the general trends about other public regulations is that the private law approach has been preferred to a public law-type of framework. A public law approach as argued for in this thesis could therefore assist towards closing this gap.

Another relevant legislation is the Children's Act 38 of 2005 (CA), which is the main Act dealing with the protection of children's rights in general. Though the CA does not specifically deal with research situations, the principles it makes provision for could be helpful in such contexts, for the protection of children who partake in research. The definition of "abuse" in s 1 of the CA includes "exposing or subjecting a child to behaviour that may harm the child psychologically or emotionally''.[139] This could therefore arguably include research-related harms (let alone the fact that the definition itself is not exhaustive).

Equally useful is the definition of "exploitation" in s 1 of the CA, which includes the "removal of body parts" from the body of the child.[140] This could be very relevant for

138 Regulation 3(f) of the Health Research Regulations.
139 S 1(1)(e).
140 S 1(1)(f)). This definition should be read together with the definition of 'removal of

research participation contexts, as some research might involve the removal of body parts. The objects' clause of the CA, which reaffirms the constitutional rights of a child as provided for in s 28 of the Constitution, is no doubt also relevant for the protection of research participants.

S 9 of the CA provides: "In all matters concerning the care, protection and well-being of a child the standard that the child's best interest is of paramount importance, must be applied*".* This provision will no doubt be the main guiding principle in all matters concerning the participation of the child in research. This means that the parents or guardians must, when taking decisions as to whether the child should participate or not, should be guided by the best interest of the child. Though the CA does not specifically define what "best interest" means, the Health Research Regulations define it as meaning "significant decisions affecting a minor's life should aim to promote, amongst others, the minor's physical, mental, moral, emotional and social welfare".[141]

Although, as indicated the CA does not specifically define what the best interests of the child mean, it does provide for factors that must be considered when the best interest of the child standard must be applied under any relevant provision of the CA. Though these factors are generic, and some of them might not be relevant to the context of research participation, there are those that could be relevant to research participation contexts.

Of similar importance is s 10 of the CA, which provides:

> Every child that is of such an age, maturity and stage of development as to be able to participate in any matter concerning that child has the right to participate in an appropriate way and views expressed by the child must be given due consideration.

This provision could address issues of assent by children who are in the position to do so. S 13(1)(c) of the CA also touches on confidentiality regarding a child's health status and that of specified persons close to the child. It provides for every child to have the right to "confidentiality regarding his or her status and the health status of a parent, care-giver or family member, except when maintaining such confidentiality is not in the best interest of the child''. Though not specifically dealing with a health research

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body parts' in the very s 1 of the CA, which means "the removal of any organ or other body part from a living person in contravention of the NHA*".*

141 Regulation 1 of the Health Research Regulations.

context, it can be useful in protecting children who take part. Not much, if any at all, of the CA has been relied on in case law dealing with health research.

As earlier indicated, PAJA, which gives effect to s 33 of the Constitution, is one of the cornerstones of judicial review, and administrative law in general. S 6 of PAJA provides for the grounds on which administrative action may be challenged. Such grounds include procedural unfairness;[142] material error of law;[143] irrationality;[144] and unconstitutionality or unlawfulness.[145] PAJA also requires that reasons be supplied, upon request, for decisions taken by administrators.[146] These provisions could be very important in regulating the conduct of stakeholders in health research.

Due to the centrality of the protection of personal information in research, the study also looks at laws related to that. A few laws protecting personal information or privacy in research exist, including the Promotion of Access to Information Act 2 of 2000 (PAIA),[147] Electronic Communications and Transactions Act 25 of 2002 (ECTA)[148] and the Protection of Personal Information Act 4 of 2013 (POPIA). These and equivalent legislations have generally not found application in case law dealing with health research.

The researcher also investigates laws dealing with discrimination. This is mainly regulated by the Promotion of Equality and Prevention of Unfair Discrimination Act 4 of 2000 (PEPUDA), which gives effect to s 9 of the Constitution. PEPUDA might therefore apply to research decisions if the decisions have elements of discrimination.

Just like the rest of pubic law, courts have not relied on these sources to resolve health research problems. The public law approach proposed here will therefore close this gap.

- South African case law

142 S 6(2)(c) of PAJA.
143 S 6(2)(d).
144 S 6(2)(f)(ii).
145 S 6(2)(i).
146 S 5.
147 Although PAIA is mainly aimed at promoting access to information, it does make provision for the protection of certain information.
148 SS 50 and 51 of ECTA. These sections have now been repealed by POPIA (see schedule to POPIA).

Not enough South African case law directly dealing with health research matters could be found. One important case directly dealing with health research is that of *Venter v Roche Products (PTY) LTD* (A11/2014) [2014] ZAWCHC 157 (22 October 2014) (Roche case). The clinical trial was sponsored by a Swiss-based company. The sponsoring company had Roche, the respondent in this application, as their local representative in South Africa. The respondent had an agreement to conduct clinical trials with the GVI Oncology (the second defendant). When the participant developed research-related injuries, the company agreed to pay for the direct medical costs, though after some hesitation. The appellant claimed not just for direct medical costs. As appears in the discussion in chapter 4, the court relied on a narrow private law framework to rule against the research participant.

The court decision throws in more confusion concerning the nature of the relationships and obligations amongst different stakeholders in health research. The approach in the decision shows the weaknesses of relying on the private law, more in particular, the contractual law approach to research obligations, as such an approach makes it difficult sometimes to detect a relationship giving rise to legal obligations.

Apart from the cases specifically dealing with health research, there are cases not specifically dealing with health research, but whose principles could be useful in the resolution of problems dealing with health research. The cases covered in the research include *Barkhuizen v Napier* 2007 (5) SA 323 (CC);[149] *Jansen Van Vuuren NO v Kruger* 1993 (4) SA 842 (A);[150] *Afrox Healthcare BPK v Strydom* 2002 (6) SA 21

[149] Which deals with the impact of the constitution and its values on the law of contracts. Although the court pointed out that agreements whose enforcement is unfair or unjust might not be given effect to by the courts, the court however held that on the facts before it there was no evidence suggesting that the enforcement would be unfair or unjust.

[150] The case dealt with the right of privacy, and the duties a doctor has towards his patient. On the facts here a doctor had disclosed his patient's HIV status to third parties. The court held that the right to privacy had to be respected. It further held that doctors had to uphold certain professional ethical standards. The disclosure of the patient's HIV status to third parties was therefore found to be unreasonable and therefore unjustified. The court held that the doctor's obligations were however not absolute, therefore meaning that a doctor would have been justified in such disclosure if obligations to society were greater in weight than those to his patient, which was not the case here. Also see Carstens P and Pearmain D *Foundational Principles of South African Medical Law* (LexisNexis Durban 2007) 962.

(SCA),[151] *Botha and Another v Rich* NO 2014 (4) SA 124,[152] *Carmichele v Minister of Safety and Security and Another (Centre for Applied Legal Studies Intervening)* 2001 (4) SA 938 (CC)[153] and *Fose v Minister of Safety and Security* 1997 (3) SA 786 (CC).[154]

1.10.2 African instruments

- African Charter on Human and People's Rights

The African Charter on Human and People's Rights (1981) (ACHPR) does not have any specific provision dealing with the protection of research participants.[155] The ACHPR however makes provision for non-discrimination and equality.[156] These provisions could be important in case the selection of research participants is done in such a way that vulnerable persons like children and displaced persons are used, when other persons less vulnerable could best be used. It could, based on these provisions, be argued that they are being unfairly discriminated against based on age (in the case of children) or status of diminished capacity (for both children and displaced persons).

Equally important is the provision dealing with the protection of one's dignity, which will be relevant in the protection of both children and displaced persons partaking in research.[157] And so are the provisions prohibiting exploitation, which could be useful

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151 The SCA in this case had to decide on the permissibility or otherwise of exemption clauses, which the respondent (plaintiff in the trial court), the injured patient, was not aware of. The respondent said as part of his argument that such a clause was contrary to public policy or public interest and the Constitution, considering the unequal bargaining power between the two parties. The court held that in deciding on whether or not the contractual clause undermined community interests or not, the court had to consider the constitutional values. On the facts however, the court did not find anything wrong with the contractual clause. Also see Hawthorne L and Pretorius C.J *Contract Law Case Book* 3rd Ed (Juta Cape Town 2010) 215.

152 The case revolves around the fairness of contracts. The court had to decide on the fairness of a forfeiture clause in a contract. The court held that the principle of reciprocity should be relaxed under certain circumstances, if its applicability would be unfair, where its enforcement could lead to injustice.

153 The court case here pointed out the need for the development of the common law (delictual principles in this case) in line with the constitutional demands, as required in terms of s 39(2) of the Constitution. It further said that the development of the common law is peremptory rather than discretionary.

154 The case revolved around whether a claimant, who made allegations of torture and assault by the police may claim constitutional damages in addition to the common law damages. The court held that in principle constitutional damages should be available to a person whose rights have been infringed. The court held however that on the facts of the case it was not necessary to award constitutional damages.

155 Maswanganyi *Health research in Africa* 426.

156 Arts 2 and 3 of the ACHPR.

157 Art 5.

in the protection of these research participants.[158] The ACHPR further provides for the protection of the right to the liberty and security of persons, which could be helpful in the protection of children and displaced persons partaking in research.[159] The ACHPR, however, has not yet found application in the courtroom in the resolution of health research problems.

- African Charter on the Rights and Welfare of the Child (1990)

The African Charter on the Rights and Welfare of the Child (1990) (the ACRWC) provides for a generic framework for the protection of children. It therefore does not specifically deal with issues related to the protection of research participants. However, its extensive generic child protection framework could be useful as regards the protection of research participants, more so where children are involved. Of importance is that the ACRWC makes provision for the child's best interest principle.[160] This provision will certainly be very useful in the protection of children who partake in research. The ACRWC also provides for the protection of a child's privacy. This is an important provision in the context of research participant protection.

Where parents, legal guardians or close relatives of a child who is a refugee, or internally displaced, cannot be found, the child "shall be accorded the same protection as any other child permanently or temporarily deprived of his family environment for any reason".[161] Although it is not clear how precisely the provision would apply in the context of research participation, it could probably apply in instances where the question might arise as to who must give informed consent for the child's participation in the research when the parents, legal guardians or close relations cannot be traced. Regarding the application of the ACRWC in general, there is no instance known at this stage where the courts applied the instrument in the resolution of health research problems.

- Protocol to the African Charter on Human and People's Rights on the Rights of Women in Africa (2003)

158 Art 5.
159 Art 6.
160 Art 4 of the ACRWC.
161 Art 23(3) and (4).

The Protocol to the African Charter on Human and People's Rights on the Rights of Women in Africa (2003) (the Women's Rights Protocol), though covering other generic issues concerning the protection of women's rights, does also touch partly on the protection of women in research situations. Article 4(2)(h) of the Women's Rights Protocol requires states to take measures to "prohibit all medical or scientific experiments on women without their informed consent". The Women's Rights Protocol also generally provides for the protection of women against all forms of exploitation, inhuman and degrading treatment.[162] This position could be very useful in the protection of research participants.

Regarding the application of the Women's Rights Protocol to health research matters, preliminary research shows that courts have not invoked the instrument in the resolution of such matters.

- The African Union Convention for the Protection and Assistance of Internally Displaced Persons (2009)

The AU Convention for the Protection and Assistance of Internally Displaced Persons (2009) (AU Displaced Persons Convention) does not make specific provision for the protection of research participants, but the principles it provides for could be relevant for the protection of research participants too. The Convention makes provision for the protection of internally displaced persons. The Convention in particular protects displaced persons from being unfairly discriminated against.[163] The Convention also provides for respect "for the principles of humanity and human dignity of internally displaced persons".[164] Of importance is the Convention's provision for states to respect international humanitarian law.[165] These principles could be useful in the protection of research participants. The principles have however also not found some application by the courts when dealing with health research matters.

- *Other regional instruments*

Apart from the mostly African regional instruments discussed above, this research also, for comparative purposes, looks at the other regional instruments, including the

162 Arts 4(1) and 3(3) of the Women's Rights Protocol.
163 Arts 5(1) and 3(1)(d).
164 Art 3(1)(c).
165 Art 3(1)(e).

European Convention on Human Rights (1950) (ECHR)[166] (an instrument of the Council of Europe), Charter of Fundamental Rights of the European Union (2000) (CFREU) (an instrument of the EU),[167] the EU's General Data Protection Regulation of 2016 (GDPR), the American Convention on Human Rights (1969) (ACHR),[168] the American Declaration of the Rights and Duties of Man (1948) (American Declaration),[169] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Medicine (1997) (Oviedo Convention)[170] and those other regional instruments of relevance to health research.

1.10.3 International instruments

- The United Nations Charter

Although the Charter of the United Nations (1945) (CUN)[171] does not specifically deal with issues relating to the protection of research participants, it sets the tone for the human rights framework that came after World War II.[172] The CUN, together with the

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166 De Schutter O *International Human Rights Law: Cases, Materials, Commentary (*Cambridge University Press Cambridge 2010) 20.

167 Despite Brexit there could, as pointed out in chapter 5, still be instances where CFREU, linked to the European Union, could be relied on by the UK.

168 It should be noted that the US has not ratified this legally enforceable convention, see Diab J "United States ratification of the American Convention on Human Rights" 1992 *Duke Journal of Comparative and International Law* 322-343. Also see http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1318&context+djcil (Accessed 15 February 2022). Also see De Schutter *International Human Rights Law* 27. The USA's reluctance to ratify the ACHR, despite its reasonably good systems within her own jurisdiction, might place into question her general commitment to the international human rights system, which may include the human-rights approach to protection of stakeholders in health research.

169 This is an instrument of the Organization of American States (OAS). It is not a legally-binding instrument, but remains influential in shaping the human rights thinking within its region.

170 http://www.coe.int/en/web/conventions/full-list/-/convetnions/treaty/164 (Accessed 23 February 2017). Also see Byk C "The European Convention on bioethics" 1993 *Journal of Bioethics* 13 - 16 https://www.ncbi.nlm.gov/pmc/articles/PMC1376161/pdf/jmdeth00286-0015.pdf (Accessed 23 February 2017). https://www.ncbi.nlm.gov/pmc/articles/PMC1376161/pdf/jmdeth00286-0015.pdf (Accessed: 23 February 2017). It should also be noted that the UK has not ratified the Oviedo Convention, therefore, bringing into question its commitment to human rights approach, and public law approach in general, to bioethical matters. Also see Commission of the Bishops' Conference of the European Community "An Overview Report on Bioethics in the European Union" 2009 http://www.comece.eu/dl/KIMkJKJOIIkJqx4KJK/20091029PUBIO_EN.pdf (Accessed 5 March 2017).

171 The concept CUN is, unless the context indicates otherwise, used interchangeably with the concept of UN Charter.

172 One is however not unaware of earlier human rights instruments like the Magna Carta, Human Rights Act and the Petition of Rights in England; the Declaration of the Rights of man and of the Citizen in France and other earlier human rights frameworks in the US and other nations. These instruments may as well have set the tone, but the post- World War II instruments like

Universal Declaration of Human Rights (1948) (UDHR), are therefore a good baseline for the discussion of human rights. The CUN's preamble states:

> We the peoples of the United Nations determined…to reaffirm faith in fundamental human rights, in the dignity and worth of the human person, in the equal rights of men and women and of nations large and small,…

Articles 1, 55 and few other articles of the CUN also talk to issues of human rights. This no doubt sets the tone for the UDHR, which followed not long after the adoption of the CUN. Though the UDHR was originally not intended to be a legal document, but simply a moral framework, its content later informed other international, regional and national instruments with more legal content.[173] The CUN has however also not been a source of reference by the courts when dealing with health research matters.

- Universal Declaration of Human Rights

It should be noted at the outset that although the UDHR was not originally intended to be a legal instrument, its principles have shaped the national laws of many countries, therefore making their provisions of legal significance. Most importantly, the UDHR has been highly regarded within the UN circles.[174] Even though the UDHR does not specifically deal with the protection of research participants, its general human rights framework could be equally applicable to the protection of research participants. Article 1 of The UDHR provides for the equality and non-discrimination for everyone.

This will imply that in the selection of research participants, researchers should not do so in ways that unfairly discriminate against children, including displaced children. Article 12 of the UDHR also protects everyone from undue interference with his or her privacy. This provision will be useful in the protection of research participants, as researchers are required to protect the privacy and confidentiality of the research participants. The instrument has however also not been relied on in cases dealing with health research, both in South Africa and the other two countries of comparison.

- International Covenant on Economic, Social and Cultural Rights

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the Charter of the United Nations and the Universal Declaration of Human Rights had comparatively more immediate impact on the human rights tone that followed thereafter.

173 Brownlie I (ed.) *Basic Documents in International Law* 4th Edition (Oxford University Press Oxford 1995) 255.

174 Brownlie *Basic Documents in International Law* 255.

The International Covenant on Economic, Social and Cultural Rights (1976) (ICESCR) does not have any specific provision focusing on the protection of research participants. Its general human rights provisions could however be useful in the protection of research participants. The ICESCR requires states parties to it not to apply the rights it provides for in a discriminatory manner (implying unfairly discriminatory manner) on some specified grounds.[175] This provision could ensure that research participants are for example, not selected in an unfairly discriminatory manner. It could equally be useful to prevent research that does not have any scientific basis but to promote racism, sexism, or some form of prejudice against any specific communities.[176]

The protection of non-nationals is also considered, as art 2(3) of the ICESCR provides: "Developing countries, with due regard to human rights and their national economy, may determine to what extent they would guarantee the economic rights recognized in the present Covenant to non-nationals". This international instrument has also not been used by the courts in the resolution of health research matters.

- International Covenant on Civil and Political Rights

The International Covenant on Civil and Political Rights ((1976) (ICCPR), though not specifically dealing with the protection of research participants, does however touch in part on the protection of research participants. Article 7 of the ICCPR provides:

> No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.

Although the importance of this type of provision has been explained already elsewhere in this research, when dealing with the requirement of informed consent in research, it suffices to mention that art 7 of the ICCPR is one of the sections within the ICCPR that cannot be limited even in times of emergencies as envisaged in art 4(1).[177]

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175 Art 2(2) of ICESCR.

176 This is important given the history of some race-based research, as happened during the World War II in Germany, which resulted in the Nuremberg Trial.

177 Art 4(1) of the ICCPR provides: "In time of public emergency which threatens the life of the nation and the existence of which is officially proclaimed, the States Parties to the present Covenant may take measures derogating from their obligations under the present Covenant to

Article 4(2) of the ICCPR excludes the possibilities of limiting the right provided under art 7. Just like the other international instruments discussed above preliminary research shows that the courts have not yet used the ICCPR in resolving health research questions.

- The Convention on the Elimination of All Forms of Discrimination against Women

The Convention on the Elimination of All Forms of Discrimination against Women (1979) (CEDAW) does not have any specific provisions dealing with the protection of research participants. The whole of the CEDAW deals with non-discrimination of women and their equality with men. It therefore provides for measures that need to be taken to ensure that such equality and non-discrimination are realized. These provisions could be useful in ensuring that even in research contexts women, more in particular girl children, are not unfairly discriminated against. This could be useful in the way selection is done for participation in research. This could also be important for displaced women, who could be exploitable if not protected. Just like the other international instruments discussed above, preliminary research points towards the non-usage of the CEDAW in case law.

- Universal Declaration on Bioethics and Human Rights: UNESCO

The Universal Declaration on Bioethics and Human Rights (2005) (the UNESCO Bioethics Declaration) is, as the title suggests, a UNESCO document focusing on the human rights aspects of bioethics. It identifies specific bioethical principles, some of which overlap with the other bioethical principles discussed earlier in this chapter.[178] These include human dignity and other rights; maximization and minimization of benefits and harms respectively; autonomy; consent; respect for human vulnerability; respect for privacy and confidentiality; respect for equality, justice and equity; respect

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the extent strictly required by the exigencies of the situation, provided that such measures are not inconsistent with their other obligations under international law and do not involve discrimination solely on the ground of race, colour, sex, language, religion or social origin".

178 One should also note other UNESCO documents like the UNESCO International Declaration on Human Genetic Data (Genetic Data Declaration) which, although only focusing on research where human genetic data is used, could also be valuable for research in general. Article 19 of the Genetic Data Declaration, for example provides for the sharing of benefits between the communities whose data have been used and the international community (one supposes that the latter will also include the researcher).

for non-discrimination and non-stigmatization; respect for cultural pluralism and diversity; human solidarity; promotion of health and social development; sharing of benefits; protection of future generations and the protection of the environment. Most of these principles are also provided for in the Constitution of the Republic of South Africa and international human rights instruments, though they could be named differently in these other instruments. Preliminary research shows that the UNESCO Bioethics Declaration has also not been a source of reference by the courts in the resolution of health research problems.

- Convention on the Rights of the Child

The United Nations Convention of the Rights of the Child (1989) (CRC) makes provision for the protection of children. The CRC does not, however, specifically deal with the protection of children in research contexts. The principles it provides for could however be used for the protection of children partaking in research. In particular, the CRC makes provision for the consideration of the best interests of the child when dealing with matters concerning a child.[179] The CRC also provides for the protection of the privacy of the child.[180] This will be important in case of research participation. Art 12 of the CRC makes provision for the participation of the child in matters concerning the child. This provision will no doubt assist in encouraging the voices of the children who partake in research, through assent. The CRC, based on research, has not yet found some application in the courtroom in the resolution of health research matters.

- UN Guiding Principles on Internal Displacement

The UN Guiding Principles on Internal Displacement (2004) (UNGIDP) makes provision for the protection of internally displaced persons against a variety of abuses. The UNGIDP does not however speak directly to issues related to research ethics. Article 11(1) of the UNGIDP provides for everyone to enjoy the right to dignity and to physical, mental and moral integrity. It further protects internally displaced persons against torture, cruel, inhuman or degrading treatment, amongst other protections.[181] These provisions could be useful in the protection of internally displaced persons

179 Art 3 of the CRC.
180 Art 16.
181 Art 11(2) of UNGIDP.

partaking in research. The principles are in fact consistent with principles in other instruments specifically dealing with the protection of research participants.[182] Just like these other international instruments research shows that the UNGIDP has not found some application in the courtroom, when the courts decide on health research matters.

- Other relevant international law instruments

This research where necessary also looks at other relevant international law instruments not directly dealing with health research issues, but whose general principles could be relevant to the resolution of health research issues. For example, the International Convention on the Elimination of all Forms of Racial Discrimination (1966) (ICEFRD), a UN instrument dealing with generic principles against racial discrimination, could also be of assistance.

1.10.4 Foreign law

- The legal position in the UK

A comparison with the UK requires that one understands the structure of the English legal system (the most dominant within the UK). English law is based on the common law, and therefore mainly un-codified.[183] With the UK having been previously part of the EU and having ratified or being a signatory to some of its major conventions and related instruments, its legal system has no doubt also been influenced by these instruments. The UK has in particular passed the Human Rights Act 1998 (HA),[184] whose purpose is to give effect to some of the fundamental rights provided under the ECHR.

The UK also has its own internal framework dealing with health research issues. Its Medical Research Council has related guidelines to protect health research

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182 Note should also be taken of the Protocol on the Protection and Assistance to Internally Displaced Persons (2006) (PPAIDP), which is the protocol to International Conference on the Great Lakes Region (ICGLR). Though the ICGLR, and by implication the PPAIDP, do not apply directly to South Africa, it is important for comparative reasons. This is even more so that it expressly incorporates the UNGIDP.

183 Note that there are various senses in which the concept of common law could be used. Being uncodified or unwritten (in the sense of not being made by parliament) is one of the senses in which the concept could be used and, unless the context indicates otherwise, it is in that context that the concept is used in the study.

184 This is one of many other laws the UK passed as a result of its membership of the EU, including the European Communities Act, 1972.

participants. There is also the Nuffield Council on Bioethics, which is just an advisory body, but whose framework has had a significant influence on a number of countries.[185] Other advisory bodies in the UK include the Medial Ethics Committee of the British Medical Association, the Human Fertilization and Embryology Authority, the Ethics and Governance Interim Advisory Group, the UK Biobank and the Human Genetics Commission.[186]

The UK has several laws impacting on health research such as the Care Act of 2014 (the Care Act). The Care Act creates the Health Research Authority (the HRA),[187] whose functions are to coordinate and standardize practices around health and social care research,[188] regulate the functioning of RECs,[189] participate "as a member of the United Kingdom Ethics Committee Authority"[190] and make approvals relating to the processing of a patient's confidential information.[191]

Another important legislation in the context of health research is the Data Protection Act of 2018 (the DPA), which replaces the Data Protection Act of 1998 (the old DPA). The DPA provides for the fair and lawful processing of personal information, with a data subject's consent forming one of the central bases.[192] The DPA in the main gives effect to the General Data Protection Regulations (GDPR).[193] The DPA also provides for the rights of a data subject, including the right to correct personal information in the hands of a data controller.[194] The personal information protected under the DPA must be about a particular 'identified or identifiable living individual'.[195] The DPA further

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185 Meslin EM and Johnson S "National Bioethics Commissions and Research Ethics" in Emanuel EJ et al. (eds) *The Oxford Textbook of Clinical Research Ethics* (Oxford University Press New York 2008)187 - 197.

186 Meslin and Johnson "National Bioethics Commissions and Research Ethics" 194.

187 S 109(1) of the Care Act.

188 S 110(1)(a).

189 S 110(1)(b).

190 S 110(1)(c).

191 S 110(1)(d).

192 S 2(1)(a) of the DPA.

193 S 1(2) of the DPA. This therefore implies that the main data protection principles provided for in art 5 of the GDPR are also applicable here, with some adaptations. In fact, even those chapters and parts of the DPA that are mainly directed at national security, defence (chapter 3), law enforcement (part 3) and intelligence gathering (part 4) do provide for equivalent, though slightly structured, principles as those of GDPR. The GDPR data protection principles, which will be reflected on in chapter 8 (international legal framework) and where necessary chapter 5 (on the English law position), are briefly as follows: lawfulness of processing; purpose limitation; storage limitation; accuracy; information integrity and confidentiality and data minimisation (art 5(1) of the GDPR).

194 S 2(1)(b) of the DPA.

195 See the definition of 'personal data' in s 3(2) of the DPA. Further see the definitions of

provides for the Information Commissioner, whose primary function is the monitoring and enforcement of the application of the DPA.[196]

Regarding its giving effect to the GDPR, the DPA clarifies how the GDPR will be applied and where necessary, supplemented. The DPA therefore in the process also provides for the circumstances where procession will not be in compliance with the GDPR.[197] In the main, the DPA gives effect to the GDPR's data protection principles.

The DPA in particular deals with how the GDPR's provision dealing with transfer of personal data will apply, by providing for the making of regulations stating the circumstances under which the transfer of personal information to a third country or international organization will be considered necessary on grounds of public interest.[198] Where no enactment requires such transfers, the DPA in like manner provides for the making of regulations indicating the circumstances where the transfer of data may be considered unnecessary.[199] The DPA further provides for the making of regulations to restrict transfer of personal data to a third country or international organization if the transfer will not comply with an adequacy decision in terms of s 45(3) of the GDPR.[200] The DPA makes provision for the restriction of transfer of personal data if it is considered necessary for reasons of public interest.[201]

It further deals with the exemptions applicable in the case of processions that involve research. It provides processions that are necessary for the conduct of historical research or scientific studies.[202] The DPA also makes provision for an Information

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'identifiable living individual' and 'data subject' in ss 3(3) and 3(5) of the DPA respectively. The emphasis on the 'living' of the person whose information is protected, in both the definitions of 'personal data' and 'data subject', implies that the information about persons who are already deceased is not protected? This appears problematic, given that the revelation of information about the deceased could also indirectly reveal certain facts about those still alive. If, for example, the HIV status of the deceased is revealed it could also indirectly reveal the possible HIV status of the surviving spouse of the deceased.

196 S 2(1)(c) of the DPA.

197 The formulation of s 19(2) of the DPA, which provides that procession will not be in compliance with art 89(1) of the GDPR if it causes substantial damage or distress to the data subject better illustrates this point.

198 S 18(1)(a) of the DPA.

199 S 18(1)(b).

200 S 18(2)(a).

201 S 18(2)(b).

202 S 19(1)(b) of the DPA (this section should be read together with the conditions set out in Part 1 of Schedule 1 to the DPA, which also restate these principles. Further see s 10(1) and (2) of the DPA)). Also see s 87(4)(a) (ii) of the DPA which, though regulating the processing of personal information in the context of intelligence services, treats processing for research or scientific purposes as not being incompatible with the principles of purpose specification and

Commissioner, which serves as the supervisory authority in the UK, as contemplated in art 51 of the GDPR.[203]

Because this research emphasises the protection of children in health research, the study also looks at those laws and related instruments specifically dealing with the protection of children, though not specifically dealing with health research. These instruments include the Children Act 1989, Children Act 2004, Female Genital Mutilation Act 2003, etc.

- The legal position in the USA

The USA has been very rich with human rights instruments since the 1700s. These include the American Declaration of Independence (1776) and the Constitution of the United States of America (1787) (the US Constitution). These instruments do not, however, directly deal with health research issues although some of the principles outlined in them could be of value to the resolution of health research problems. The equality treatment, for example, provided in these instruments could be equally applicable to a health research situation.

The regulatory framework directly relevant to bioethics started in the 70s, although the events that triggered the regulatory framework occurred some years before that. The legislation includes the National Research Act 1974, the Federal Regulations (the Common Rule) and regulations by specific agencies like the FDA (see some brief discussion of these in the historical background above). Given that the study places emphasis on the protection of children partaking in health research, the study also looks at some generic legislation dealing with the protection of children. US instruments dealing with the protection of personal information are also looked at, and these include the EU - US Privacy Shield Framework Principles (the Privacy Shield).[204] These instruments are contrasted with the position in South Africa and the UK.

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compatibility as provided for in s 87(1) of the DPA. Though the DPA treats these two principles as one principle, namely the 'second data protection principle', this principle is arguably like the two principles in s 13, read with s 14, of POPIA, namely the principles of purpose specification and further processing limitation.

203 Arts 114 and 115 of the DPA.

204 This is a framework issued by the USA Department of Commerce, requiring USA companies to commit to protect personal information collected from the EU. Para 14 of the Privacy Shield also touches on the protection of personal information related to research.

1.11 Chapter outline

Chapter one: Introduction and background

This chapter introduces the study. The chapter in particular looks at the background; research questions; literature review; aims; methodology and limitations of the study.

Chapter two: Historical background to the regulation of the protection of research participants

This chapter deals with the historical background to the whole study. It starts off by looking at the history of research atrocities and the historical movement towards regulating the conduct of research and then identify the various historical tendencies that dominated specific periods.

Chapter three: Existing theoretical approaches and their limitations

This chapter examines the various ethical and legal theories and principles dealing with the conduct of health research. The strengths and limitations of these approaches are also looked at.

Chapter four: Existing South African legal framework regulating health research

This chapter looks at the existing South African legal framework dealing with health research. The chapter looks at the common law, legislation, case law and the Constitution. Ethical guidelines provided for in various instruments, though not necessarily having the force of law, are also looked into.

Chapter five: An examination of the UK legal position

This chapter examines the UK legal position regulating health research. Some relevant ethical frameworks applicable in the UK are also looked at.

Chapter six: An examination of the USA legal position

This chapter examines the American legal position regulating health research. While the focus is mainly on the federal legal position, the chapter does also touch on laws from specific states where this becomes relevant to the study. Some ethical frameworks in the US are also looked at.

Chapter seven: Comparative analysis

This chapter discusses and contrasts the findings in chapters four to six, i.e. for the three countries under comparison. The extent to which the laws of the three countries support or negate the PLA is also highlighted where necessary.

Chapter eight: International legal framework

The chapter looks at the international legal position (both intercontinentally and regionally) dealing with health research. The chapter first looks at regional instruments adopted by regional bodies like the AU, EU and OAS, and then compare them. The chapter then looks at international instruments adopted by international bodies like the UN and related bodies.

Chapter nine: The proposed public law approach towards health research

This chapter discusses the plausibility of a public law approach to health research. The chapter further outlines the implications of a public law approach on specific areas relevant for health research.

Chapter ten: Conclusions and recommendations

This chapter concludes the study and makes recommendations. It also states, in brief, the possible areas of future research.

1.12 Conclusion

This chapter introduced the study on the plausibility of a public law approach to health research. It examined, at a preliminary level, the state of the law at national, comparative and international levels, about the applicability or otherwise of the public law approach to health research. The chapter also examined, at a preliminary level, the existing theoretical frameworks, both in law and ethics, governing the conduct of health research. The preliminary research shows that the existing legal framework is dominated by a private law approach to health research. The existing ethical framework also shows what the various theories, if used in isolation, might not provide an adequate protection to stakeholders in health research, more especially research participants. The next chapter deals with the historical background to health research.

CHAPTER TWO: HISTORICAL BACKGROUND TO THE REGULATION OF THE PROTECTION OF RESEARCH PARTICIPANTS

2.1 Introduction

It is apt here to start off by drawing some wisdom from Søren Kierkegaard's often quoted expression of life being 'understood backwards' but 'lived forward'.[205] This quote affirms the role of history, being to inform society about the past, so as to assist the society to use the understanding of that past to understand and shape the present, and then understand and shape the future. The attempt to understand the past must not be made outside the context of that past. The context in which historical events happened remains central to the examination of the historical past. Michael Oakeshott puts it thus: "History I take to be a mode of thought in which events, human actions, beliefs, manners of thinking, are considered in relation to the conditions, or the circumstantial context, in which they appeared."[206] This approach to historical enquiry is equally important to the study of the history of bioethics. The examination and evaluation of its past therefore consider the context in which it happened. This is the approach this chapter takes.

The chapter examines the historical evolution of bioethics. It starts off by examining the general history of law and ethics which may, though indirectly, impact on bioethics (this is discussed under 'general background to law and ethics'). It then focuses on the more specific history of bioethics (this is discussed under 'historical background to bioethical questions').[207] The chapter, unless the context requires otherwise, mainly focuses on the historical part of bioethics that is of relevance to the shaping of bioethics in the three countries under comparison in this research, namely South Africa, the USA and the UK. In addition to the specific legal and ethical history of the three

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205 Martin L *Famous Quotes* (2009). Available from: https://www.philosophybasics.com. (Accessed 15 September 2019). Further see Day JK "Transforming criminal lives: a narrative study of selves, bodies and physical activity" (Doctoral Thesis University of Exeter 2012). Though various authors have captured this quote slightly differently, the substance, as captured here, remains the same.

206 Michael O *Lectures in the History of Political Thought* (Imprint Academic Com Exeter 2006) 31.

207 In the context of the discussion in this chapter, unless the context indicates otherwise, bioethics or bioethical questions refers to those aspects, more especially legal and ethical, that have a direct bearing on the questions of health or medicine. This is as opposed to the aspects discussed in 2.2 which, though relevant to issues of health or medicine do not themselves, unless the context otherwise indicates, directly deal with issues of health or medicine. They become applicable to issues of health or medicine mainly indirectly.

countries, the chapter also focuses on the international (including regional) historical angle of bioethics. Most importantly the chapter, to place the discussion in context also discusses, in brief, the various research atrocities that triggered the legal and ethical responses that are alluded to in the chapter.

2.2 General background to law and ethics

2.2.1 The general historical position

Although the specific regulation of the protection of research participants is a very recent phenomenon,[208] not only in South Africa, but also in other countries and at international level, general laws and related instruments that could be relevant to certain types of conduct in health research existed some centuries, and even some millennia back. Some of the notable instruments, as per existing historical records, in the era before Christ (BCE) include the Code of Hammurabi (of Babylonia, developed and used around 1750BCE)[209] and the Hippocratic Oath (developed around 400BCE).[210]

Philosophers in this period also played a leading role. These include Greek philosophers like Aristotle and Plato,[211] and the Roman philosopher Cicero. Aristotle wrote extensively on justice and equality. He for example, in one of his writings argues "But justice is the bond of men in states, and the administration of justice, which is the determination of what is just, is the principle of order in political society" (footnotes omitted).[212] His concept of both justice and equality, though, was problematic if viewed by today's standards. Aristotle for example found it natural for other persons to be

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208 In fact, it could be safely considered a 20th century phenomenon, having mainly formally started, as the discussion below shows, in the post-World War II era.

209 Https://www.history.com/topic/ancient-history/hammurabi. (Accessed 27 January 2020).

210 Https://www.britannica.com/topic/Hippocratic-oath. (Accessed 27 January 2020).

211 Plato and Aristotle, alongside Socrates have played a leading role in philosophy, they were not the first Greeks to do so. There were several philosophers that also played a leading role before these latter philosophers, during what has come to be called the pre-Socratic period. The difference however, is that the pre-Socratic philosophers focused more on natural philosophy (or closer to modern language, physics) rather than ethics and related fields like logic, though they did not completely ignore the latter (Barnes J *Early Greek philosophy* 2nd rev ed (Penguin Classics London 2001) xiv. Unless the context requires otherwise, this research therefore does not focus on the Pre-Socratic Greek philosophy.

212 Aristotle *Politics* (Translated from the original Greek by Jewett B) (Dover Publications New York 2000) 30.

enslaved. He also equally found it natural for women to be treated unequally with their male counterparts. He said, for example:

> Again, the male is by nature superior, and the female inferior; and the one rules and the other is ruled; this principle, of necessity, extends to all mankind.[213]

Though these views were expressed outside the context of research, there is no reason he would not have so believed in the context of research. His views were not necessarily universal at the time.[214] His views, not necessarily universal though, remain the most publicized of what the thinking was around his era.

Another prominent philosopher of the same era, Plato, had supported slavery.[215] Although his conception of equality in general was problematic as it appears qualified in ways that cannot be acceptable today (for example his support of slavery), his argument for the equality of women with men could be considered revolutionary by the standards of the time.[216] Although he considered women weaker than men in some respects, he argued for gender parity in a number of areas, including in respect of aspects like politics, education and training.[217]

Of more interest in the case of bioethics is that even during that era, Plato did conceive of the notion of informed consent by patients when treated by their doctors, although it appears that as a matter of practice at the time, there was a differentiation between treatment of a slave by a slave doctor, and treatment of freeman by a doctor who was a freeman.[218] Plato does appear to, though reluctantly and ambiguously, prefer a situation where the same standards applied for the two categories of doctors (note,

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213 Aristotle *Politics* 33.

214 For example, Aristotle does concede that other thinkers held different views on the same issues, more especially as it relates to whether or not it was natural to enslave other people. He says in this regard: 'Others affirm that the rule of a master over slaves is contrary to nature, and that the distinction between slave and freeman exists by law only, and not by nature; and being an interference with nature is therefore unjust' (Aristotle *Politics* 30).

215 Plato *The Laws* (Translated from the original Greek by Saunders TJ) (Penguin Books London 1970) 214 & 444.

216 Questions have even been asked in scholarly circles as to whether or not Plato could be considered a feminist, for the position he took at the time (see also McAfee N "Feminist Philosophy'' 2018 *Stanford Encyclopaedia of Philosophy.* https://Plato.stanford.edu/archives/fall2018/entries/feminist-philosophy (Accessed 1 March 2020).

217 Also see Borghini A *Plato and Aristotle on women: selected quotes* (2019). Available from: https://www.thoughtco.com/plato-aristotle-on-women-selected-quotes/2670553 (Accessed 1 March 2020).

218 Plato *The Laws* 136. Further note Plato's talk of two categories of doctors, one free doctor, and the other by implication slave doctor. He also divides the patients into slave patients and free patients).

however, that the practice at the time appears to be what was so described. This is important today if one considers the notion of equal or comparable standards of care).

Outside Greece, still during the ancient period, Roman philosophers like Cicero also played a leading role in shaping thinking in the ancient times, specifically his approach to the theory of natural law.[219] Natural law theory shall be reflected on in detail in chapter three, which deals with the various theoretical approaches to health research law and ethics. If one were to describe the dominant tendency in this era, one would categorize it as more deterministic. Determinism's[220] powering forces include transcendentalism,[221] and to some extent natural law. (In the modern era Marxism was also deterministic, to the extent that it reduces most, if not all problems of society to economic exploitation by the capitalist classes).[222]

Another tendency that could be considered dominant in this era was paternalism.[223] Paternalism's propellers include divine law; natural law; traditionalism and society and patients' traditional trust in the work of physicians. Instruments like the Hammurabi Code and the Hippocratic Oath (HO) (as it appeared before later amendments) could be viewed as being paternalistic. Hard paternalism could arguably be said to have been dominant in the classical period, until the beginning of the modern era, where rationalism, which is one of the propelling forces in the *laissez faire* approach below, started taking root.[224]

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219 Buckle S "Natural Law" in Peter Singer (ed) *A Companion to Ethics* (Blackwell Publishing Oxford 1991) 164. Of importance in the context of health research is the attribution to him of the phrase '*salus populi supremo lex esto*', which translates as 'let safety of the people be the supreme law' see Whirter RC ''The history of bioethics: implications for current debates in health research'' 2012 *Perspectives in biology and medicine* 330. https://muse.jhu.edu/article/490975/pdf (Accessed 19 March 2020).

220 'Determinism' means, in the main, that causes are pre-determined. This, taken to the extreme, negates the idea that human beings can ever freely will whatever they do (also see https://dictionary.cambridge.org/dictionary/english/determinism (Accessed 14 March 2020). 'Determinism'. Https://www.britannica.com/topic/determinism (Accessed 14 March 2020). Further see Curd *Argument and Analysis* 355.

221 'Transcendentalism', at least as used in this context, is the tendency to believe strongly in the spiritual, arguably the supernatural, as opposed to what can be verified physically or by our sense experiences. See https://www.merriam-webster.com/dictionary/transcendentalism (Accessed 14 March 2020).

222 Also see Edwards AB "Legal theory'' in Hosten WJ, Edwards AB, Bosman F and Church J *Introduction to South African law and legal theory* 2nd ed (Butterworths Durban 1995) 112.

223 This implies a tendency by the state or society in general to behave, in its dealing with the people in general, like a parent would do over his or her children. The State or society would often justify its actions on the basis that the actions are done for the benefit of the persons affected. See https://www.dictionary.com/browse/paternalism (Accessed 14 March 2020).

224 https://www.philosophybasics.com/movements_rationalism.html (Accessed 14 March

Other instruments in the early years (understandably in the first millennium after Christ) include the Bible and the Koran. In the latter years (around 1215) came the Magna Carta[225] in England. The Petition of Right (1628) and the Human Rights Act (1689) followed, again in England, around the 17th century.[226]

Philosophers around the beginning of the modern era, which included the enlightenment era, also produced writings that were to later influence human rights thinking, many revolutions and the content of human rights instruments of many countries.[227] These philosophers include John Locke, Montesquieu, David Hume, Thomas Hobbes, Jacques Rousseau, Immanuel Kant, etc. The outcome of the thinking during this period, and the period that followed this period until the 70s of the 20th century (when protectionism arguably set in), could be described as being *laissez faire* (for convenience, the researcher here sometimes uses the word *laissez fairism*, so as to emphasize its strong ideological content).[228] Forces contributing to this approach include rationalism,[229] liberalism and libertarianism.[230] The categorisation of this period as being *laissez faire* should not be read to mean that this *laissez fair* approach applied in all countries, and that paternalism was absent. It simply means that governments were generally not involved in regulating what the researchers had to do. In the case of medicine in general, because of the requirement of adherence to the HO, the tendency remained paternalistic.[231]

2020).

225 The *Magna Carta* is arguably one of the early instruments that informed modern thinking around human rights. See Bingham T *The rule of law* (Penguin Books London 2011) 10. Although Bingham here discusses the contribution of the *Magna Carta* towards the development of the concept of the rule of law, the discussion may by implication be applicable to the role of *Magna Carta*, though conservative by modern standards, in the development of human rights law.

226 A brief History of Human Rights. https://www.humanrights.com/what-are-human-rights/brief-history/magna-carta.html (Accessed 29 February 2020).

227 Some notable revolutions to be influenced by philosophers include the French and American revolutions, both occurring in the 18th century.

228 '*Laissez Faire'*, a French concept literally meaning 'leave to do', essentially means that there should be little interference from government in individual affairs (see Mclean I and Mcmillan A (eds) *Concise dictionary of politics* 3rd ed (Oxford University Press New York 2009) 297.

229 Rationalism, which emphasised reason, arguably thrived during the era of Enlightenment, which was itself regarded as the age of reason (See https://www.philosophybasics.com/movements_rationalism.html. Also see https://www.history.com/topics/british-history/enlightenment (Accessed 14 March 2020).

230 Abuses of contracts to corner patients or participants by agreement is more likely to happen in more libertarian environments than in less libertarian environments.

231 Benatar SR "Ethical challenges for health care in South Africa'' in Van Rensburg HCJ (ed) *Health and health care in South Africa* (Van Schaik Publishers Pretoria 2004) 564.

As earlier indicated, out of this thinking came several human rights instruments, including the American Declaration of Independence (1776). The Declaration was followed by the American Constitution in 1787 (which incorporated the Bill of Rights through a series of Amendments as from 1791), the French Declaration of the Rights of Man and of the Citizen (1789) and later the Declaration of the Rights of Woman and of the (Female) Citizen (Woman's Declaration).[232]

Although these earlier instruments influenced thinking in the realm of politics[233] they, apart from the HO,[234] did not (at least directly) influence thinking in the field of health research ethics. Although health research started taking root in the 17th century,[235] considerations of research ethics appear to have been very low at this stage. During this period, only isolated cases of concerns for ethical issues were raised by researchers like Jenner, who discussed some of the risks associated with research with the research participants.[236] Even Jenner himself did not appear to consider the mere inclusion of children in research as raising ethical concerns, due to their increased vulnerability.[237] It can also be gleaned from the circumstances of the time that the ethical issues were left to the conscience of the researchers themselves, rather than a matter of public interest that required public regulation.

Further, despite this limited interest in ethical issues in research in the 17th century, instead of things improving in the succeeding centuries, things became worse. In the 19th century child research, more especially in the US, took place in paediatric

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232 The Declaration of the Rights of Woman and of the (Female) Citizen was the product of the work of Olympe De Gauges, which she developed by way of a pamphlet in 1791. The Woman's Declaration was modelled on the French Declaration of the Rights of Man of the Citizen. (See Cokely CL "Declaration of the Rights of Woman of the (Female) Citizen" Available from: https://www.britannica.com/topic/Declaration-of-the-rights-of-woman-and-of-the-female-citizien (Accessed 27 February 2020).

233 One should, however, note that even in the field of politics, these instruments still did not address some of the problems of the time, either within the instruments themselves, or through lack of implementation. Certain problems of the time therefore remained. Common problems in the 18th century include racialism, sexism, socio-economic status e.g. slavery not outlawed still, issues of disability not touched on, and so are other modern prohibited grounds of discrimination. These instruments therefore mainly retain the class, racial and gendered character that was dominant in most societies at the time.

234 One should however always bear in mind that even though the Hippocratic Oath had a significant influence on health research, it did not itself directly deal with health research, but with biomedical issues other than health research.

235 As to the earlier research in medicine, see Fleischman AR and Collogan LK ''Research with Children'' in Emanuel EJ et al. (eds) *The Oxford Textbook of Clinical Research Ethics* (Oxford University Press New York 2008) 447.

236 Fleischman and Collogan *Research with Children* 447.

237 Fleischman and Collogan *Research with Children* 447.

hospitals, without ethical considerations.[238] The same trend continued in the early to mid-20th century (around the World War II era) where researchers, more especially in the US, conducted research on smallpox, yellow fever, polio and other communicable diseases, without ethical considerations.[239] If anybody (outside the researchers themselves) ever raised concerns for ethics in research, this mainly came from protest movements.[240] There was, in general, no public regulation of the issues.

Outside the US there were also early developments in Prussia, in 1891, when the Minister of Interior made a pronouncement against using patients against their own will in research.[241] In 1900 there was a formal regulation of non-therapeutic research, requiring informed consent.[242] In 1931, Germany also had health research regulations, which at the time were considered even stricter than the Nuremberg Code that came later on.[243]

The earlier legal and ethical instruments mentioned above do not appear to have influenced the thinking towards concern for ethical and human rights issues in

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238 Fleischman and Collogan *Research with Children* 447. One should further take note of the experiment conducted in 1822 by the US army soldier, William Beaumont, on a wounded French-Canadian voyageur. Beaumont used a contract to trick the participant into consenting to the experiment, see Lederer SE "Walter Reed and the yellow fever experiments" in Emanuel EJ *et al* (eds) *The Oxford Textbook of Clinical Research Ethics* (Oxford University Press New York 2008) 12. One describes this usage of contracts to trick participants as, for lack of a better concept, contractism. Contractism as used here should not be confused with related concepts of contractarianism and contractualism, which have been used in political philosophy to justify or provide an account for the authority of the state or origin of the state. One does, however, also recognise that contractarianism has, beyond being the theory of justification, also been used to explain certain phenomena e.g. the fact that a particular group may have contracted to dominate another group (in other words, it could explain possible conspiracies). See also Cudd A and Eftekhari S "Contractarianism" 2017 *Stanford Encyclopaedia of Philosophy* https://plato.stanford.edu/entries/contractarianism (Accessed 19 March 2020). Contractism, however, is not meant to serve any of these purposes. It is used here mainly to highlight a particular tendency or leaning during a particular period i.e. the tendency towards the use of contracts in ways that are self-serving.

239 Fleischman and Collogan *Research with Children* 447.

240 Fleischman and Collogan *Research with Children* 447. The focus of these protest movements was even limited in scope, as the protestors were mainly concerned about the involvement of children and animals in research and were therefore not necessarily concerned about research atrocities in general.

241 Royal College of Physicians *Guidelines on the Practice of Ethics Committees in Medical Research with Human Participants 4th ed* (Royal College of Physicians London 2007) 1. https://shop.rcplondon.ac.uk/products/guidelines-on-the-practice-of-ethics-committees-in-medical-research-with-human-participants?variant=6364998469 (Accessed 4 March 2020.

242 RCP *Medical Research Guidelines* 1.

243 RCP *Medical Research Guidelines* 1. It could therefore be inferred from this that although the regulations existed in Germany they were not necessarily complied with. It could further be inferred from this that the approach to health research in Germany then was not human rights based, and therefore, consistent with the public law approach contemplated in this thesis.

research. Though the instruments earlier could probably have influenced the development of the Geneva Declaration of the Rights of the Child (1924) and the formation of the League of Nations (this though appears empty of human rights ideas) in the aftermath of the World War I, it appears that until the aftermath of the World War II the earlier human rights instruments, more especially the 18th century human rights instruments, had very little impact on the thinking across the world, with the exception perhaps of the anti-colonial movements, and only also to a limited extent.[244]

The post-World War II era saw a revolution in the development of human rights instruments, some taking some clues from the 18th century American and French human rights instruments. Perhaps the devastation caused by this war knocked into people's consciousness that disrespect for human rights is to the disadvantage of all, and that the converse also holds true, namely that respect for human rights was to the advantage of all. Hence, the new race for rights instruments development, rather than the armament, and sometimes 'colony-grabbing', race that preceded the two World Wars.

The United Nations Charter (1945) kicked-started the post-World War II rights' instruments race, followed by the Universal Declaration of Human Rights (1948) and other international instruments.[245] These two instruments, especially the latter, shaped many other human rights instruments, whether at country-level (including at the level of extra-parliamentary political movements),[246] regional level or international level.

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244 For example, the African National Congress developed the Bill of Rights in 1923, but this was not well developed by modern standards. This was followed by a document called the African Claims, in the early 1940s, which was equally not comprehensive by modern standards. The language of rights adopted in the earlier centuries, more especially, the 18th century, may arguably have had some impact on these latter instruments, though indirectly. See Everratt D "The Freedom Charter in historical perspective'' in Steytler N (ed) *The Freedom Charter and beyond: Founding principles for a democratic South African legal order* ('Wyvern Publications Cape Town 1991) 21. See also Nthai SA "A Bill of Rights for South Africa: an historical overview". https://www.sabar.co.za/law-journals/1998/november/1998-november-vol011-no2-pp142-143-and-147.pdf (Accessed 17 March 2020).

245 The international legal position is further reflected on below.

246 For example, in 1955 a grouping of anti-apartheid movements at the Congress of the People gathering in Kliptown in South Africa, drafted and adopted the Freedom Charter which even by modern standards is one of the comprehensive human rights documents, focusing on values like non-racism, etc., which became important later in the new Constitutional arrangements in South Africa (though a few aspects of the documents reflect more sentiments of the time than of the modern challenges). The key participants at the Congress of the People included the African National Congress, the South African Coloured People's Congress, the South African Congress of Democrats, the South African Indian Congress and the South African Congress of Trade

In America, the Civil Rights Act was enacted in 1964, in response to the concerns of the African American Civil Rights Movement at the time. Up till this stage the only human rights instrument of direct relevance and significance to the protection of research participants was the Nuremberg Code (1947) (if one discounts the earlier German framework referred to above), which was developed by a military tribunal set up to deal with the atrocities the German-based physicians committed during the course of World War II (which was briefly reflected on in chapter one).[247] Apart from this Code, not only was there no instrument specifically dealing with the protection of research participants, but none of the instruments outlined above, starting from the Code of Hammurabi, specifically dealt with the issue of research participants. Several other research atrocities than the German war-related atrocities, some of which are discussed below, occurred many years before, during and after World War II (i.e. even after some of the modern human rights instruments were in existence).

The exposure of research scandals in America (not linked to the World War II) a few years after the Nuremberg Trial led to the formulation of new instruments, specifically dealing with the protection of research participants (to be discussed in detail in the specific chapters).[248] The scandals led to the Belmont Commission, which produced the Belmont Report.

In South Africa the ideology of *Apartheid*, and in some instances, some inherited colonial laws, took the centre stage until formally changed in 1993, when the new constitutional dispensation was, as appears below, ushered in. The pre-constitutional ideology therefore affected various aspects of the legal system and the daily operations within society at large, including in the field of medical practice.[249] The

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Unions (See https://www.sahistory.org.za/articles/congress-people-and-freedom-charter (Accessed 16 March 2020). See further https://www.nelsonmandela.org/news/entry/freedom-charter-60th-anniversary (Accessed 16 March 2020. (Though not all sources list the South African Congress of Trade Unions as one of the participating Congresses, it does appear that they, together with the Federation of South African Woman, were in one way or another involved in the activities of the Congress of the People. Further see Everratt D "The Freedom Charter in historical perspective'' in Steytler N (ed) *The Freedom Charter and beyond: Founding principles for a democratic South African legal order* (Wyvern Publications Cape Town 1991) 34.

247 Also see Govender S "The Protection of genetic privacy in South Africa: towards a legislative response based on a cross – jurisdictional review of legal developments" (PHD Thesis University of the Witwatersrand 2012) 73.

248 The revelations of research atrocities were mainly done by Henry Beecher in journal article (see Beecher HK "Ethics and clinical research" 1966 *N Engl J Medicine* 1354 – 1360).

249 Note for example the dilemma that Professor Barnard and his team had in their choice of which donor to accept in the 60s, because of the fear, understandably at the time, of potential racial backlash. See Styan J *Heartbreaker: Christiaan Barnard and the first heart transplant*

status of women, more especially Black women, in the conclusion of legal acts was for example, affected.[250] The non-recognition of customary marriages at the time did not only negatively affect women, but it also negatively affected children born out of such marriages, as they could technically be treated as illegitimate children.[251] Research ethics guidelines during that period could also not escape the effect of the laws existing at the time.[252] In general, in so far as customary law is concerned, it was therefore not only customary marriages that were affected. Customary law during the time was only recognised to the extent that it was not repugnant to public policy as understood at the time.[253]

2.2.2 Regional and international framework

2.2.2.1 European regional framework

The European continental framework of relevance to this study begins in the 50s of the 20th century i.e. in the post-World War II era. There are two separate but interconnected streams that have shaped the development of European law, namely: one under the COE and another under the EU (referred, in the earlier years, to as the European Community, or something of that sort bearing the word 'Community'). Though the two European bodies have overlapping membership, the COE had a broader scope and more membership than that of the EU. The earlier human right instrument of relevance to the study is the ECHR. This is just a more generic human rights instrument rather than one specifically dealing with biomedical matters.

(Jonathan Ball Publishers Johannesburg 2017) 89. Further note the poor handling of the death of former activist, Steve Biko in 1977, where there was an initial reluctance by the medical profession to discipline those who were involved, until a group within the medical profession took the matter to court to force an action on the matter (See Benatar SR ''Ethical challenges for health care in South Africa'' in Van Rensburg HCJ (ed) *Health and health care in South Africa* (Van Schaik Publishers Pretoria 2004) 565.

250 Dhai A "The evolution of research participant protections in South Africa'' 2017 *SAMJ* 571.

251 Dhai "The evolution of research participant protections in South Africa'' 2017 571.

252 Dhai "The evolution of research participant protections in South Africa'' 2017, Dhai notes in this regard how the SAMRC research ethics guidelines at the time were also negatively affected, as they also had to comply with the laws of the time.

253 Taiwo EA ''Repugnancy clause and its impact on customary: comparing South African and Nigerian positions: Some lessons for Nigeria'' 2009 *Journal for Juridical Science* 89 – 115. Note, however, that the author here argues how the repugnancy clause, still applicable in Nigeria, may not necessarily have had the same negative effect there has it has done in South Africa.

The instrument directly relevant to biomedical matters, under the auspices of the COE, is the Oviedo Convention (1997), which came into operation in 1999.[254] The more generic human rights instrument under the auspices of the EU is the European Charter of Fundamental Rights and Freedoms (2000). Other important instruments under the auspices of the EU include the Directive 95/46/EC, which was recently repealed by the 2016 GDPR (both these instruments deal with the protection of personal information). The more specific instrument under the EU is Directive 2001/20/EC of the European Parliament and of the Council (2001) (the 2001 Clinical Trials Directive), which came into operation on 1 May 2004.[255] Commission Directive 2005/28/EC further augments the 2001 Clinical Trials Directive by providing more guidance on the latter's provisions.[256] The 2001 Clinical Trials Directive has also since been repealed by Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 (2014 EU Clinical Trials Regulations).

2.2.2.2 African regional framework

Within the African region most of the instruments of relevance are the generic human rights instruments,[257] most of which have briefly been reflected on in chapter one. These instruments will further be investigated in detail in relevant chapters to follow.

2.2.2.3 Inter-American regional framework

Just like in the African region there is not much, apart from the generic human rights ones, of instruments specifically dealing with bioethical matters in the inter-American region. The relevant generic instruments have been briefly reflected on in chapter one,[258] and will further be reflected on in the upcoming relevant chapters where this becomes necessary.

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254 Https://www.coe.int//en/web/bioethics/oviedo-convention (Accessed 6 March 2020). See also Byleveld D and Sethe S "The European Community Directives on Data Protection and Clinical Trials'' in Emanuel EJ *et al*. (eds) *The Oxford Textbook of Clinical Research Ethics* (Oxford University Press New York 2008) 181.

255 Article 22 of Directive 2001/20/EC of the European Parliament and of the Council (2001). https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-dir_2001_20/dir_2001_20_en.pdf (Accessed 7 March 2020). Also see Byleveld and Sethe *European Community Directives* 180.

256 Https://eur-lex.europa.eu/eli/dir/2005/28/oj (Accessed 7 March 2020).

257 These include the African Charter on Human and People's Rights (1986); the African Charter on the Rights and Welfare of the Child (1990) and the Convention for the protection and assistance of internally displaced persons (2009).

258 These include the American Convention on Human Rights (1969) and American Declaration of the Rights and Duties of Man (1948).

2.2.2.4 International framework

A number of international instruments, some of which were already referred to above, including the UN Charter, the UDHR, the ICESCR made provision for the protection of human rights, and this protection, though general was, and still is, relevant for the protection of research participants, as most of these issues affecting research participants are also human rights issues. These instruments are discussed in detail in the relevant chapter on the international legal framework.

2.3 Historical background to bioethical questions

2.3.1 The earlier period

Although the history of bioethics as an organised discipline is very recent,[259] problems and thinking about issues relevant to bioethics, date back to time immemorial. Even though the concept of bioethics may not have been used at the time, issues of life, privacy, dignity, justice, etc., which are central to people's health, have existed as long as human and other living beings existed.[260] Questions around these issues have also attracted both philosophical and regulatory attention during the ancient, medieval and modern times (the three historical periods). Because it is not possible to go back many years on the issue in this research, unless the context requires otherwise there will be reflection only on some notable writings, including the Hammurabi Code and the HO.

As indicated earlier, most of the regulatory and ethical instruments before did not, until the mid-50s of the 20th century, deal directly with bioethical issues. The earliest known of the regulatory instruments is the Hammurabi Code. Firstly, though the Hammurabi Code does touch on how patients should be treated, it does not touch on the matter in the context of health research. Secondly, the Hammurabi Code was explicitly

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259 The concept of bioethics as an organised discipline began in the late 60s, with the establishment of two research institutes namely Hastings Center and the Kennedy Institute of Ethics in the US, established in 1969 and 1971 respectively (see Scher S and Kozlowska K ''The rise of bioethics: a historical overview'' in *Rethinking health care ethics* (Palgrave Pivot Singapore 2018) https://links.springer.com/chapter/10.1007/978-981-13-0830-7_3 (Accessed 19 March 2020). Note, however, that although the concept is said to have formally begun in the late sixties, the concept was first used by Fritz Jahr, who used its German equivalent in some articles in 1927, 1928 and 1934 (See Gordon J "Bioethics'' *Internet Encyclopaedia of Philosophy* Https://www.iep.utm.edu/bioethic/ (Accessed 19 March 2020).

260 https://shodhganga.inflibnet.ac.in/bitstream/10603/192258/6/06_chapter%201.pdf (Accessed 19 March 2020).

hierarchal in its approach to the treatment of patients. It, for example, explicitly provided for a differentiated treatment for patients who were slaves and those who were not. This means that even if these principles were to be applied in the context of health research, they would have been problematic in that they would have been unfairly discriminatory. Its provisions were therefore not consistent with justice as understood today.

The Code was also arguably more paternalist than it was respecting persons. Informed consent did not, for example, appear to have been a requirement. Although these regulations could arguably be viewed, at least in a formal sense, as public law regulations, they were not consistent with the public law approach as contemplated in this research, which must be consistent with human rights, justice and public interest.

As alluded to earlier another instrument which, though not directly dealing with health research, dealt with bioethical issues is the HO which though, as earlier indicated was developed in the 400 BC era, was revised many times thereafter.[261] The HO has become the guiding framework, and has been adopted by the WMA, which it did in 1948, but which it last revised in 2017.[262] The HO, even in its original form, went a long way towards addressing issues that are still relevant today. The HO, for example, provided for privacy (sacredness) and what could be interpreted today as beneficence and non-maleficence. The HO was, however, short of meeting human rights standards as understood today.

As indicated earlier, the Oath was paternalistic. It for example, without providing for exceptions, prohibited prescription of medicine for abortions. This would today not be viewed as respect for autonomy. Informed consent was not, or at least not clearly spelt

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261 Riddick FA "The Code of Medical Ethics of the American Medical Association" 2003 *Ochsner Journal* 6-10 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3399321/ (Accessed 17 March 2020). One should note that the earlier response (just like the HO) was around the development of professional codes for health practitioners, medical practitioners (physicians) in particular. One such notable response in the modern era was the Code of Medical Ethics by the American Medical Association (AMA) in the mid-1800s, which drew heavily from Thomas Percival's work on Medical Ethics in 1803, which the AMA adopted in 1847 (Riddick 2003 *Ochsner* 6-10). Another response, though indirectly, was through the teachings and practices of Florence Nightingale in the mid-1800s. See www.nurse.com (Accessed 27 January 2020). Although the teachings and practices of Florence Nightingale were not mainly focused on ethical issues, at least in the traditional sense, they had implications for ethics too.

262 WMA *Modern Physicians' pledge approved by world medical association*. Https://www.wma.net/news-post/modern-physicians-pledge-approved-by-world-medical-association/ (Accessed 9 March 2020).

out as part of the pre-requisite for medical interventions.[263] Even when it allowed for privacy, its view of privacy appears not to have been grounded on the need for respect for persons, but just as part of the art of medicine, or at best as part of beneficence. As to whether or not it took a private law or public law approach, it is difficult to pigeon-hole the HO in this regard, but it appears to have had a more contractual approach, where a physician had to feel obliged to respect the oath, even for its own sake. Another value the HO appears to espouse is one of integrity, which is still important today. And so is the matter of professional competence, which it emphasises, though not so directly.

Though concerns around research activities may mainly have been raised in the later years, the research activities have always occurred, whether formally or informally.[264] In the late 1800s, William Olser, a leading physician at the time, once condemned the deliberate injection of known poisonous substances into a human being as 'criminal'.[265] As indicated earlier**,** there were also ethical guidelines in Germany in 1931, but which were never applied in practice.[266] As indicated in chapter one, Nazi experiments were conducted during World War II. In response to the Nazi war experiments the Nuremberg Code (1947) was formulated, and this Code insisted on informed consent from research participants.[267]

Other problematic research experiments did also occur during World War II by the Japanese Military.[268] Surprisingly, the Japanese war experiments did not appear to

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263 Also see what appears to be the conclusion by Dhai A and McQuoid-Mason D *Bioethics*: *Human Rights* (Cape Town Juta 2011) 69 in this regard.

264 Note for example the research in 1747 by James Lind on HMS Salisbury. See Wendler D 'Ethics of Clinical Research' 2017 *Stanford Encyclopaedia of Philosophy.* https://plato.stanford.edu/archives/win2017/entries/clinial-research/ (Accessed 17 March 2020).

265 Emanuel EJ *et al.* (eds) "Introduction*"* in Emanuel EJ *et al*. (eds) *The Oxford Textbook of Clinical Research Ethics* (Oxford University Press New York 2008) 3.

266 Wendling PJ "The Nazi Medical Experiments'' in Emanuel EJ *et al*. (eds) *The Oxford Textbook of Clinical Research Ethics* (Oxford University Press New York 2008) 19. These guidelines even went to the extent of providing for consent on the part of the subject or the subject's legal representative. It also provided for extra protection in case of research on children or young people (See Wendling *The Nazi medical experiments* 19).

267 Wendling *The Nazi medical experiments* 18. Though the direct outcome of the Nazi medical Experiments is the Nuremberg Code; the indirect outcome is the rise in human right consciousness in general. See also Hosford B *Bioethics committees: the health care provider's guide*. (Aspen Systems Corporation Maryland1986) 22. The Nuremberg Trial has arguably been very central in shaping the post-World War II international law (see also Dugard J *International law: A South African Perspective* 2nd ed (Juta Cape Town 2000) 236. Further see Whittock M *A brief history of the Third Reich: the rise and fall of the Nazis.* (Robinson London 2011) 302.

268 Emanuel *Introduction* 4.

have attracted the same attention as the Nazi war experiments. It also appears that the Tokyo Tribunal, which investigated the Japanese war experiments, did not sufficiently, if it did at all, focus on the research aspects as the Nuremberg Tribunal did. The reasons for this failure could be attributed to a number of factors namely, the destruction of some of the evidence by the Japanese military around the time of the end of the War; the immunity given by the US to Japanese military on biological war atrocities and the then emerging Cold War between the then Union of Socialist Soviet Republics (USSR) and the US.[269]

2.3.2 Evolution of bioethics in the United States of America

The sixties saw the revelations of past research scandals in the US.[270] This was done mainly through an article by Beecher, in the *New England Journal of Medicine*.[271] The studies revealed in the publication, were conducted without the research participants being informed about the risk associated with the participation, i.e. the studies were conducted without informed consent. There were also revelations in the early 70s through a story revealed to the press by one Peter Buxton, an employee of the then US Public Health Service (PHS) (now department of Health and Human Services), about the Tuskegee Syphilis Study, which led to the cessation of the study.[272]

There was also a scandal related to the Jewish Chronic Disease Hospital, which in response led to the insistence on informed consent, amongst other requirements

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269 Tsuchiya T "The imperial Japanese Experiments in China'' in Emanuel EJ *et al*. (eds) *The Oxford Textbook of Clinical Research Ethics* (Oxford University Press New York 2008) 35 & 41. The behaviour of the US was allegedly motivated by the need to catch-up with the USSR with regard to research on biological war at the time. Another, more subtle reason, could be that the US itself, as transpired some years later, was already involved in, or had at least condoned, some questionable medical experiments at home.

270 One should note, however, that the regulatory response in the US was not only as a result of the revelations of the research scandals. The increase in organ transplants at the time, more particularly heart transplants, did play its part in this regulatory response. For example, in 1968, just a few months after the first successful heart transplant (which was done in South Africa) the US Congress pushed for a Bill to assess the ethical and legal issues around the conduct of heart transplant research (see Brink JG "The first heart transplant and further advances in cardiac transplantation at Groote Schuur Hospital and the University of Cape Town'' 2009 *Cardiovascular Journal of Africa* 31 - 35. Https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4200566/ (Accessed 17 March 2020).

271 Emanuel *Introduction* 4.

272 Jones JH "The Tuskegee Syphilis experiment'' in Emanuel EJ *et al*. (eds) *The Oxford Textbook of Clinical Research Ethics* (Oxford University Press New York 2008) 89.

imposed.[273] So did the Tuskegee[274] revelations lead to the promulgation of the National Research Act of 1974 (NRA) in 1974, which makes provision for the US National Commission, which produced the Belmont Report in around 1979.[275] The Belmont Report in turn produced some ethical requirements, including the requirement of informed consent (as part of respect for persons, benefice and justice).[276] The Belmont Report recommendations were codified into Federal Regulations in 1981, and again in 1991.[277] There was a revised version of the Federal Regulations in 2009, which revisions became effective in 2009.[278]

The Federal Regulations have come to be known as the Common Rule, whose latest version was finalised in 2018.[279] Another relevant framework is the 2016 Privacy Shield, developed by the US Department of Commerce, which creates a data protection framework in the US for data transferred from the EU.[280] Another important milestone in health research in the US is the apology by the former American President, Bill Clinton in 1997, about the Tuskegee Study.[281] Of further importance is

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273 Emanuel *Introduction* 4.

274 The Tuskegee Study was one of the longest studies, beginning somewhere around 1930 to early 70s, therefore lasting for about 42 years (See Pence GE ''the Tuskegee Study'' in Beauchamp *et al* (eds) *Contemporary Issues in Bioethics* 7th ed (Wadsworth Cengage Learning Belmont 2008) 47. The Tuskegee Study used African Americans as study subjects (Pence *The Tuskegee Study* 47). The Tuskegee was as badly managed, as it can be gleaned from the following: ''Except for an African American Nurse, Eunice Rivers, who was permanently assigned to the study, there was no continuity of medical personnel. There was no central supervision; there were no written protocols; no physician was in charge. Names of the subjects were not housed at any one location or facility…'' (Pence *The Tuskegee Study* 49). Mostly importantly, the study used deception amongst its mechanisms to ensure participation (Pence *The Tuskegee Study* 49).

275 Beauchamp TL "The Belmont Report'' in Emanuel EJ *et al*. (eds) *The Oxford Textbook of Clinical Research Ethics* (Oxford University Press New York 2008) 149.

276 Beauchamp *Belmont Report* 150.

277 Porter JP and Koski G ''Regulations for the Protections of Human in Research in the United States: The Common Rule'' in Emanuel EJ *et al*. (eds) *The Oxford Textbook of Clinical Research Ethics* (Oxford University Press New York 2008) 158.

278 HHS *Pre-2018 Requirements*. Https://www.hhs.gov/ohrp/regulations-and-policy/regulations/regulatory-text/index.html (Accessed 7 March 2020).

279 HHS *Pre-2018 Requirements*. Https://www.hhs.gov/ohrp/regulations-and-policy/regulations/regulatory-text/index.html (Accessed 7 March 2020).

280 One should more particularly note para 14 of the Privacy Shield, which deals with health research, but mainly from the angle of data protection. Also see EU – US Data Transfers. https://ec.europa.eu/info/law/law-topic/data-protection/international-dimension-data-protection/eu-us-data-transfers_en (Accessed 23 February 2020). Apart from the EU – US Privacy Shield, note should be taken of the Swiss – US Privacy Shield Framework (2017), which provides for the protection of data transferred from Switzerland to the US (See International Trade Administration: The EU-US Privacy Shield and Swiss – US Privacy Shield Frameworks. https://www.privacyshield.gov/welcome (Accessed 16 March 2020).

281 William J Clinton, 1997. In Apology for the Study Done in Tuskegee in Beauchamp *et al. Contemporary Issues in Bioethics* (2009).

the opinion of the National Bioethics Advisory Commission, which advised the American president in the post-90s.[282] The framework discussed above is further augmented by case law, which will be discussed in later chapters dealing with American law.

2.3.3 Evolution of bioethics in the United Kingdom

Although the background to health research regarding other countries, more particularly the US, are also relevant to English health research law, there is here a need to reflect specifically on the English biomedical law in brief. Various laws could be said to find the basis for English law. These include the *Magna Carta*; the English Common law, the English Bill of Rights, etc. Though relevant, they do not specifically deal with health research issues.

The English's early ethical code (apart from the more generic legal framework applying to everyone) is the Percival's Code of 1803. The Code was drafted by Thomas Percival, a physician, to deal with ethical issues in medicine. The drafting of the Code was necessitated by the squabbles the doctors had amongst themselves during the outbreak of the typhoid and typhus epidemic in the UK.[283] The Percival Code principally followed the tradition of the HO in the sense of emphasising the duty of beneficence rather than autonomy and related rights like the rights of informed consent.[284] This however, as Veatch observes, is not necessarily the correct reading of the Code (Percival's) given that the Code also made reference to the benefiting of society.[285] The Code however, just like the HO, could be said to have promoted a more paternalistic approach, rather than a libertarian approach.

Modern English biomedical law could be traced back to 1963, when the UK Medical Research Council (UK MRC) published a statement in this regard, titled:

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282 National Bioethics Advisory Commission. 2001. Protecting Research Participants - A time for Change. In Beauchamp *et al*. *Contemporary Issues in Bioethics* (2009). Similarly note the report of the Advisory Committee on Human Radiation Experiments (Advisory Committee on Radiation Experiments: Final Report. 1995 in Beauchamp *et al*. *Contemporary Issues Bioethics* (2009).

283 Veatch RM *The Basics of Bioethics* 3rd ed (Pearson New York 2012) 15.

284 Veatch *Basics of Bioethics* 15.

285 Veatch *Basics of Bioethics* 25 (footnote 7).

Responsibilities in Investigations in Human Subjects.[286] In 1967 the Royal College of Physicians (RCP) issued its own report dealing with the need for oversight by research ethics committees (RECs).[287] The RCP further made guidelines in this regard in 1973, which guidelines were endorsed by the UK's Department of Health and Social Security in 1975.[288] The Department of Health, in conjunction with its counterpart in Wales and Scotland, issued its own guidelines namely: the Local Research Ethics Committees, which recommended the reconstitution of RECs so as to align them with the Department of Health's own guidelines.[289] In 1984 the RCP then published the first edition of the Guidelines on the Practice of Ethics Committees in Medical Research with Human Participants.[290]

In 2000 the Department of Health established the Central Office for Research Ethics Committees (COREC) whose role was to oversee the work of RECs, mainly in England.[291] In 2001 COREC issued guidelines entitled: Governance Arrangements for NHS RECs (GAFREC), which was not long after the publication of the document entitled: Research Governance Framework for Health and Social Care, in the same year, which outlined the responsibilities, standards and accountability in research.[292]

The European Commission's Clinical Trial Directive was also given effect to under UK law through the enactment of the Medicines for Human Use (Clinical Trials) Regulations 2004 (s1 2004/1031), which came into operation in May 2004.[293] The UK Ethics Committees Authority (UKECA) was also created, with its own standard operating procedures applicable to (NHS)[294] research reviewed by the NHS RECs.[295] COREC is now the National Research Ethics Service (NRES).[296] The Health Minister also established an advisory committee, called: the Ad Hoc Advisory Group on the

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286 Royal College of Physicians *Guidelines on the Practice of Ethics Committees in Medical Research with Human Participants* (Royal College of Physicians London 2007) 1.

287 RCP *Medical Research Guidelines* 1.

288 RCP *Medical Research Guidelines* 1.

289 RCP *Medical Research Guidelines* 1.

290 RCP *Medical Research Guidelines* xiii.

291 RCP *Medical Research Guidelines* 2.

292 RCP *Medical Research Guidelines* 2.

293 RCP *Medical Research Guidelines* 2.

294 This implies that research not under the auspices of the NHS (National Health Service), e.g. privately funded research, is not overseen by these RECs. One should therefore note here some parallel between this approach and that in the US, which is slightly different from the approach in South Africa. This aspect will be reflected on in the chapters dealing with comparative positions.

295 RCP *Medical Research Guidelines* 2.

296 RCP *Medical Research Guidelines* 2.

Operations of NHS Research Ethics Committees, in 2004.[297] Other relevant laws passed include the 2018 DTA; the Human Tissue Act of 2004 (HTA) and the Mental Capacity Act of 2005 (MCA).[298] These frameworks will further be augmented by case law, which will be discussed in the chapter dealing with the UK law.

2.3.4 Evolution of bioethics in South Africa

Although the history of South African law dates back to many centuries ago, in the field of health research the formal regulatory response also, just like that of the US and the UK, substantially begins around the 1970s.[299] The research activities have been alive even before the 70s with, for example, the first heart transplant being successfully performed in South Africa, by Professor Chris Barnard at the Groote Schuur Hospital in the late sixties.[300] The tough race in the field of heart transplant was no irrelevant matter in the need for regulation in the later years. Henry Beecher's article in *The New England Journal of Medicine*, published in June 1966, whose revelations of research atrocities pushed governments, in particular the US government, towards more regulation of health research, does touch on the problem of the increase in heart research.[301] During this period, the legal and ethical framework for research was not that strict.[302]

The regulatory response (or at least some guidelines) specifically relevant to South African context began with the publication of the first edition of the booklet in 1977 by the SAMRC, a statutory body charged with the conduct, funding and, by implication,

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297 RCP *Medical Research Guidelines* 2.

298 RCP *Medical Research Guidelines* 3. Further note some parallels, though with some slight differences in some cases, in the other 'states' of the UK like Scotland, Wales and Northern Ireland, see RCP *Medical Research Guidelines* 3.

299 Note, however, isolated cases were the University of the Witwatersrand in South Africa established a Research Ethics Committee around 1966, not long after the revelations of scandals by Henry Beecher. See Dhai A "Exploitation of the vulnerable in research: responses to lessons learnt in history'' 2017 *SAMJ* 473.

300 Styan J *Heartbreaker: Christiaan Barnard and the first heart transplant* (Jonathan Ball Publishers Johannesburg 2017). South African's first kidney transplant had been done earlier in 1966, at the Johannesburg General Hospital, now renamed Charlotte Maxeke Johannesburg Hospital (Styan *Heartbreaker* 77).

301 Beecher 1966 *N Engl J Medicine* 1354 – 1360. Also see Harkness J, Lederer SE & Wikler D "Laying ethical foundations for clinical research" 2001 *Bulletin of the World Health Organization* 365 – 372.

302 Styan *Heartbreaker* 69. This laxity in the legal and ethical framework governing health research was not only in the case of research on human beings, but also research on animals. This can be evidenced by the ease with which research was conducted at the time (See Styan *Hearbreaker* 69 and 76).

supervision of health research.[303] One should also note that the regulations before this period did not pay much, if any at all, attention to the protection of research participants.[304] The booklet was followed by subsequent editions,[305] and is now in its fourth edition.[306] At a legislative level the South African Medical Research Council Act 58 of 1991[307] (SAMRC Act) was also passed, which replaced the South African Medical Research Council Act 19 of 1969.

In 1994 there was a new dispensation, underpinned by constitutionalism. It began with the interim Constitution[308] and later the final Constitution.[309] The new constitutional framework provided the tone for what had to happen even in the area of health research. As indicated in chapter one, the NHA was promulgated and came into operation in 2004. The NHA makes provision for the establishment of the NHREC, which oversees REC. The NHREC also has its own research ethics guidelines.

The Department of Health developed the 2004 Ethics in Research (which have now been replaced by the 2015 Ethics in Research[310]). The Department of Health further developed guidelines (the South African Good Clinical Practice Guidelines in 2020 (the 2020 Clinical Trial Guidelines), replacing the 2006 Clinical Trial Guidelines (the latter had itself replaced the earlier version published in 2000).[311] In 2014 regulations, the Health Research Regulations,[312] governing the conduct of research, were passed

303 SS 4 and 17 of the South African Medical Research Council Act 58 of 1991.

304 For example, though there was a legislation establishing the Council for Scientific and Industrial Research Act 33 of 1945 (CSIR Act), the focus of that legislation was not on the ethical aspects of Research. See Dhai A *Evolution of research protections* 571. The Current version of the CSIR Act, namely the Council for Scientific and Industrial Research Act 46 of 1988, which replaces the Council for Scientific and Industrial Research Act 82 of 1984, also says very little, if any at all, about oversight over the conduct of research. Also see Dhai A "The evolution of research participant protections in South Africa'' 2017 *SAMJ* 571.

305 First edition was in 1977, second edition in 1987 and the third edition in 1993. The fourth edition, though undated, is set to have been issued around 2002, and revised in 2004, see Dhai *An Evolution of research protections* 572.

306 SAMRC *Book 1: Guidelines on Ethics for medical research: general principles including research on children, vulnerable groups, international collaboration and epidemiology*. https://www.samrc.ac.za/sites/default/files/attachments/2016-08-29/ethicsbook1.pdf (Accessed 11 March 2020).

307 Section 17 of the SAMRC Act provided for control by the SAMRC Board over the conduct of research conducted by the SAMRC or conducted on its behalf.

308 Constitution of the Republic of South Africa Act 200 of 1993 (Interim Constitution).

309 Constitution of the Republic of South Africa, 1996 (the Constitution).

310 Department of Health *Ethics in Health Research: Principles, Processes and Structures* (Department of Health Pretoria 2015).

311 Department of Health *South African Good Clinical Practice Guidelines* (Department of Health Pretoria 2006) 2.

312 Regulations Relating to Research with Human Participants, 2014.

in terms of the NHA. The Department of Health has also developed a charter for patients' rights, namely The Patients' Rights Charter, which outlines general protection mechanisms for patients.[313] Though the provisions of The Patients' Rights Charter are more generic, they may also be relevant to a health research context. These frameworks are also augmented by other, usually more generic legal frameworks like POPIA,[314] PAJA,[315] CA,[316] etc. The above framework is further augmented by case law as briefly highlighted in chapter one and which will, together with the rest of the framework, be further discussed in chapter four, dealing with South African law.

2.3.5 Evolution of bioethics at international level[317]

Though the HO, the Hammurabi Code, Nuremberg Code and the work of other similar tribunals like the Tokyo Tribunal, as discussed earlier, were not necessarily international in the sense of being created by formal international bodies, their effect (at least in the case of the first three) have had an international impact. Below is an exposition of those instruments that were international in both form and effect.

In 1948, just a few months before the adoption of the UDHR by the UN, the WMA adopted the Declaration of Geneva: Physician's Oath (1948) (the Physician's Oath).[318] The Physician's Oath makes the following principles central: the service of humanity; respect and gratitude (to one's teachers as a physician); conscience; dignity (implying self-respect and honour in this context); patient-centredness; maintaining the honour and nobleness of the profession; fostering the spirit of collegiality; adhering to the principle of non-discrimination and equality; respect for human life; and respect for natural law.

One should note here that although these principles are also relevant for health research, the focus of the Declaration was not specifically on health research, but on the ethics of physicians in general. The WMA also adopted the International Code of

313 Department of Health *The Patients' Rights Charter*. https://www.idealhealthfacility.org.za/docs/posters/PATIENTS%20RIGHTS%20CHARTER%20%20Eng.pdf (Accessed 12 March 2020).
314 Protection of Personal Information Act 4 of 2013.
315 Promotion of Administrative Justice Act 3 of 2000.
316 Children's Act 38 of 2005.
317 For convenience, developments at regional level have mainly been discussed under the general background in 2.2 above.
318 Moodley K (ed) *Medical Ethics, Law and Human Rights: A South African Perspective* (Van Schaik Publishers Pretoria 2010) 357.

Medical Ethics (ICME) in 1949.[319] The ICME, just like the Physician's Oath, mainly deals with medical rather than health research issues. The first post-World War II framework dealing with research ethics, under the auspices of the WMA is (arguably) the Declaration of Helsinki, as discussed below.

In 1964 the WMA adopted an instrument: Ethical Principles for Medical Research Involving Human Subjects (the Declaration of Helsinki).[320] The Declaration of Helsinki is discussed in detail in chapter three.

Some of the responses to the scandals were more specifically dedicated to health research while others, though generic, also referred to health research issues. An example of the earlier international instruments which, though generic, referred to health research is the ICCPR. The ICCPR which, though first initiated immediately after the World War II but only adopted in 1966 and came into operation in 1976, made reference to the prohibition of the conduct of experiments without consent.[321] However, in the context of war, the first instrument to make reference to the protection of research participants from torture in the form of medical experiments is the Geneva Convention Relative to the Protection of Civilian Persons in times of War of 12 August 1949 (the Geneva War Convention).[322]

As observed in chapter one, neither the slightly earlier instruments, the IMT (the Nuremberg Tribunal) nor the IMTFE (the Tokyo Tribunal), make any reference to medical experiments or informed consent. Given that the ICCPR was only adopted later in the 70s (and only even then not giving much detail on this issue[323]), why was there some reluctance in general, more especially within the UN structures, outside of

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319 https://www.wma.net/wp-content/uploads/2016/11/Decl-of-Geneva-v1948.pdf (Accessed 03 February 2020).

320 The Helsinki Declaration was preceded by the resolution of the WMA in 1954, which also briefly touched on health research issues (For a discussion of these principles, see Ashcroft RE "The Declaration of Helsinki'' Emanuel EJ *et al*. (eds) *The Oxford Textbook of Clinical Research Ethics* (Oxford University Press New York 2008) 142.

321 Article 7 of the ICCPR, which prohibits torture, inhuman and cruel treatment or punishment, also specifically prohibits forced medical or biological experiments i.e. without free consent. Although, unlike the Geneva War Convention, this provision was not a direct response to the atrocities of the World War II, it must be understood in the context of the very same mischief that was associated with the war, which was the use of such experiments as a form of degrading and inhuman punishment, as witnessed during the World War II.

322 Art 32 of the Geneva War Convention.

323 Whether details are better than just a mere reference in a section is of course a debatable issue. However, one is of the view that given what happened in the World War II regarding human participants, something more could have been done at UN level, at the earliest possible time.

the war situation, to deal comprehensively with the question of protection of research participants? Did the UN also adopt a reactive approach, just like the rest of the world did on the question of bioethics?

Apart from the ICCPR the UN, through UNESCO, has some declarations and recommendations directly impacting on bioethical matters, but it currently does not have any convention (at least one having direct impact on health research matters). In the case of Recommendations, there is Recommendation on the Status of Scientific Researchers (RSSR) (this however mainly focuses on the protection of the status of scientific researchers, a matter not irrelevant for bioethics). The protection of scientific researchers has an indirect impact on the quality of their work, and therefore the protection of participants in research. Article 29(a) of the RSSR also even specifically provides for the need to not only protect scientific researches, but also "all other persons likely to be affected by the scientific research and experimental development in question." UNESCO has the following declarations, which bear some relevance to bioethical matters: The Universal Declaration on Bioethics and Human Rights (2005); the International Declaration on Human Genetic Data (2003) and the Universal Declaration on the Human Genome and Human Rights (1997). There are, as indicated in chapter one, also the CIOMS Guidelines,[324] developed in collaboration with the WHO.[325]

2.4 CONCLUSION

This chapter examined the historical foundations of the health research regulatory framework of various countries as well as regional and international (intercontinental) frameworks. It started off by reflecting on the classical ethical and legal instruments like the Hammurabi Code and the Hippocratic Oath. The chapter further reflected on some of the leading philosophers like Plato, Aristotle and their thoughts on ethical and legal issues at the time. Though the determination of social categories is not a precise matter the chapter concludes by summarising, not in any particular order (given the existence of some elements of these tendencies in almost all the historical periods

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324 Proposed Guidelines for Biomedical Research involving Human Subjects (2002) (the 2002 CIOMS Guidelines), now replaced by the 2016 CIOMS Guidelines.

325 Idanpaan-Heikkila JE and Fluss SE "International ethical guidance from the Council for International Organization of Medical Sciences" in Emanuel EJ *et al*. (eds) *The Oxford Textbook of Clinical Research Ethics* (Oxford University Press New York 2008) 168 - 173).

under discussion, albeit in different shape), the dominant tendencies that shaped the various historical periods discussed above.

The first of these dominant tendencies include determinism, more dominant in the classical period. The second of these tendencies is paternalism.[326] Paternalism's propellers include divine law; natural law; traditionalism and society and patients' traditional trust in the work of physicians. In the modern era colonialism, absolutism (authoritarianism) and apartheid were other propellers of paternalism. Another tendency is the *laissez faire* approach. As indicated earlier *laissez fairism*, at least in its strongest sense, arguably came to a (relative) end in the early 70s. As indicated earlier, the existence of the *laissez faire* approach during the period above does not necessarily mean that other tendencies like paternalism were absent. It simply means that the state in general left researchers to do as they wish.

The last tendency identified here is protectionism. The preference for the word protectionism, rather than protection, is to emphasise the fact that the tendency was not necessarily a positive one. Protectionism signifies that protection becomes an end in itself, rather than one of the means to a greater end (being the health and wellbeing of society, which can only be assured when there is a balance between protection mechanisms and the stimulation of health research).[327] What would have inspired protectionism? Because of the scourge, in the form of scandals, that the research world was faced with there may have arisen a need to be seen to be doing something, i.e. to be on the right side of the rights' currency that was sweeping the world.[328]

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326 This implies a tendency by the state or society in general to behave, in its dealing with the people in general, like a parent would do over his or her children. The State or society would often justify its actions on the basis that the actions are done for the benefit of the persons affected. (Also see https://www.dictionary.com/browse/paternalism (Accessed 14 March 2020).

327 Note for example how strict legal and ethical framework arguably made a difference as to where the first heart transplant would be. Raymond Hoffenberg, one of the health researchers in the 60s based at the University of Cape Town appears to hold this view when he says: " ...the Americans were worried about the ethical and legal challenges pertaining to heart transplantation and were beaten by Barnard because of this" (Styan *Heartbreaker* 69 and 89). Of course, American legal and ethical frameworks at the time could only be viewed as strict by the standards of the time but were weak by today's standards. Protectionism could arguably be said to have started in the 70s.

328 Also note how, as indicated above, the establishment of the Research Ethics Committee at the University of the Witwatersrand (Wits) in the mid-60s was also a response to the revelations of scandals by Beecher at the time (see Dhai *Exploitation of the vulnerable* 473). However, although Dhai refers to the kind of response Wits initiated as a form of protectionism, the concept of protectionism as used in this study does not refer to any form of protection, but only that form of protection that goes beyond what is necessary to protect the participants. Unless the context indicates otherwise, it is in the latter context that the researcher uses this concept in

Researchers, regulators and IRBs alike had to be seen to be protecting the autonomy of research participants. They could, in the process have gone overboard, therefore turning protections to be what they patently sought to avoid: paternalism. This form of paternalism could best be described as neo-paternalism, as it is not as obvious as the traditional paternalism. Over-protectionism further risks the tendency for researchers to comply with the letter, rather than the spirit, of the law i.e. complying for its own sake, or at worst, only for self-protection against future liabilities. A public law approach that seeks to create a balance between protections and health research advancement, without being neo-paternalistic, is therefore sought. The next chapter examines the theoretical ethical and legal frameworks governing health research, as well as their limitations.

the rest of the study.

CHAPTER THREE: EXISTING THEORETICAL APPROACHES AND THEIR LIMITATIONS

3.1 Introduction

The field of health research has long raised critical questions, from both the perspective of law and ethics. These questions have, amongst other questions, thought to enquire into the nature of obligations the various stakeholders to health research have and the theories and principles, both in law and ethics, appropriate to satisfactorily explain these obligations. Various theories have therefore been generated to try and confront these questions. Having examined the historical evolution of law and ethics in chapter two, this chapter examines the various theories and principles governing health research. The chapter starts off by examining the nature of both ethics and law (including the relationship between the two). The chapter then examines the various theories and, where necessary and only briefly, principles.

The examination of the theories and principles shall require not only that one examines as to what theories adequately account for the justification of certain actions or disposition, but also the applicability of these principles to various biomedical contexts. One then examines the limitations of each of the theories under discussion and styling these limitations as possible objections to the theories. The examination of these limitations then paves the way for the development of the Public Law Approach (PLA), to be discussed in the latter chapters. Although legal theories and ethical theories differ, most do overlap. This chapter, however, examines them differently, unless the context requires otherwise.

3.2 The nature of law and ethics

3.2.1 Meaning of law and ethics

Law could be defined as those enforceable rules regulating human conduct.[329] Moral rules (ethics) have traditionally been defined as those rules regulating human conduct and not enforceable by the state, but followed out of a person's conscience.[330] Although the two systems of thought have traditionally been differentiated in this way,

329 Hahlo HR and Kahn E *The South African legal system and its background* (Juta Cape Town 1968) 3.

330 Hahlo and Kahn *South African legal system* 4 & 6.

i.e. based on whether part of the rules is enforceable (legal rules) and another unenforceable (moral rules), the plausible view could be that the differences should be understood along these lines: moral rules include legal rules, i.e. moral rules are the bigger 'brother' of legal rules, rather than being seen as different from them. The law, the 'smaller' brother, therefore, does not always seek to enter every part of the terrain of the bigger brother. In other words, law does not always seek to regulate every morality.[331]

This might at first sight create some confusion, given that legal rules are enforceable, while moral rules, which are the bigger brother of legal rules, are not enforceable. The argument for the position that legal rules are part of moral rules, despite the former being enforceable and the latter not, could run like this: moral rules include legal rules. Legal rules are enforceable. However, despite that it is not required that moral rules be enforceable, the enforceability of some moral rules, e.g. legal rules, does not disqualify them from being moral rules.[332] In other words, there should be no confusion between the existence of moral rules not being dependant on enforceability, and the absence of enforceability being a requirement for the existence of moral rules.

The latter position is a false understanding of moral rules. Such a construction, one submits, further confuses something not being required (which is what enforceability is to moral rules) and something being impermissible (which is not what enforceability is to moral rules). Enforceability is therefore neither required nor impermissible for the existence of moral rules. Unless the context suggests otherwise, the two concepts are therefore here used with this meaning in mind.

3.2.2 Relationship between law and ethics

The relationship between law and ethics requires one to pose two distinct but interconnected questions, namely whether law can serve as the foundation of ethics (using where necessary South Africa as, and only as, an example) and then whether ethics can serve as the foundation of law. The question around the relationship

331 Beauchamp *et al* (eds) *Contemporary Issues in Bioethics* 7th ed (Wadsworth Cengage Learning Belmont 2008) 31.

332 Of course, there could be an objection to this line of thought if examples could be presented that there are areas of activity regulated by law, but which are not the concern of morality at all, i.e. areas of activity that are morally insignificant but still regulated by law. Such examples could therefore, successfully refute the argument one makes here that (all) law is part of moral rules.

between law and ethics is not unlike the common but complex chicken and egg priority debate.

What is the legal foundation of ethics? In other words, what is the relationship between legal foundation and the ethical framework that emerges out of that? One argues here that such a relationship does exist. For example, the Post-World War II era, which produced certain international legal instruments, including the UN Charter, led to consciousness around, and helped shape, certain ethical frameworks. Ethical instruments like the Nuremberg Code and other similar Codes were arguably a product of such consciousness.

In South Africa the ushering in of a new democracy in 1994 also led to new thinking around ethical issues. Because all law and conduct had to comply with the new constitutional framework, the ethical instruments developed thereafter therefore encompassed human rights principles (though not necessarily in the shape contemplated in the PLA. The ethical instruments did not, for example, in the main encompass the public interest law, administrative justice, or the *Ubuntu*-based angles).

Though it is not always easy to show, by way of examples, the influence of ethics on law, it is self-evident that moral rules do impact on law-making. Historically, religion-based ethics like Christianity influenced the legal system at the time leading, for example, to the prohibition of the charging of interest,[333] and this appears to have been the case even under Islamic law.[334] Natural law tradition, which was arguably an ethical framework, influenced the human rights law in the later years.[335] About the relationship between law and norms (most, if not all, moral rules arguably fall under the category of norms) John Drobak says:

> Norms and law do have an impact on each other. Sometimes the law can be a strong influence on a change in norms by forcing a change in conduct that gradually becomes accepted throughout or by inducing a change in the perceptions about the propriety of certain conduct. Changes in social norms regarding the use of seatbelts and smoking in public places are examples of this. Of course, the law can rarely change norms, even over decades, without the

333 *The Morality of Moneylending: a short history (Part 2)*. https://newideal.aynrand.org/the-morality-of-moneylending-a-short-history-part-2/ (Accessed 4 August 2020).

334 Also see Ryan PJ *Usury: A moral concern for Jews, Christians and Muslims.* https://www.fordham.edu/download/downloads/id/3481/spring/2014_lecture.pdf. (Accessed 4 August 2020).

335 Buckle S "Natural law'' in Singer P (ed) *A companion to ethics* (Blackwell Publishing Oxford 1991) 166.

> concomitant influence of education, propaganda, peer pressure, and other similar forms of social persuasion. The influence in the other direction, however, is much stronger because much of the law reflects society's values and norms.[336]

Reinforcing certain aspects of what Drobak argues for above, on the influence of norms on law, Amartya Sen says: "Even if we do not want to go as far as Cicero in claiming that 'the good of the people is the chief law', it is hard to deny the role of established norms in influencing legislation and judicial interpretation''.[337] (Original footnotes omitted.)

One of the well-known ethical instruments, developed at an international level and having an impact on the development of legal frameworks, is the 1948 UDHR. In other words the UDHR, though originally developed as an ethical rather than a legal framework, later influenced the development of a number of both national and international legal instruments.[338] The UDHR has itself *de facto* been given the status of a law by being, for example, cited by courts of law.[339]

3.3 What are the limits of law?

From time to time questions do arise as to when government, other regulators and society should intervene to control an individual. This question is even more important in the context of health research, where regulatory authorities may want to intervene to regulate how researchers should conduct themselves in relation to research participants. Discussions around questions of this nature often revolve around legal moralism and legal paternalism. The discussion here, however, mainly revolves around legal moralism i.e. when can the law intervene to restrict individual liberty?[340] Various principles have been developed to answer this question.

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336 Drobak JN "Introduction" in *Norms and the Law* (Cambridge University Press New York 2006) 1.

337 Sen A "Normative evaluation and legal analogues" in Drobak JN (ed) *Norms and the Law* (Cambridge University Press New York 2006) 248; further see Oosthuizen LM *Media Ethics in the South African Context: An Introduction and Overview* (Juta Cape Town 2002) 62.

338 Brownlie I (ed) *Basic documents in International law* 4th ed (Oxford University Press New York 1995) 255.

339 The UDHR is for example cited in *Van Eerden v Minister of Safety and Security* SCA (2002) para 15. The UDHR is further referred to in the preambles of both the ICESCR and the ICCPR. It is further referred to in the UN General Assembly Resolution creating these two international human rights instruments (for these instruments and the resolution, see Brownlie *Basic documents in International law* 263).

340 A detailed theoretical focus on paternalism is not considered necessary here. The concept in the main means interfering in a person's affairs with a view to helping that person. On whether it is justifiable or not, one is of the view that it should be justified to interfere in a person's affairs if it is necessary to prevent harm (necessity), and it is in the public interest (public interest). For

Stuart Mill has offered the 'harm principle' in answer to this question. In other words, the law may only intervene for the purposes of preventing harm to others, rather than preventing harm to oneself.[341] In other words, based on this principle, a person cannot be prevented from harming himself. In the context of health research, a research participant may not be prevented from consenting to a risky experiment.

Another principle is one offered by Joel Feinberg, namely the 'offense principle'.[342] Based on this principle, regulators may intervene to prevent an offence to others. Another principle is one offered by Patrick Devlin, namely the common morality.[343] Based on this principle, regulators may intervene to protect common morality.[344] This means that once a particular activity is found not to be consistent with what is understood to be common morality, such an activity may not be allowed. Devlin in fact also believes that there is no sphere of life beyond the reach of law.[345]

None of these principles factor in the notion of public interest, in other words where the regulators could be required to intervene based on public interest. A pubic law approach to this will therefore consider public interest when guiding whether or not regulators and other relevant stakeholders have to intervene to regulate the conduct of stakeholders in health research. This will better provide guidance as to what stakeholders in health research, more especially health regulators in this case, must expect.

3.4 Ethical theories

As indicated in chapter one, various ethical theories exist. These include deontology, utilitarianism, virtue ethics, social contract theories, etc.[346] This section gives a detailed

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a discussion around paternalism see Dworkin R "Paternalism'' 2017 *Stanford Encyclopaedia of Philosophy.* https://plato.stanford.edu/entries/paternalism/ (Accessed 4 August 2020). Further see Beauchamp *et al Contemporary Issues in Bioethics* 33.

341 See Stanton-Ife J "The limits of law" 2006 *Stanford Encyclopaedia of Philosophy.* https://plato.stanford.edu/entries/law-limits/ (Accessed 4 August 2020). Also see Maswanganyi *Health research in Africa* 428. Also see *Mill JS On Liberty (1859)* (Batoche Books Kitchener 2001) 13. Further see Swanepoel M "Law, psychiatry and psychology: a selection of constitutional, medico-legal and liability issues" (LLD Thesis University of South Africa 2009) 245.

342 Stanton-Ife https://plato.stanford.edu/entries/law-limits/ (Accessed 4 August 2020).

343 Stanton-Ife https://plato.stanford.edu/entries/law-limits/ (Accessed 4 August 2020).

344 Stanton-Ife https://plato.stanford.edu/entries/law-limits/ (Accessed 4 August 2020).

345 Stanton-Ife https://plato.stanford.edu/entries/law-limits/ (Accessed 4 August 2020).

346 Other theories like Ubuntu (which is part of the communitarian framework), discussed in chapter one, is not discussed here but will be reflected on again in chapter 9, as part of the PLA proposed in this dissertation.

exposition of these theories. The discussion focuses on the general description of the theory in brief, its main claim, its strengths, possible objections (limitations) to the theory and the justification for an alternative theory, so as to cure the identified objections to the theory (unless the context indicates otherwise, the concept of objections and weaknesses are used interchangeably in this chapter). The implications of each theory for health research are, where appropriate, also integrated into this discussion.

3.4.1 Utilitarianism

Utilitarianism, a type of consequentialism, is one of the action-defining theories using utility as a starting point.[347] Its main claim is that an action is right if its consequences (utility in this instance) are good.[348] The opposite is also true, namely that an action is wrong if its consequences are bad. The theory's leading proponents include Jeremy Bentham and Stuart Mill.[349]

The theory provides a better account for the resolution of conflicting moral principles and moral situations. In other words, it provides a plausible explanation in case there are conflicting ends or utilities by simply opting for the best utility. This could be very important in the context of health research, where conflicting moral decisions, creating what is often referred to as moral dilemmas, emerge from time to time. For example, a dilemma does arise as to whether to respect the principle of autonomy through truth-telling so as to secure informed consent and therefore ensuring that the research participants do partake in the study *vis-à-vis* the principles of beneficence and non-maleficence.

In other words, if truth be told, participants might decide not to participate and therefore undermining the benefits potentially resulting from the research. The non-participation may also potentially result in harm to the community, including those who have chosen

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347 This is principally Jeremy Benham's approach to this notion (see Harrison R "Bentham, Mill and Sidwick" in Bunnin N and Tsui-James EP (eds) *The Blackwell companion to philosophy* (Blackwell Publishers Oxford 1996) 627 – 629.

348 Goodin RE "Utility and the Good" in Singer P (ed) *A companion to ethics* (Blackwell Publishing Oxford 1991) 241.

349 Sinnott-Amstrong W "Consequentialism'' 2019 *Stanford Encyclopaedia of Philosophy.* https://plato.stanford.edu/entries/consequentialism/ (Accessed 6 August 2020).

not to participate under circumstances where participation was necessary.[350] The theory therefore better accounts for both harm avoidance (non-maleficence) and doing good (beneficence), but it will of course be a matter of interpretation whether or not this will be the case. Related to the preceding point, the theory better accounts for why investigators may use placebos in health research.

As alluded to in passing above, this theory provides a better account for the use of deceptive research under certain circumstances. The theory may also better account for the conduct of research in emergency situations. It may further account for research into pandemics like Ebola, the Corona Virus, etc., where compliance with the strict rules of research may produce undesired outcomes. The theory, therefore, in general, better accounts for why deviations from certain principles could be justifiable, if it promotes the best utility (this is of course within the constraints that the theory does not accommodate respect for human rights).

The theory may also better account for how researchers might respond to demands by law enforcement agencies to reveal law-breaking activities revealed to the researcher by the research participant. A utilitarian might respond to the demand by opting for what will yield the best consequences, even if it means refusing to disclose the information.

Despite the strengths above there are notable weaknesses. One of the theory's weaknesses is that it does not properly account for how the actors must protect human rights.[351] In the context of health research this has far-reaching implications. If this theory were to be used in isolation, the researchers and other stakeholders could easily violate human rights, for example, the right to privacy. Despite possibilities that the theory may be formulated in a language that takes care of rights if such rights protection produces good this does not satisfactorily address the concern that the theory's mode of thought puts rights protection at risk.[352] Equally, the theory may not properly account for why respect for autonomy, including respect for informed consent,

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350 Definis-Gojanovic M *Truth-telling in Medicine: Medical Humanities IV* (2014-2015). https://www.powershow.com/view4/75df3b/Mjc0m/Truth-telling_in_Medicine_ppt_powerpoint_presentation (Accessed 31 July 2020).

351 Rachels J and Rachels S *The elements of moral philosophy* 6th ed (McGraw-Hill New York 2010) 112.

352 For the possibility of the theory's formulation in a rights language, also see Sinnot-Amstrong https://plato.stanford.edu/entries/consequentialism/ (Accessed 6 August 2020).

would be necessary, more so if this does not bring the best utility. Its justification and motivation for why people must act justly may also be weak: bringing happiness to many people does not necessarily equate to acting justly.[353]

The theory's supposed objectivity, and therefore disconnect from the actor, also means that the qualities of the actor are irrelevant.[354] In the context of health research, where qualities of a researcher like suitable qualifications, expertise and experience are critical, this theory may be found wanting. The theory's only focus on consequences further makes the theory reductionist and therefore rendering it an incomplete theory. Both the principles, as provided for by deontology, and traits of character, as provided for by virtue ethics, are important in the assessment of the moral worthiness of a researcher. It is also unclear, in the utilitarian theory, how the relationship and obligations amongst different stakeholders in health research should be.

As simple utilitarian calculation could lead to abuses of the principle itself. In the absence of checks and balances, a need for a PLA seems better as it brings with it (constitutional) principles of accountability and transparency. The requirements of proportionality, as implied in human-rights based approaches may therefore help mitigate against any possible excesses brought about by the theory. An alternative theory is also necessary to cure the theory's incompleteness.

3.4.2 Deontology

This theory uses, as its starting point, principles and duties.[355] Kantianism, a version propounded by Immanuel Kant, one of its leading proponents, is one of its popular versions.[356] Kantianism's approach to compliance with duties and principles is very strict (absolute), and therefore allowing for very few, if any, exceptions. This is in line with Kant's principle of the categorical imperative.[357]

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353 Rachels and Rachels *The elements of moral philosophy* 111.

354 Pence G "Virtue Theory'' in Singer P (ed) *A companion to ethics* (Blackwell Publishing Oxford 1991) 252.

355 O'Neill O "Kantian Ethics'' in in Singer P (ed) *A companion to ethics* (Blackwell Publishing Oxford 1991) 176.

356 O'Neill *Kantian Ethics* 175.

357 O'Neill *Kantian Ethics* 176.

The principle of the categorical imperative argues for the universality of principles, meaning that if a person develops a particular principle for others, he must also intend (will) that such a principle (maxim) apply to him too.[358] This speaks to consistency of principles. He also developed the principle of respect for persons, in terms of which a person should not be used only (simply) as a means to an end, but also as an end himself or herself.[359] This principle is in contrast to utilitarianism, which allows for good ends to justify the means used.

The deontological theory may be summed up as follows:

Firstly, it claims that an action is right if the actor complies with certain duties and principles, and wrong if the actor fails to comply with such duties and principles. Secondly, the theory claims that the duty or principle a person adopts must be universal. Thirdly, it claims that a person should not be used only as a means to an end but also as an end itself. Lastly, the theory is *a priori* and relies exclusively on pure reason, rather than on empirical facts.[360]

A deontological approach is more consistent with human rights protection. This is very helpful in the context of health research. The theory's principle of respect for persons, of which the principle of autonomy and the latter's associated principle of informed consent are part, has already formed the building blocks of bioethics.

The theory has, however, notable weaknesses as well. The theory, despite being more consistent with human rights protection, tends more towards individual human rights protection than a collective approach. Its rigid approach to compliance with duties and principles also makes it difficult to be responsive to a variety of contexts.[361] A rigid approach may therefore make it difficult for the creation of exceptions that may make it possible to conduct research during public health emergencies like Ebola or COVID

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358 O'Neill *Kantian Ethics* 177.

359 O'Neill *Kantian Ethics* 178. Maswanganyi JV "Gender testing connected to sporting events: an examination of some legal and ethical issues" in Delener NJ, Fuxman L, Lu FV and Rodrigues S (eds) *Exploring the possibilities for sustainable future growth in business and technology management. Seventeenth Annual Conference Readings Book Peniche/Lisbon, Portugal July 7th – 11th, 2015* (Global Business and Technology Association New York 2015) 435. As indicated in chapter 1, the principle of respect for persons could also be understood as just another, but less strict, version of the principle of categorical imperative, with the principle of universal law being the stricter version.

360 Russel B "A *priori* justification and knowledge'' 2020 Stanford *Encyclopaedia of Philosophy.* https://plato.stanford.edu/entries/apriori/ (Accessed 6 August 2020).

361 O'Neill *Kantian Ethics* 182.

19, where certain rules may need to be relaxed to fit the context of the study. Its inflexibility may further make it difficult to accommodate vulnerabilities from research participants like children and women, including those who might be displaced.

The theory further has difficulties in resolving conflict of principles and duties.[362] In fact the theory has no clear, if any, mechanism of doing so. For example, in the case of research into pandemics like COVID19, the theory could face difficulties as to whether the focus should be on the protection of privacy, as against the protection of life, to which research of the pandemic might lead. Related to this, is the theory's inability to deal with conflict of principles arising from instances where law enforcement agencies demand that researchers reveal what they came across while interviewing a research participant. They might not know whether to respect the principles of privacy or being law-abiding researchers.

Just like utilitarianism, deontology's claim to objectivity and disconnection from the agent of the action renders the theory inappropriate in instances where the agent's qualities are relevant.[363] As indicated in the case of utilitarianism, this makes the theory deficient in the health research context, where the qualities of the researcher, including qualifications and appropriate experience, are necessary.

The theory's only focus on actions, and its exclusive reliance on adherence to principles and duties, further makes it reductionist and therefore an incomplete theory. In the context of health research an assessment of consequences of the actions and the trait of character of the researcher may sometimes be necessary. The theory could further be said to be reductionist in its exclusive reliance on *a priori* facts and pure reason. While these aspects may be important in the assessment of the conduct of a researcher, they are not enough. Empirical facts may also be crucial in the assessment of the conduct of the researcher.

Deontology's lack of emphasis on a collective approach to human rights, its inflexibility, its incompleteness and its inability to provide a mechanism for conflicting principles and duties may be cured by a PLA.

3.4.3 Virtue ethics

362 O'Neill *Kantian Ethics* 182.
363 Pence *Virtue theory* 252.

The virtue ethical theory takes the agent of an action as its starting and focal point. Instead of focusing on the actions of a person, it focuses on that person's character trait.[364] Once the person's character is good, the theory takes it for granted that the actions of the person are also good, without having to examine the actions. The theory's main claim is therefore that a virtuous person is, by reason of being virtuous alone, a virtuous actor. The theory's leading early proponents include Greek philosophers Aristotle, Plato and Socrates.[365] Its modern proponents include MacIntyre and Anscombe.[366]

The theory provides a plausible account for why people act in a particular way (this has generally been referred to as moral motivation).[367] The theory further provides a plausible account for justified partiality i.e. why people act partially towards other people.[368] This can be important in the case of health research, as it may properly account for why a researcher has to conduct himself or herself differently towards persons with whom the researcher has a professional relationship, namely the research participants.

The theory's focus on traits of character, which implies habituality, rather than a focus on a single act or event, also suggests that the theory is comparatively more holistic in scope than both utilitarianism and deontology, and other competing theories like the social contract tradition. In the context of health research this means that it may not be enough that a particular researcher acted honestly in relation to a particular event, but that the researcher has a general disposition towards acting honestly most of the time.

The theory is however weak in guiding actions.[369] In other words the theory cannot tell us as to when specific virtues become applicable.[370] In the health research context a

364 Rachels and Rachels *The elements of moral philosophy* 160.
365 Pence *Virtue theory* 251.
366 Pence *Virtue theory* 250.
367 Rachels and Rachels *The elements of moral philosophy* 168.
368 Rachels and Rachels *The elements of moral philosophy* 169.
369 This problem (of poor action guidance) could of course be cured by formulating the specific virtues on terms that allow for the virtues to define an action. One should note for example Aristotle's formulation of the virtue of justice (or what he sometimes refers to as a principle of justice) this way. Note, particularly, reference to 'just acts' and 'just deeds' in Aristotle *The art of rhetoric* (Translated from original Greek, with introduction and notes, by Lawson-Trancred HC) (Penguin Books London 2004) 124 - 126.
370 Rachels and Rachels *The elements of moral philosophy* 171.

researcher might, for example, know that there is a virtue of wisdom, but the researcher might not necessarily know as to when such wisdom becomes applicable, nor will the health regulators easily know whether a researcher who has acted in a particular way properly exercised the virtue of wisdom. It may also be difficult, based on this theory, to understand what the nature of the relationship and obligations are, amongst the different stakeholders to health research. The theory may therefore also be considered incomplete based on this aspect alone.

The theory cannot properly resolve conflict of virtues. In the context of health research a researcher might know that there are virtues of honesty and loyalty, but might not know which of the two virtues should take precedence in case of conflict.[371] In the context of health research for example, the researcher might come across falsification of data by a colleague, which might necessitate that such a researcher report the matter to the authorities (including the employer if both are employees of a particular organisation).

Reporting the matter, say to outsiders in case of employees, might undermine the virtue of loyalty to the employer, while not reporting it might undermine the virtue of honesty. The theory might also not properly address problems associated with mandatory disclosures, i.e. where law enforcement agencies demand that research participants disclose information revealed to the researcher by the research participant. The virtuous researcher might not know whether to respect privacy (and the trust the research participant expects from the researcher) or to be honest and comply with the law.

The theory may also be considered reductionist, and therefore making it an incomplete theory also on this ground, for its sole reliance on virtues in its assessment of moral worthiness. While consequences and adherence to principles as preached by utilitarianism and deontology, respectively, are also insufficient when used alone, they are not irrelevant in the assessment of the conduct of researchers towards research participants and other stakeholders, therefore making their absence in virtue theory problematic. The theory's weaknesses, more in particular its reductionist approach

371 Rachels and Rachels *The elements of moral philosophy* 171.

and its inability to provide proper guidance for actions in specific situations could be cured by the development of an alternative theory, as discussed in chapter 9.

3.4.4 The social contract theory

Although the social contract theory has over the years taken various strands, including the strands of *contractarianism* and *contractualism*, the theory mainly seeks to use contractual principles to define people's relations to a particular authority (particularly a state, in the context of political obligations, but the theory has been used to also define other obligations like moral obligations). It seeks to advance the view that when a person is born into a particular state or community, he or she agrees to be bound by the rules of the state or community (the authority). His or her obligations to the authority are therefore based on the existence of such a social contract.

The theory's leading proponents include Thomas Hobbes, John Rawls, John Locke and Jean-Jacques Rousseau.[372] These and other philosophers have had different conceptions about the state of nature and the starting point (initial position, original position, etc.), and even the motivation for the coming into being of a social contract. Just to give a few examples in the case of the state of nature, Rousseau has argued that in the state of nature, men have natural liberty (which is limitless, as opposed to the civil liberty, guided by the general will as espoused in the social contract, which is available in a civil state).

Thomas Hobbes, on the other hand, viewed the state of nature as solitary, chaotic and brute.[373] Though the formulation of the state of nature by the two philosophers may appear different at first sight, they do not differ so fundamentally, except for different

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372 Also see Aristotle's views on the conception of the law, which might be considered to have a (social) contractual leaning. He says: 'Now law is either particular or general. By particular law I mean the written laws in a constitution, and by general I mean those unwritten laws which are held to be agreed by all men' (Aristotle *The Art of Rhetoric* (Translated from original Greek, with introduction and notes, by Lawson Tancred HC (Penguin Books London 2004) 111. He further says: '…and in general the law itself is a kind of contract, so whatever weakens or removes contracts weakens or removes the laws' (See Aristotle *The Art of Rhetoric* 133). Plato and Socrates also, in addition to grounding their obligations to authority on gratitude, also tended towards contractual leaning. This could be inferred from Socrates's dialogue with Crito in Plato's dialogues, where Socrates's failure to escape from the Republic is considered to be some form of consent to the laws of the state (see Plato "Crito'' In Capaldo N, Kelly E &. Navia L E (Eds), *Journeys through Philosophy. A Classical Introduction* (pp.77-83). Revised ed. (New York Prometheus Books 1982) 82.

373 Rachels and Rachels *The elements of moral philosophy* 81.

emphases. The common thread in Rousseau and Hobbes's conception of the state of nature remains that there were no controls in such a state of nature. The motivation for moving out of the state of nature is also not fundamentally different from that of Rousseau. Hobbes reasons that the movement from the state of nature is motivated by self-interest and the need to benefit from the cooperation (with the self-interest being the main reason).[374] Rousseau reasons that movement from the state of nature is motivated by the fact that self-preservation is no longer possible in such a state. Building his argument for a social contract, Rousseau says:

> I assume men arrived at the point where the obstacles impending their preservation in a state of nature prevail, through their resistance, over the forces each individual can deploy to maintain himself in such a state. The primitive state can therefore no longer subsist, and mankind would perish if it did not change its way of being.[375] (Original footnotes omitted.)

Rousseau then further motivates for the mobilisation and aggregation of new forces, which requires that there be 'cooperation of many'.[376] He then seeks to explain the solution to the problem as follows:

> How to find a form of association that will, with the whole common force, defend and protect the person and goods of each associate, and through which each individual, while uniting with all, will nevertheless obey himself alone and remain as free as before? Such is the fundamental problem to which the social contract gives the solution.[377]

One can therefore conclude from the articulation of the position by the two that the motivation for moving from the state of nature in both cases was self-preservation and the need for cooperation (although Rousseau appears to place less emphasis on individual self-preservation). What is, however, not clear from the position by both philosophers is whether the contract contemplated here is an actual (historical) contract, a hypothetical contract or an implicit contract.[378]

The position articulated by John Rawls has a slightly different approach, more especially in relation to the original position, which he considers to be hypothetical. He also considers the movement from the original state to be motivated by rationality (pure reason) rather than self-interest.[379] The position advanced by Rawls therefore

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374 Cudd A and Eftekhari S "Contractarianism'' 2017 *Stanford Encyclopaedia of Philosophy.* https://plato.stanford.edu/entries/contractarianism/ (Accessed 3 August 2020).

375 Rousseau J *Of the Social Contract and Other Political Writings* (Penguin Books London 2012) 19.

376 Rousseau *The Social Contract* 19.

377 Rousseau *The Social Contract* 19.

378 Cudd and Eftekhari https://plato.stanford.edu/entries/contractarianism/ (Accessed 3 August 2020).

379 Cudd and Eftekhari https://plato.stanford.edu/entries/contractarianism/ (Accessed 3 August

represents the contractualist version of the social contract theory while that pursued by Hobbes is that of contractarianism.[380]

The common thread amongst all the social contract theorists, however, remains that the basis for obligations is contractual. Although social contract theories have mainly been developed with political obligations in mind, they are adaptable to other social relations, including moral obligations.

The theory is plausible in clarifying the basis for obligations, but only at a more abstract level. Parties will be obliged because they have agreed to the content of those obligations.[381] This may therefore be helpful in health research, in understanding the nature of their relationship and obligations (though only at an abstract level).

Despite this strength, Thomas Hobbes's notion of an unlimited sovereign[382] could present some difficulties. In case of atrocities committed under the auspices of the state the theory does not appear to provide for proper account on how the sovereign, to whom all the power is given by the contractors, will itself be held liable. This could pose some problems, even in a research context, where the state, which fits the criteria of a sovereign, has committed some atrocities. How will such a state be held liable? In the case of Nazi experiments, where the state was also involved, the theory would not have supported the prosecutions, as the sovereign would not be held liable.

The need for further adaptation may itself present difficulties, and therefore be one of the major weaknesses, given the ambiguity of the theories, even within the sphere of political obligations themselves. It may for example, based on the general requirements of the theory, not be clear as to what the precise content of the obligations, beyond the abstract level, are. The theory therefore does not clarify what to expect in a particular situation, so as to guide not only the conduct of the parties, but also those who must enforce compliance with the arrangements. This could be problematic in a health research context where not only the parties themselves must

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380 Cudd and Eftekhari https://plato.stanford.edu/entries/contractarianism/ (Accessed 3 August 2020).

381 Also see related positions in Rachels and Rachels *The elements of moral philosophy 87.*

382 *Waluchow W "Constitutionalism" 2017 Stanford Encyclopaedia of Philosophy.* https://plato.stanford.edu/entries/constitutionalism/ (Accessed 3 August 2020).

know what to do, but also the regulatory authorities must know as to when to enforce or not to enforce compliance.

The theory is reductionist, and therefore incomplete, for its confinement of solutions for all the problems to contractual arrangements. This may be problematic in health research context where clearly defined rules are required to guide actions. The theory also does not clearly address the 'capacity' (or ability) question, in other words it does not clearly address how those who do not have the capacity to enter into relationships, including children, mentally incapacitated persons and other living species that also need protection, will be protected.[383] This objection will however only be sustained if the contract contemplated is an actual, rather than hypothetical or implicit contract.

The weaknesses associated with the social contract theory, more especially the theory's incompleteness, make the development of an alternative theory necessary.

3.5 Ethical principles

While ethical principles are related to, and mainly derived from, ethical theories, it is necessary to articulate them separately, but only in brief here, as the principles have been covered in detail in chapter one. Some of the principles will be touched on in the subsequent chapters as and when this becomes necessary. Some of the key principles include the four biomedical principles, as espoused by Beauchamp & Childress,[384] namely autonomy, justice, beneficence and non-maleficence.

Other principles, though they could be linked to the four biomedical principles, include principles of informed consent, privacy, confidentiality, social justice, scientific validity, etc. Most of the latter principles are also espoused by Ezekiel Emanuel,[385] while some are found in several instruments by governments, professional bodies and other related bodies. In the main, these principles are not adequate to deal with certain situations including the accommodation of communal interests in research. The PLA seeks to address some of the deficiencies.

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383 Rachels and Rachels *The elements of moral philosophy* 95. See also Cudd and Eftekhari *Contractarianism*.

384 Beauchamp and Childress *Principles of Biomedical Ethics* 38.

385 Emanuel EJ, Wendler D and Grady C "An ethical framework for biomedical research" in Emanuel EJ et al. (eds) *The Oxford Textbook of Clinical Research Ethics* (Oxford University Press New York 2008)123 -135.

3.6 Legal theories

While various legal theories exist, the study here only outlines those theories considered relevant for the questions relating to oversight in health research. The study therefore only focuses on libertarianism, liberalism, socialism, natural law theory, legal positivism and the human rights approach. The study briefly looks at each theory and its implications for the protection of stakeholders in health research.

3.6.1 Libertarianism

This theory advocates for the maximization of individual liberties (or freedoms), and minimization of the role of government.[386] Maximization of freedoms also implies the maximization of the freedom to contract, and minimization of any government intervention to regulate the conduct of parties to contracts. This therefore favours a private law approach as a resolution to problems. One of its leading proponents is Robert Nozick.[387]

One of the theory's notable strengths is that it favours respect for autonomy, and therefore respect for other related principles like privacy and informed consent. In a health research context, the theory could better protect research participants, including their privacy.

The theory, however, also faces some criticism which is that the theory assumes that stakeholders interact from a position of equality (advantage). In fact, even in instances where it is known that they do not come from the same position of equality, libertarianism may still discourage any form of added protection to the participants, more so if the actors are all private persons.[388] In the case of health research, where research participants may be vulnerable, libertarianism may not support added protection mechanisms to the vulnerable participants, because all parties are presumed to be equal, even if their relative inequalities may be inferred from

386 See Wolff J "Libertarianism" in Craig E (ed) *The shorter Routledge encyclopaedia of philosophy* (Routledge London 2005) 576 – 577.

387 Van Der Vossen B "Libertarianism'' 2019 *Stanford Encyclopaedia of Philosophy.* https://plato.stanford.edu/entries/libertarianism/ (Accessed 1 August 2020). Other thinkers who have propounded the idea include Thomas Reid, Immanuel Kant, Richard Taylor and C.A. Campbell (see Curd *Argument and Analysis* 425).

388 Baggini J *Ethics: the big questions* (Quercus London 2012) 103.

circumstances. The theory's pre-occupation with liberty is therefore too narrow to resolve a variety of problems in various contexts.

The theory further assumes that the government is inherently powerful and evil, and the private persons are less likely to be powerful and evil. The theory also overemphasises individualism and individuality at the expense of common goods. The theory's private law emphasis implies that the public interest, even where this is necessary, is treated as irrelevant. In the context of health research this could leave research participants vulnerable to exploitation if the parties are not equal partners.

It further has no clear framework for defining the nature of the relationship and obligations in health research, beyond what is implied that individualism will take a centre stage. The weaknesses associated with the theory necessitate the development of an alternative theory.

3.6.2 Liberalism

Liberalism could take various forms.[389] It could take the form of classical liberalism and modern liberalism.[390] Classical liberalism tends towards a more limited government, and emphasises liberties, including market fundamentalism or economic liberalism.[391] This form of liberalism is closer to, if not the same thing as, libertarianism.[392] Modern liberalism is what is sometimes called welfare liberalism or liberal egalitarianism.[393] Welfare liberalism appears more associated with the ideas of John Rawls while, as pointed out earlier, libertarianism is often associated with the ideas of Robert Nozick.[394] Despite liberalism's varied forms, its main claim is that

389 It should in fact also be noted that it is sometimes difficult to know whether a particular activity constitutes a liberal leaning or not, as the label of liberalism more often than not comes from its opponents (see Waldron J "Liberalism" in Craig E (ed) *The shorter Routledge encyclopaedia of philosophy* (Routledge London 2005) 570 – 576.

390 Heywood A *Politics* 2nd ed (Palgrave Macmillan 2002) 45.

391 Heywood *Politics* 45. Also see Jackson RJ and Jackson D *An Introduction to Political Science: Comparative and World Politics* 4th ed (Prentice Hall Toronto 2003) 162 -165.

392 Also see Wolff *Libertarianism* 576 – 577.

393 Heywood *Politics* 46; further see Gaus G, Courtland SD and Schmidtz D "Liberalism'' 2018 *Encyclopaedia of Philosophy* https://plato.stanford.edu/entries/liberalism/ (Accessed 1 August 2020).

394 The division between Rawls' approach and that of Nozick is very relevant to the way American Constitutionalism should be interpreted, as the Republicans there could, arguably, be viewed as more libertarian, while the Democrats could, arguably, be viewed as more liberal.

freedom is at the centre of an individual, for whose interference there must be justification.[395]

Liberalism's libertarian component may assist in rights protection, including respect for autonomy. This could be helpful to research participants. This, though, could also be used by researchers to demand non-interference by regulators. Its welfare component could assist, though in a limited sense, in protecting vulnerable persons, including research participants, who enter specific relationships with researchers.

Despite some of its notable strengths, the theory's over-emphasis on maximum freedom and suspicion of government interference means that vulnerable persons may generally not be protected. Despite modern liberalism's welfare component, its positive impact remains limited when applied within the broader framework of liberalism, therefore making vulnerable research participants less protected. In other words, it does not go far enough to take positive measures that ensure that the most vulnerable in medical research are protected. In fact, merely maximizing individual freedom is not enough to resolve problems holistically.

Because of the varied strands of liberalism, it is often difficult to know what to expect from the theory, on a day-to-day basis, therefore making it difficult to know what to do in specific situations. The nature of the relationship and obligations amongst the different stakeholders in health research might therefore be rendered unclear. The weaknesses associated with the theory therefore serve as a justificatory basis for the development of an alternative theory.

3.6.3 Socialism

Though socialism has various strands, its popular strand is that advocated by Karl Marx.[396] Marx reduced all problems of society, more especially the working class, to economic determinism, in terms of which he viewed the problems of the working class as the product of economic exploitation by the bourgeoisie or capitalist class.[397] He

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395 Gaus, Courtland and Schmidtz *Liberalism* https://plato.stanford.edu/entries/liberalism/ (Accessed 1 August 2020).

396 Though there is no consensus whether Critical Legal Studies Movement (CLS), a scholarly movement in the US in the 70s, is linked to Marxism or not, one takes the position that it is linked to Marxism. See Van Blerk AE *Jurisprudence: An Introduction* (LexisNexis Durban 1998) 151.

397 Also see Edwards AB "Legal theory'' in Hosten WJ, Edwards AB, Bosman F and Church J *Introduction to South African law and legal theory* 2nd ed (Butterworths Durban 1995) 112.

treated ideology as some form of false consciousness that represented interests of a particular class, being the bourgeoisie.[398]

In relation to law and morality, his claim was therefore that these, alongside ideology, had to be rejected, for being a product of the capitalist economic base structure.[399] He argued for a classless, communist society. The road to communism requires socialism, in which the state shall intervene in the process of economic production.[400] In a communist society law, just like the state on which it is dependent, becomes unnecessary.[401]

Socialism, and Marxism in particular, arguably represents what could be called anti-establishment theories, in other words those theories whose mode of thought is radically different from the existing dominant theories like libertarianism and liberalism. The theory has arguably influenced the development of other anti-establishment theories like the Critical Legal Studies Movement (CLS); Critical Race Theory and feminism.[402]

Marxism's deconstructionist force may assist decision-makers in appreciating the conditions of the most vulnerable in society, therefore igniting a need for the implementation of a mechanism that may assist in the protection of such people, including the implementation of socio-economic rights where necessary. This may be important in the context of health research, where the distorted power-relations between research participants and other stakeholders may be lurking, and therefore requiring the deconstructionist force that socialism, more in particular Marxism, brings with.

One of its notable weaknesses includes the fact that it is reductionist by way of reducing all problems to economic problems. It therefore makes it difficult for the

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398 Edwards *Legal theory* 112 - 113.

399 Wood A "Marx against morality'' in Singer P (ed) *A companion to ethics* (Blackwell Publishing Oxford 1991) 511, 513 & 515; also see Van Blerk *Jurisprudence* 142. Further see Edwards *Legal theory 117 – 121, for* a discussion of Evgeny Pashukanis's commodity exchange theory of law.

400 During this transitional period, law was considered to be necessary (also see Edwards *Legal theory* 114 - 117.

401 Also see Hunter R "Marxism and public law" (2017). https://legalform.blog/2017/10/23/marxism-and-public-law-rob-hunter/ (Accessed 24 February 2022). For Marx's attitude towards law, private property and the state in a communist society also see Marx K *Early Writings* (Translated from original German by Rodney Livingstone and Gregor Benton, with introduction by Lucio Colletti) (Penguin Books London 1992) 58 – 60 and 345 - 358.

402 Also see Edwards *Legal theory* 145.

theory to account for other types of problems. Although economic problems are not irrelevant defining most, if not all, problems along these lines may be unhelpful in the context of health research. It further overemphasises communalism at the expense of individuality. Related to this is Marxism's rejection of rights. This may have negative implications in health research context where rights, including respect for autonomy, is also important. In its hard version, socialism is also too idealistic, therefore making it difficult to apply the theory to the day-to-day problems encountered in health research. It is therefore also difficult to define the nature of the relationship and obligations amongst the various stakeholders in health research. The deficiencies identified in relation to socialism call for the development of an alternative theory.

3.6.4 Natural law theory

The natural law theory is 'ought to'-based. Its starting point is what the law ought to be, meaning what the law ought to be then becomes the law. Natural law theory therefore appeals to morality for its existence.[403] This law, more especially in the Ancient Greek period was, it appears, considered a higher law (which Aristotle referred to as general laws) capable of overriding man-made laws (which he referred to as particular laws).[404]

One of natural law theory's notable strengths includes the fact that it is consistent with human rights thinking and constitutionalism in general. In the context of health research, the theory may therefore be useful in the protection of relevant stakeholders. On a related point, the theory has been used by some, including philosophers like Rousseau, to fight oppression.[405] The theory may therefore appeal to those engaged in health research to protect research participants. The theory provides a simple and comprehensible moral motivation for the compliance with obligations. The theory may also provide a better response in instances of mandatory disclosures. In other words,

403 Heywood *Politics* 302.

404 See for example, Aristotle's approach to this. He says: "If the written law is contrary to our position, we must use the general law and principles of greater equity and justice, and claim that this is the meaning of the 'to the best judgement' principle, that the juror should always follow the written laws, that equity is permanently valid and never changes, nor does the general law (for it is natural), whereas the written laws often do,...' (See Aristotle *The Art of Rhetoric* 130). Further see Aristotle "Book Five" in Griffiths T (ed) *The Nicomachean ethics* (Translated from the original Greek by Rackham H) (Wordsworth Classics Hertfordshire 1996) 126 -127, in what also appears to be his conception of natural law.

405 Rousseau J *Of the social contract and other political writings* (translated from original French by Hoare Q (Penguin Books London 2012) 23-27.

because of its recognition of law's moral base, the theory may provide for a better account for why researchers may refuse to disclose information revealed by research participants, if such a revelation is considered immoral.

One of the theory's shortcomings, however, lies in its character of being a double-edged sword.[406] Related to this point is the fact that its precise content is not clear, therefore making its implementation difficult. The theory is, as happened in the past, vulnerable to being abused. For example, natural law theories have been used to justify slavery and oppression of women.[407] With this line of thought, the theory might not properly account for the protection of other vulnerable persons like children, including those displaced.

In a health research context, it may also happen that those who appeal to this theory might ill-treat homosexuals, on the pretext that what the latter do is not, according to the perpetrator of the ill-treatment, consistent with nature. With lack of precise content about what is expected under natural law, the relationship and obligations amongst the various stakeholders in health research might also not be clearly defined.

The theory, by only grounding all solutions on appeal to nature, is reductionist and therefore incomplete. Related to this is the fact that other philosophers have regarded the appeal to nature as a commission of naturalistic fallacy, i.e. deriving moral conclusions purely out of nature or making an unjustified or irrelevant appeal to nature, to ground one's argument. It is therefore considered problematic to make moral judgements from (non-moral) facts.[408]

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406 See Van Blerk AE *Jurisprudence: An Introduction* (LexisNexis Durban 1998) 2, who shows how natural law theory has both created enabling ground for revolutions and conservatism alike. This problem, in one's view, results from the abstract, less action-guiding nature of the theory.

407 Also see the position by Aristotle, whose views on women was also no better off, who justified slavery on natural law ground (see Aristotle *Politics* (Translated from the original Greek by Jewett B) (Dover Publications New York 2000) 32. Another leading Greek philosopher, Plato, had also arguably supported slavery, and his position on equality in general was a bit dubious by modern standards (see Plato *The Laws* (Translated from the original Greek by Saunders TJ) (Penguin Books London 1970) 410. With regard to equality Plato, calling it 'strict justice' says this: 'He must always make justice his aim, and this is precisely as we've described it: it consists of granting the 'equality' that unequals (sic) deserve to get' (Plato *The Laws* 184).

408 For further information about 'naturalistic fallacy', see Duncan I *Rights* (Acumen Stockfield 2008) 39. Further see Pigden CR "Naturalism" in Singer P (ed) *A companion to ethics* (Blackwell Publishing Oxford 1991) 422 & 423.

One of the requirements of natural law, according to some of its leading proponents, including Plato and Cicero, is that it is unchanging and eternal.[409] If this is taken to be the case, it means that it is not capable, or at least not easily capable, of being adapted to new situations. Given the weaknesses identified above, the development if an alternative theory may be called for.

3.6.5 Legal positivism

Legal positivism cannot be understood in isolation from positivism, which Heywood[410] defines as "the theory that social and indeed all forms of enquiry should adhere strictly to the methods of the natural sciences". Adhering 'to the methods of the natural sciences' implies treating law as hard facts, devoid of moral properties.[411] Heywood's definition of positive law captures this point, and what appears to be the concept of legal positivism.[412] Heywood defines positive law as "a system of enforceable commands that operates (sic) irrespective of their moral content".[413] Its main claim is therefore that moral worthiness is irrelevant in determining law's validity.

The theory may serve as a good action guide and therefore close the loopholes often left by the usually broad-ended frameworks like natural law theory. The theory may also provide a simple (and critics might call it a simplistic) response to the question of why persons must abide by the law, namely that they must do so because it is law, irrespective of its moral worthiness. The theory may also provide proper guidance on the nature of the relationship and obligations amongst the various stakeholders in health research.

The theory has some notable weaknesses. In the sphere of interpretation the theory has led to a very narrow approach to interpretation, with adherents to this theory taking a more literal approach to interpretation than a purposive approach.[414] This may present difficulties to vulnerable stakeholders in health research, who may require a line of interpretation that is holistic, and therefore taking their plight into account.

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409 Buckle S "'Natural law'' in Singer P (ed) *A companion to ethics* (Blackwell Publishing Oxford 1991) 162 & 164.

410 Heywood *Politics* 429.

411 Legal positivism's starting point therefore is 'what is' the law, rather than 'what ought to be' the law, a departure from the more, ought-based, naturalistic thinking about the law.

412 Heywood *Politics* 429.

413 Heywood *Politics* 429. Also see Heywood *Politics* 302.

414 Botha C *Statutory Interpretation*: *an introduction for students* 5th ed (Juta Cape Town 2012) 92.

The theory's conception that law must be made by a sovereign body could imply that the sovereign body is not bound by such a law, a line of thought arguably pursued by John Austin.[415] If this is the case, it might be difficult for the theory to hold the executive and other bodies which might fit the criteria of a sovereign, accountable, more especially where research atrocities may have occurred under their control.

Its rigid and narrow conception approach may also, overall be inconsistent with constitutionalism, at least in the South African sense. Its undermining of the moral content of the law might also not be very useful in the protection of participants in health research. This conception of the law might in general also make the theory unresponsive to grave injustices. Nazi law would, for example, have been respected, despite that such a law would in substance not have been a law. John Dugard has this to say about such a law:

> Radbruch had been dismissed from his professional post at the University of Heidelberg by the Nazis, and after the war argued that Hitler's laws had failed to qualify as 'law' at all because they violated fundamental principles upon which legal norms are based. Law was not simply a cluster of legal rules and principles to be given to a given factual situation, as I had been taught at Stellenbosch. Radbruch taught that there were higher norms by which the validity of laws was to be evaluated and weaknesses measured.[416]

The theory's notable weaknesses call for the development of an alternative theory to cure some of the defects.

3.6.6 A human rights approach

This approach in the main requires that a person's rights (justified claims),[417] whenever available to that person, must be respected. As indicated above, there is some historical relationship between the human rights approach to law and the natural law theory. The human rights approach could take dual, and even multiple, dimensions:

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415 Waluchow W *"Constitutionalism" 2017 Stanford Encyclopaedia of Philosophy.* https://plato.stanford.edu/entries/constitutionalism/ (Accessed 3 August 2020). Further see Wacks R *Philosophy of law: a very short introduction* (Oxford University Press New York 2006) 25.

416 Dugard J *Confronting apartheid: A personal history of South Africa, Namibia and Palestine* (Jacana Pretoria 2018) 12. Dugard then continues to make the same observation about Apartheid laws.

417 This is not intended to provide a full analysis of the concept of rights. For a full analysis see Campbell K "Legal rights" 2017 *Encyclopaedia of Philosophy.* https://plato.stanford.edu/entries/legal-rights/ (Accessed 5 August 2020).

individualist, collective, hybrid or even pluralist (in the sense of having elements of the various approaches) shapes.

The human rights approaches envisaged in the American and French historical human rights instruments, namely the American Declaration of Independence and Declaration of the Rights of Man and of the Citizen respectively, took a more individualist shape, with a focus more on the negative protection of rights, and only a limited number of these rights was included in these instruments.[418] The rights protected this way have come to be known as negative rights or first generation rights.

The post-World War II era instruments, more especially international instruments, included positive rights (second generation rights) in addition to the negative rights. Second generation rights mainly consist of socio-economic rights, as opposed to first generation rights that mainly comprise civil and political rights.[419] The South African constitution not only includes first- and second-generation rights, but also includes what has come to be known as third generation rights. Third generation rights include rights relating to the protection of the environment.[420]

What is important in the case of the South African human rights framework is that all the three categories of rights are justiciable. These rights, in the main, also apply horizontally. Due to the problem inherent in making clearly definable social categories of ideas, it is difficult to pigeonhole the South African Constitution in any single ideological category.[421] It is perhaps safe to say it is pluralist (or, depending on the angle from which one looks at it, at least hybrid), i.e. some sort of a social cocktail containing some elements of libertarianism, liberalism and social democratic ideals.[422]

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418 Almond B ''Rights'' in Singer P (ed) *A companion to ethics* (Blackwell Publishing Oxford 1991) 260.

419 CDDRL *Second and Third Generation Rights in Africa*. https://cddrl.fsi.stanford.edu/research/second_and_third_generation_rights_Africa (Accessed 3 August 2020). Also See *Second Generation of Human Rights.* https://humanrights.fandom.com/wiki/Second_Generation_of_Human_Rights (Accessed 3 August 2020).

420 CDDRL https://cddrl.fsi.stanford.edu/research/second_and_third_generation_rights_Africa (Accessed 3 August 2020).

421 Also see Karl Klare's observation about such a difficulty (Klare KE "Legal culture and Transformative Constitutionalism" 1998 *SAJHR* 146 – 188).

422 One will therefore when discussing this aspect, unless the context indicates otherwise, use the concepts of hybridity and plurality interchangeably despite that they do not, outside this context, mean the same thing.

Some authors have considered the South African human rights framework as falling within the liberal framework.[423]

Although, as indicated above, the different instruments may cover a wide variety of rights the general tendency, whenever there is a talk of human rights, is the apparent overemphasis on the individualist conception of rights.

As to the strengths of the theory, as the name itself suggests, the theory is very plausible in the protection of human rights. In the context of health research this becomes very useful in the protection of the autonomy of research participants. The theory is also very good as an action guide, and therefore enabling stakeholders to health research to know what to do in specific situations. The theory also does provide a clear guidance on the nature of the obligations that stakeholders in health research have.

Some notable objections to the theory exist. As the theory does not concern itself with a person's trait of character, but on the person's actions, this becomes problematic in health research contexts where the qualities of a researcher, including qualifications, experience and expertise are relevant. An individualist orientation of rights may also, sometimes, not adequately address situations where a collective approach is necessary. For example, a research participant in a research dealing with abortion issues may be free in terms of the human rights framework to abort without consulting the husband, but the decision does also have an impact on the husband. An individualist orientation of rights might further, if used in isolation, not adequately protect vulnerable research participants. Unless public interest is infused into the thinking, the rights framework further might not provide a better response as to what should happen in instances of mandatory disclosures, where law enforcement officers demand disclosure of information revealed by research participants during research.

Although the human rights approach does go a long way in the protection of the rights of research participant, it is not enough when used alone. This therefore necessitates

423 Modiri JM "Law's Poverty'' 2015 *PER/PELJ* 224 – 273. Also see Sibanda S "Not purpose-made! Transformative Constitutionalism, post-independence constitutionalism and the struggle to eradicate poverty" 2011 *Stell LR* 482 – 500.

the development of a more comprehensive theory that will address some of the shortcomings of the approach and other theories discussed above.

3.7 Some key legal principles

Just like in the case of ethical theories, there are also notable legal principles, some of which could be derived from some legal theories. Some of these legal principles will no doubt overlap with the ethical principles discussed above. Because of the difficulty in outlining most of the relevant principles here, they will be discussed as and when it becomes necessary in specific contexts within different chapters.

For the purposes of this chapter it suffices to simply outline these principles in broad terms: These include constitutional principles; common law contractual principles; common law delictual principles; administrative law principles (including those under PAJA and under the principle of legality). As earlier indicated, the specific principles will be dealt with in specific chapters. Apart from the common law principles most of the principles above have not yet found application in case law dealing with health research. A PLA proposed in this thesis seeks to address some of these deficiencies.

3.8 Conclusion

The chapter looked at the various theories and where necessary some principles, both in law and ethics, relevant to health research. One has, in the process, observed the general tendency of most of the traditional theories to be reductionist, i.e. reducing a complex problem to a single phenomenon. For example: utilitarianism reduces all problems and solutions to consequences while deontology, and Kantianism in particular, reduces all problems and solutions to a categorical respect for duties and principles. Virtue theory does the same and reduces all problems and solutions to virtues and their opposite, vices. Social contractual theories reduce everything to agreements.

Natural law theorists reduce everything to what accords with nature, while Marxism reduces everything to economics. Rights theories reduce everything to compliance with rights. Libertarianism and liberalism’s pre-occupation with individual freedom is also not enough to resolve problems in a variety of contexts. In the case of legal positivism, though its approach is not necessarily reductionist, its approach in general is too rigid to accommodate a variety of contexts.

In the sphere of the limits of law (at least in so far as the regulation or enforcement of morality is concerned), Stuart Mill's harm principle also reduces the solution to the prevention of harm to others, while Joel Feinberg's offense principle reduces the solution to offence to others.

The theories and principles discussed above do not themselves, when used individually, therefore adequately deal with some of the common biomedical problems. This inadequacy needs to be cured. It is this gap that the PLA, which is a cluster of principles, accommodating some of the principles above, seeks to close. The next chapter discusses the South African law and other regulatory frameworks.

CHAPTER FOUR: THE SOUTH AFRICAN LEGAL FRAMEWORK REGULATING HEALTH RESEARCH

4.1 Introduction

The preceding chapter dealt with the theoretical foundations of health research, both from the point of view of law and ethics. This chapter looks at the South African law dealing with health research. It further looks at ethical codes, i.e. ethical principles and rules found in specific instruments which though not necessarily having the force of law, provide the same guidance as legal instruments. The approach that this legal and ethical framework adopts, and the adequacy of this framework in handling health research problems, are looked at. A discussion of South African law revolves around the key sources of law namely the common law, legislation, case law and the Constitution. A discussion of ethical instruments revolves around national instruments developed by government or professional bodies (or where necessary by other relevant bodies).

The chapter starts off with the discussion of the general SA legal framework, and then focus in the main on the protection of children, including displaced children; approaches to human dignity; approaches to equality; approaches to judicial review; the right to health care; approaches to remedies; approaches to information protection and access as well as approaches to research oversight. The chapter ends off with the discussion of SA ethical framework, followed by the conclusion of the chapter.

4.2 South African legal framework

Before the discussion of the various aspects relating to the regulation of health research it is apt to first discuss, in brief, the overarching South African legal framework. South African law is mainly shaped by the South African constitutional framework, under which the Constitution is the supreme law. The Constitution makes provision for several values, including human dignity, equality, promotion of fundamental human rights and freedoms, non-racialism, non-sexism and the supremacy of the Constitution.[424] The principle of constitutional supremacy is a departure from the pre-94 principle of parliamentary supremacy. This has implications

[424] S 1 of the Constitution.

on a variety of aspects, including the interpretative approach, legal standing, appropriate remedies, etc.

The post-94 interpretive approach is largely purposive,[425] while issues of legal standing and appropriate remedies also take a public interest law angle.[426] The equality provision takes both a formal and substantive approach.[427] The Constitution also has horizontal application,[428] in addition to the vertical application. It provides for a general limitation clause, which therefore requires a two-stage approach to rights analysis.[429] The Constitution also expressly provides for, though non-mandatory, the consideration of comparative law and the mandatory consideration of international law in the interpretation of the Bill of the Rights and by implication other instruments like legislation.[430]

This constitutional framework does inform the approaches to a variety of bioethical questions. Following below is then a discussion of the various areas of the law regulating the conduct of health research.

4.2.1 Protection of children

4.2.1.1 Common law

One of the vexing questions around the protection of children is the extent to which the current laws, and the Constitution in particular, protect unborn children. These questions could arise in various contexts, including the context of abortion. In order to resolve this question, one of the oldest common law principles, namely the *nasciturus* fiction (or rule in the case of those who have made some adaptation to this), often comes to the fore. The *nasciturus* fiction, as articulated in *Pinchin v Santam*,[431]

425 This is mandated by s 39 of the Constitution.
426 This can be inferred from ss 38 and 172 of the Constitution, respectively.
427 This can be inferred from s 9(2) which provides for both positive measures to redress the imbalances of the past and the full enjoyment of equality, and s 9 (1), (3) and (4), which provides in the main for formal aspects of equality (or non-discrimination).
428 S 8 of the Constitution.
429 See *S v Makwanyane* 1995 (3) SA 391 (CC) para 100.
430 S 39(1)(b) and (c). This is not necessarily the approach in other jurisdictions like the US. In fact, the US's approach to international law is arguably more cautious, if not sceptical. For example, while South Africa has generally approached international human rights instruments with open arms, the US has been reluctant to ratify some instruments, including the Rome Statute and the UN Convention on the Rights of the Child (in the latter case see Archard DW "Children's Rights" 2018 *Encyclopaedia of Philosophy.* https://plato.stanford.edu/entries/rights-children/ (Accessed 14 February 2021)).
431 *Pinchin v Santam* 1963 (2) SA 254 (W).

provides that an unborn child is only protected if it is born alive, and the child must have been conceived at the time when the benefits being claimed accrued.[432]

What this means is that if the child is not born alive, there is no protection for the child during the period of pregnancy. Related to the line of thought in this principle is that an unborn child lacks legal personality, and therefore cannot be said to have rights, duties or capacities.[433] In other words, the ability to acquire rights, duties and capacities is the basis for the acquisition of legal personality. Legal personality, according to existing law, only begins at birth.[434] Other cases, including the *Christian League of Southern Africa v Rall,*[435] also rejected the claim that an unborn child may acquire rights. In the constitutional era the Court in *Christian Lawyers Association of South Africa v Minister of Health*[436] also held, in the context of a challenge to abortion laws, that an unborn child is not a legal subject capable of acquiring rights.[437] Though

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432 Heaton J *The South African law of persons* 3rd ed (LexisNexis Durban 2009) 12. For further discussion on the status of unborn children, also see Himonga C "Unborn persons'' in Du Bois F (ed) *Wille's principles of South African law* 9th ed (Juta Cape Town 2007) 161 – 164.

433 Heaton *Law of persons* 2.

434 Heaton *Law of persons* 7.

435 *Christian League of Southern Africa v Rall* 1981 (2) SA 821 (O). *Further see* Heaton *Law of persons 23.*

436 *Christian Lawyers Association of South Africa v Minister of Health* 1998 (4) SA 1113 (T).

437 Also see Carstens P and Pearmain D *Foundational Principles of South African medical law* (LexisNexis Durban 2007) 83. The court here appears to take a more positivistic approach to the question whether or not a foetus should be afforded legal protection. Ignoring context in legal interpretation is not consistent with the Constitution's endorsement of purposive approach to interpretation. Focusing on context would have forced the court to enquire into the problem thought to be addressed by the various provisions in the Constitution, more in particular the provision dealing with the protection of children. Why would the Constitution emphasise the protection of children, arguably based on their vulnerability, but be said not to cover the same beings in their earlier stages of development, where they could even be more vulnerable? It is doubtful that this could have been the purpose of the Constitution. The court's illustration of rights that would clearly not apply to a foetus, even if such rights are granted to everyone is a bit misguided: the difficulties of applying such rights could also be faced in the case of a one day old child; as for such a child other rights like the right to freedom of assembly, expression, etc., are also meaningless. The rights of a detained, accused or arrested person will also be meaningless to such a child. Some rights are easier to apply to everyone than others. The right to life is one such a right that applies, or ought to apply, to everyone. Apart from an incorrect interpretation approach the court followed there appears, from the judgement and those supporting this and other related judgments, to exist some fear that if a foetus is recognized as a legal subject, this shall automatically undo the rights that pregnant women are entitled to (see for example, Pickles C "Termination of pregnancy rights and foetal interests in continued existence in South Africa: Choice on Termination of Pregnancy Act 92 of 1996" 2012 *PER/PELJ* 417 and 427, where a suggestion is even made that the recognition of foetus rights would mean that women would not even be allowed to abort even if their lives are at risk, or where there was rape or incest). This line of thought is flawed. If a foetus is recognized its rights shall, just like the rights of any other legal subject, be also limited where necessary. If a woman's health was threatened the foetus's rights have to be limited and the health of the pregnant woman be saved. Where there was rape or incest, this would ordinarily lead to traumatic situations, psychological torture and other problems also impacting on the woman's health. The rights of the foetus will also need to be limited in such a situation. The same may apply where there is a likelihood that the foetus's health

in a criminal law context, the High Court in *S v Mshumpa*[438] also refused to recognise a foetus as a legal subject, by declining to convict of murder persons who killed a foetus.[439] What are the limitations of the *nasciturus* fiction (and other rules built around it)?

The best way to deal with the limitations around the *nasciturus* fiction is to deal with the criteria for the acquisition of legal personality, and therefore broadening the meaning of a legal subject to cover unborn children.[440] The theory around the acquisition of legal personality simply tells us that only those having the ability to acquire rights, duties and capacities qualify. The theory does not, however, tell us why only these criteria should find the basis for the acquisition of legal personality. Nor does the theory tell us what the differences are, based on these criteria, between a child conceived, for example, for nine months but not yet born, and one born a few minutes later. Do these two differ in terms of their abilities to acquire rights, duties and capacities?

These criteria ought to be discarded and the enquiry then becomes, not whether a being can acquire rights, duties and capacities, but whether the being, firstly has a life (whether before or after birth); secondly whether the being is objectively capable of living i.e. capable of having a life (life capability or potential), or is expected to live (expectation of life). The second leg of the enquiry then becomes whether or not this life capability or expectation of life is an interest requiring protection (the last two questions of the second leg of the enquiry may be relevant in dealing with the early

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will be at serious risk. Its rights will need to be limited to protect the foetus and the interest of the woman. In other words, principles of necessity will come to play in such situations. This means that where it is objectively unnecessary for termination of pregnancy to take place (including one based on vague reasons like socio-economic circumstances, more especially taking into account that in South Africa there is assistance for children by the state, including the provision of child grants), the interests of the pregnant woman ought to give way to public and community interests. The best approach to the issue of the protection of the interests of a foetus and those of a pregnant woman must never create a false dilemma. It is possible for the two interests to co-exist.

438 *S v Mshumpa* 2008 (1) SACR 126 (E). Further note *Road Accident Fund v Mtati* [2005] 3 ALL SA 340 (SCA), where the applicant (defendant in the court *a quo*), had raised a special plea that the child born with brain damage was not a person as defined in the Multilateral Motor Vehicle Accident Act 93 of 1989, as the child was injured while not yet born. Both the court *a quo* and the SCA rejected the special plea.

439 Pickles 2012 *PER/PELJ* 426.

440 Historically some forms of unfair discrimination were justified by merely excluding a category of beings from a particular class of protected beings. Slavery, for example, was justified by merely excluding slaves from the category of persons. It therefore required no further justification to enslave those who were not classified as persons.

stages of conception, where technical issues could exist about whether a being is at that stage alive or not, therefore necessitating the question of capability and/or expectation).

If any one of the three questions are answered in the affirmative, it then follows that the unborn child must be protected. This approach then makes the *nasciturus* fiction, and other rules built around it, redundant. It kills the fiction! One could also pose a question: what then is the general principle for the protection of unborn children? If it is accepted that unborn children should be treated the same way as born children, there is no need to have a different principle to protect them. The other principles currently applicable for the rest of the children, more especially the best interest of the child principle, should equally apply in the case of unborn children, with some adaptations required by the context. This approach could be useful in the protection of unborn children in the context of health research involving unborn children or pregnant women.

4.2.1.2 Constitutional framework

One of the most important provisions in the Constitution is one related to the protection of children. Section 28 in particular protects children from neglect, ill-treatment, degradation and abuse.[441] It further provides for a child to access basic health care services.[442] It, most importantly, provides for the best interest of the child to be considered in every decision concerning a child.[443] In the context of health research, questions may arise as to whether the participation of children in research is in the best interest of the child, or whether it is a just a mere exploitation (abuse), neglect, or ill-treatment of the child.

Questions may also be asked whether payment of the research participants as incentives, where the research participants are children, could be in violation of the spirit of these provisions. These questions could become even more important when the children so participating are displaced children, who are usually more vulnerable

441 S 28(1)(d) of the Constitution.
442 S 28(1)(c).
443 S 28(2).

than those not displaced. An answer to these questions will depend on the facts of each case.

4.2.1.3 Legislative framework

Various legislations also provide for the protection of children. One of the most important legislations dealing with the protection of children is the Children's Act 38 of 2005 (the CA).[444] In the main the CA requires that in all activities and decisions concerning a child, the best interests of the child must be at the centre.[445] This principle may therefore also be critical in the protection of children used in health research. The CA further requires the participation of the child in decisions affecting the child, to the extent that the maturity, age and stage of development of the child allows for such participation.[446] In the health research context this creates space for the assent of the child, even when the parent or someone else authorised has given consent to participation in research.

Although the CA does not specifically touch on questions of consent by children to partake in health research, it does specifically provide for the giving of consent by children, as young as 12, to medical treatment, if the child is mature and of mental capacity to appreciate the risks, benefits, social and other related implications of the medical treatment.[447] While it could be argued that these principles should equally

444 Another important legislation is the NHA, which sets out the conditions under which research on minors should be conducted, whether for therapeutic or non-therapeutic purposes (see s 71 (2) and (3)). The NHA is however discussed in detail below, under research oversight.

445 S 9 of the CA. In the context of research, this has been understood to mean the research must not be opposed to '*the individual minor's best interest*' (see para 3.2.2 of the 2015 Ethics in Research).

446 S 10 of the CA.

447 S 129(2) of the CA. A similar provision exists for the child's consent to surgical operation if, in addition to the requirements as prescribed for the consent to medical treatment, the child is also assisted by the parent or guardian (see s 129(3). The parent or guardian of the child is however still required to consent to the child's medical treatment or surgical operation if the child is below 12 or, if above 12, is not sufficiently mature or lacks capacity to appreciate the risks, benefits, social and other related implications of treatment or operation (see s 129(4) and (5)). Further alternative forms of consent, under various circumstances, are provided for, which may be given by the superintendent of a hospital (or a person in charge of the hospital); the court (high court or children's court) or the Minister (see s 129(6), (7), (8) and (9). S 130 provides for a related framework on HIV testing, with changes required by the context. Apart from the CA, one should also note the Choice on Termination of Pregnancy Act 92 of 1996, which grants a minor girl, irrespective of age, the right to terminate pregnancy. Further see Dhai A and McQuoid-Mason D *Bioethics, Human Rights and Health law* (Juta Cape Town 2011) 78. One should further note that the attempt to challenge the constitutionality of allowing a minor girl to consent to abortion was unsuccessful in *Christian Lawyers Association of South Africa v The Minister of Health (Reproductive Alliance as Amicus Curiae)* 2005 (1) SA 509 (T). Further see Heaton *Law of persons 21.*

apply to a child's participation in research the counter argument, which this dissertation supports, is that the implication of participation in health research is more complex to understand than the implication of participating in medical treatment or a surgical operation. In addition, medical treatment or a surgical operation often has more direct benefits to the child than health research, whose benefits are often generalised. It would have been prudent if the legislature had clarified the issue of child participation in research in the CA.

The CA further requires that the rights provided for in s 28 of the Constitution be given effect to.[448] This no doubt further strengthens the protection of children participating in health research against abuse and neglect. The CA also makes provision for reporting obligations by certain persons, including a medical practitioner who works with a child, if they become aware of the child having been abused or neglected deliberately.[449] Although this provision does not expressly include researchers as some of those who must report, there is no doubt that when the researcher also assumes the capacity of those mentioned in the section, e.g. being a medical practitioner or a dentist, the person will be required to report such abuse or neglect.

S 141 of the CA further obliges social workers or social service professionals to report contravention of the Act, e.g. where a child has been used as a child labourer.[450] Along the same line of thought advanced above in the case of reporting obligations about researchers who are also medical practitioners, researchers who also serve as social workers or social service professionals may equally be required to report such contraventions of the Act.[451]

It is regrettable that the section is not formulated in a permissive way to cover even persons who are not directly mentioned in the section. This does not, however,

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448 S 6(2)(a) of the CA. It should be noted that in substance the purpose of the CA as a whole is not just to give effect to s 28 of the Constitution, but also to the rest of the Constitution, more in particular the Bill of Rights. For example, the substance of s 15 of the CA, which takes a public interest approach to the enforcement of children's rights, in the main mirrors s 38 of the Constitution.

449 S 110(1). Also see s 288 of the CA, which has a similar related obligation in the case of persons becoming aware of a child being trafficked.

450 S 141(2). Other legislations providing for reporting obligations meant to protect vulnerable persons include the Criminal Law (Sexual Offences and Related Matters) Amendment Act 32 of 2007 (CLAA), more in particular s 54 thereof.

451 It should be noted that while these reporting obligations have implications on the privacy of the research participants, the obligations could be viewed as promoting public interest.

completely exclude any possibility that researchers, who do not directly fall under the above categories, might be covered. If the provisions are read purposively a possibility exists that covering researchers might not be found to be outside the purpose of that Act.

4.2.1.4 Implications for health research

Most of the general principles outlined above dealing with the protection of children will be of importance to the protection of children participating in health research. Most importantly, the principle of the best interest of the child, and the principle advocating child participation in decisions involving a child, which are generally consistent with the PLA framework contended for in this thesis, will play a key role in the protection of children participating in research.

4.2.1.5 The protection of displaced children

The common law framework dealing with other categories of persons is, with some necessary adaptations, applicable to displaced children (or displaced persons), therefore not meriting a separate focus on that. Regarding the legislative framework, there is no specific legislation dedicated to the protection of displaced children in general, nor is there any in the context of health research. Legislations like the Immigration Act 13 of 2002 and Refugee Act 130 of 1998 (in the case of displaced persons from other countries) do not speak to issues of protection of displaced persons during health research, nor do they even directly deal with questions of displacement in general.[452] Other relevant legislation dealing with other persons may therefore find application. These may include the CA,[453] PEPUDA, the NHA, etc.

In the case of the constitutional framework, though there is no specific constitutional provision dealing with the protection of displaced persons, most of the generic constitutional provisions discussed in this research will become applicable.[454] These

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452 In fact, South Africa is not listed amongst those countries that have specific laws dealing with displaced persons, at least in a direct sense (see Ferris E *Comparative perspectives on laws and policies addressing internal displacement*. https://www.brookings.edu/wp-content/uploads/2016/06/0627_turkey_ferris.pdf Accessed 18 February 2021. For further information around displaced persons, also see *Protecting internally displaced persons: A manual for law and policymakers (2008*). https://www.brookings.edu/wp-content/uploads/2016/06/10_internal_displacement_manual.pdf. Accessed 18 February 2021.

453 The CA may be critical in the protection of displaced persons, including street children.

454 S 28(2) of the Refugee Act even specifically restates the Bill of Rights' applicability to refugees.

include the right to human dignity; children's rights; the right to equality; the right to privacy and the right not to be subjected to medical experiments without consent. It is important to note, however, that the factor of displacement increases the degree of vulnerability, which therefore demands greater protection of children in this category. Researchers may therefore need to adapt the generic principles meant to protect research participants in general, to the situation of a displaced child, with far more additional caution than would apply to those not displaced.

4.2.2 The right to health care services

4.2.2.1 Common law

Under the common law access to health care is mainly governed by the law of contract i.e. the person may demand access to health services if there is a contractual obligation to supply such services. The general principles of delict may also become applicable, but mostly to the extent that they create claims for damages against those who injure a person. Further discussion on the common law is thus unnecessary in this regard.

4.2.2.2 Constitutional framework

S 27(1) and (2) of the Constitution provides for the state to provide health care services to everyone within its available means.[455] The Constitution further entitles everyone to "emergency medical treatment", in the sense of not being refused such.[456] One of the leading cases in emergency medical treatment is the case of *Soobramoney*.[457] In this case the applicant needed dialysis treatment at a state hospital but this was denied; firstly, because dialysis was not an emergency treatment as understood under s 27(3) of the Constitution[458] and secondly, because of the scarcity of resources.[459] The court also emphasised the need to show deference to decisions of political and functional organs in matters of this nature.[460]

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455 S 27(1)(a) and (2) of the Constitution.

456 S 27(3).

457 *Soobramoney v Minister of Health (Kwazulu-Natal)* 1998 (1) SA 765 (CC).

458 *Soobramoney v Minister of Health* paras 13 and 21. The Court instead opined that the claim could be dealt with in terms of the more generic s 27(1) and (2), which provides for the state to provide health care services within the available resources (see *Soobramoney v Minister of Health* para 22).

459 *Soobramoney v Minister of Health* paras 11 and 24.

460 *Soobramoney v Minister of Health* paras 29 - 30.

Another case dealing with access to health care is the *Treatment Action Campaign (No.2),*[461] in terms of which the government was forced to remove restrictions on the roll-out of nevirapine to HIV positive mothers in the public health facilities so as to reduce mother-to-child transmission, in compliance with both ss 27 and 28(1)(c) of the Constitution.[462] The provision is given effect to by the NHA, which is discussed below.

4.2.2.3 Legislative framework

The main legislation giving effect to the right to health care services is the NHA, which particularly gives effect to the constitutional provisions relating to health care services, as provided for in s 27 and the right of children to basic health care services as provided for in s 28(1)(c) of the Constitution.[463] S 5 of the NHA also specifically provides for the right of everyone not to be refused emergency medical treatment. Apart from these more generic provisions the NHA further deals with aspects more directly relevant to the health research context, and these are dealt with in detail under the research oversight discussion below.

4.2.2.4 Implications for health research

What are the implications of the constitutional and legislative provisions relating to the right to health care services and the relevant cases discussed above, in the context of health research? These provisions and the cases can be the basis for the researchers to argue that excluding a particular population from research could be a denial of this right (because it will be difficult for them to access certain services unless their health conditions are properly understood). They could, based on the same provisions, arguably be forced to provide post-research benefits to the population from whom the research participants were selected, a position more consistent with the PLA contemplated in this thesis. In the case of emergency treatment, questions could be asked around the obligations of researchers who are physicians (or health care professionals in general) around this. What are their obligations in case a research participant requires emergency medication, but which does not arise from the conduct

461 *Minister of Health and Others* v *Treatment Action Campaign and Others (No 2)* 2002 (5) SA 721.

462 S 28(1)(c) of the Constitution deals with the rights of children to basic health care services, basic nutrition, shelter and social services.

463 S 2(c) of the NHA, read with the Preamble to the Act.

of the experiment, i.e. it is not a research-related injury? Could this provision then create more obligations than is often the case? It appears that it does.

4.2.3 Judicial review

4.2.3.1 Common law

It is possible that a person might be dissatisfied about a decision taken by a public functionary. Such a person may want the decision to be set aside. Such a decision may then be taken on judicial review.[464] Various routes, which other scholars have called pathways, may be pursued.[465] These include taking the review under the common law; in terms of s 33 of the Constitution; in terms of the principle of legality; under PAJA (which is further discussed in detail below) and in terms of special review provisions under specific legislation.[466]

Before the new constitutional era judicial reviews were mainly, if not only, available through the common law, as part of the superior courts' inherent power.[467] Some of the common law grounds, which are in the main built around the principle of *ultra vires*, were articulated in the early years in *Johannesburg Consolidated Investment Co v Johannesburg Town Council*.[468] Such grounds included non-compliance with a statute; manifest illegality and gross irregularity.[469] One should also add here that non-compliance with the principles of natural justice, including the *audi alteram partem* and *nemo iudex* principles, is also a common law ground of review.[470] The former requires

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464 For the concept of judicial review, see Hoexter C *Administrative law in South Africa* 2nd ed (Juta Cape Town 2012) 113.

465 Hoexter *Administrative law* 113.

466 Hoexter *Administrative law* 113.

467 Hoexter *Administrative law* 115.

468 *Johannesburg Consolidated Investment Co v Johannesburg Town Council* 1903 TS 111. Also see Hoexter *Administrative law* 112 and 115.

469 Hoexter *Administrative law* 115.

470 See also Devenish GE *Interpretation of Statutes* (Juta Cape Town 1992) 179. The concern however, about the applicability of the principle (at least in so far as the *audi alteram partem* rule was concerned) was that the principle could be dispensed with if the legislative intent clearly so stated (Devenish *Interpretation of Statutes* 179). The Appellate Division (AD) in *South African Defence and Aid Fund & Another v Minister of Justice* 1967 (1) SA 263 (A) even went further and held that the principle may only apply if it is implied by legislation (see Devenish *Interpretation of Statutes* 180). However, the Court in *Attorney-General, Eastern Cape v Blom & Others* 1988 (4) SA 645 (A) arrived at a contrary conclusion, namely that where a decision under a statute affects a person's liberty or property, the principles of natural justice apply unless they are excluded expressly or by implication in the statute (Devenish *Interpretation of Statutes* 181). A further limitation to the application of the principle of natural justice was that it was said to be not applicable where the relationship was governed by contractual principles. This was the position in *Sibanyoni & Others v University of Fort Hare* 1985 (1) SA 19 (C).

that both sides of the story (of the disputing parties) be heard while the latter prohibits a person from presiding over a matter in which that person has an interest.

4.2.3.2 Constitutional framework

In the new constitutional era judicial review is now governed by the Constitution, with the rest of the sources of law, including the common law, then shaped by the Constitution.[471] Direct reliance on the Constitution is mainly through ss 33 and 1(1).[472] As indicated earlier PAJA, which is designed to give effect to s 33 of the Constitution, also has its own grounds upon which judicial review may be pursued. PAJA is discussed separately below under legislation.

Some reflection on the principle of legality is necessary here. The principle of legality is part of the constitutional principle of the rule of law.[473] The principle has mainly been used to challenge exercises of public power, including a challenge to own decision,[474] where PAJA is not applicable. The Constitutional Court has said in this regard:

However, the AD in *Administrator, Transvaal and Others v Zenzile and Others* 1991 (1) SA 21 (A) reached a slightly different conclusion, arguably partly on the fact that in this case the statute, the Public Service Act, which was also applicable to the relationship did not, whether expressly or by implication, exclude the principles of natural justice (Also see Devenish *Interpretation of Statutes* 183). In *Lunt v University of Cape Town* 1989 (2) SA 438 (C), the court also held that the fact that a relationship was governed by contract did not exclude the application of the *audi alteram partem* principle (Devenish *Interpretation of Statutes* 183; also see a related discussion in Van Zweel M "The relationship between PAJA and the Labour Relations Act with specific reference to CHIRWA v TRANSNET LTD & OTHERS [2008] 2 BLLR 97 (CC) (LLM Thesis North - West University 2008) 6 - 10). Another problematic nature about the application of the rule is that in *Maluleke v Minster of Internal Affairs* 1981 (1) SA 707 (B) it was said that the rule did not apply to aliens, as it was not applicable to those who, like aliens, did not have rights under the doctrine, at least under the Bophuthatswana Aliens and Travellers Act 22 of 1979, a statute apparently inconsistent with the Bophuthatswana Constitution at the time (see Devenish *Interpretation of Statutes* 183).

471 *Pharmaceutical Manufacturers Association of South Africa and Another: In re Ex Parte President of the Republic of South Africa and Others* 2000 (2) SA 674 (CC) para 44.

472 S 33 of the Constitution deals with the right to a fair, lawful and reasonable administrative action as well as the right to be supplied with written reasons upon request. S 1(c) of the Constitution provides for the constitutional value of the rule of law (alongside that of constitutional supremacy). It is this rule of law that has given rise to the principle of legality, which has been relied on as a ground of review in those instances where PAJA cannot be relied on (see Hoexter *Administrative law* 123 - 125).

473 Also see Price A "Rationality review of legislation and executive powers: Poverty Alleviation Network and Albutt'' 2010 *SALJ* 581.

474 For a challenge to own decision, or for what has come to be called self-review, see *Altech Radio Holdings (Pty) Limited and Others v City of Tshwane Metropolitan Municipality* (1104/2019) [2020] ZASCA (5 October 2020), where the City of Tshwane sought to challenge its own earlier decision, though its attempts were unsuccessful as the High Court decision that ruled in its favour was, on the facts of the case, overturned on appeal. Further see *State Information Technology Agency SOC Limited* 2018 (2) SA 23 (CC) paras 38 - 41, where the

> It seems central to the conception of our constitutional order that the Legislature and Executive in every sphere are constrained by the principle that they may exercise no power and perform no function beyond that conferred upon them by law. At least in this sense, then, the principle of legality is implied within the terms of the Interim Constitution. Whether the principle of the rule of law has greater content than the principle of legality is not necessary for us to decide here. We need merely hold that fundamental to the Interim Constitution is the principle of legality.[475]

The principle (or test) of rationality has been very central in defining the principle of legality. The principle of rationality requires that the exercise of power (or the taking of decisions) "be rationally related to the purpose for which the power was conferred".[476]

4.2.3.3 Legislative framework

As indicated earlier, the main legislation giving effect to s 33 of the Constitution is PAJA. PAJA creates, or at least affirms, several constitutional principles. Apart from the constitutional principles of reasonableness, lawfulness, procedural fairness and the right to be given reasons, PAJA also seeks to promote the values of accountability, openness and transparency.[477]

The principles of reasonableness, lawfulness, procedural fairness and the right to be given reasons exist in relation to an administrative action. The concept of administrative action, which has been the subject of judicial focus, therefore requires some brief reflection. An administrative action is in substance a decision or omission to take a decision, by a decision-maker in terms of a particular governing legal framework, when such a decision or failure to take the decision 'adversely affects the rights' of persons and 'has a direct, external legal effect'.[478] The governing legal framework in terms of which the decision could be taken could be the Constitution, a provincial constitution, legislation, or an agreement, etc.

PAJA provides for three dimensions to the definition: firstly when organs of state exercise 'power in terms of the Constitution or a provincial constitution';[479] secondly when organs of state exercise public power or perform public function in terms of

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court held that a review of own decision by an organ of state is permissible, though this should be pursued under the principle of legality rather than under PAJA.

475 *Fedsure Life Assurance Ltd and Others v Greater Johannesburg Transitional Metropolitan Council and Others* 1999 (1) SA 374 (CC) para 58.

476 *Democratic Alliance v President of South Africa and Others* 2013 (1) SA 248 (CC) para 27. Further see *Albutt v Centre for the Study of Violence and Reconciliation and Others* 2010 (3) SA 293 (CC).

477 The Preamble to PAJA.

478 S 1 of PAJA.

479 S 1(a)(i).

legislation[480] and thirdly when any other person, including a natural person and a juristic person, exercises public power or performs a public function in terms of an empowering provision.[481] It is implicit from the definition that the decision-maker must at least be exercising public power.

One is however, of the opinion that even private power, if such power has the same effect comparable to public power, must also be included in the definition. To do otherwise makes the definition unduly limiting to s 33 of the Constitution, therefore exposing PAJA to potential unconstitutionality. It has thus been left to the courts to creatively deal with the problem of the narrowness of the definition by using the various routes, as discussed earlier, available for judicial review, namely the common law, the principle of legality, special statutory review, and direct reliance on s 33 of the Constitution.[482] The courts may also cure this problem by, as required by s 39 of the Constitution, interpreting PAJA in consistence with s 33 of the Constitution.[483]

PAJA provides for various grounds of review, some of which overlap. The most important of these grounds include non-compliance with a mandatory and material condition and procedure;[484] absence of authority (including improper delegation);[485] bias on the part of the decision-maker;[486] procedural unfairness;[487] material error of law;[488] wrong, irrelevant or arbitrary reason;[489] illegality;[490] irrationality;[491] failure to

480 S 1(a)(ii).
481 S 1(b) of PAJA. The first two of the dimensions are often not contentious, except in those instances where, in the case of the second category, it is contested whether the power they have exercised is public power or private power. The third is often the most contentious i.e. it is often contentious as to who belongs to that category.
482 Also see Hoexter *Administrative Law* 248.
483 Also see Hoexter *Administrative Law* 250.
484 S 6(2)(b) of PAJA.
485 S 6(2)(a)(I) and (ii).
486 S 6(2)(a)(iii).
487 S 6(2)(c).
488 S 6(2)(d).
489 S 6(2)(e)(i) - (vi).
490 S 6(2)(f)(i).
491 S 6(2)(f)(ii).

take a decision;[492] unreasonableness;[493] unconstitutionality[494] and unlawfulness.[495] As earlier indicated, PAJA provides also for the giving of written reasons by the decision-maker.[496]

PAJA further provides for the courts or relevant tribunals to order just and equitable remedies if any of the grounds stated in s 6 are applicable.[497] The just and equitable remedies may include ordering the relevant decision-maker to give written reasons for the decision;[498] a temporary interdict or another appropriate temporary relief;[499] directing the decision-maker to desist from acting in a particular way;[500] declaration of rights;[501] setting aside of the decision[502] and, in the case of the failure to take a decision, also mandating the relevant decision-maker to take a decision.[503]

It is important to note that before any action is instituted under PAJA the party instituting the action must, unless exempted from doing so in the interests of justice, first exhaust internal remedies provided for by a particular law.[504]

4.2.3.4 Implications for health research

Is PAJA applicable to research decisions? The answer is PAJA has direct relevance for research purposes. As indicated in chapter one, a public law approach in the form of administrative law has not been used in the context of health research. What has been used instead has been the private law approach, mainly using contracts, and sometimes using delictual principles. The private law approach, to the exclusion of public law approaches like the administrative law approach, was more evident in *Venter v Roche Products (Pty) Ltd* (A11/2014) [2014] ZAWCHC 157 (22 October

492 S 6(2)(g). This provision should be read with s 6(3) of PAJA, dealing with instances where the failure occurred while there was no stated period within which the decision had to be taken, in which case the litigant may allege unreasonable delay on the part of the decision-maker and instances where the law stated the period within which the decision had to be taken, in which case the litigant may allege that the decision-maker still has a duty to take the decision despite the expiry of the period.

493 S 6(2)(h).

494 S 6(2)(i).

495 S 6(2)(i).

496 S 5.

497 S 8.

498 S 8(1)(a)(i).

499 S 8(1)(e).

500 S 8(1)(b).

501 S 8(1)(d).

502 S 8(1)(c).

503 S 8(2)(a).

504 S 7(2)(a) - (c).

2014), as briefly reflected on in chapter one, and reflected on below. PAJA may play an important role in the review of protocols by RECs, which often will be exercising public power or performing a public function in terms of a legislation or an empowering provision, more so because most RECs belong to public institutions like universities, which arguably qualify as organs of state.[505]

The review and approval decisions of research by institutions like South African Health Products Regulatory Authority (SAHPRA), previously the Medicines Control Council (MCC)[506] will no doubt constitute administrative actions as contemplated in PAJA. And so are the decisions of the NHREC, including its audit decisions. The grounds of review as per PAJA may play an important role in laying the basis for challenging those research-related decisions that constitute an administrative action. Similarly, the administrative law approach could play an important role in fostering accountability and transparency, through the request for the reasons for the administrative action taken. An administrative law approach could further play a critical role in the crafting and shaping of the remedies in case one of the stakeholders has been wronged. These remedies, which are not limited to private law remedies, should be just and equitable.[507] One should note that, as discussed elsewhere in this thesis, in addition to reliance on PAJA a litigant is free to use other routes, including the common law, the principle of legality, special statutory reviews and s 33 of the Constitution, provided the principle of subsidiarity[508] is respected. The approach to judicial review, if it were to be used in the context of health research, could substantially support the PLA framework contended for in this thesis.

4.2.4 Human dignity

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505 This could be inferred from s 239(b)(ii) of the Constitution, which includes in its definition of organs of state 'any other functionary or institution exercising a public power or performing a public function in terms of any legislation'.

506 See the discussion of the role of SAHPRA below, as provided for under both the *Medicines and Related Substances Control Act 101 of 1965* (MSA) and the *Health Research Regulations*. Also see SAHPRA "About us''. https://www.sahpra.org.za/who-we-are/ (Accessed 24 December 2021).

507 S 8 of PAJA. This is also within the spirit of orders expected under s 172(1)(b) of the Constitution.

508 The principle, in the main, requires that the more particular framework, whether of institutions or laws, should be preferred to the more general (see a detailed exposition of this principle in the minority but persuasive judgement by Cameron J in *My Vote Counts NPC v Speaker of the National Assembly and Others* [2015] ZACC 31 (30 September 2015), more particularly at para 46.

4.2.4.1 Common law

Dignity, just like privacy, is recognized under common law as falling under the broader concept of *dignitas*.[509] An injury to a person's dignity could take various forms, but mainly centred around insulting, belittling or being contemptuous of one's dignity.[510] Being a type of a delict, most of the general principles applicable to a delict also apply here, therefore making it unnecessary to have a detailed discussion of this. The constitutional approach to dignity follows below.

4.2.4.2 Constitutional framework

Just like equality, human dignity is provided for both as a right and as a value. Most importantly, the Constitution treats human dignity as inherent,[511] as opposed to being merely contingent (i.e. as opposed to where its protection is dependent on some other factors). Human dignity is arguably the most important of the rights in the Bill of Rights.[512] Most of the rights like the right to privacy, right to life, etc. are closely linked to the right to human dignity.[513] The right to informed consent (covered under the right to freedom and security of the person in the Constitution) is also very closely linked to the right to human dignity. In *S v Makwanyane* the court emphasised this point when it, referring to human dignity, said:

> This right therefore is the foundation of many of the other rights that are specifically entrenched in Chapter 3.[514]

This has far reaching implications in the context of health research.

4.2.4.3 Legislative framework

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509 Neethling J and Potgieter JM *Neethling – Potgieter – Visser Law of delict* 6th ed (LexisNexis Durban 2010) 346. For further detailed discussion on human dignity under both the common law and the constitution see Ackermann L *Human dignity: lodestar for equality in South Africa* (Juta Cape Town 2012) 86 – 180.

510 Neethling and Potgieter L*aw of delict* (6th ed) 346.

511 S 10 of the Constitution.

512 Also see Dzingwa SO "The desirability of consistency in constitutional interpretation" (LLD Thesis University of South Africa 2011) 154.

513 See *S v Makwanyane* 1995 (3) SA 391 (CC), where the court, as per Chaskalson P, says at para 144: "The rights to life and dignity are the most important of all human rights, and the source of all other personal rights in Chapter Three. By committing ourselves to a society founded on the recognition of human rights we are required to value these two rights above all others".

514 *S v Makwanyane* 1995 (3) SA 391 (CC) para 328.

There is no specifically dedicated legislation dealing with human dignity. Other legislation dealing with other aspects do, however, provide for human dignity. PEPUDA, which is specifically dedicated to equality issues, does also touch on human dignity.[515]

4.2.4.4 Implications for health research

The provision for human dignity under both the common law and the constitution, as well as the link between dignity and equality, as provided by PEPUDA, is arguably consistent with the PLA framework argued for in this thesis. This could therefore play an important role in the protection of health research participants. The problem, though, is that human dignity has not yet been relied on in the context of health research litigation in South Africa.

4.2.5 Equality

4.2.5.1 Common law

Not much coherent approach on equality issues has been developed under the common law. The matter therefore need not be taken any further in this regard.

4.2.5.2 Constitutional framework

Equality issues in South Africa are mainly regulated by the Constitution, which provides for this as both a right and a value. Equality may take various shapes, in the form of formal and substantive equality.[516] The former focuses more on processes, while the latter more on outcomes. The Constitution's theory of equality is more substantive than formalist. S 9 of the Constitution therefore makes express provision for the full enjoyment of equality, and for the recognition of past imbalances.[517] In other words, the Constitution does allow what philosophers have called justified partiality[518] or preferential treatment.[519] This approach to equality is important also in the context

515 S 2(b)(iv), read with para (b)(ii) of the definition of prohibited grounds in s 1, of PEPUDA.

516 As observed above, while s 9 (2) arguably provides for substantive equality, s 9 (1), (3) and (4) mainly arguably reflects formal equality.

517 S 9(2) of the Constitution.

518 Philosophers like Thaddeus Metz have taken this view, arguing that African ethical framework better accounts for why there should be partiality in favour of certain categories of persons, including a doctor's partiality in favour of his or her own patient (see Wareham CS "Partiality and distributive justice in African bioethics" (2017). https://pubmed.ncbi.nim.nih.gov/28349324/ (Accessed 16 January 2021).

519 Also see Baggini J *Ethics: the big questions* (Quercus London 2012) 102, for the notion of

of health research. For example, an unfair selection of research participants could be problematic for not being in line with this provision.

While in South Africa some of the equality provisions might be taken for granted because the principle of equality has generally become acceptable, it might not be the case in some countries. For example, if one were to conduct research amongst homosexuals in a country where homosexuality is still viewed with hostilities even by the authorities, one could imagine (hypothetically) a situation where a researcher might be forced to reveal information as to sexual orientation of the participants, with a view to prosecuting the participants. The centrality of equality in the Constitution could also be gleaned from the fact that, as earlier indicated, apart from it being provided for as a right, it is also one of the Constitution's values. This means that even when the courts and other forums are interpreting other provisions of the Bill of Rights, equality issues should be born in mind. The equality provision in the Constitution is given effect to in terms of various legislations, the most important of which is PEPUDA, as discussed under legislation below.

4.2.5.3 Legislative framework

S 9 of the Constitution provides for legislation to be passed to deal with issues of discrimination and affirmative action. PEPUDA is one of the legislations[520] giving effect to this constitutional provision.[521] PEPUDA is more generic, therefore dealing with issues of equality in all sectors, except those sectors specifically covered by other legislations like the Employment Equity Act. PEPUDA prohibits the state or any person from unfairly discriminating against any person.[522] The unfair discrimination prohibited is one based on prohibited grounds, which means that it is not every form of discrimination that is prohibited.

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justified discrimination.

520 Other legislations, which deal with equality only in specific contexts, include the Employment Equity Act 55 of 1998, which deals with equality issues at the workplace, and the Broad-Based Black Economic Empowerment Act 53 of 2003, which deals with issue of Black economic advancement in general. These statutes are however not directly relevant to the present study, and shall therefore not be further touched on, except where the context so requires.

521 Although PEPUDA's primary object could arguably be said to be to give effect to s 9 of the Constitution, it further gives effect to other constitutional provisions, in particular ss 10 and 16(2)(c) of the Constitution, which protect human dignity and prohibits hate speech respectively (see s 2(a), read with s 2(b)(iv) and (iv) of PEPUDA)).

522 S 6 of PEPUDA.

4.2.5.4 Implications for health research

The equality framework, more in particular that provided for under PEPUDA, may play an important role in the protection of health research participants. Although PEPUDA does not, except for a provision in its illustrative list,[523] specifically focus on issues of protection of research participants, its general principles on equality remain relevant for the protection of research participants.

One area of examination where this could be relevant is the relationship between race discrimination and research participation. Race-based experiments were once the feature of science in the better part of the 20th century including the research experiments during the World War II in Germany and the Tuskegee experiments which, as already indicated in chapters one and two, had racial connotations.[524] The prohibition of unfair discrimination on the ground of race therefore discourages situations where there could be racial bias in the selection of research participants as well as the treatment of the participants once they have been recruited. Mainly selecting certain members of a racial group as research participants could, for example, unfairly impose on that group burdens of research, while the under-inclusion of members of such a group could lead to the unfair denial of benefits for the group. This might then constitute unfair discrimination based on race, even if the decisions complained of appear neutral.[525]

Another area of examination is the relationship between gender discrimination and research participation. The same issues as discussed above in respect of the relationship between race and research participation apply in the case of gender and research participation. However, the increased vulnerability of women will have to be considered. Those who are displaced, more especially children must be given even more attention. The framework under PEPUDA, which is arguably more consistent

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523 See Item 3(a) of the Schedule to PEPUDA, which considers subjecting persons to experiments without their informed consent one of the examples of practices that could be considered unfair as contemplated in s 29 of PEPUDA.

524 Moodley K "Research Ethics and Scientific integrity" in Moodley (Ed) Moodley (ed) K *Medical Ethics, Law and Human Rights: A South African Perspective* (Van Schaik Publishers Pretoria 2010) 317 - 321. It is already almost a settled point that the Jews were also targeted as a group during some of the atrocities in Germany at the time.

525 S 7(c) of PEPUDA.

with the PLA contended for in this thesis, may therefore be important in the protection of women partaking in research.

4.2.6 Privacy and protection of personal information

4.2.6.1 Common law

In terms of the common law a person has the right not to have his privacy, which falls within the broader concept of *dignitas*, violated.[526] One should start off by briefly discussing the meaning, scope and nature of privacy. The meaning of privacy is not clear-cut, therefore leading to divergences around its meaning, scope and even around its importance and independent existence as a right.[527] One of the leading proponents of the view that privacy does not have its independent existence is Judith Thompson.[528] Thompson, in the main, argues that privacy is not unique but just part of other rights like the right to property and the right to be left alone.[529] This argument is misplaced, as this problem is not unique to privacy, but to other rights too i.e. most other rights provide for what may also overlap with other rights.[530]

When tackling the question of privacy, one may first have to understand its nature, namely whether it is a condition (a state of affairs), an interest, a right, a legitimate (reasonable) expectation or a combination of all these. These elements may therefore assist in the construction of the definition.[531]

One of the leading cases dealing with privacy under the common law is *Jansen Van Vuuren NO v Kruger.*[532] In this case a doctor (first defendant in the trial court) had disclosed the HIV status of his patient (plaintiff in the trial court). The doctor knew of the HIV status while the plaintiff was the doctor's patient. The action was, in the main,

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526 Neethling J and Potgieter JM *Neethling – Potgieter – Visser Law of delict* 6th ed (LexisNexis Durban 2010) 347. For further discussion of privacy under the common law, see Burns Y *Communications law* 3rd ed (Lexis Nexis Durban 2015) 231.

527 Further see Innes JC *Privacy, Intimacy and Isolation* (Oxford University Press New York 1992) 3 - 4.

528 Thompson JJ "*The right to privacy*" 1975 *Philosophy & Public Affairs* 295 - 314.

529 Thompson 1975 *Philosophy & Public Affairs* 306, 310 & 313.

530 For further criticism of Thompson's argument, see DeCew J "Privacy'' 2018 Stanford Encyclopaedia of Philosophy https://plato.stanford.edu/entries/privacy/ *(*Accessed 14 February 2021).

531 Note for example that Parent talks about privacy as a condition (see Moore AD "Privacy: its meaning and value'' 2003 *American Philosophical Quarterly* 215). How we categorise privacy will however also depend on whether we look at it from a legal perspective or from a philosophical (or ethical) perspective.

532 *Jansen Van Vuuren NO v Kruger* 1993 (4) SA 842 (A).

based on *actio injuriarum*. Though the court in the main accepted that there are circumstances where disclosure in the public interest could be a successful defence in such an action, this could not be sustained on the facts. The court therefore held that the plaintiff's right to privacy had been violated and awarded him damages in the amount of R5 000.

4.2.6.2 Constitutional framework

As indicated in chapter one, s 14 of the Constitution provides for the right to privacy, including the right not to have one's private communication infringed.[533] Another provision also relevant to the protection of privacy is the one dealing with the protection of a person's integrity, both bodily and psychologically.[534]

4.2.6.3 Legislative framework

One of the main statutes dealing with the protection of personal information is POPIA.[535] It seeks to limit access to information. Providing access to information is therefore only an exception under the Act. Opening information for access therefore requires some justification.

POPIA identifies eight conditions for the protection of personal information, which include processing limitation; data subject participation; accountability; information quality; openness; security safeguards; purpose specification and further processing limitation.[536] These conditions are subject to certain exceptions (or grounds of justification). While the exceptions are in different sections and serving purposes as are required by the context of specific sections, there appears to be a general and sometimes overlapping thread connecting these exceptions. These include consent;[537] necessity required for the performance of a contract; protection of data

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533 S 14(d) of the Constitution.

534 S 12(2).

535 Of course, various other legislations do touch on certain aspects of the protection of personal information, including PAIA, NHA and the Statistics Act 6 of 1999 (Statistics Act). For example, S 3(2) of the Statistics Act provides for the confidentiality of information collected from respondents. PAIA and the NHA are discussed in this thesis, in various contexts.

536 Adams & Adams "South Africa: Commercial law in South Africa" (2018). https://www.mondaq.com/southafrica/contracts-and-commercial-law/766214/commercial-law-in-south-africa (Accessed 19 March 2022).

537 Although s 1 of POPIA requires the consent to be 'specific', in addition to being 'voluntary' and 'an expression of will', it is unclear as to how this will be interpreted in the context of health research, i.e. how it relates to other categories of consent like blanket consent, broad consent, tiered consent and dynamic consent. Academic opinion on this question diverges (for this

subject's legitimate interest; compliance with public law duties required for or imposed on public bodies; compliance with legal obligations by the responsible party and protection of legitimate interests of the responsible party or a third party to whom information has been supplied.

These exceptions are mainly covered under s 11 of POPIA, which is arguably the most generic of the sections, as it deals with limitation on processing in general. Grounds of justification covered in other sections include national security and crime detection; public interest and research, historical or statistical purposes (which are also treated as part of public interest in the context of exemptions but treated separately from public interest in other contexts).

With respect to research exceptions overall, POPIA provides for research-specific exceptions in the case of procession of general personal information; in the case of special personal information, in the case of personal information of children and in the context of the s 37 exemptions. The exceptions and exemptions do not have the same qualifications. Some research purpose exceptions are only applicable if there are enough safeguards for the protection of the data subjects (by guarding against the records being used for a purpose other than the research purpose);[538] some are silent on this qualification[539] and others provide for a different qualification.[540]

In the case of processing special personal information, the research purpose exception is also further qualified by the research being in the public interest or where obtaining consent would be difficult, and where there are sufficient safeguards for the protection of the data subject's privacy.[541] The research purpose exception relating to the procession of inherited characteristics also does not have a qualifier. The research

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divergence, more particularly as to whether POPIA accommodates broad consent already accepted under the SA national guidelines, including the 2015 Ethics in Research, see Thaldar D and Townsend B "Exempting Health Research from the consent provisions of POPIA'' 2021 *PER/PELJ* 1 – 31.

538 S 14(2) of POPIA.

539 S 18(4)(f).

540 S15 provides, as qualification for the exception, that the further processing solely, in case of research, be for research purposes and that it must not be published in identifiable form (Also see Swales Lee "The Protection of Personal Information Act 4 of 2013 in the context of health research: Enabler of privacy rights or roadblock?" 2022 *PER/PELJ* 16).

541 S 27. Note here that the research purpose, to qualify for exception, must serve public interest, while under the section 37 exemptions, research purpose might itself include public interest. This formulation could potentially create confusion around POPIA's approach to the concept of public interest.

purpose exception in the case of procession of personal information concerning children also has a qualifier like the procession of special personal information in general.[542]

POPIA provides for various rights of the data subject, including the right to be notified about the collection, unauthorized access or acquisition of his or her personal information.[543] POPIA further makes provisions for several institutions to deal with various aspects related to the Act. These include the Information Regulator and, though linked to the former, an enforcement committee.[544] The Information Regulator is an independent body whose powers, duties and functions are mainly to ensure compliance with POPIA and PAIA.[545]

As indicated earlier another statute relevant to the protection of personal information is PAIA which, though its primary objectives are to promote access to information, also provides for the protection of personal information under certain circumstances. PAIA provides for mandatory protection of a third party's privacy, if such party is a natural person, where such disclosure would be an unreasonable disclosure of that person's personal information (including instances where the information relates to a deceased person).[546] PAIA further provides for mandatory protection of a third party's commercial information where such disclosure is likely to cause harm to the third party, including that third party's commercial interests.[547]

PAIA further provides for mandatory protection of information supplied by the third party in confidence, and the disclosure of which is not in the public interest.[548] The Act further provides for refusal of access if the request is frivolous or vexatious or the meeting of the requests 'would substantially and unreasonably divert the resources of the public body'.[549] PAIA further makes provision for the protection of research

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542 S 35 of POPIA.

543 S 5(a)(i) and (ii). Further see other rights in s 5(b) – (i) of POPIA.

544 S 50.

545 S 39 read with ss 40 and 43.

546 See s 34. See however the exceptions under s 34(2). Also see S 63(1), read with s 63(2), which have related provisions applicable to information held by private bodies.

547 S 36(1). See the exceptions under s 36(2), read with s 36(3). S 64(1), read with s 64(2) and (3) and s 68(1), (2) and (3), which have equivalent provisions relating to information held by private bodies.

548 S 37(1). See the exceptions under s 37(2) of PAIA. Further see equivalent provisions in s 65 of PAIA, relating to information held by private bodies.

549 See s 45. There does not however appear to be an equivalent provision relating to information held by private bodies.

information of a third party, including information about the subject matter of the research.[550] In the case of health records, access to a record may even be denied to the owner of the record if access thereto could harm the requester.[551]

It should be noted that PAIA makes a distinction between requests to public bodies and private bodies. A stronger justification is required from a requester for information held in a private body, who must indicate that he or she needs the record to exercise 'any' rights.[552] PAIA further makes provision for the notification of third parties by the information officer, about the fact that the information officer is considering a request for an access to a record.[553]

4.2.6.4 Implications for health research

The protection of personal information is very central to the conduct of health research, therefore making both POPIA and PAIA very important to the conduct of health research. One of the biggest challenges will be the way these legislations have to be interpreted. POPIA, overall, appears to be treating research as exceptional, and requiring lesser protection. PAIA does not have similar exceptions. What then are the implications of POPIA's research exceptionalism, and PAIA's silence on these exceptions? One can conclude that POPIA provides (or risks being interpreted that way), for reduced protection to research participants. On the other hand PAIA, which in the main promotes access to, rather than protection of, information, is comparatively more likely to offer protection than POPIA. Despite POPIA's research exceptionalism, which may reduce protection to research participants, overall the legal framework providing for both protection of information and access to information is consistent with the PLA framework contemplated in this thesis.

4.2.7 South Africa's theory of remedies

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550 S 43. Further see equivalent provision in s 69 of PAIA, which deals with access to information held by a private body.

551 S 30. What biomedical theory would be applicable in this case? Beneficence; non-maleficence and paternalism could arguably be candidate theories in this regard.

552 S 50(1). Because the section speaks of any rights, rather than the requester's rights, it is unclear if the rights to be exercised are necessarily those of the requestor. It is probably not. Think for example of the rights of the requestor's child, for whom the requestor may be acting.

553 S 47, read with ss 48 and 49, of PAIA. Further see equivalent provisions in ss 71 to 73 of PAIA, with respect to information held by private bodies.

When persons are aggrieved, they should be able to claim effective remedies. Various sources of law therefore provide for remedies.

4.2.7.1 Common law

4.2.7.1.1 Delictual remedies and some limitations

As earlier indicated delict, alongside contract, has dominated the largely private law approach to health research. For an aggrieved person to succeed in a delictual claim the person must prove the existence of certain general elements, namely an act, wrongfulness, fault or culpability (in the form of either intention or negligence), causation and damages (harm).[554] These requirements are now shaped by the constitutional framework. As part of their mandate to develop the common law to be consistent with the Constitution, as required of them in terms of s 39(2) of the Constitution, the courts have developed the common in ways that broaden some of the requirements of delict, more particularly the requirement of wrongfulness.[555]

Regarding constitutional remedies by way of damages, courts have yet to provide a clear direction in this regard. The matter came before the Constitutional Court in *Fose v Minister of Safety and Security,*[556] where the court had to decide whether a litigant who suffered damages out of police assault could, in addition to the damages claimable under the common law, claim constitutional damages. The court also had to answer a related question whether a litigant could claim punitive constitutional damages.

The court, in relation to the first question, held that although constitutional damages were not claimable in the present case, it was possible to award them in future cases where the facts so justified.[557] The court therefore held in this regard that once a person was awarded damages under the common law principles the person cannot again claim constitutional damages, as the person's constitutional rights shall have

554 Neethling J and Potgieter JM *Neethling – Potgieter – Visser Law of Delict* 7th ed (LexisNexis Durban 2015) 4. This approach, of prescribing general requirements should be contrasted to the English law position, whose approach to delict is more casuistic, i.e. more individualized (see Neethling and Potgieter *Neethling – Potgieter – Visser Law of Delict* 4).

555 This has happened in several decisions, including *Carmichele v Minister of Safety and Security (Centre for Applied for Applied Legal Studies Intervening)* 2001 (4) SA 938 (CC), *Van Eeden v Minister of Safety and Security (Women's Legal Centre Trust, as Amicus Curiae)* 2003 (1) SA 389 (SCA), etc.

556 *Fose v Minister of Safety and Security* 1997 (3) SA 786 (CC).

557 *Fose v Minister of Safety and Security paras 60 – 61.*

been vindicated by the awarding of the delictual damages relating to the same constitutional rights.[558] The court further expressed doubt about whether or not it would be appropriate, for the purposes of appropriate relief as contemplated in s 7(4),[559] to award constitutional damages 'even in the case of the infringement of a right which does not cause damage to plaintiff', so as to vindicate such a right.[560]

In relation to the question of punitive constitutional damages,[561] the court rejected the availability of this remedy, more so if it is taken into account that such a punishment has criminal procedural law implications.[562] Though some ambiguity remains as to whether there could be circumstances where punitive damages could be claimable in the future, the rejection appears more forthright than its possible acceptance.[563]

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558 *Fose v Minister of Safety and Security* 1997 (3) SA 786 (CC) para 67. This cautious approach is taken further in *Residents of Industry House, 5 Davies Street, New Doorfontein, Johannesburg and Others v Minister of Police and Others* [CCT 136/20) [2021] ZACC 37 (22 October 2021) paras 91 - 92 and 97. The position appears to be that the remedy could be available but is seldom available where common law remedies are already available to vindicate the right concerned. Further see this line of reasoning in *Thubakgale and Others v Ekurhuleni Metropolitan Municipality and Others (CCT* 157/20) [2021] ZACC 45 (7 December 2021) paras 121; 157 – 158; 169; 175 – 176 and 196 – 197.

559 As this case was decided under the Interim Constitution, the reference in this regard is to the section in the Interim Constitution. S 7 (4) of the Interim Constitution, an equivalent of s 38 of the Final Constitution, deals with the appropriate relief a person whose rights have been infringed or threatened may seek. It is however apt to say here that even though the court appears to adopt the attitude that constitutional damages outside the common law route are not available, this appears to be what the court decided specifically on the facts of this case. The court was just reluctant to settle the point for future cases. This attitude could be inferred from the court's passing remark that 'it is unnecessary, however, to decide this issue in the present case' (*Fose v Minister of Safety and Security* para 68*).* Further see a related attitude at para 74.

560 *Fose v Minister of Safety and Security* para 68*.*

561 It is not clear in the case how the court distinguishes punitive constitutional damages and additional constitutional damages (i.e. constitutional damages in addition to the damages under the common law) and even ordinary constitutional damages (i.e. constitutional damages claimed independently of any other claim for damages, but without claiming common law damages).

562 *Fose v Minister of Safety and Security* paras 70 and 73*.* The court's over-reliance on the dichotomy between civil and criminal law (which also implies the dichotomy between private law and pubic law respectively) appears a complete misdirection, as there are other punitive costs that are awarded outside the criminal law processes without raising similar concerns as the court raises e.g. punitive costs orders in civil proceedings. But also note the court's view at para 74*,* which may suggest that the court was as yet reluctant to settle the point for future cases, but only decide on the limited question that was before it. The court says (and this appears to also apply to the question of punitive constitutional damages): "The question in this case must perforce a narrow one because the issue before the court is very limited. Accordingly, the question of damages in relation to the breach of other chap 3 rights,…cannot and ought not to be decided now''.

563 See in particular the concurring judgment by Didcott J in *Fose v Minister of Safety and Security* Paras 84 and 87 – 88, whose rejection is more forthright, while Kriegler J's concurring judgement cautions against this outright rejection (see paras 92 and 103). On the general objections to punitive damages, see para 65.

The High Court in *Dendy v University of the Witwatersrand*[564] also found the awarding of constitutional damages inappropriate where other alternative remedies are available.[565] The Court further found it inappropriate to ground the action of infringement of dignity on the violation of all fundamental rights.[566] The question of constitutional damages further arose in *President of the Republic of South Africa and Another v Modderklip Boerdery*[567] where the Constitutional Court, confirming an earlier SCA decision in the case, held that constitutional damages were claimable where there was no other remedy.[568]

The scope of damages a litigant might claim was, however, broadened in *Families of Mental Health Care Users Affected by the Gauteng Mental Marathon Project v National Minister of Health of the Republic of South Africa and Others* (Life Esidimeni),[569] an arbitration case, so as to also include constitutional damages.[570] The approach in Life Esidimeni has implication in the case of health research, as this may make it easier for research participants to find protection. The problem is that the courts have not taken this approach in the context of health research. In the *Roche* case the approach of the court was too narrow, relying mainly on narrow delictual principles. Questions around the development of the common law were not even raised. This approach places the protection of research participants at risk.

4.2.7.1.2 Contractual remedies and their limitations

A contract remains one of the most important instruments regulating relations between parties. For a contract to be legally binding it must meet certain requirements. These include the existence of consensus (agreement); serious intention to conclude the

564 *Dendy v University of the Witwatersrand* 2005 (5) SA 357 (W).

565 *Dendy v University of the Witwatersrand* para 58. Also see paras 45 and 46. Further see Neethling J, Potgieter JM and Scott TJ *Casebook on the law of delict: Vonnisbundel oor die deliktereg* 5thed (Juta Cape Town 2013) 46.

566 Neethling, Potgieter and Scott *Casebook on the law of delict* 46.

567 *President of the Republic of South Africa and Another v Modderklip Boerdery (Pty) Ltd* 2005 (5) SA 3 (CC) paras 20, 57- 58 and 68.

568 For a further discussion on constitutional damages, also see Currie I and De Waal J *The Bill of Rights handbook* 5th ed (Juta Cape Town 2005) 223 – 224.

569 *Families of Mental Health Care Users Affected by the Gauteng Mental Marathon Project v National Minister of Health of the Republic of South Africa and Others* (Unreported). www.saflii.org/images/LifeEsidimeniArbitrationAward.pdf (Accessed 18 January 2022).

570 See particularly *Life Esidimeni* paras 211 – 219. It is important to note that in this case the arbitrator did not, in the main, make the constitutional damages dependent on the non-existence of other (common law) remedies.

contract;[571] the contract must be capable of performance; the contract must be lawful; the parties must have contractual capacity to conclude the contract and lastly, where the specific contract concluded requires some formalities like writing or notarial execution, such formalities must be complied with.[572]

While parties are under the notion of freedom to contract at liberty to contract as they wish, this position is on the assumption that the parties are interacting on an equal position of strength. There are therefore instances where a contract that complies with all the requirements of a contract may be challenged. Equally, there are instances where a contract that is short of some of the requirements of a contract might be relied on by one of the parties to vindicate his or her rights. What is arguably a public law approach in this instance led to departure from some principles like lawfulness e.g. in *Kylie v Commission for Conciliation, Mediation and Arbitration and Others*,[573] a labour law case, the court allowed the employee to claim remedies in terms of an unlawful contract. Despite this position in some fields, the court has not taken the same approach in resolving biomedical questions, where such an approach is even more necessary.

Indemnity and other restrictive clauses often bring tension between contracts and public policy. In other words, when restrictive clauses are found in contracts, questions often arise as to whether they are in line with public policy or offend against such. Although even in the pre-constitutional era, under the common law, clauses in contracts that offended against public policy were not enforceable, the post-constitutional era changes the content of the public policy.[574] The post-constitutional public policy infuses constitutional values into the concept.[575] A number of court

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571 This requirement is not necessarily applicable in countries like England, for in terms of the doctrine of consideration (which is inapplicable in South African law) the latter does not consider serious intention to conclude a contract sufficient, unless the there is some consideration given (see Fouché MA *et al* "Requirement for a valid contract: serious intention'' in Fouché MA (ed) *Legal Principles of contracts and commercial law* rev 6th ed (LexisNexis Durban 2007) 41.

572 Fouché MA *et al* "Requirement for a valid contract: formalities'' in Fouché MA (ed) *Legal Principles of contracts and commercial law* rev 6th ed (LexisNexis Durban 2007) 91.

573 *Kylie v Commission for Conciliation, Mediation and Arbitration and Others* 2010 (4) SA 383 (LAC), more particularly at para 34, where the court endorsed the position in *Jajbhay v Cassiem* 1939 AD 537, where the latter court had ruled in favour of the relaxation of *par delictum* rule where justice and public policy so require. Further see *Kylie* v *Commission for Conciliation, Mediation and Arbitration and Others* para 56.

574 *Bredenkamp and Others v Standard Bank of South Africa Ltd* 2010 (4) SA 468 (SCA*)* para 38. Further see *Barkhuizen v* Napier 2007 (5) SA 323 (CC) paras 28 - 29, 30 and 36.

575 *Bredenkamp and Others v Standard Bank of South Africa Ltd* para 39.

decisions, though often on the facts holding that the restrictive clauses that came before them were permissible for not offending against public policy, have mostly emphasised the point that the new content of public policy must have constitutional values as its starting point.[576]

One of the reasons for the courts' support of exemption clauses is that they are consistent with respect for autonomy which, in the context of contracts, translates into the freedom of contract. This is therefore also considered to be one of the constitutional values, namely the value of freedom as contemplated in s 1 of the Constitution (the autonomy argument). This has arisen in some of the cases, including Cameron J's 'separate but concurring judgement' in *Afrox Healthcare Bpk v Strydom.*[577] A key argument against exemption clauses is that they may be unfair against parties who are not negotiating from an equal position of power (the unequal bargaining power argument).

In *Botha and Another v Rich NO and Others*[578] the Constitutional Court had, on appeal to it, to decide whether or not a party (a purchaser) to an instalment sale agreement who had defaulted after she had already paid more than half the purchase price could be denied the right to have the property registered in her name and also forfeit the money paid in terms of a cancellation clause. The court, relaxing the principle of the reciprocity of contracts (which could have entitled the seller to demand that before the

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576 *Afrox Healthcare Bpk v Strydom* 2002 (6) SA 21 (SCA) para 18. In this case the respondent had suffered damages due to the alleged negligence of the appellant, a hospital (which the court however found could not be proved). The respondent had however signed an exemption clause indemnifying the hospital. The respondent sued based on public policy (that the exemption clause offended public policy), the unequal bargaining power with the appellant and the absence of good faith. Respondent, though succeeding in the high court, failed on all three grounds in the SCA (see Hawthorne L and Pretorius C.J *Contract Law Case Book* 3rd Ed (Juta Cape Town 2010) 215 - 216). Further note *Brisley v Drotsky* 2002 (4) SA 1 (SCA), where the court found a non-variation clause in a lease agreement to be permissible and therefore enforceable, as it was freely negotiated (therefore affirming the principle of freedom of contract), and that the question of unequal bargaining power does not arise in such a case (also see Hawthorne & Pretorius *Contract law casebook* 206 - 207). For exemption clauses, further read Kanamugire JC and Chimuka TC "The Current Status of exemption clauses in the South African law of contract'' 2014 *MCSER* 164 – 176.

577 2002 (6) SA 21 (SCA) (see also Hawthorne & Pretorius *Contract law casebook* 214 - 215). The Constitutional Court in *Barkhuizen v Napier* 2007 (5) SA 323 (CC) para 48 also took a similar line in the context of time-bar clauses in contracts, holding that such clauses are not unreasonable and unfair, and therefore not offending against public policy as now understood in terms of the Constitution. The Court, further affirmed, at para 57, the importance of the principle of *pacta sunt servanda*, which requires that contracts freely concluded should be enforced (also see Hawthorne & Pretorius *Contract law casebook* 224 - 225).

578 *Botha and Another v Rich NO and Others* 2014 (4) SA 124 (CC).

purchaser claims transfer she must also perform her obligations under the contract),[579] held that the seller was obliged to have the property registered in favour of the purchaser. The principle of good faith in contracts was emphasised.[580]

4.2.7.2 Constitutional framework

The Constitution provides a general framework in this regard, providing for everyone to have disputes that are capable of resolution through application of law to be decided in an impartial court, forum or tribunal.[581] The Constitution further provides for just and equitable remedies.[582] This creates space for flexibility in the formulation of remedies. The constitutional provision for just and equitable remedies therefore reaffirms the centrality of the concept of equity in South African law, therefore calling for its brief reflection.[583]

As will be observed in chapter five, the usage of equity principles has become entrenched in English law,[584] with which the South African and US laws are being compared. Before one discusses the South African law conception of the concept of equity, one needs to reflect on how other thinkers have understood the concept. One of the leading thinkers in this regard is Aristotle. Aristotle said:

> These then are the considerations, more or less, from which the difficulty as to the equitable arises. Yet they are all in a manner correct, and not really inconsistent. For equity, one superior to one sort of justice, is itself just, it is not superior to justice as being generally different from it.

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579 *Botha and Another v Rich NO and Others* paras 43 – 44.

580 *Botha and Another v Rich NO and Others* paras 45 – 46. Unfortunately, the majority in an earlier decision in *Everfresh Virginia Market (Pty) Ltd v Shoprite Checkers (Pty) Ltd* 2012 (1) SA 256 (CC), in the context of renewal of contracts, declined (though largely on technical grounds) to decide on whether or not the common law needed to be developed to make it obligatory for parties to negotiate in good faith. The minority decision however, without deciding the issue, went some way in motivating for the need to develop the common law in that direction. Further note a criticism of the Constitutional Court decision in *Crown Restaurant CC v Gold Reef City Theme Park (Pty) Ltd* 2008 (4) SA 16 (CC) by Barnard-Naude AJ "Oh what a tangled web we weave…" Hegemony, freedom of contract, good faith and transformation – towards a politics of friendship in the politics of contract" 2008 *CCR* 188 – 193, which dismissed an application for leave to appeal and therefore declining to decide the issue of the development of the common law, on the basis that it was raised for the first time in the application for leave to appeal. This is despite that the constitutional court had in its earlier decision in *Carmichele v Minister of Safety and Security and Another (Centre for Applied Legal Studies Intervening)* 2001 (4) SA 938 (CC) decided to develop the common law despite the issue being raised for the first time in that court.

581 S 34 of the Constitution.

582 S 172(1)(b) of the Constitution. Also see *State Information Technology Agency SOC Limited* 2018 (2) SA 23 (CC) para 53.

583 For the purposes of the discussion in this research, unless the context requires otherwise, the concepts of equity and justice, more particularly in the context of remedies, are used interchangeably. So are the concepts of 'just' and 'equitable'.

584 Martin J *The English legal system* 6th ed (Dynamic Learning London 2010) 17.

> Justice and equity are therefore the same thing, and both are good; though equity is the better.[585]

Though one agrees here about the overlap between justice and equity i.e. the one (justice) includes the other (equity), one does not agree with Aristotle's conception that one is better than the other. One takes the view that the concept will generally mean one and the same thing, therefore not ruling out the possibility that in some contexts, the concepts might share the same meaning.[586] Any enquiry into any possible differences between the two is, however, not within the scope of this research.

Aristotle further raises another point, in an attempt to also contrast the concept with law. He says in this regard:

> The source of the difficulty is that equity, though just, is not legal justice, but a rectification of legal justice. The reason for this is that law is always a general statement, yet there are cases which it is not possible to cover in a general statement...While the equitable is just, and is superior to some sort of justice, it is not superior to absolute justice, but only to the error due to its absolute statement. This is the essential nature of the equitable: it is a rectification of law where law is defective because of its generality.[587]

The context in which Aristotle conceptualises equity in this quote is arguably consistent with the way the concept has been used even in the modern era in the context of remedies. As will be observed in chapter five in the discussion of English law, the principle of equity has been used to remedy the defects left by the common law. In South African law the principle, as can be observed in the constitutional framework cited above, the concept has been used to discourage a formalistic (technical) approach to the law, but instead gives the law a substantive outlook. It has therefore brought flexibility to the way the courts craft and shape remedies. This approach has even been given effect to under some legislation, including PAJA,[588] which is also discussed elsewhere in this thesis.

4.2.7.3 Legislative framework

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585 Aristotle 'Book Five' in Griffiths T (ed) *The Nicomachean ethics* (Translated from the original Greek by Rackham H) (Wordsworth Classics Hertfordshire 1996) 133.

586 One should take note of Aristotle's usage of the word to also mean fairness, and sometimes also, equality and lawfulness. He says in this regard: 'Now we have distinguished two meanings of 'the unjust', namely the unlawful and the unequal or unfair, and two meanings of 'the just', namely the lawful and the equal or fair' (see Aristotle *Book Five* 117). Further see Martin *The English legal system* 17, for the conception of equity as fairness in England.

587 Aristotle *Book Five* 133.

588 S 8(1) and (2) of PAJA also empowers the courts to grant parties a just and equitable remedy, for disputes brought under that Act.

Some of the legislations dealing with the remedies, including PAJA, have been dealt with already under the relevant headings. The focus here is on remedies offered under consumer legislation, more in particular the Consumer Protection Act 68 of 2008 (CPA).

S 52 of the CPA provides for the court to order some remedies in case ss 40, 41 and 48 have been violated, if the Act does not already provide sufficient remedy in that regard.[589] The remedy could include a declaratory order that the conduct is a prohibited one, that it is unfair, that it is unjust or that it unconscionable or unreasonable.[590] It may further include any other remedy that the court considers to be just and reasonable.[591] The above decisions with regard to the remedies must take into account the factors in s 52(2) of the CPA, in addition to the taking into account of the principles, purpose and provisions of the Act.[592]

A close reading of the CPA shows that the jurisdictional basis for a prohibited conduct or transaction is that such a conduct or transaction is unreasonable; unfair; unjust and unconscionable. These requirements should be read disjunctively, given that they are, wherever they appear, separated by 'or'.[593] In other words, if any of these requirements is applicable to any conduct or transaction, the conduct or transaction is prohibited.

4.2.7.4 Implications for health research

The way contracts are approached has implications for stakeholders in health research. If contracts are approached very mechanically, this may result in injustice. The opposite therefore also holds true, i.e. that stakeholders in health research are likely to find protection in instances where contracts are approached with a view to securing justice in mind. To do otherwise the courts (at least in the case of the courts) might be seen to be affirming what Karl Klare accuses them of, i.e. of having a conservative legal culture.[594]

589 S 52(1) of the CPA.
590 S 52(1) read with 52(3)(a).
591 S 52(3)(b).
592 S 52(1). The factors in s 52(2) include the nature of the parties; the particular relationship; their relative bargaining power; their education; experience; etc. (S 52(2)(b)).
593 See for example, their usage in s 48(1) and (2) of the CPA.
594 Klare KE "Legal culture and Transformative Constitutionalism" 1998 *SAJHR 151.*

The trend one observes from the above cases, with perhaps the exception of *Botha and Another v Rich NO and Others,*[595] is that although the courts do refer to, and emphasise, the importance of the Constitution in shaping contract law, the tendency is still to emphasise the freedom of contract, worse of it in an individualist way, to rule in favour of those who seek to rely on the restrictive clauses.[596] This may not be beneficial to the stakeholders in health research, especially research participants.

Despite its apparent incoherence in some instances, the flexible approach adopted by the CPA, if adapted to participants in health research, could also enhance their protection, as consumers. An equity-based approach could be critical in the context of health research, as the decision-makers, including the courts, will be able to fashion whatever remedy necessary in a more flexible, rather than a rigid way. Overall, the approach to remedies, if applied in the context of health research, may go some way in supporting the PLA framework contemplated in this thesis.

4.2.8 Research oversight

4.2.8.1 Common law

The common law position, most of which has already been discussed above, has been the dominant framework used in health research, drawing more from the fields of medical malpractice and professional negligence.[597] The common law principles of contract, also as discussed above, have also been useful. One leading case where the common law principles have been the focal point is the *Roche* case**,** where the research participant was suing the researcher (GVI Oncology) and Roche Products (PTY) LTD, the local representative of a Swiss-based sponsor, F Hoffman-LE Roche AG (FHLR) for injuries sustained during experiments in SA.

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595 *Botha and Another v Rich NO and Others* 2014 (4) SA 124 (CC).

596 Further note *Everfresh Virginia Market (Pty) Ltd v Shoprite Checkers (Pty) Ltd* 2012 (1) SA 256 (CC) paras 73 - 74, where the court declined to develop the common law of contract. At face value the decision to decline was partly because the issue was raised for the first at the appeal stage, rather than at the court of first instance. The court however did reaffirm, without deciding the matter, the necessity of infusing the law of contract with constitutional values, including the values of Ubuntu, a position adopted in the earlier court decisions (see *Everfresh Virginia Market (Pty) Ltd v Shoprite Checkers (Pty) Ltd* paras 71 and 72).

597 For the difference between medical malpractice and professional negligence see Dhai and McQuoid-Mason *Bioethics* 92, where the authors in particular consider medical malpractice to also include, in addition to negligence (which is professional negligence's main thrust) and unlawfulness, the intentional causing of harm by healthcare practitioners.

The research participant claimed damages for the injuries flowing from the participation in the research, but he had been only (at least according to the respondent's version) promised compensation for medical costs. His claim was, in the main, based on an alleged tacit agreement between the research participant and the defendants (as they then were in the trial court). The alternative claims were based on *stipulatio alteri* and delict.[598] As support for the existence of a tacit agreement, the research participant placed reliance on the existence of a patient information leaflet and informed consent (PIL-ICON) and the provisions of the ABPI (Association of British Pharmaceutical Industry) Guidelines and the 2006 SA-GCP (South African Good Clinical Practice Guidelines (2006)), dealing with compensation for research-related injuries. The research participant was unsuccessful at the trial court, where the court ruled against the existence of a tacit agreement. [599]

On appeal to the full bench of the Western Cape High Court, the court found instead that the research participant could pursue his actions against the Swiss-based sponsor. It specifically considered the ABPI Guidelines and 2006 SAGCP Guidelines (referred to in this thesis as the 2006 Clinical Trial Guidelines) short of demanding any legal commitment on the part of sponsors. In so far as the status of the ABPI Guidelines was concerned, the appeal court cited with approval the decision of the British Court in *Morton James Wylie v Dr Donald Grosset, Greater Glasgow Health Board*.[600] The judgement raises a question whether or not the finding of non-existence of a contract between appellant (research participant) and the defendants means that there can be no other basis for action against the researcher and the local representative. This question is very relevant if one considers the demands that the Constitution places on the courts to develop the common law and other laws.[601] The approach of the court here has therefore, by overlooking some public law obligations imposed by the Constitution, been more formalist than substantive.

4.2.8.2 Constitutional framework

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598 *Venter v Roche Products (Pty) Ltd* (A11/2014) [2014] ZAWCHC 157 (22 October 2014) para 2.

599 *Venter v Roche Products (Pty) Ltd* para 34.

600 *Morton James Wylie v Dr Donald Grosset, Greater Glasgow Health Board* [2011] COSH 89. The correctness of the court's reliance on this decision is also in doubt, given the constitutional demands that South African courts must comply with, in addition to the demands of the ordinary law, which are not necessarily applicable in the UK context.

601 S 39(2) of the Constitution.

Apart from the values of equality and human dignity already discussed elsewhere the general constitutional values of accountability, transparency, and rule of law (including the principle of legality) may play a critical rule in ensuing that the stakeholders to health research act responsibly. S 12(2)(c) of the Constitution provides for a person not to be subjected to scientific or medical experiments without that person's informed consent.

4.2.8.3 Legislative framework

4.2.8.3.1 Medicines and Related Substances Control Act 101 of 1965

The Medicines and Related Substances Control Act 101 of 1965 (MSA) creates the South African Health Products Regulatory Authority (SAHPRA), previously the Medicines Control Council (MCC). S 15 of the MSA requires that medicines, as defined in s 1 of this Act, be registered with SAHPRA. S 35(1) (xxxix) requires that the minister, in consultation with SAHPRA, makes regulations regarding the conduct and control of clinical trials. Regulation 3(a) of the Health Research Regulations also requires that researchers, where applicable, submit research proposals to SAHPRA for approval, in addition to submission to a registered REC.[602]

4.2.8.3.2 The National Health Act 61 of 2003

The NHA is one of the most important pieces of legislation regulating issues relating to health, including health research. Most importantly, the NHA sets out, in its objective of regulating national health and providing uniform health services across South Africa, to protect, promote, respect and fulfil the rights of "vulnerable groups such as women, children, older persons and persons with disabilities".[603] However, although the NHA also covers issues of health beyond health research this discussion, unless the context requires otherwise, only focuses on those issues that deal with health research.[604]

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602 Also see para 5.5 of the 2020 Clinical Trial Guidelines.

603 S 2(c)(iv) of the NHA.

604 For a brief account of the health issues covered by the NHA, more especially those relevant to health research, see Maswanganyi JV "The protection of personal information of research participants in research conducted electronically" in Delener NJ and Schweikert C (eds) *Changing business environment: game changers, opportunities and risks. Nineteenth Annual International Conference Readings Book Vienna, Austria July 11th – 15th, 2017* (Global Business and Technology Association New York 2017) 435.

The NHA requires that where a user receives, from a particular health establishment, health services which constitute a research or are experimental in nature, the user must be duly informed about this fact.[605] An REC, the user, the health care provider in charge of the user's treatment and the head of the particular establishment must, before the provision of such services for research or experimental purposes, authorise the provision.[606]

S 71 of the NHA regulates research on a living person.[607] Apart from that such research must be conducted in a prescribed manner[608] the research must be preceded by written consent.[609] S 71 then sets out parameters for the conduct of research involving minors,[610] for therapeutic purposes. Such research must be in the minor's best interest;[611] must be conducted in a prescribed manner and per the conditions set;[612] must be preceded by consent from the minor's parent or guardian[613] and it must be preceded by the child's consent if the child does have understanding.[614]

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605 S 11(1).

606 S 11(2). Further see Swanepoel *Law, psychiatry and psychology* 270 – 290.

607 The usage of the concept 'living person' raises questions around the moral status of deceased persons. Does it mean they do not deserve protection in case of use in research? (The protection of deceased persons, limited though it appears to be, is mainly in the context of restrictions on the removal of tissues. See, for example, s 67(1)(a) of the NHA, which provides for the Minister to authorise removal of parts in a post-mortem, for purposes stated in s 64(1) of the NHA, which includes research purposes. S 62(3) of the NHA also provides for the Director-General (of Health) to, under certain circumstances, authorize a donation of tissues of a deceased person, for the purposes of research as contemplated in s 64(1) of the NHA if the deceased person's close relatives as defined in s 62(2) may not be located, after the Director-General took steps to locate them. The level of oversight in this regard i.e. in the case of research on deceased persons is weak. Further note s 61 of the NHA, which also places some restrictions on the allocation and use of human organs for certain purposes, including research purposes. Further note s 54 of the NHA, in terms of which the Minister of Health is, subject to the conditions he may set, empowered to authorise, in a government gazette, certain institutions to use bodies of deceased persons for various purposes, including research purposes.).

608 S 71(1)(a).

609 S 71(1)(b).

610 S 71(2). Though the concept of 'minor' may not always mean the same thing as the concept of a 'child', the NHA uses both concepts in what appears to be mean one and same thing. For example, although the NHA uses the concept of 'minor' many times in s 71(2) and (3), it uses the concept of 'child' once in the same sentence, but in ways which suggest that it is intended to have the same meaning as the concept of a 'minor'. For example, s 71(2)(c) of the NHA uses the concept of a 'child' in a provision speaking of the 'consent of the parent or guardian of the child' yet using the concept of a 'minor' in almost a similar context in s 71(3)(a)(iii) of the NHA. It is submitted however that the concepts are intended to mean the same thing, unless the context dictates otherwise. Also note para 3.2.2 of the 2015 Ethics in Research, which defines both concepts the same way.

611 S 71(2)(a).

612 S 71(2)(b).

613 S 71(2)(c).

614 S 71(2)(d). The latter requirement appears to refer to assent, rather than consent – otherwise it would not make sense to require consent from the minor's parent or guardian, and again

S 71 further sets out the conditions for the conduct of non-therapeutic research involving minors.[615] Such research must be conducted in the manner prescribed and the conditions set out;[616] must be conducted with the Minister of Health's consent;[617] must be conducted with the consent of the minor's parent or guardian[618] and lastly it must be conducted with the minor's consent, where the minor has the capability to understand.[619] Should there be no other requirements beyond this justifying the inclusion of children in a specific research project? What if, for example, in the case of COVID19-related research, none of the above requirements could be satisfied? It is submitted that such research be possible on the ground, for example, of public interest, so long as conditions could be set protecting as much as possible the interests and rights of the child.

The Minister shall under certain circumstances decline to give consent for the minor's participation in non-therapeutic research.[620] Under what circumstances shall the ministerial consent be withheld? It shall be withheld under any of the following circumstances: the objects of the research may still be achieved by using an adult research participant.[621] In other words, a ministerial consent shall be withheld where it is unnecessary to use a child, because the use of an adult participant may achieve the same result. A ministerial consent shall further be withheld on lack of likelihood of "significant scientific improvement" grounds i.e. where the child's participation is not likely to bring significant improvement to the "scientific understanding of the minor's condition, disease or disorder" in ways that are likely to significantly benefit the participating minor or other minors.[622] So as to protect minors, an aspect that may also

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from the minor himself or herself.

615 S 71(3)(a).

616 S 71(3)(a)(i).

617 S 71(3)(a)(ii).

618 S 71(3)(a)(iii).

619 S 71(3)(a)(iv). The same comment made above about the usage of the word 'consent' rather than 'assent', in the case of research involving minors for therapeutic purposes above is applicable.

620 S 71(3)(b). This provision is arguably peremptory, therefore not giving the Minister any discretion once any of the circumstances outlined in the subsection is present. This conclusion is arrived at despite that the word 'may', which usually signals a directory rather than peremptory intention or purpose, has been used. It is however a settled point that where the word 'may' is followed by 'not' i.e. where it is stated in a negative rather than positive form it usually, unless the context suggests otherwise, signals a peremptory intention or purpose (also see Botha C *Statutory Interpretation* 179).

621 S 71(3)(b)(i) of the NHA.

622 S 71(3)(b)(ii).

be relevant in research contexts the NHA restricts, though the Minister may authorise otherwise, removal of organs from young living persons.[623]

The Minister shall also withhold consent on "public policy" grounds.[624] The latter will be the case where the participating child's parents or legal guardian have already granted consent, but such consent is considered to offend public policy (as to when such consent may be considered to offend public policy is not clear). The facts of the case will dictate whether the consent offends or does not offend public policy. It would, however, have been better for the legislature to have outlined what those likely factors would be. Ministerial consent shall also be withheld on the ground of presence of "significant risk" to the minor's health if the minor participates in the research.[625] Lastly on ministerial consent, such consent shall also be withheld on the ground of the existence of some risk to the child which, though not as significant as that earlier mentioned, cannot be justified by the potential benefits expected from the child's participation in the research.[626]

The NHA further creates oversight mechanism over the conduct of research through provision for the establishment of the NHREC[627] located within South Africa's (National) Department of Health, and the HRECs, often referred to as RECs, which must be registered with the NHREC.[628] In terms of the NHA the NHREC is required to perform the following powers and functions: formulation of the guidelines for the operation of RECs;[629] registration and audit of RECs;[630] the setting of norms and standards for the conduct of research involving animals and human subjects;[631] adjudication of complaints around the functioning of RECs, including complaints of discrimination brought forward by researchers against RECs;[632] referral of complaints of alleged or potential violation of ethical or professional rules by health care workers to the relevant statutory health professional bodies;[633] institution of disciplinary

623 S 56(2).
624 S 71(3)(b)(iii).
625 S 71(3)(b)(iv).
626 S 71(3)(b)(v).
627 S 72(1).
628 S 73(1).
629 S 73(6)(a).
630 S 73(6)(b).
631 S 73(6)(c).
632 S 73(6)(d).
633 S 73(6)(e).

measures against those found to have violated norms, standards or guidelines for the conduct of research[634] and provision of advice to the national and provincial departments of health on research ethics.[635]

As to the RECs, their main powers and functions are mainly around reviews and approvals. The RECs in particular ensure the performance of their review powers and functions on research proposals and protocols so as to ensure that the research to be conducted contribute towards health promotion; prevention or cure of communicable and non-communicable diseases and the prevention or cure of a disability.[636] The REC further has the power and function to approve the conduct of research by a particular person in case the research proposals and protocols satisfy the required ethical standards.[637]

Lastly, one can conclude that although the NHA in general tends towards imposing what at face value are public law obligations, including for example the criminalization of unauthorised disclosure of health information,[638] these obligations are not enough to protect health research participants. The individualist orientation of the provisions may leave communities or families who have an interest in a matter not catered for. There should therefore be instances where decisions could be taken in the public or community interest, rather than only in the individual or personal interests of the specific actors.

4.2.8.3.3 Health research regulations

The Regulations Relating to Research with Human Participants, 2014 (Health Research Regulations), enacted in terms of the NHA, also make provisions prescribing how researchers should conduct health research. The Health Research Regulations, in the main, provides for about ten principles that should guide the conduct of research.[639] Some of these principles are however, substantially an elaboration of

634 S 73(6)(f).
635 S 73(6)(g).
636 S 73(2)(a).
637 S 73(2)(b).
638 S 17(2). Provisions like s 46 of the NHA, which also requires private health establishments to provide insurance cover to indemnify any users for any harm or damage they may suffer, arising from the wrongful conduct of the employers or staff members of the establishment, may also be said to promote a public law approach to obligations: private health establishments have no choice but to provide such a cover.
639 Regulation 2 of the Health Research Regulations.

some of the existing principles covered in other instruments, including South African, some foreign and international instruments, some of which are covered in later chapters. These include the fair selection of research participants;[640] a balanced assessment of risks and benefits;[641] the requirement of informed consent;[642] respect for research participants' rights, including privacy, dignity, equality and bodily integrity;[643] a sound scientific methodology;[644] a review by an independent REC[645] and suitable experience and qualifications on the part of the investigator.[646]

The rest of the principles in the Health Research Regulations are the requirement for making provision for compensation for injuries resulting from the research (if the research poses more than the minimal risk);[647] the need for the responsiveness of the research to the health priorities of the participating communities, the research participants and the rest of the population[648] and the compliance with South African Department's National Guidelines for research involving human participants.[649]

The Health Research Regulations make provision for the protection of vulnerable persons by guarding, amongst other things, against the unjustified inclusion of vulnerable persons in research,[650] while also guarding against systematic exclusion of

640 Regulation 2(e). This is principle is also part of the principle of justice, which is provided for in other instruments like the Belmont Report (which is discussed in chapter six).

641 Regulation 2(d). This principle is also part of other instruments like the Belmont Report, categorized under the principle of beneficence.

642 Regulation 2(f). This principle is part of the broader principle of respect for persons, which is provided for in other instruments like the 2015 Ethics in Research and the Belmont Report.

643 Regulation 2(h). This principle is an elaboration of the principles of respect for persons, and in the case of equality it is part of the principle of justice, as provided for in other instruments like the 2015 Ethics in Research.

644 Regulation 2(c). This principle is also included in other instruments like the Clinical Trial Guidelines and the Helsinki Declaration.

645 Regulation 2(g). This principle is also included in other instruments like the Clinical Trial Guidelines and the Helsinki Declaration. Para 23 of the Helsinki Declaration in particular provides for the REC to be independent of the sponsors and researcher, and to be free from any undue influence.

646 Regulation 2(j). This principle is part of the principle of investigator competence as provided for in other instruments like the Clinical Trial Guidelines. The Helsinki Declaration also provides for the supervising physician or health care professional to be competent and suitably (appropriately) qualified, experienced and trained (see para 12 of the Helsinki Declaration).

647 Regulation 2(i) of the Health Research Regulations.

648 Regulation 2(b). This provision appears to balance both the interests of society and those of the research participants.

649 Regulation 2(a).

650 Regulation 2(b).

such persons from research.[651] Research involving vulnerable persons must be responsive to their needs, and the RECs must pay special attention to the needs of such persons, so as to minimize their exposure to risk.[652] Appropriate consent procedures commensurate with the circumstances of vulnerable persons must be followed.[653]

The Health Research Regulations then outline the requirements to be satisfied for the conduct of research in respect of specific categories of vulnerable persons namely minors;[654] adults with diminished capacity;[655] prisoners[656] and persons in hierarchical or dependent relationships.[657] The Health Research Regulations further provide for details on the basis of which the research participant or his legally authorised representative must give informed consent.[658] As indicated earlier in the discussion of principles, the Health Research Regulations also provide for an independent ethical review of the research protocols, by a registered REC.

Given that the NHA[659] places restrictions on the conduct of non-therapeutic research involving minors, by requiring a ministerial consent, the Health Research Regulations restate this requirement and provide for the process of giving effect to the requirement.[660]

4.3 Ethical instruments regulating health research

Various (South African) ethical codes and instruments regulate the conduct of stakeholders in research. Although some of these instruments do not (necessarily) have the status of law, the instruments have far-reaching effect on how the stakeholders in research must conduct themselves. In fact, non-compliance with some of these instruments might attract sanctions. These instruments (some of which have

651 Regulation 4(b).
652 Regulation 2(d).
653 Regulation 2(d).
654 Regulation 4.1.
655 Regulation 4.2.
656 Regulation 4.3.
657 Regulation 4.4.
658 Regulation 5.
659 S 71(3)(a)(ii) of the NHA.
660 Regulation 7. The Health Research Regulations further clarify the issue of delegation, namely that the Minister's power to consent may be delegated in terms of section 92(a) of the NHA, therefore alleviating the possible beaurocracy that were to arise if consent were to be always sought from the Minister directly.

been referred to in chapters one and two) include the 2015 Ethics in Research; the South African Good Clinical Practice Guidelines (2020) (2020 Clinical Trial Guidelines) which, as indicated in Chapter One, replaced the 2006 Clinical Trial Guidelines;[661] the Guidelines of the Health Professions Council of South Africa and the South African Medical Research Council Guidelines on the Responsible Conduct of Research (SAMRC Guidelines).

4.3.1 South African Good Clinical Practice Guidelines

As observed in chapter one, the South African Good Clinical Practice Guidelines (2020) (2020 Clinical Trials Guidelines)*[662]* is one of the leading instruments regulating the ethical conduct of research. It sets out a number of principles, including the principles of transparency;[663] beneficence;[664] non-maleficence;[665] justice;[666] informed consent;[667] independent reviews by RECs;[668] prior approval by relevant bodies including SAHPRA;[669] appropriate study designs;[670] balanced assessment of harm and benefit;[671] appropriate qualifications and competence on the part of the investigator;[672] regular monitoring of the study[673] and respect for persons, including dignity and autonomy (which also includes respect for privacy).[674] The 2020 Clinical Trials Guidelines further provide that clinical trials be registered on the South African National Clinical Trial Register, located in the Department of Health.[675]

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661 See the Preamble to the Clinical Trial Guidelines (the 2020 version). The 2006 Clinical Trial Guidelines had itself replaced an earlier version published in 2000 (see the Preamble to the 2006 Clinical Trial Guidelines).

662 Though compliance with the 2020 Clinical Trial Guidelines is stated to be compulsory (as per para 1.3), therefore implying some legal force, these guidelines are still discussed in this thesis as part of the ethical guidelines, as their structure and formulation arguably present them as ethical guidelines, rather than as regulations (in any way, for the purposes of this discussion it does not matter much as to whether they are legal or merely ethical guidelines).

663 Through mainly the publication of trial results, as well as release and reporting of trial results (see paras 6.15 and 6.16 of the 2020 Clinical Trial Guidelines).

664 Para 2.1.2 of the 2020 Clinical Trials Guidelines.

665 Para 2.1.2.

666 Para 2.1.2.

667 Paras 2.5 and 5.9.

668 Para 2.6.

669 Para 6.2.3.

670 Para 2.2.

671 Para 2.3.

672 Para 5.2.

673 Para 6.11.

674 Para 2.1.2.

675 Para 4.4.

In the case of research on minors, additional requirements are prescribed namely, that in addition to the consent by relevant persons that the law grants the power to consent on the minor's behalf e.g. parent or legal guardian, the participating minor must give assent.[676] Apart from the consent and assent requirements the 2020 Clinical Trials Guidelines further require that the research must not present a greater risk than a minimal risk i.e. the anticipated risk must be negligible.[677] Where the anticipated risk is more than negligible, it is then expected that the study must be likely to yield some direct benefit to the participating minor.[678] Where, however, the study is neither likely to yield direct benefits to the participating minor, nor exposing the minor to risks that are less than negligible, the study may still be justified on the basis that it is likely to lead to the production of generalisable knowledge (a point tending towards support for the PLA theory argued for in this thesis).[679] Whichever of the scenarios is applicable above, the protocol must still disclose enough details to justify the inclusion of the minors in the study.[680] In all instances involving research with minors, the research, including observational research, must not be contrary to the interests of the minor.[681] The guidelines further provide for the payment of incentives for participating in research, provided the incentives are carefully considered not to induce participants to undervalue, ignore or minimize the potential risks posed by the trial.[682] With regard to the payment of compensation for injuries during research, the 2020 Clinical Trial

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676 Para 3.2.5.2. Note however that the definition of a minor has now been aligned to that of the CA and the Constitution, i.e. being below 18 years of age, rather than being one below the age of 21, which the 2006 Clinical Trials Guidelines provided for, which was obviously problematic, unless the intention of the 2006 Clinical Trials Guidelines was not to treat the concept of a minor and a child (the latter being already statutorily defined) as synonymous.

677 Though clearly articulated in the 2006 Clinical Trials Guidelines, this is now only provided for in the 2020 Clinical Trials Guidelines through reference to *the* 2015 Ethics in Research (see para 3.2.2. of the 2020 Clinical Trials Guidelines, read with para 3.2.2.1 (b) of the 2015 Ethics in Research. Also see 2.3.1 of the 2006 Clinical Trials Guidelines).

678 Though also clearly articulated in the 2006 Clinical Trials Guidelines, this is now only provided for in the 2020 Clinical Trials Guidelines through reference to the 2015 Ethics in Research (see para 3.2.2. of the 2020 Clinical Trials Guidelines, read with para 3.2.2.1(b) of the 2015 Ethics in Research. Also see 2.3.1 of the 2006 Clinical Trials Guidelines).

679 Though clearly articulated in the 2006 Clinical Trials Guidelines, this is now only provided for in the 2020 Clinical Trials Guidelines through reference to the 2015 Ethics in Research (see para 3.2.2. of the 2020 Clinical Trials Guidelines, read with para 3.2.2.1(b) of the 2015 Ethics in Research. Also see 2.3.1 of the 2006 Clinical Trials Guidelines).

680 Though also clearly articulated in the 2006 Clinical Trials Guidelines, this is now only provided for in the 2020 Clinical Trials Guidelines through reference to the 2015 Ethics in Research (see para 3.2.2. of the 2020 Clinical Trials Guidelines, read with para 3.2.2.1 (a) of the 2015 Ethics in Research. Also see 2.3.1 of the 2006 Clinical Trials Guidelines).

681 See para 3.2.2.1 of the 2015 Ethics in Research.

682 Para 2.7 of the 2020 Clinical Trials Guidelines.

Guidelines only provide for this indirectly, as they only require insurance coverage by sponsors to cover the injuries.[683]

The 2020 Clinical Trials Guidelines do not make specific provision for displaced persons, displaced children in particular, therefore leaving them to rely on the application of the same principles as apply to the rest. The 2020 Clinical Trials Guidelines do speak of the accommodation of special groups, which could arguably also include displaced children.[684]

4.3.2 The 2015 Ethics in Research

As indicated in the earlier chapters, the 2015 Ethics in Research[685] is another South African instrument providing for the ethical framework for the conduct of health research. The framework covers both research involving humans and research involving the use of animals.[686] The 2015 Ethics in Research prohibits retrospective granting of approvals by RECs.[687] The framework further highlights the core values, which are also supported by the NHREC, that ought to underpin health research.[688] These values include scientific merit and integrity; respect; beneficence and justice.[689]

The 2015 Ethics in Research identified three (or four if non-maleficence is treated as separate) bioethical principles, namely the principle of beneficence and non-maleficence; the principle of distributive justice and the principle of respect for persons.[690] Though these principles are at face value similar to the principles identified in other jurisdictions (which will be reflected on in later chapters), this may not necessarily mean that their content as intended to be applied in different countries is identical, given other principles in the different countries that might influence the content of these principles.

The 2015 Ethics in Research conceptualises beneficence as the promotion of benefit as against harm i.e. it promotes the maximization of benefit and the minimization of

683 Para 10.2 of the 2020 Clinical Trial Guidelines.
684 Para 3.1, read with para 3.4, of the 2020 Clinical Trials Guidelines.
685 Department of Health Ethics in Health Research: Principles, Processes and Structures (Department of Health Pretoria 2015).
686 Para 1.1.7 of the 2015 Ethics in Research.
687 Para 1.1.11.
688 Para 1.3.3.
689 Para 1.3.3.
690 Para 2.1.

harm, for the research participants,[691] while conceptualising non-maleficence (which the framework apparently treats as part of the principle of beneficence) as the prevention of the deliberate act of doing harm.[692]

The 2015 Ethics in Research conceptualises justice as equality.[693] This approach could be problematic, as sometimes the concept (of justice) could mean fairness rather than mere equality. One is aware that the concept of 'fair' is also used in the framework, but its usage appears to assume that it means the same thing as equality, which arguably has a narrow content than fairness.

Lastly on the question of principles, the 2015 Ethics in Research conceptualises the principle of respect for persons as including not only respect for autonomy, but also respect for dignity.[694] Because dignity is arguably broader than the concept of autonomy, its inclusion here is significant. However, its conception of autonomy, within the broader concept of respect for persons generally takes the same line as that taken by instruments in other jurisdictions (for example the Belmont Report in the US, as will be shown in chapter six). Firstly, such a conception is one that focuses, in the main, on the liberty of the research participant to make informed choices without being coerced to do so, if such research participants are capable of making such choices.[695] Secondly, in the case of those with diminished decision-making capacity it focuses, in the main, on their protection from harm.[696] The principle of autonomy then requires, in the latter case, that such persons be assisted (often by legally authorized representatives) in the decision-making process.[697]

The 2015 Ethics in Research further requires the interests of research participants to, as a matter of general rule, 'outweigh the interests of science and society'.[698] Most

691 Para 2.1.
692 Para 2.1.
693 Para 2.1.
694 Para 2.1.
695 Also see para 2.1 of the 2015 Ethics in Research. This individualist conception could be problematic as it could undermine the interests of the community and therefore not be in the spirit of the PLA argued for in this thesis.
696 Para 2.1.
697 Paras 28 – 30 of the Helsinki Declaration, to be discussed in chapter eight.
698 Para 2.1 of the 2015 Ethics in Research. This provision, in the context of the discussion of the promotion of public interest appears to run counter to such a principle. It is unclear how this point is reconcilable with para 1.6.8 of the 2015 Ethics in Research, touched on below, which requires review committees to also promote societal interests.

importantly, the 2015 Ethics in Research further conceptualises respect for autonomy as also including respect for the interests of the researchers.[699]

The 2015 Ethics in Research reaffirms the NHA's provision that RECs be established, or at least that there be access to such RECs, in all establishments where health research is conducted.[700] The framework further reaffirms the position of the NHA that all RECs reviewing health research involving human subjects must be registered with the NHREC, which the NHA also gives authority to set norms and standards for the conduct of health research involving human subjects.[701]

Restating the position of the NHA, the 2015 Ethics in Research further provides for a framework guiding the ethical review of health research involving humans.[702] The 2015 Ethics in Research provides for health research not to commence unless it has been preceded by ethical review by an REC, which must be registered with the NHREC.[703] As stated earlier, research proposals must be reviewed for the future, rather than backwards.[704] Ethical review committees must not, in their review work, only focus on ethical issues, but they must also focus on scientific issues, so as to ensure the scientific validity of the proposed study, taking into account the discipline within which the study falls.[705]

The RECs must also, in their review work, advance 'important social and ethical values'.[706] This could be critical in the assessment of the question whether or not review committees should promote public interest, and therefore more consistent with the PLA contemplated in the thesis. And so are its provisions encouraging key role-player engagement.[707] The 2015 Ethics in Research further provides that when assessing the risks and benefits that the research participants may suffer, the review committees must not only focus on the interests of present research participants, but also on wider societal interests and interests of future generations, which the review

699 Para 2.1. This appears an unusual departure from the position in other instruments, which tend to only focus on the autonomy of the research participants.
700 Para 1.4.2.
701 Para 1.4.3 read with para 1.4.1.
702 Para 1.6.
703 Paras 1.6.1 and 1.6.2 of the 2015 Ethics in Research.
704 Para 1.6.5 read with para 1.6.9.
705 Para 1.6.4 read with para 1.6.7.
706 Para 1.6.7.
707 Para 2.3.3.

committees think of hypothetically.[708] This aspect is arguably more consistent with the PLA contemplated here, for its focus on interests far beyond those of an individual, or a narrow grouping of stakeholders.

Overall, it appears that although the 2015 Ethics in Research does at face value go some way in taking a PLA angle to it, some of its provisions like suggesting the interests of research participants should take precedence over those of 'science and society' may be problematic, and therefore negate the general public law angle appearance that 2015 Ethics in Research portrays. These apparent contradictions should therefore be sorted out.

4.3.3 Guidelines of the Health Professions Council of South Africa

The HPCSA has several guidelines directed at professions affiliated to this body. Some of the guidelines are generic, while others do make specific reference to health research context.

One of the guidelines is the HPCSA's Confidentiality: Protecting and Providing information (Booklet 5) (The HCPSA's Booklet 5) which, as its name suggests, makes provision for the protection of (personal) information, in particular the confidentiality of information of a person.[709] The HPCSA's Booklet 5 does however provide for exceptions to the general rule of information protection.[710] These exceptions include disclosures following a court order;[711] disclosures in terms of a statute;[712] disclosures in terms of the patient's express consent;[713] disclosures in terms of a parent or a guardian's written consent in case of a minor under the age of 12;[714] disclosures in the public interest[715] and disclosures in terms of the executor or next of kin's written consent, in case of a deceased person.[716] The HPCSA's Booklet 5 further provides for

708 Para 1.6.8.
709 Para 1.2, read with para 3.1, of the HPCSA's Booklet 5.
710 Para 1.2 read with para 3.2.
711 Para 3.2.2.
712 Para 3.2.1.
713 Para 3.2.4.
714 Para 3.2.5.
715 Para 3.2.3 read with para 8.2.2.5. Further note para 3.3, which provides for the meaning of public interest in the context of the HPCSA's Booklet 5 which, interestingly, includes not only harm to the public (or other persons), but also harm to the patient himself or herself.
716 Para 3.2.6.

the conditions under which a health care professional may provide information to another person for research, study or clinical (medical) audit purposes.[717]

In the case of disclosures based on public interest some balancing act must specifically be struck as between the public interest in disclosing the information and the public interest in not disclosing the information. For the information to be disclosed on this ground, the public interest in disclosing the information must therefore outweigh the public interest in not disclosing the information.[718]

Where a particular research project is dependent is on specific information and it is not practically possible to secure the patient's consent, the researcher may still use the information, provided the information is anonymised.[719] In such a situation the relevant REC must be specifically made aware of this deviation.[720] Express consent should be secured before the publication, whether in journals or newspapers, of a patient's information, irrespective of whether or not the information is potentially identifiable.[721] There may be disclosure to employers, under certain circumstances, without the patient's consent.[722]

It should be noted that even after a patient has died, a health care practitioner still has an obligation to maintain the confidentiality of information.[723] Disclosure may however be made where necessary, as dictated by circumstances.[724] The circumstances of such disclosure (and usage where applicable) include the disclosure for research, education or clinical audit purposes, provided there is approval from an REC, in which case the publication of anonymised information could be permissible.[725] This approach does tend, to some extent, to support a PLA. Other bases of disclosure could include public health surveillance provided that such surveillance has been approved by an

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717 Para 8.2.3.4.
718 Para 8.2.4 read with paras 9.1.1.4 and 9.1.1.5.
719 Para 9.1.3.
720 Para 9.1.3.
721 Para 9.1.3.
722 Para 9.2.3.
723 Para 9.5.1 of the HPCSA's Booklet 5. This protection of information relating to the deceased is consistent with s 34(1) of PAIA, which also makes provision for the protection of information belonging to a deceased person.
724 Para 9.5.1.
725 Para 9.5.2.2.

REC.[726] This approach tends to support a PLA, provided it still respects some human rights principles.

There are further circumstances under which there may be forced disclosure of a patient's information. A health care practitioner may be forced to disclose information through a court order.[727] A health care practitioner may also be forced to disclose information in compliance with some statutory provisions, e.g. those, like the provisions of the CA, as discussed above, prescribing reporting obligations for abuse of children and provisions and legislation requiring the notification of certain diseases.[728] There may also be forced disclosures to regulatory bodies as required by law, if this is determined to be necessary to protect the patient or other people's health.[729]

Where the health care practitioner uses electronic means in processing information, the health care practitioner should take precautionary measures to ensure the safety of such information.[730]

HPCSA's General Ethical Guidelines for Health Researchers (Booklet 13) (HPCSA's Booklet 13) in the main provides for the ethical (and even legal) framework for the conduct of health research. It requires health care practitioners to fulfil its obligations towards individuals and society.[731] Paragraph 3.3 of the HPCSA's Booklet 13 provides for a need to comply with ethical guidelines, so that the law and science not be negatively affected.[732] Provision is also made for the protection of vulnerable research participants. [733] Apart from the standard principles of bioethics provided for by most bioethical instruments,[734] the HPCSA's Booklet 13 provides for the need for the research to promote the social value of research, in particular the need for the research

726 Para 9.5.2.4.
727 Para 10.2.
728 Para 10.1.
729 Para 10.4.
730 Para 11.
731 Para 2.1 of the HPCSA's Booklet 13.
732 Para 3.3
733 Para 3.1.
734 The standard bioethical principles mainly cover the principles of beneficence, justice, non-maleficence, and respect for autonomy. Although the principles of beneficence and non-maleficence are reformulated here as the principle of best interest or well-being, their core essence remains (see para 4 of the HPCSA's Booklet 13).

objectives to be in line with SA's national health research priorities, as contemplated in the NHA.[735]

The HPCSA's Booklet 13 provides for a number of duties placed on researchers, including the placing of the interests of the research participants above all other interests[736] and respecting the trust that research participants place in the researchers.[737] Researchers must report any violations of the right of research participants as well as, where necessary, seek appropriate redress for such violations.[738] Researchers must not unduly induce persons into partaking in research.[739] Researchers must however reasonably compensate research participants for the expenses or lost income incurred, arising from partaking in the research.[740] Researchers must also provide participants with compensation for research-related injuries,[741] insurance cover[742] and post-research treatment.[743]

While securing consent process researchers must inform the research participants about the fact that the confidentiality of certain information might be restricted if there are certain requests from certain bodies, as required by law.[744] While the HPCSA's Booklet 13 does not have detailed provisions specifically dealing with children, it does recognise that special attention be given to persons with diminished capacity like children.[745]

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735 Para 5. This approach no doubt tends towards the PLA proposed in this thesis.

736 Para 6.1.1. What are the implications of this in the context of the public interest approach? In other words, what happens if the interests of society were to outweigh those of the research participant? This provision could be problematic, as it may negate the HPCSA's perceived tendency towards the PLA.

737 Para 6.1.2.

738 Para 6.1.9. This provision is even more important in the case of children, more especially displaced children, who may be easily induced into partaking in research for financial gain.

739 Para 6.1.12.

740 Para 6.1.10.

741 Para 6.1.11.

742 Para 6.1.11.

743 Para 6.1.13.

744 Para 6.3.13 of the HPCSA's Booklet 13. What are the implications of this in the context of the PLA?

745 Para 6.3.8. Further see a more elaborate discussion of approaches to informed consent in the case of children, as discussed in HPCSA's Seeking Patient's Informed Consent: The Ethical Considerations (Booklet 4) (HPCSA's Booklet 4), which is basically a restatement of the provisions around the CA and Choice on Termination of Pregnancy Act, already discussed under the protection of children in this chapter (see paras 8.5 and 9 of HPCSA's Booklet 4).

The HPCSA's Booklet 13 requires that researchers adhere to ethical guidelines in instances where the ethical standards are higher than those provided for in the law.[746] Health researchers are further required to respect the environment and the public when conducting their research. This includes ensuring that researchers dispose of health care waste in ways that are considerate to the environment and in accordance with the legally acceptable framework. [747]

4.3.4 The South African Medical Research Council Guidelines

According to the South African Medical Research Council Guidelines on the Responsible Conduct of Research (SAMRC Guidelines) researchers are expected to respect biomedical principles related to the protection of human participants.[748] This includes the prior approval of the research protocols, including the amendments to such protocols, by the relevant ethics review committees dealing with research involving humans.[749] The SAMRC Guidelines further require honesty by researchers in various aspects of the conduct of research, including the dissemination of research information.[750] They further require accuracy and objectivity in the reporting of research findings.[751]

The SAMRC Guidelines further require a responsible communication of research results to various stakeholders.[752] They further require, where practicable, engagement of members of the public or public representatives from the communities where researchers conduct their research.[753] Researchers must strive to minimize the exposure of human participants and the rest of the environment to harmful biological agents, as contemplated in the SAMRC's Guidelines on Ethics for Medical Research: Use of Biohazards and Radiation, Book 4 (2002).[754]

The SAMRC Guidelines emphasize the importance of the shared responsibility between the researchers (principal investigators and other persons involved in the

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746 Para 9.4.2 of the HPCSA's Booklet 13. This approach, which is more substantive than formalistic, would have led to a different result if it were adopted in *Venter v Roche Products (Pty) Ltd.*

747 Para 12 of the HPCSA's Booklet 13.

748 Para 5.5.2, read with para 5.5.5, of SAMRC Guidelines.

749 Para 5.5.6.

750 Para 5.5.3.

751 Para 5.5.3.

752 Para 5.5.7.

753 Para 5.5.8 of SAMRC Guidelines.

754 Para 5.5.9.

research) and RECs.[755] No research should be conducted without being first reviewed by an REC registered with the NHREC.[756] The benefit of the study to the community must outweigh the risk the study poses to the participants.[757] In so far as respect for privacy and confidentiality is concerned, compliance with POPIA is required.[758]

Researchers must ensure fairness and relevance in the selection of research participants, and must take care not to unduly use vulnerability to exclude persons from specific populations.[759] Researchers are also required to follow the spirit, rather than merely the letter, of the regulations and good science.[760] They, as a result, must ensure that they only allow what they consider to be necessary and relevant research.[761]

The general observation is the SAMRC Guidelines, do go beyond research participant-centeredness and take a communitarian approach, where relevant stakeholders like communities are engaged. The SAMRC Guidelines also emphasise the importance of the relationship between human agents and the environment.

4.4 Conclusion

This chapter looked at the various South African legal and ethical frameworks regulating health research, the approach they take and, in brief, the adequacy of these approaches. In the main, the research shows that while there is a variety of laws taking a public law approach in South Africa, including the Constitution, PEPUDA and PAJA these laws have not, as can be gleaned from the *Roche* case, found any application in the resolution of health research problems. The common law, private law-based approach remains dominant. As to the ethical instruments though they too, in the main, have been found to be helpful in providing guidance in the conduct of health research these instruments' general lack of legal force has been their major weakness. In the *Roche* case the court also relied, amongst other reasons, on the 2006 Clinical Trials

755 Para 6.1.
756 Para 6.2.
757 Para 6.5.
758 Para 6.6. One wonders if compliance with the latter is sufficient, given that POPIA more often than not takes what one considers to be research exceptionalism, where there is a general pattern of 'exempting' processing for research and related purposes from the application of its provisions, therefore reducing the level of protection to research participants.
759 Para 6.7.
760 Para 6.4.
761 Para 6.4.

Guidelines' lack of legal force or commitment (at least in so far as payment of compensation for injuries was concerned) in denying the research participant his claim. The overall conclusion from this chapter is therefore that the public law approach is not yet used adequately, if at all, in the resolution of health research problems, therefore leaving the more individualist-oriented common law's private law approach almost intact. This leaves persons, more especially displaced children, partaking in health research more vulnerable. The next chapter examines the legal position in the UK.

CHAPTER FIVE: EXAMINATION OF THE LEGAL POSITION IN THE UNITED KINGDOM

5.1 Introduction

Chapter four examined the South African legal and ethical framework regulating health research. In doing so the chapter had to first identify and examine South Africa's over-arching legal theoretical framework as well as the ethical framework contained in specific instruments. This chapter looks at the UK legal position and other regulatory frameworks.[762] It starts off by identifying and examining the UK's over-arching theoretical framework. The chapter then looks at general laws relevant to health research; the specific laws dealing with health research and the specific ethical instruments governing health research. The general approach to the UK law on issues of health research and the adequacy of the laws are also examined.

5.2 The general theory of United Kingdom law

It should be stated from the onset that the UK does not have a written constitution, although there is sometimes reference to an English Constitution (or the Constitution of the UK), based on a collection of principles that have been recognised over a number of years.[763] Dicey describes the nature of the English Constitution as follows:

> The Constitution was marked by more than one transcendent quality which in the eyes of our fathers raised it far above the imitations, counterfeits, or, parodies, which have been set up during the last hundred years throughout the civilized world; no precise date could be named as the day of its birth; no definite body of persons could claim to be its creators, no one could point to the document which contained its clauses; it was in short a thing by itself, which Englishmen and foreigners alike should "venerate, where they are not able presently to comprehend".[764]

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762 As indicated in chapter one, unless otherwise indicated and justified by the relevance of a particular legal position, the law reflected in this chapter is mainly English law, which predominantly applies in England and Wales (also see acknowledgement of this position in Library of Congress *Children's Rights: United Kingdom* (England and Wales). https://www.loc.gov/law/help/child-rights/uk.php# (Accessed 5 April 2021). In fact, most UK legislations appear to treat England and Wales as one jurisdiction for legal purposes.

763 Waluchow W *"Constitutionalism"* 2017 Stanford Encyclopaedia of Philosophy. https://plato.stanford.edu/entries/constitutionalism/ (Accessed 20 February 2021). Of course, the question of whether or not the UK has a constitution or not shall for the better part of the future remain debatable, as it has been in the past (see for example, De Tocqueville A "Judicial power in the United States, and its influence on political society" in Griffith T (ed) *Democracy in America* (Wordsworth Classics Hertfordshire 1998) 44, for the author's reluctant, or at least ambiguous reference, many years back, to the existence of an English Constitution)).

764 Dicey AV *An introduction to the study of the law of the constitution* (with introduction by Wade ECS) 10th ed (Macmillan Education London 1959) 3.

While some, if not most, of the principles found in the UK constitution are derived from common law, there are those that are derived from some written instruments like the *Magna Carta*; the Petition of Right and the Bill of Rights.[765] The UK recognises the common law (or case law) (as the better part of English law is reflected through case law the two concepts will therefore in the English law context, unless the context indicates otherwise, be used interchangeably); custom; the law of equity; UK legislation and European law. In case of any conflict between the common law and legislation the latter applies, and in such instance the legislation must expressly change the common law.[766] In case of any conflict between the common law and the law of equity, the law of equity must prevail.[767]

The UK uses the system of parliamentary supremacy (under the Westminster system of government) which makes legislation more valued than other sources of law. The principle of parliamentary supremacy, as discussed below under interpretation, makes it difficult for the courts to invalidate legislation.[768] The courts may, however, enquire into whether or not an Act of Parliament is incompatible with European law, in particular the European Convention of Human Rights.[769] The courts may then, if they so find, declare the specific Act of Parliament incompatible.[770] Such a declaration of incompatibility does not however affect the validity or continued operation of such an Act of Parliament.[771]

What is UK law's approach to the hierarchy of laws? In other words, what happens when various sources regulating the same aspect conflict? Are there clear rules in this regard like the SA version of the principle of subsidiarity? As appears below under the discussion of 'equity', this principle (equity) often conflicts with the common law. Such

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765 Waluchow https://plato.stanford.edu/entries/constitutionalism/ (Accessed 20 February 2021). In fact, statutes and conventions too are part of what makes up the UK Constitution (see Masterman R *The UK Supreme Court: Constitutional Court in all but name? (2019)*. https://www.dur.ac.uk/international/global-lectures/comment/?itemno=402221 (Accessed 11 May 2021).

766 Martin J *The English legal System* 6th ed (Hodder Education London 2010) 88. Also see Law Wales *The three branches of government*. https://law.gov.wales/three-branches-governemnt/ (Accessed 26 January 2022).

767 S 49(1) of the Senior Courts Act 1981 (SC Act). This applies mainly to England and Wales.

768 Law Wales https://law.gov.wales/three-branches-governemnt/ (Accessed 26 January 2022).

769 Law Wales https://law.gov.wales/three-branches-governemnt/ (Accessed 26 January 2022). Also see ss 3 and 4 of the Human Rights Act 1998 (HR Act).

770 S 4(4) of the HR Act.

771 S 3(2), read with s 4(6), of the HR Act. Also see Finch E and Fafinski S *Legal Skills* 3rd ed (Oxford University Press New York 2011) 28.

conflict is resolved in favour of the use of equity principles. Are there then no generic principles that seek to provide guidance not only in the case of a conflict between equity principles and the common law, but also in other instances? The legal position in this regard is not very clear in the UK.[772] This lack of clear guidance, at least generally, as to which instrument must apply where multiple instruments exist may, in the context of health research, create confusion for stakeholders partaking in the research.[773]

What is the approach to questions of *locus standi* (legal standing)? The UK law position can now be mainly sourced from the HA, which gives effect to the ECHR, which the UK has ratified.[774] If a person alleges that a right under the ECHR (or a Convention right) has been violated the person may bring such a matter before the court, provided that the person is a victim of the unlawful act complained of.[775]

What is the approach to questions of legal interpretation? Because of the UK's historic system of parliamentary sovereignty, the approach of the courts towards interpretation is heavily influenced by the system.[776] The courts, when interpreting a particular legislation, have to give effect to the intention of the legislature, as opposed to the purpose of the legislation.[777] Legislation is viewed as an embodiment of the will of

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772 One needs to understand that any conflict of laws has far-reaching implications, for example, a possible conflict of forums; of remedies; of time (prescription) periods, causes of action, etc. Such a principle is even far more important for a country like the UK, which has a multiplicity of legislations, sometimes dealing with the same, or related, issues. For example, as appears below, there is more than one Act, with almost related short titles (names), dealing with children's affairs (these are the Children Act 1989 and Children Act 2004).

773 Note however that in the context of European law vis-à-vis UK law, the principle of the margin of appreciation applies. For further details about this principle, see *R (on the application of Elan-Cane) v Secretary of State for the Home Department* [2021] UKSC *56* para 77, which is a form of interpretation allowing the European Court to defer to the domestic courts of contracting states under certain circumstances.

774 Brownlie I (ed) *Basic documents in international law* 4th ed (Oxford University Press Oxford 1985) 328.

775 S 7(1)(b) of the HR Act, read with art 34 of the ECHR. With regard to class actions the position is however, except for competition law-related cases, by no means clear. In the competition sector, class or related actions are regulated by the Competition Act 1998. For a detailed exposition of the legal framework governing collective actions in the UK and a few other countries, see *Lloyd v Google LLC* [2021] UKSC 50 paras 3 and 24 – 83.

776 Botha C *Statutory Interpretation*: *an introduction for students* 5th ed (Juta Cape Town 2012) 91.

777 Botha *Statutory Interpretation* 92. The textual approach (using intention of the legislature as the starting point) has however not always been the English norm. This norm only started after what has been dubbed the Glorious Revolution, i.e. the Revolution of 1688, which led to the dethroning of King James II, and eventually giving parliament some supremacy over the monarchy (see Glorious revolution (2019). https://www.history.com/topics/british-history/glorious-revolution (Accessed 15 August 2020). The purposive approach was in use before the Glorious Revolution. The purposive approach first found its explicit judicial support in *Heyday's Case* (1584) 3 Co Rep 7a at 7b (76 ER 637) (see Botha *Statutory Interpretation*

parliament or another authorised law-making body,[778] and by implication that of the people. In order words, the courts in the main use a text-based approach, rather than the text-in-context approach.[779] The former is more literal in approach, rather than purposive.[780]

This limited approach makes it difficult for the courts to enquire into the merits of a particular legislation. The system gives the judiciary limited law-making power, if this law-making power must lead to the invalidation of legislation. This means that the notion of judicial overreach (judicial activism) and its counterpart, judicial restraint, might not be understood the same way in a parliamentary sovereignty, as it is understood in a constitutional democracy. And so is the notion of the separation of powers not the same as is applicable between the two systems (courts are, for example, in a constitutional democracy likely to stretch into the terrain that is often reserved for both the executive and the legislature). English law is further associated with certain presumptions that favour the state, some of which may undermine the rule of law.[781]

Another important aspect in English law is its approach to the rule of law. The UK constitutionalism, in the limited way in which it is used, is guided by the rule of law,[782]

152; also see Devenish GE *Interpretation of Statutes* (Juta Cape Town 1992) 19; further see Hahlo HR and Kahn E *The South African legal system and its background* (Juta Cape Town 1968) 184. There are also cases in the recent past where the purposive approach was used, as was the case in *Pepper v Hart* [1993] 1 All ER 42 (Also see *Pepper v Hart [1993] 1 All ER 42.* https://learninglink.oup.com/static/5c0e790eddf00160f35ad/casebook_70.htm (Accessed 24 January 2022). Further see Lee N "A purposive approach to the interpretation of tax statutes?'' 1999 Statute L. Rev 124 – 143).

778 Botha *Statutory Interpretation* 92.

779 Botha *Statutory Interpretation* 92.

780 Botha *Statutory Interpretation* 94.

781 Devenish *Interpretation of Statutes* 200 - 205.

782 Also see Dicey *Law of the Constitution* 184. Though there are differing conceptions of the concept of rule of law, even within similar systems of government, it could fairly be understood as meaning the supremacy of law, against the arbitrary exercise of power by those in authority. This could roughly be part of what Dicey proposed, limiting though his proposition was, in his analysis of the English Constitution (See Schreiner OD *The Contribution of English Law; and the rule of law in South Africa* (Juta Cape Town 1967) 74 – 79)). The definition would clearly not have contemplated the way the concept is used in constitutional democracies whose constitutions place positive duties on those governing to implement socio-economic changes. In fact, Dicey appears to have not considered countries with written constitutions to have the ideal rule of law (see Schreiner *Contribution of English Law* 75 - 76). Dicey's approach was later arguably corrected by the definition adopted by the International Commission of Jurists in Delhi in 1959, which conceived of the rule of law as also encompassing the socio-economic aspects, an approach however criticised by Schreiner for going too far (see Schreiner *Contribution of English Law* 81 – 86). For the various meanings of rule of law, further see Dicey *Law of the Constitution* 202 – 205.

a fact the Constitutional Reform Act 2005 (CRA) reaffirms.[783] The rule of law under the system of parliamentary sovereignty will certainly not be the same as that under the system of constitutional supremacy. The UK's usage of the system of parliamentary sovereignty therefore has implication on her conception of the rule of law.

Overall, it can be observed from above that the principle of the sovereignty of parliament remains one of the dominant tenets in English law. This has, in addition to its impact on the conception of the rule of law, far-reaching implications on other principles, including judicial review, interpretive frameworks and many other principles. A related dominant feature in English law is the over-cautious approach to the use of human rights language. This has the effect that those aspects of human life which need to be protected through the human rights framework suffer. Although English law does a have strong public law approach, through for example the regulation of various aspects through legislation, its strong parliamentary sovereignty and cautious human rights approach mean that its PLA is one short of human rights and the protection through the courts of law could also be weakened.

One of the Implications for health research in this regard is therefore that laws that poorly protect research participants might not be easily challenged in the system of parliamentary sovereignty, as applicable in the UK. The over-cautious approach to the human rights language means that the rights of the research participants may not receive maximum protection. Though the over-cautious approach of the UK towards the rights' language could arguably be remedied by the application of European law, which already has rights' language, three factors may weaken the application of European law in the UK namely, the doctrine of the margin of appreciation;[784] the ineffectiveness of the declaration of incompatibility of UK law (as it does not invalidate

783 S 1 of the CRA.

784 See in particular *R (on the application of Elan-Cane) v Secretary of State for the Home Department* [2021] UKSC 56 paras 77 and 82. Apart from the doctrine of margin of appreciation (which is mainly the doctrine of subsidiarity), Caldeira GA and Gibson JL further identify accountability and transparency as further factors or principles influencing what they call 'Euro-scepticism', which one thinks may (with some adaptations given that the UK is no longer part of the EU) equally be applicable for the UK in its relation to Europe (see Caldeira GA and Gibson AL "Democracy and legitimacy in the European Union: the Court of Justice and its constituents" 1997 *International Social Science Journal* 209 - 224.

the incompatible law)[785] and the fact that UK Courts are sometimes allowed the latitude to depart from the European Court jurisprudence where this is necessary.[786]

5.2.1 An approach to the protection of children

5.2.1.1 Common law

Several common law principles around consent will be applicable in the case of children, therefore strengthening protection to children. English law however arguably does not accord legal personality to an unborn child.[787] This may therefore weaken protection of such children in several contexts.

5.2.1.2 Legislative framework

Towards the end of the 1980s the UK passed the Children Act 1989 (the 1989 CA), a compressive legislation dealing with the welfare of children.[788] The main principle governing the treatment of children under the Act is the welfare of the child.[789] As part of determining the welfare of the child in specific contexts, the decision-maker has to ascertain the feelings and wishes of the child.[790] Some years later the UK passed the Children Act 2004 (the 2004 CA) which, instead of repealing the 1989 CA, improves on it, by amongst other provisions creating additional institutional mechanism for the protection of children including the creation of the Children's Commissioner.[791] The 2004 CA specifically requires the Children's Commissioner to prioritise the interests of children in his or her activities.[792]

In addition to the legislations above, the Female Genital Mutilation Act 2003 (FGMA) criminalises the mutilation of genitals of girls, irrespective of whether or not it is done as part of a customary practice or a ritual.[793] The prohibition does not, however, apply

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785 See S 3(2), read with s 4(6), of the HR Act.

786 See in particular *R (on the application of Elan-Cane) v Secretary of State for the Home Department* [2021] UKSC 56 para 101.

787 Riordan C *The Legal rights of unborn babies* (2004). https://www.cambridgenetwork.co.uk/news/the-legal-rights-of-unborn-babies. (Accessed 5 April 2021).

788 ADCS "Reflections on the Children Acts 1989 & 2004'' (2019). https://adcs.uk/general-subject-refections (Accessed 26 April 2021).

789 S 1(1) and (2) of the 1989 CA.

790 S 1(3) of the 1989 CA.

791 S 1 of the 2004 CA.

792 S 2B (1) of the 2004 CA. Further note ss 5, 6 and 7 of the 2004 CA, and their application to the various parts of the UK Union.

793 See in particular s 1(1) and (5).

where the mutilation is done by approved health professionals and for the purposes of physical or mental health, or for purposes related to birth or labour.[794] The FMGA creates reporting obligations, to the police, on the part of those who work in a regulated profession (including health professionals) and who become aware of the genital mutilation.[795] Because such a reporting obligation has the potential to undermine the privacy of those about whom the report is made, the FGMA specifically provides that the disclosure made under the Act shall not be construed as breaching any confidentiality or restrictions on the disclosure of information.[796] This may go a long way in protecting young girls, including those who are at risk of being subjected to mutilation as part of research.

The HR Act's provisions which, as earlier alluded to, give effect to the ECHR, are also relevant to the protection of children.

5.2.1.3 Children's protection under the United Kingdom's continental and international obligations

The 2004 CA specifically requires the Children's Commissioner to have some regard, in its consideration of the interests of children, to the UN Convention on the Rights of the Child (1989). The ECHR's provisions also find some direct application, based on the direct effect given effect to it in terms of the HR Act. Some of the ECHR's relevant provisions include the right to life,[797] the right to privacy,[798] protection from torture and inhuman or degrading treatment or punishment[799] and protection from non-discrimination.[800] The continental framework under the ECHR is however not clear about the legal position of children in general, nor is it clear about the status of unborn children.

5.2.1.4 Implications for health research

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794 See particularly s 1(2), (3) and (4).

795 See particularly s 5B (1), (2), and (5).

796 S 5B (7). It could be interesting how a further potential conflict could be resolved in instances where the mutilation was done in countries that still do not outlaw the practice and the victim later becomes a UK resident (which therefore triggers the applicability of the FGMA). Could this person still insist on her confidentiality being protected? (The disclosure in such a case does not necessarily prevent the practice, as the practice took place outside the UK).

797 Art 2 of the ECHR.

798 Art 8 (1).

799 Art 3.

800 Art 14.

Although both the 1989 CA and the 2004 CA do not specifically focus on health research issues, their focus on the importance of the welfare of the child could be very relevant in the protection of the child in health research. The same applies to the ECHR, which also does not specifically deal with health research issues, but whose other principles are also relevant to health research. The FGMA also goes a long way in protecting young girls from potential abuse, and such protection will therefore extend to those participating in the health research.

Perhaps one of the key problems observed under the UK's approach to the protection of children is that there is less emphasis on the rights' language in so far as the protection of children is concerned. This could itself weaken the protection of children, including those partaking in health research. A further aspect that could weaken the protection of children is the lack of any coherent framework around the protection of unborn children, who may be affected by research under certain circumstances. This means that although the UK at face value does have a strong intervention through public law, the content of this pubic law, which is short of a strong human rights element, is not in line with the PLA contemplated in this thesis.

5.2.1.5 The protection of displaced children

There is no legislation, or any other law specifically dedicated to the protection of displaced children in the UK. The existing laws protecting children in general will therefore be used. In the context of health research, however, because of the unique situations that displaced children often find themselves in, these general laws might not be enough to provide such protection.

5.2.2 Judicial review

5.2.2.1 Common law

The main ground of judicial review under the common law has broadly been one of *ultra vires*.[801] More particularised, the grounds take the following form: illegality; irrationality and improper procedures.[802] With the influence of European law,

801 The traditional ground of review in English law has been lawfulness, which avoided any enquiry into the merits of decisions. This traditional notion has however been gradually departed from (See also Turner ID "Judicial review, irrationality, and the limits of intervention by the courts'' 2010 *Kings Law Journal* 311 – 331).

802 See Law Teacher *Grounds of judicial review* (2019).

proportionality is also increasingly becoming part of UK law.[803] Illegality and irrationality have been classified as part of substantive grounds of review while some of the traditional principles of natural justice, namely the a*udi alteram partem*[804] rule and the rule against bias,[805] have generally been treated as procedural.

5.2.2.2 Legislative framework

There is no legislation specifically dedicated to judicial review in the UK. However, some statutes do touch on certain aspects relating to judicial review. One of these legislations include the Tribunals, Courts and Enforcement Act 2007 (TCEA) which provides for specific remedies that the Tribunals (First-tier and Upper Tribunals) may grant upon application for review.[806] The Senior Courts Act 1981 (SC Act) also provides for judicial review, including the various remedies the courts may grant.[807]

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https://lawteacher.net/free-law-essays/constitutional-law/grounds-of-judicial-review-constitutional-law-essay.php (Accessed 25 April 2021). Although the grounds of review are sometimes grouped into both substantive and procedural grounds, it is not necessary in this discussion to focus on those broad categories (see for example, Loveland I *Constitutional law, administrative law and human rights: A critical introduction*. 2nd ed. (Oxford University Press Oxford 2012) 445)). It should be noted that the various grounds of review remain overlapping (see also Loveland *Constitutional law* 446. Further see *Associated Provincial Picture Houses Ltd v Wednesbury Corporation* [1948] 1 KB 223; [1947] 2 ALL ER 680 (CA). Also see Hoexter C *Administrative Law in South Africa* 2nd ed (Juta Cape Town 2012) 346).

803 Public Law Project "An introduction to judicial review". (2018) 21. www.gov.uk/government/publications/administrative-court-judicial-review-guide (Accessed 15 April 2021. Further see The Independent Review of Administrative law. (2021) 50. https://assets.publishing.service.gov.uk Accessed 29 April 2021. Also see Public Law Project "Guide series: An introduction to judicial review'' (2019). https://publiclawproject.org.uk/content/uploads/2019/02/Intro-to-JR-guide-1.pdf. (Accessed 24 January 2022). Also see Loveland *Constitutional law* 445. On the discussion of proportionality, which is understood to play a critical role in the balancing of various rights and interests, further see Rautenbach I "Proportionality and the Limitation clauses of the South African Bill of Rights'' 2014 *PER* 2229 – 2267. Though the meaning of the concept appears to be fluid and context-dependent, one generally understands it to be centred on the necessity of means, while its closest ally, rationality could generally be understood as centred on the assessment of fitness (appropriateness) of the means in relation to the ends sought to be achieved (see also Hoexter *Administrative law* 340 - 346).

804 This is a rule requiring that both sides in a dispute must be heard (see Loveland *Constitutional law* 477).

805 This might take various dimension, including the avoidance of conflict of interests; being a judge in one's own case, etc. (For a further dimension to the notion of bias, see also Loveland *Constitutional law* 502 – 508, and the cases cited therein. Further see Beatson J and Mathews MH *Administrative law: cases and materials* 2nd ed (Clarendon Press Oxford 1997) 279 – 303). Further see Bailey SH, Jones BL and Mowbray AR *Cases and Materials on Administrative law* 3rd ed (Sweet & Maxwell London 1997) 418 – 537. These principles could be very critical in the day-to-day work of a research ethics committees, or other decisions by various stakeholders in health research).

806 S 15 of the TCEA.

807 See in particular s 31 of the SC Act. S 31A of the SC Act, which provides for the transfer of a case from the High Court to the Upper Tribunal under certain circumstances. For remedies further see s 29 of the SC Act.

The Constitutional Reform Act 2005 (CRA) which, as earlier indicated, restates the importance of the rule of law and the independence of the judiciary, remains very important for judicial review, given the centrality of both the rule of law and the independence of the judiciary in judicial review.

The Civil Procedure Rules 1998 (CPR) also deals with the procedural aspects of judicial review.[808] The HR Act also deals with the reviewability of decisions not in compliance with the ECHR.[809]

5.2.2.3 The United Kingdom's continental obligations

As alluded to earlier, as part of giving effect to continental obligations, the UK Parliament passed the HR Act, which specifically gives effect to the ECHR. As partly alluded to earlier, the violation of the rights under the ECHR may give rise to judicial review.[810]

Section 6 of the HR Act provides the basis for the control of power exercised by public authorities. The HR Act considers unlawful any conduct by public authorities which is inconsistent with the rights in the ECHR.[811] The provision does, however, permit the conduct if the conduct is provided for in law, to the extent that 'the authority could not have acted differently'.[812]

Of further importance is that the exercise of power by the Courts, in the UK situation, is also regulated by s 6.[813] Of further interest is the fact that Parliament is excluded in the UK from this control (the reason for this could be based on the notion of constitutional supremacy *vis-à-vis* parliamentary supremacy).[814] Private acts are, by implication, also excluded from the control contemplated in this section.[815]

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808 See in particular Rule 54 of the CPR. https://www.justice.gov.uk/courts/procedure-rules/civil-rules/part54#54.1 Accessed 3 April 2021.

809 Law Teacher Judicial Review in the United Kingdom (2019). https://www.lawteacher.net/free-law-essays/constitutional-law/judicial-review-in-united-kingdom-law-essays.php (Accessed 30 April 2021). Further see s 7(1) and (4) of the HR Act.

810 See particularly s 7(1), (3) and (4) of the HR Act.

811 S 6.

812 S 6(2)(a).

813 S 6(3)(a).

814 S 6(3)(b), read with s 6(6).

815 S 6(5), which specifically excludes a person from being a public authority if the act of the person is private.

5.2.2.4 Implications for health research

Though the UK, as observed, does provide for judicial review, its approach to judicial review is a bit conservative, partly because of the UK's system of Parliamentary sovereignty. The UK's adoption of the ECHR does not resolve this problem, given that, as indicated earlier, the incompatibility between UK law and the ECHR does not invalidate UK law. The way the doctrine of appreciation is used could also reduce the effectiveness of reliance on the ECHR. The fact that the UK courts may sometimes depart from the jurisprudence of the European Court may also undermine the effectiveness of reliance on European law. Judicial review without a very strong human rights element does not adequately cement the PLA contemplated in this thesis.

The conservative approach towards judicial review means that not much can be gained from it in the context of the protection of health research participants. Even as a matter of practice, as it appears in the case of *Morton James Wylie v Dr Donald Grosset, Greater Glasgow Health Board* [2011] COSH 89, administrative law principles, often associated with judicial review, do not feature in deciding health research questions.

5.2.3 Approach to human dignity

5.2.3.1 Common law

The English law position with regards to human dignity is very unclear. What is (perhaps) arguably clear is that the vocabulary of human dignity, though recently emerging, has not yet occupied a central place in English law, at least in a direct sense.[816]

5.2.3.2 Legislative framework

There is currently no legislation in the UK expressly providing for human dignity.[817] The Equality Act 2010 (EA), which provides for equality issues, does not directly link

816 Duprė C "What does dignity mean in a legal context'' (2011) https://www.theguardian,com/commentisfree/libertycentral/2011/mar/24/dignity-uk-europe-human-rights (Accessed 28 April 2021).

817 Cooper J "Dignity, the right to life and the Coronavirus'' Oxford Human Rights Hub (2020). http://Ohrh.law.ox.ac.uk/dignity-the-right-to-life-and-the-coronavirus/ (Accessed 30 April 2021).

equality to dignity issues, as often happens in other equality laws in other jurisdictions.[818] Not even the HR Act, which gives effect to the ECHR, makes express provision for it.

5.2.3.3 The United Kingdom's continental obligations

The ECHR, which as earlier indicated the HR Act gives effect to, does not make express provision for human dignity. Respect for human dignity can then arguably be inferred from other provisions like that dealing with prohibition of torture or inhuman and degrading treatment[819] and the one dealing with respect for privacy.[820] Though its extent of applicability to the UK is unclear, English Courts do however make reference to the Charter of Fundamental Rights of the European Union (2000) (CFREU), which does expressly provide for human dignity.[821]

5.2.3.4 Implications for health research

Human dignity has become central in the protection of research participants, especially under international law. The absence, or at least reluctant presence, of human dignity vocabulary in English law, therefore, has serious implications for the protection of research participants.[822] It has the potential of reducing their protection. The absence of emphasis on human dignity, which is very critical in both private law and public law, means that the PLA contemplated in this thesis is also lacking in the UK's approach to the protection of human beings in general, and research participants in particular.

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818 For example, SA's PEPUDA, which as indicated in chapter four, though dealing with equality issues does also touch on issues of human dignity. At international level, art 1 of the UDHR also ties equality to dignity by providing that '*all human beings are born free and equal in dignity*…'.

819 Art 3 of the ECHR.

820 Art 8.

821 This was the case in *A & Ors, R (on the application of) v East Sussex County Council & Anor* [2003] EWHC 167 (Admin) (18 February 2003). Art 1 of CFREU makes provision for human dignity. The uncertainty around the applicability of CFREU to the UK has even been fortified by the passing of the European Union (Withdrawal) Act 2018 (EUWA), following the UK's withdrawal from the EU (otherwise known as Brexit), which though specifically excluding CFREU from UK's domestic law after exit day (being 29 March 2019), does retain some of the fundamental principles which exist 'irrespective of the Charter' (see particularly s 5 (4) and (5), read with s 6, of EUWA. See also Schedule 1 to EUWA. Further see ss 19 and 20)).

822 The absence of express recognition, though itself problematic does not of course mean that it is not recognized at all, as there is some casual reference to it in some cases. For some casual reference to human dignity, also see *Campbell v MGN Ltd* [2004] UKHL 22; [2004] 2 AC 457 para 50, as cited in *Lloyd v Google LLC* [2021] UKSC 50 para 97.

5.2.4 An approach to equality protection

5.2.4.1 Common law

The English Common law arguably lays claim to equality before the law.[823] This may therefore, though very vaguely, permeate into other areas of human life.

5.2.4.2 Legislative framework

One of the main statutes dealing with equality issues is the EA, which repeals the various laws dealing with equality, including the Disability Discrimination Act 1995; Race Relations Act 1976; Sex Discrimination Act 1986 and Equal Pay Act 1970.[824] The EA prohibits direct discrimination based on a number of grounds, referred to as protected characteristics, which are race, disability, age, gender reassignment, sex, sexual orientation,[825] marriage and civil partnership and religion or belief.[826]

The EA does not provide for a general defence in case of the direct discrimination based on these grounds.[827] The EA provides for a general defence in the case of indirect discrimination.[828] The EA places some obligations on the public sector entities to implement the provisions of the Act.

5.2.4.3 The United Kingdom's continental obligations

Given the fact that the HR Act gives effect to the ECHR, the latter's equality provisions become important to the UK. Art 14 of the ECHR prohibits discrimination on various grounds namely race, language, religion, sex, colour, political or other opinion, national or social origin, property, birth or other status and association with a national minority.

5.2.4.4 Implications for health research

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823 This can be inferred from Dicey's conception of English law as subjecting everyone equally before the law (see Schreiner *Contribution of English Law 77*).

824 Schedule 27 to the EA.

825 One should take note of the overlapping nature of the concept of sexual orientation with that of sex in ss 12 and 11 of the EA respectively.

826 S 4 of the EA.

827 Only in relation to some grounds namely, age, is there a ground of justification based on the proportionality of the means in relation to the legitimate ends to be served by the discrimination (see s 13(2) of the EA).

828 S 19(2)(d) of the EA, which creates room for proportionality of the means in relation to the legitimate aim to be used as a ground of justification for all the listed grounds of justification.

The protection of equality may be very important in the context of health research, where there should be no discrimination on a variety of characteristics. However, the EA's closed list means that those discriminated based on other discriminatory grounds like health status (including HIV status) and socio-economic status might not be easily protected.[829] Although the ECHR is more expansive in its list of prohibited grounds of discrimination, its effect is mitigated by the fact that its compatibility with the national (domestic) law does not invalidate the national law. The very generally cautious approach of the UK towards human rights also means that the kind of equality envisaged here is not fully located within the language of rights, nor is it strengthened by such a language. The UK approach therefore arguably presents a very restrictive, if not a weaker, version of equality. With equality being one of the key elements of the human rights philosophy, which is a key part of the PLA contemplated in this thesis, the restrictive approach to equality will likely undermine the protection of research participants.

5.2.5 The right to health care

5.2.5.1 Common law

The UK, it appears, does not have a common law right to health care. This does not mean that such a right cannot arise from other common law obligations like contracts and torts, where such an obligation arises from a particular context.

5.2.5.2 Legislative framework

There is arguably no legislation providing for the right to health care in the UK, at least to the extent in which it is understood in a human rights sense.[830] This is so despite the fact that the HR Act, which itself does not provide for the right to health care, gives

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829 The obligations placed by s 1 of the EA on public sector institutions, which requires such institutions, when taking decisions of a strategic nature, to do so in ways that reduce the inequalities of outcome, is not enough to allay this fear. In fact, the mere fact that this type of an obligation is only placed on public sector institutions and that the failure by such institutions to comply does not give rise to a private law action, is itself problematic (see s 3 of the EA).

830 Also see Library of Congress https://www.loc.gov/law/help/child-rights/uk.php# (Accessed 5 April 2021). This does not however mean that there are no legislations that touch, whether directly or indirectly, on issues related health (see for example, s 2(3)(a) of the Children Act 2004, which requires the Children's Commissioner to take children's interests, including those relating to health, into account when discharging his or her functions.)

effect to the ECHR. The problem is that the ECHR itself, as explained below, does not make specific provision for the right to health care.

5.2.5.3 The United Kingdom's continental obligations

As earlier alluded to, the ECHR does not make specific provision for the right to health care. This does not mean that rights related to health care may not be claimed under other provisions. The right to life;[831] non-discrimination provision;[832] the right not to be tortured or treated degradingly or inhumanly[833] and the right to privacy[834] are some of the rights that could be relied on with respect to health-related issues, but these rights stop short of, on their own, creating a sufficient basis for one to demand access to certain health services. As pointed out earlier, add to this the fact that the declaration of incompatibility arising from the conflict between UK domestic law and the ECHR does not invalidate the domestic law.

Although the direct applicability of the CFREU is not too certain, the courts do sometimes refer to it.[835] This could then create the basis for the right to health care, as the CFREU does make provision for it.[836]

5.2.5.4 Implications for health research

The absence of a clear right to health care in UK law makes it difficult for the research participants to be afforded enough protection. The mere fact that the courts may sometimes rely on the CFREU is not enough to fortify such protection. Though legislations exist dealing with health issues in general, which means that there is a strong public law approach present therein, the reluctance towards defining such health issues along the human rights language does weaken the PLA contemplated in this thesis.

5.2.6 Protection of personal information and access to information

831 Art 2(1) of the ECHR.
832 Art 14.
833 Art 3.
834 This right can be proportionately limited in the interest, amongst other things, of 'the protection of health' (see art 8(2) of the ECHR).
835 One of such cases where reference was made is *A & Ors, R (on the application of) v East Sussex County Council & Anor* [2003] EWHC 167 (Admin) (18 February 2003).
836 Art 35 of the CFREU.

5.2.6.1 Common law

There is no general common law right to privacy, at least under the law of tort, in the UK.[837] This does not however mean that personal information cannot be protected under other principles of the common law. Protection of such information is still possible, though in a limited sense, under the law of confidence, contract, trust or even property law.[838] As such information is mostly protected under the common law of confidence, its brief discussion here is necessary. For the claimant to successfully secure the protection of personal information, the claimant must show that the information sought to be protected is capable of being protected; was obtained or used in breach of confidence and that the defendant is bound by a legal obligation to respect the confidentiality.[839]

The defences available to a defendant who is accused of having accessed confidential information include consent (or authorisation); public interest; promotion of freedom of expression; giving effect to several other equity-based defences and compliance with a statutory obligation[840] or a court order.[841]

Regarding access to information, there is no clearly defined general common law right providing for such access.[842] Legislation therefore provides guidance in this regard.

5.2.6.2 Legislative framework

The main statutes dealing with protection of information and information access are the 2018 DPA and the Freedom of Information Act 2000 (FOI Act) respectively. As indicated in chapter one, the DPA replaces the 1998 old DPA. The DPA in the main gives effect to, and in some instances supplements, the GDPR, which the old DPA did

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837 Library of Congress "Online privacy law: United Kingdom" https://www.loc.gov/law/help/online-privacy-law/2012/uk.php# (Accessed 30 April 2021). Further see Bently L and Sherman B *Intellectual Property Law* 2nd ed (Oxford University Press New York 2004) 995 – 998.

838 Bently and Sherman *Intellectual Property Law* 994. Also see *Lloyd v Google LLC* [2021] UKSC 50 para 97.

839 Bently and Sherman *Intellectual Property Law* 993 & 998.

840 A typical example here could be disclosures in line with reporting obligations in terms of the Female Genital Mutilation Act 2003, which requires members of the regulated profession to report acts prohibited under that Act to the police.

841 Bently and Sherman *Intellectual Property Law* 1039 - 1046.

842 See however "UK court finds common law right to information (2014)" http://www.freedominfo.org/2014/03/uk-court-finds-common-law-right-information/ (Accessed 1 May 2021).

not take account of, as the GDPR was promulgated after the old DPA came into effect.[843] The main focus of the DPA is ensuring that those processing personal information do so fairly and lawfully, where the data subject's consent is also required.[844] The DPA further provides for the rights of data subjects.[845] These rights in the main include accessing personal information by the data subject and the rectification of personal information by the data subject.[846]

Apart from the courts, the DPA provides for some other key institutional arrangements namely the Information Commissioner (Commissioner) and the Tribunals. Both the Commissioner and Tribunals may play an important role in the enforcement of compliance with the DPA. Apart from the courts,[847] the Commissioner is the main supervisory authority in the UK, for purposes envisaged in the GDPR.[848] It is also the primary actor in the enforcement of compliance with the DPA.[849] Tribunals, whether first-tier or Upper Tribunal, may be involved if proceedings in relation to matters arising from the DPA are brought before them, where this is applicable.[850]

The DPA provides for the territorial scope within which those involved in the processing of personal information may be held accountable in the UK. Section 207 makes the DPA only applicable to the processing of personal information 'in the context of the activities of an establishment of a controller or processor in the United Kingdom' irrespective of where the processing takes place.[851] This means that the DPA becomes applicable, under this provision, solely by virtue of the processor or controller being in the UK, if the processing is 'in the context of' that establishment in the UK.

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843 S 1(3) of the DPA.

844 S 2(1)(a).

845 S 2(1)(b).

846 S 2(1)(b). These aspects are further dealt with in arts 15 to 17 of the GDPR. Further see other sections of the DPA dealing with these aspects in the contexts of law enforcement (ss 45 to 47 of the DPA) and Intelligence gathering (in particular ss 94 and 100 of the DPA).

847 The courts already possess jurisdiction in terms of s 180 of the DPA.

848 S 115(1).

849 SS 142 to 161 of the DPA.

850 See also the definition of 'Tribunal' in s 205 (1) of the DPA. Further see ss 201 to 203 of the DPA. Further see s 166 of the DPA, which may require the Commissioner to take measures to respond to a data subject's complaint.

851 S 207(1) and (2) of the DPA. This framework is adopted from the framework created by the GDPR (see art 3(1) of the GDPR)).

It is unclear what 'in the context of' means, but one could argue that it means 'at the instance of' (or at least 'as a result of') the establishment in the UK, so as to create a causal link between alleged conduct of the processor and the procession itself. This line of conception could be very important in the context of multisite research activities, where processing may take place in one country, but those who initiated it are in the UK (the DPA could then become applicable on this ground alone). The other ground on which the DPA may become applicable is where the offering of the goods or services to the data subjects, or the monitoring of the data subjects' behaviour, takes place in the UK, even if the controllers or processors are not based in the UK.[852]

As indicated in chapter one, the DPA also regulates the transfer of personal data from the UK to another country or to an international organisation.[853] This may be done by making regulations providing for the conditions under which this may be necessary, and likewise, conditions under which this might be unnecessary, in the public interest.[854] Regulations may likewise be made to restrict the transfer of certain categories of personal information, on the ground of public interest, or based on the failure to satisfy the GDPR's adequacy requirements.[855]

This has implication in the context of health research, as personal information might be moved from one country to another, therefore making it necessary to have enough guidelines to protect research participants. As alluded to in chapter one, the DPA further allows processions that are considered necessary for the purposes of conducting research or scientific studies.[856] It should further be noted that one of the conditions for the research exemptions in Part 1 of Schedule 1 to the DPA is that the research must be in the public interest.[857]

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852 S 207(3) of the DPA (this is substantially a restatement of the GDPR position (see art 3 (2) of the GDPR)).

853 S 18.

854 S 18(1).

855 S 18(2).

856 S 19(1) (b) of the DPA, read with Part 1 of Schedule 1 to the DPA.

857 Part 1(4)(c) of Schedule 1 to the DPA. The only question arising then would be as to what the conception of public interest as envisaged in this provision is. Though stated in a different context, the attempt to outline what would possibly constitute substantial public interest (and therefore not simply public interest) conditions in Part 2 of Schedule 1 to the DPA is so wide, and perhaps loose, that the concept may end up meaning almost anything that the decision-makers want it to mean.

Another statute relevant to the protection of information and access is the FOI Act. The FOI Act in the main provides, upon request, for access to information held by public bodies.[858] Compliance with the FOI Act mainly takes two forms, namely confirmation or denial about the existence of the requested information[859] and the communication of such information to the requester if such information exists.[860] These requirements do not have to be complied with if a relevant body seeks certain information it reasonably requires in order to comply with the request, but the requestor fails to supply the information.[861] Compliance with s 1(1)(a) of the FOI Act becomes inapplicable where an absolute exemption as provided in the Act[862] applies, or where the public interest in not complying with the requirement of confirmation or denial overrides the public interest in disclosing the existence of the information.[863]

Following the same line of reasoning, section 1(1)(b) of the FOI Act is inapplicable where an absolute exemption applies, or where public interest in applying the exemption overrides the public interest in allowing access to the information.[864] The request for information must be done in writing.[865]

Public bodies may further be exempted from providing information as requested if the cost of compliance exceeds a particular prescribed limit.[866] Public bodies are further not required to provide requested information if the request is vexatious.[867] They are also not required to provide requested information if the requests, substantially identical to previous requests, are repeated, unless a reasonable time has lapsed since the compliance with the last request occurred.[868]

The FOI Act provides for the establishment of an Information Commissioner and the Information Tribunal, which were referred to as the Data Protection Commissioner and

858 S 1 of the FOI Act.
859 S 1(1)(a).
860 S 1(1)(b).
861 S 1(3).
862 Also see s 2(3) of the FOI Act, which provides for the sections that the Act considers conferring absolute exemption.
863 S 2(1).
864 S 2(2).
865 S 8(1)(a).
866 S 12.
867 S 14(1).
868 S 14(2).

Data Protection Tribunal respectively under the Old DPA, before the coming into operation of the FOI Act.[869]

The FOI Act further provides for a number of exemptions.[870] It provides for exemption in the case where the information is reasonably accessible by other means.[871] FOI Act further makes provision for exemption where the requested information is already planned for future publication, irrespective of whether or not the date for such a publication is determined.[872] Information supplied by, or relating to, security services (i.e. information supplied by bodies engaged in security issues) as contemplated in the FOI Act is also exempted.[873] Where information is not already exempted under s 23(1) of the Act it may qualify for exemption if the information is required for the pursuit of national security purposes.[874]

Exemption is also available where the disclosure of the information could be prejudicial to the defence interests of the UK as defined in the FOI Act.[875] Information is further exempted if its disclosure would be detrimental to the UK's international relations.[876] Confidential information received by the UK from another state or from international organization or international court is also exempted from disclosure.[877] Information is also exempted if its disclosure would be detrimental to the relations within the UK.[878] Information is further exempted if its disclosure would be detrimental to the UK's economic interests or those of any of its constituent parts.[879] Information would also be exempted if its disclosure would undermine law enforcement activities.[880]

Most importantly, information would be exempted if its disclosure would be detrimental to the health and safety of individuals.[881] Information would further be exempted if a public body would be obliged to release the information to the public in terms of

869 S 18(1) and (2). Also note the functions of the Information Commissioner in s 47.
870 These are mainly covered from ss 21 to 44, but only some of them are touched on here.
871 S 21(1).
872 S 22.
873 S 23(1) and (3).
874 S 24(1).
875 S 26(1) and (2). Should there be health research conducted within the military itself, as the military establishments often do, this exemption, though legitimate, also has the potential of being used to shield any research atrocities that may occur.
876 S 27(1).
877 S 27(2).
878 S 28(1) and (2). This ground is arguably too wide, and risks being abused.
879 S 29(1).
880 S 31.
881 S 38(1).

environmental regulations.[882] An exemption also exists if the information was received in confidence from another person, whether a public body or not, if the disclosure of the information would lead to a legal action by another person, based on a breach of confidence.[883] The FOI Act further provides for the exemption of information constituting a trade secret or whose disclosure may endanger another person's commercial interests.[884] Information is further exempt if its disclosure would contravene a particular legislation.[885] Information would further be exempt if its disclosure would lead to contempt of court proceedings.[886]

5.2.6.3 The United Kingdom's continental obligations

Due to the HR Act giving effect to the ECHR by incorporating the latter into the UK law, the privacy provision in Art 8 of the ECHR also applies to the UK. The ECHR also provides for the use of confidentiality, when provided for in a law, as a possible limitation on the right to freedom of expression.[887]

5.2.6.4 Implications for health research

The common law protection of confidentiality will play a key role in the protection of research participants. So are the provisions of the DPA and FOI Act. Overall, however, the absence of human rights language in both the common law and legislative frameworks may weaken the level of protection to be afforded to research participants.

What about the provision for public interest in both the DPA and the FOI Act? Although both the DPA and FOI Act do refer to public interest, the notion of public interest mostly comes to the fore as a defence or exception (exemption) to the default position, therefore unduly narrowing down the way the concept ought to apply. Again, although the DPA's emphases on general safeguards are built around issues that focus on

882 S 39(1).

883 S 41(1)(a) and (b). This could be critical in the context of health research, in that information belonging to health research participants could be shielded from being accessed by others on request. This however could also be a double-edged sword, in that atrocities by researchers could also be protected from disclosure.

884 S 43(1) and (2). This exemption could potentially shield any abuses by researchers and sponsors from access by whistle-blowers, therefore weakening protection afforded to research participants.

885 S 44(1)(a). What about when the disclosure could be inconsistent with other laws than enacted laws, e.g. the common law? It is arguable that the same principle will apply.

886 S 44(1)(c).

887 Art 10 of the ECHR.

public interests, it might not necessarily be the public law approach contemplated in the PLA in this dissertation. The number of exemptions offered under the FOI Act also have the potential to undermine transparency, with the result that research atrocities may be shielded. However, the use of the public interest yardstick in weighing whether information should be disclosed or not under the FOI Act is a welcome position.

5.2.7 *Approach to remedies*

5.2.7.1 Common law

Historically English common law only limited its remedies to damages, therefore leaving the litigants without remedies in a number of instances.[888] Equity law principles were therefore developed to cure this deficiency.[889] The equity law therefore created new remedies, which include injunctions; rescission; rectification and specific performance.[890] As indicated earlier, in case of any conflict between the common law and equity, the latter reigns supreme. An issue that has received some attention in the UK courts is the question of vindicatory damages.[891] The UK Supreme Court has been forthright in the rejection of vindicatory damages.[892] As to exemplary (punitive) damages there is no outright rejection of such in UK law, as these may be awarded under certain circumstances.[893]

It often happens that contracting parties provide for the exclusion of liability under certain circumstances. The common law does not provide for a general principle for the outlawing of exemption clauses based on unfairness or unreasonableness.[894] Some answers therefore must be sought from legislation.

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888 Martin *The English legal system* 19.

889 Martin *The English legal system* 19.

890 Martin *The English legal system* 19 - 21.

891 The concept of constitutional damages is here avoided because of the nature of UK constitutional framework, which as earlier indicated differs from that of SA and the US in that it is unwritten (see use of the concept of vindicatory damages in *Walumba Lumba (Congo) 1 and 2 v Secretary of State for the Home Department* [2011] UKSC 12 para 97).

892 See *Walumba Lumba (Congo) 1 and 2 v Secretary of State for the Home Department* [2011] UKSC 12 para 101, where the court as per Lord Dyson saw '*no justification for letting such an unruly horse loose*' on the UK law. Also see *Lloyd v Google LLC* [2021] UKSC 50.

893 See *Walumba Lumba (Congo) 1 and 2 v Secretary of State for the Home Department* [2011] UKSC 12 para 150, and the cases cited therein, including *Rookes v Barnard [1964] AC 1129*.

894 See also Law teacher "Exclusion clauses lecture'' (2018). https://www.lawteacher.net/lectures/contract-law/construction/exclusion-causes (Accessed 2 April 2021.

5.2.7.2 Legislative framework

The TCEA provides for some remedies namely a mandatory order; quashing order; prohibiting order; a declaration and an injunction, which the Upper Tribunal may grant.[895] The SC Act also provides for similar remedies.[896] So as to mitigate the impact of judicial review on decisions by public authorities, there have been recent calls for the amendment of the relevant legislations, in particular the SC Act, regulating the quashing order remedies (which set aside decisions). Reforming such orders will enable the courts to make such orders suspended for a period so as to enable decision-makers to cure the defect that the orders seek to address.[897]

Regarding exemptions, one of the legislations dealing with exemption clauses, by outlawing the exclusion of liability under certain circumstances, is the Unfair Contract Terms Act 1977 (UCTA).[898] Though it is doubtful if there are any instances where UCTA could be directly applicable to a researcher-research participant relationship,[899] its principles around control of exemption clauses could be adapted to such a relationship, therefore protecting research participants. UCTA does not outlaw exemption (indemnity clauses) completely but allows them if they meet the reasonableness test.[900] Where such contracts have clauses that exclude liability in case of breach of contract, such clauses are of no effect in law.[901]

Another statute dealing with exemption clauses is the Consumer Rights Act 2015 (CR Act). Unlike UCTA, which focuses on relations between businesses, the CR Act regulates relations between a trader and a consumer,[902] therefore creating an indirect

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895 S 15(1) of the TCEA.

896 S 31 of the SC Act.

897 See *The Independent Review of Administrative law* (2021). https://assets.publishing.service.gov.uk (Accessed 29 April 2021).

898 Law teacher https://www.lawteacher.net/lectures/contract-law/construction/exclusion-causes (Accessed 2 April 2021.

899 This doubt arises from the limited nature of the application of certain parts of the Act, in particular s 1(3), read with s 2(3), which limits the application of Part 1 of the Act to 'business liability', therefore implying that both parties to the contract will have to be acting 'in the course of business' as defined in the Act. Also see the definition of 'business' in s 14 of UCTA. Further see the definition of 'customer' in s 17 of UCTA which, though applicable to Part II of the Act which mainly applies to Scotland, does clarify the issue of who is protected under the Act.

900 SS 6(1A) and 7(1A) and (4) of UCTA. Further see s 11 and Schedule 2 of UCTA. In principle, reasonableness and fairness run through the conditions under which exclusion of liability should take place.

901 S 16(1)(b) of UCTA which, though mainly applying to Part II applicable to Scotland is also relevant to the context of the Act as whole.

902 S 1(1), read with s 2(2) and (3), of the CR Act.

scope for the CR Act to apply to research participants who might be acting as consumers in a specific situation. The CR Act also considers certain terms and notices as unfair.[903] Such contracts do not have any binding effect on the consumers.[904] The CR Act also makes contracts (for the supply of certain services) of no effect (in the sense of being not binding on the consumer) in case such contracts limit liability of the trader.[905] The principle of fairness therefore arguably runs through the CR Act, which the latter also obliges a court to enquire into in relation to specific terms of a contract.[906]

5.2.7.3 The United Kingdom's continental obligations

In terms of the HR Act, which gives rise to continental obligations by giving effect to the ECHR, where a public authority has committed an unlawful act, including a proposed act, the court may grant any remedies that it considers just and appropriate.[907] There is, however, a proviso that damages may only be awarded by a court that is competent to make an order of damages or compensation in civil proceedings.[908] There is a further proviso that damages may only be awarded if 'the court is satisfied that the award is necessary to afford a just satisfaction to the person in whose favour it is made'.[909]

5.2.7.4 Implications for health research

Although most of the remedies outlined above could be considered useful even in the context of health research, they have generally not been applied in that context. The ECHR remedies may or not be applied by the courts, as incompatibility between the ECHR and domestic law does not lead to the invalidity of the domestic law, which therefore means that where the remedies under the domestic law are not sufficient, resort to the ECHR remedies is not obligatory.

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903 S 62 of CR Act. Further see Part 1 of Schedule 2 to the CR Act, which outlines examples of what may be considered to be unfair.

904 S 62(1) and (2).

905 S 57. The deliberate focus only on the supply of services in this thesis arises from the fact that the other parts of the CR Act focus on the supply of goods and digital content, which comparatively might not bear direct relevance to questions of researcher–participant relationship.

906 S 71.

907 S 8(1) of the HR Act.

908 S 8(2).

909 S 8(3).

The regulation of exemption clauses, though also potentially useful in the context of health research, was arguably not developed having health research in mind, therefore making the applicability of such laws to such a context a matter of speculation, dependent on how the courts will approach a specific case. Notwithstanding these limitations, the framework's public law approach could be very helpful in defining the content of the obligations between the various stakeholders in research.

5.2.8 The regulation of research oversight

There is arguably no specific common law principle governing the oversight of research in the UK. The common law principles discussed in relation to the aspects above will however become applicable.

5.2.8.1 Common law

Various common law principles, some of which have already been discussed above, will be applicable in research oversight, including principles around consent to decision-making[910] and the common law principle of confidentiality.[911] These principles need not be further detailed here. It is apt here to reflect on one of the notable cases directly dealing with health research oversight in the UK, being the case of *Morton James Wylie v Dr Donald Grosset, Greater Glasgow Health Board* [2011] COSH 89, decided under Scottish law.

In this case the pursuer (claimant) participated in a clinical trial (sponsored by Schwarz, a German company), from which he developed uncontrollable gambling habits leading to considerable financial losses. He sought to claim compensation from the investigators and the institution that had links to the research. The pursuer did not join the sponsors of the clinical trial in the action. The pursuer based the claim on the existence of a unilateral obligation, as a result of the promise of compensation made in the informed consent leaflet. The pursuer also relied on contract, in the alternative. The informed consent form said that compensation was to be made in accordance with the ABPI Guidelines.[912]

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910 Paras 5.1.1 and 5.1.3a of the MRC *Ethics Guide: Medical Research Involving Children* (MRC Children's Guide).

911 Para 2 of *MRC Ethics Series: Using information about people in health research.* https://mrc.ukri.org/documents/pdf/using-information-about-people-in-health-research/ (Accessed 4 April 2021).

912 Association of British Pharmaceutical Industry (*ABPI) Guidelines for Phase 1 Trials* (London

The court ruled that the relationship between the pursuers and the defenders was a contractual one. The court, however, ruled that the terms of the contract, as in the participant information sheet, read with the ABPI Guidelines to which it referred, did not provide for a legally enforceable obligation to pay compensation. The court was silent on the precise nature of the relationship between the claimant and the sponsors, but only mentioning in passing that there was no contractual relationship. Even more silent was the court on the nature of the relationship between the sponsors and investigators and their employers (the defenders in this case).

A ruling by the court on the nature of the relationship between the sponsors and the defenders would have shed some light on the nature of the relationship between the sponsors and the claimant. For example, if the relationship between the sponsors and the defenders could be one of agency, in respect of their dealings with the claimant, the conclusion that there is a contract between the claimant and the sponsors would become irresistible. The court's direction on this point was necessary, given that the Participant Information Sheet mentioned the sponsors as those who would be responsible for the payment of the compensation. This is even more so that one of the arguments of the defenders, which the court rejected, was that it was the sponsors that ought to have been sued, rather than the defenders. Digging deeper into the relationships between these stakeholders was therefore no small issue.

As indicated earlier, the pursuers in this case relied on a unilateral obligation (which, though not necessarily a contract in UK law, could be a contract in South African law, as the latter, unlike its UK counterpart, does not have the doctrine of consideration) and, in the alternative, a contract. The contractual, more especially the traditional contractual, approach appears a bit limiting. The parities here never sought to rely on public law grounds, which could arguably have changed the way the decision could have gone.

5.2.8.2 Legislative framework

ABPI 2007).

One of the important statutes dealing with biomedical issues is the HTA, which regulates the use, and storage and removal for use, of human material and material from the body of deceased persons, which may only be done with appropriate consent as defined in the Act.[913] The consent may come from the persons whose human material or bodies are affected.[914] In case of children, they can also give such consent if the material is affected while they are still alive except where, for various reasons contemplated in s 2(3), a person with parental responsibility may have to consent.[915] Where the child has since died and the purpose of the use or storage for use is one for public display, not for anatomical examination nor one falling under excepted material, such a consent of the child will need to be in writing.[916]

The requirement of 'appropriate consent' does not apply in case the use or storage for use of human material from a living person, as contemplated in ss 1(1)(d) and (f), is for the purposes of research related to disorders or how a human body functions.[917] The HTA further prohibits the 'non-consensual analysis' and use of a person's DNA, which constitutes an offence.[918] The prohibition does not however apply in the case of 'use for an excepted purpose', which includes analysis for research purposes in connection with human disorders or the functioning of a human body.[919]

Another important legislation touching on health research is the Care Act 2014 (Care Act), which provides for the establishment of the HRA.[920] The Care Act then provides for the functions of the HRA.[921] The HRA standardizes and co-ordinates the practice regarding how health and social care research should be regulated.[922] The HRA further deals with the approval of processions involving confidential information.[923] The HRA sets outs as one of its objectives the encouragement and facilitation of the

913 S 1 of the HTA.
914 S 3 of the HTA, which regulates consent by adults whose material or bodies are affected.
915 S 2(3).
916 S 2(4) and (5).
917 S 1(7) and (8), read with s 1(9). Further see s 1 (9A), which creates further exceptions in case the *Human Fertilization and Embryology Act 1990* requires consent for the use of such material.
918 S 45(1) read with s 45(4).
919 Item 6 of Sch 4 to the HTA.
920 S 109(1) of the Care Act. Also see s 111 of the Care Act, which identifies a number of institutions relevant for research, in addition to the HRA.
921 S 110.
922 S 110(1)(a).
923 S 110(1)(d).

conduct of safe and ethical research, thereby protecting the participants, future participants and the general public, as well as promoting the interests of these persons.[924]

The promotion of transparency in research is also part of the HRA's latter objective.[925] What does transparency in research entail? It entails the following: that the research be registered;[926] that the results of the research be disseminated and published;[927] that there be access to the data on which the research was based;[928] that information relating to the research be provided to the research participants at the end of the research;[929] and that access be provided to the tissue used in research, 'for use in future research'.[930]

The HRA is also required to publish a framework on governance principles relating to health research and social care research.[931] The HRA must further publish a framework on the requirements that must apply to those conducting health research and social care research.[932]

The HRA must ensure that the RECs it has established or recognized do their ethical review work efficiently and effectively.[933] The HRA must publish a framework called the REC Policy Framework, outlining the requirements which RECs are expected to comply with.[934] The HRA must further overseer the RECs' compliance with these requirements.[935] The requirements the HRA sets out in a REC Policy Document framework referred to earlier must not be inconsistent with those set out for RECs in the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031).[936]

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924 S 110(2)(a) and (b).
925 S 110(2)(b).
926 S 110(7)(a).
927 S 110(7)(b).
928 S 110(7)(c).
929 S 110(7)(d).
930 S 110(7)(e). It is unclear here as to whom the access must be provided to, for future use in research: Is it to the general public, to the research participants, or to researchers? It appears to be to researchers.
931 S 111(5)(a).
932 S 111(6)(b).
933 S 112(1).
934 S 112(3)(a).
935 S 112(3)(b).
936 S 112(6).

The HRA is further required to indemnify those involved in the work of the RECs (i.e. members) it has established or recognized against any liability for losses or damage that a third party may have suffered while performing its functions pertaining to the ethical review of health research and social care research.[937] The HRA must publish guidelines on cases where it considers ideal, i.e. as a matter of good practice, though not legally required, to seek approval of an REC.[938] The HRA must further publish guidelines on cases where it is legally required for persons conducting health or social care research to seek REC approval before conducting the research.[939]

The HRA, upon application, has the power to recognize a group of persons as an REC.[940] The HRA may not do so unless it is satisfied that the REC will comply with the REC policy document as developed by the HRA[941] and that there is a demand for such a committee.[942] It is possible for the HRA to revoke the recognition it granted if it is satisfied that the REC is not complying with the REC policy document the HRA developed;[943] the REC is neither carrying on its functions nor, if it does, does it properly carry out such functions[944] and where on any other ground the HRA deems it necessary or appropriate that such a recognition be revoked.[945] The HRA further has the power to establish RECs, for the purposes of performing the functions as required in the Care Act, or as (other) laws may provide.[946] The HRA also has the corresponding power to de-establish (abolish) the RECs.[947]

A further legal instrument relevant for health research is the Medicines for Human Use (Clinical Trial) Regulations (2004) (The UK Clinical Trial Regulations), which principally deals with the regulation of the conduct of health clinical trials in the UK. In the main, the UK Clinical Trial Regulations aim to give effect to Directive 2001/20/EC.[948] The UK

937 S 112(9).
938 S 113(1)(a).
939 S 113(1)(b).
940 S 114.
941 S 114(2)(a).
942 S 114(2)(b).
943 S 114(5)(a).
944 S 114(b).
945 S 114(c).
946 S 115(1).
947 S 115(3).
948 See the Explanatory Note to the UK Clinical Trial Regulations. There have also been arguably cosmetic amendments to the UK Clinical Trial Regulations, through the Medicines for Human Use (Clinical Trials) (Amendment (EU Exit) Regulations 2019, so as to give effect to the European Union (Withdrawal) Act 2018 (EUWA) (See Explanatory Memorandum to the

Clinical Trial Regulations create the United Kingdom Ethics Committees Authority (UKECA) whose principal function is to establish, recognize and monitor ethics committees.[949] In its establishment function UKECA has the power to establish ethics committees for specific areas in the UK or for the entire UK.[950] It may also establish such committees for specific categories of clinical trials.[951] UKECA further has the powers to vary the areas and categories of clinical trials in respect of which committees have been established[952] as well as de-establish such committees.[953]

UKECA is also empowered to recognize, upon application, ethics committees, if satisfied that the Committee will be able to perform its functions as required in the UK Clinical Trial Regulations and its relevant Schedules.[954] UKECA is further empowered to vary or revoke the recognition of committees.[955] UKECA further has the power to monitor the adequacy or otherwise of the functioning of ethics committees.[956] UKECA is further empowered to advise and assist ethics committees in the execution of their functions.[957]

Clinical trials may not be initiated or conducted unless there is an approval from an ethics committee or an appeal panel as contemplated in the UK Clinical Trial Regulations[958] and a licensing authority.[959] The UK Clinical Trial Regulations further prohibit the recruitment or advertisement inviting research participants unless there has been an approval from an ethics committee or an appeal panel as contemplated in terms of Schedule 4 to the UK Clinical Trial Regulations.[960] It taking its decision an ethics committee shall take into account factors enumerated in regulation 15(5) of the

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Medicines for Human Use (Clinical Trials) (Amendment (EU Exit) Regulations 2019 (https://www.legislation.gov.uk/uks/2919/744/pdfs/uksiem_20190744_en.pdf. (Accessed 12 May 2021).

949 Regulation 5(1) of the UK Clinical Trial Regulations.
950 Regulation 6(1)(a).
951 Regulation 6(1)(b).
952 Regulation 6(2)(a).
953 Regulation 6(2)(b).
954 Regulation 7(1).
955 Regulations 7(5) and 8.
956 Regulation 10(1).
957 Regulation 10(2).
958 Though regulation 12(3) (a) only speaks of the ethics committee or the appeal panel giving a favourable opinion (and not approval), the context of the provision suggests that this refers to approval.
959 Regulation 12(1) and (3).
960 Regulation 12(2) and (3)(a).

UK Clinical Trial Regulations.[961] Most importantly, where the subject of the research is a minor and the committee does not have amongst its ranks a person with expertise in paediatric care issues, the committee may before providing its opinion seek 'advice on the clinical, ethical and psychosocial problems in the field of paediatric care which may arise in relation to that trial'.[962]

As partly alluded to earlier, the UK Clinical Trial Regulations also set out conditions and principles under which a minor, whom the framework defines as a person below the age of 16,[963] can be included as a research participant. These conditions, outlined in Part 4 of Schedule 1 to the UK Clinical Trial Regulations, include the fact that the minor should not be given incentives except where this is required as part of compensation for loss or injury.[964] One of the critical principles is that patient interests must always prevail over those of science and society.[965]

UK Clinical Trial Regulations further prohibit the supply of investigational products to an investigator, research participant or any other person connected with the study, for use in clinical trials unless the conditions provided for under paragraph 13(2) of the UK Clinical Trial Regulations have been satisfied.[966] The UK Clinical Trial Regulations further prohibit any person from conducting a trial, or performing the functions of a sponsor, unless such persons act 'in accordance with the conditions and principles of good clinical practice'.[967]

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961 In the committee's evaluation of risks and benefits and capability of some subjects to give informed consent, the conditions and principles in Schedule 1 to the UK Clinical Trial Regulations will also be considered. See further comment on these conditions and principles below.

962 Regulation 15(6). This provision could play a key role in ensuring that the interests of children partaking in the research are protected.

963 See the definition of minor in regulation 2(1) of the UK Clinical Trial Regulations. This definition should be contrasted with the English common law framework, which regards a person as a minor if below the age of 18 (See para 5.1.3a of the MRC Children Guide). Though the UK Clinical Trial Regulations do not directly deal with issues of displaced children, the general principles discussed above may be adapted to deal with such children, though this approach may be inadequate.

964 See item 8 of Part 4 of Schedule 1 to the UK Clinical Trial Regulations. For adults with capacity and those without capacity, see Parts 3 and 5 of Schedule 1 to the UK Clinical Regulations respectively. For conditions and principles that apply to all clinical trials, see Part 2 of Schedule 1 to the UK Clinical Trial Regulations.

965 Item 16 of Part 4 of Schedule 1 to the UK Clinical Trial Regulations (it is unclear why this principle is emphasised mainly, if not only, in the case of minors and incapacitated adults (see item 15 of Part 5 of Schedule 1 to the UK Clinical Trial Regulations).

966 Regulation 13(1) and (2).

967 Regulation 28(1).

The UK Clinical Trial Regulations also make it an offence for a person to contravene certain provisions specified in these regulations.[968] The UK Clinical Trial Regulations further provide for penalties in case of the commission of an offence.[969] The penalties differ, depending on whether the conviction was one of summary conviction[970] or conviction on indictment.[971] In the former case, the penalty could be a fine not exceeding the relevant prescribed maximum or to an imprisonment not exceeding three months, or to both a fine and imprisonment.[972] In the latter case the penalty could be a fine or imprisonment not excepting two years or to both a fine and an imprisonment.[973] Where a person is charged with an offence for contravening the criminal provisions of the UK Clinical Trial Regulations, it may be legitimate for that person to raise the defence of due diligence i.e. that the person took 'all reasonable precautions and exercised all due diligence' to ensure that the person does not commit that offence.[974]

The MCA is another legal framework relevant to biomedical matters. The MCA deals in the main with the protection of persons who lack capacity to make certain decisions, against decisions that may adversely affect them. It covers both decisions in the context of research, and those outside the context of research. Unless the context justifies otherwise, only those aspects that relate to research activities are covered in this discussion. The MCA starts off by outlining general principles guiding the interaction with persons who lack capacity to take decisions.[975] One such principle is that there is an assumption that a person has capacity, unless the contrary is shown.[976] Another principle is that a person cannot be considered as lacking capacity for decision-making without having first done everything possible to assist him.[977]

A further principle is that a person cannot be treated as lacking capacity for decision-making solely on the basis of the unwise decisions he makes.[978] Acts done in the name

968 Regulation 49(1).
969 Regulation 52.
970 Regulation 52(a).
971 Regulation 52(b).
972 Regulation 52(a).
973 Regulation 52(b).
974 Regulation 51(1).
975 S 1 of the MCA.
976 S 1(2).
977 S 1(3).
978 S 1(4).

of the person lacking decision-making capacity must be done in that person's best interests.[979] The best interests of the person lacking decision-making capacity must be given priority before the doing of any act or taking of any decision.[980] While the above principles are generic in nature, they are equally relevant to the research context. Because participation in research requires that the participants have capacity to consent, or withdraw from participation, these principles will guide such a process.

One should then now deal with provisions of the MCA that specifically deal with research. The MCA prohibits 'intrusive research' on a person who lacks capacity to consent.[981] This prohibition does not apply where the intrusive research is conducted as part of an approved research project as provided for in ss 31, 32 and 33 of the MCA.[982] The MCA defines as intrusive research that would have been unlawful if it were conducted on persons having decision-making capacity, without their consent.[983] However a clinical trial conducted in terms of the UK Clinical Trial Regulations, or any other regulations designated as clinical trial regulations for the purposes of this provision, does not qualify as a research for the purposes of s 30 of the MCA.[984]

The MCA sets out pre-requisites for involvement in the research of a person lacking capacity, without which the appropriate body as defined in s 30(4) of the MCA may not approve the research.[985] Firstly, the research must relate to the research participant's impaired condition[986] or the treatment of the condition.[987] Secondly, reasonable grounds must exist for believing that the research with comparable results may not be conducted on a person having the decision-making capacity.[988] The research must, without imposing disproportionate burden, be potentially beneficial to the research participant.[989] If the research does not satisfy the preceding requirements, it must at least potentially produce (generalisable) knowledge about the treatment or causes of the conditions affecting others in the same situation, or about the care for such

979 S 1(5).
980 S 1(6).
981 S 30(1).
982 S 30(1)(a) and (b).
983 S 30(2).
984 S 30(3) read with s 5.
985 S 31(1).
986 S 31(2)(a).
987 S 31(2)(b).
988 S 31(4).
989 S 31(5)(a).

persons.[990] If the potential benefit is only generalisable knowledge, the potential risk to the research participant must not be more than negligible;[991] the research participant's freedom and privacy must not be significantly interfered with[992] and that the research will not be too restrictive or invasive.[993]

The MCA provides for additional safeguards for research participants lacking decision-making capacity.[994] In particular the MCA provides for the research participant lacking decision-making capacity not to be forced (or allowed) to continue where it is clear that the person does not want to continue, unless the researcher's actions are intended to protect the research participant from harm, pain or discomfort.[995] A researcher is further not allowed to perform any act inconsistent with the research participant's advance decision which still has some validity[996] or any other statement by him not yet withdrawn, and he being aware of such instruments.[997]

The MCA further provides for the interests of the research participants to override those of science and society.[998] The MCA further makes it an offence for the research participant to be ill-treated or neglected.[999] The resultant penalties arising out of this could either be a fine not exceeding the prescribed amount or imprisonment not exceeding 12 months or both, in the case of a summary conviction.[1000] In the case of conviction following an indictment, the penalties could be a fine not exceeding a prescribed fine, or to imprisonment not exceeding 5 years.[1001]

5.2.8.3 The United Kingdom's continental obligations

The continental obligations mainly arise from the Directive 2001/20/EC (at least before the repeal). As indicated earlier, the UK Clinical Trial Regulations were an attempt to give effect to the Directive 2001/20/EC which has, as already indicated, itself been repealed by the Regulation (EU) No. 536/2014 of the European Parliament and of the

990 S 31(5)(b).
991 S 31(6)(a).
992 S 31(6)(b)(i).
993 S 31(6)(b)(ii).
994 S 33.
995 S 33(2)(a).
996 S 33(2)(b)(i).
997 S 33(2)(b)(II).
998 S 33(3).
999 S 44(2).
1000 S 44(3)(a).
1001 S 44(3)(b).

Council of 16 April 2014 (2014 EU Clinical Trials Regulations). The relevant continental instruments will however be discussed in detail in chapter 8.

5.2.8.4 Implications for health research

The framework has far-reaching implications for stakeholders to health research. The common law framework, including the leading case[1002] discussed above, does not provide adequate protection to the participants in health research.[1003] Such a framework also does not provide much towards a public law approach. The Legislative framework does make attempts to protect research participants. Although the legislative framework, including the MCA, also provides for the interests of the research participants to be above those of society, on the whole the framework takes a public law approach, more particularly in the balancing manner in which it deals with the protection of those lacking decision-making capacity to participate in research.

5.3 Ethical instruments

Various ethical instruments specifically deal with health research. These include the RCP Guidelines;[1004] UKRIO's Code of Good Practice for Research: Promoting good practice and preventing misconduct (2009) (UKRIO's Code of Good Practice);[1005] UK MRC Guidelines;[1006] the UK Health Departments' Governance Arrangements for

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1002 Morton James Wylie v Dr Donald Grosset, Greater Glasgow Health Board [2011] COSH 89.

1003 Although the common law does, as indicated earlier, provide for consent to decision-making, which is an aspect of respect for autonomy, it remains inadequate in providing protection. The decision of the court itself, which is a statement of the common law, shows that sole reliance on the common law contractual principles, rather than also on public law obligations, limits the protection to research participants in that the remedies themselves will be limited.

1004 Briefly touched on in chapter two, therefore requiring no further reflection here.

1005 This also provides the framework for the conduct of research. It in the main restates some of the established principles for the conduct of health research, including the consideration of the vulnerability of the participants in research, including children (see para 3.7.1). UKRIO's Code of Good Practice further provides that participants' dignity, wellbeing, rights and safety be given primacy (see para 3.7.1). The framework further provides for the obtaining of informed consent from research participants after following appropriate procedures that consider the capacity of the participants (see paras 3.7.6 and 3.7.10); and the approval of research by research ethics committee (RECs) (see para 3.7.9). The framework further provides for respect for the security and confidentiality of personal data (see para 3.7.3). For further details see UK Research Integrity Office *Code of Good Practice for Research: Promoting good practice and preventing misconduct* (2009). https://ukrio.org/publications/code-of-practice-for-research/ (Accessed 9 May 2021).

1006 There are various guidelines under the UK MRC, including those governing research on those lacking capacity to consent (see MRC *Guidance on patient consent*. https://mrc.ukri.org/research/policies-and-guidance-for-researchers/guidance-on-patient-consent/ (Accessed 28 March 2020). Further see MRC *MRC Ethics guide 2007: medical research involving adults who cannot consent*. https://mrc.ukri.org/documents/pdf/medical-research-involving-adults-who-cannot-consent/ (Accessed 28 March 2020). There is also

Research Ethics Committees: 2020 edition (2020)) (which is further discussed below) and The Concordat to support research integrity.[1007]

Amongst these instruments, the Health Departments' Governance Arrangements for Research Ethics Committees: 2020 edition (2020) (the UK Governance Arrangements) is critical. The UK Governance Arrangements was formulated by the health departments (or their equivalents) in the constituent countries of the UK (the UK Health Departments) and revises the earlier framework, the 'Governance Arrangements for Research Ethics Committees: a harmonized edition (2011), so as to deal with various aspects around the governance of RECs and related issues.[1008] The framework is a policy document that started operating on 20 July 2021, in the whole of the UK.[1009] The UK Governance Arrangements provides in the main for a Research Ethics Service, comprising RECs and (head) offices responsible for the coordination of 'the development and management' of the way research ethics committees operate.[1010]

While the UK Governance Arrangements does consider the interests of science and society, in case of conflict these interests must yield to those of the research participants, whose dignity, safety, well-being and rights must be respected.[1011] In

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guidance by the MRC on the use of personal information in medical research (See MRC *Personal information in medical research*. https://mrc.ukri.org/research/documents/pdf/personal-information-in-medical-research/ (Accessed 28 March 2020). There are also guidelines concerning research involving children. (See MRC *MRC Ethics guide: medical research involving children* (touched on in brief below)). https://mrc.ukri.org/documents/pdf/medical-research-involving-children/ (Accessed 28 March 2020). The UK MRC also has general research ethics guidelines namely the *Good research practice: principles and guidelines*, which apply to MRC-funded research (See MRC *MRC ethics series. Good research practice: principles and guidelines*) https://mrc.ukri.org/publications/browse/good-research-practice-principles-and-guidelines/ (Accessed 28 March 2020). There are also guidelines regulating the conduct of those funded by Research Councils UK (See *RCUK policy and guidelines on governance of good research conduct*. https://www.ukri.org/files/legacy/reviews/grc/rcuk-grp-policy-and-guidelines-updated-april-17-2-pdf/ (Accessed 28 March 2020).

1007 This is a statement of commitments by various research institutions in the UK, including Universities UK, Welcome Trust, UK Research and Innovation (UKRI) and various other key players in research. One of the commitments is that researchers maintain the highest standards of research integrity, which includes 'care and respect for all participants in research, and for the subjects, users and beneficiaries of research…' (See Universities UK *The Concordant to support research integrity* (2019) 6. https://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2019/the-concordant-to-support-research-integrity.pdf (Accessed 28 March 2020). The position arguably tends towards the PLA contemplated in this thesis.

1008 Para 1.3.3 of the UK Governance Arrangements.

1009 Para 1.3.

1010 Para 1.1.2.

1011 Paras 3.2.1 and 3.2.2.

respect for the principle of justice**,** the risks and benefit of participating in research should be fairly distributed. This means that no section of the population should be overrepresented or underrepresented in research, a factor that RECs should consider in their review of research proposals.[1012]

Of further importance is the independence of the RECs[1013] and their composition. The composition of the RECs should be diverse.[1014] This requires that the composition be broadly representative of various levels of expertise, experiences and backgrounds.[1015] The appointment of such persons must also be fair and transparent.[1016] REC members must further, as a condition of appointment, agree to undergo appropriate training when required.[1017] REC members are also required to maintain confidentiality in the work they do as REC members.[1018] REC members must be assured about their indemnity against potential liabilities, by way of a 'personal statement' and its conditions, from an appointing authority.[1019] Perhaps controversially, the UK Governance Arrangements treats REC membership and activities as volunteer work i.e. members should not (not need not be) be paid for performing their review work as REC members, as that work is 'required by section 2'.[1020] (One assumes here that by 'section 2' is referred to 'paragraph 2' of the UK Governance Arrangements). Nor, perhaps even more controversially, should RECs charge any fees, other than reimbursements, for the work they conduct as RECs.[1021] What are the implications of these requirements for private RECs, who might conduct REC activities as part of income generating activities? Does it mean that there is no room for such types of RECs in the UK?

The UK Governance Arrangements further provides that RECs do not have to ethically review science.[1022] What if the science is so bad that it raises ethical questions? As

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1012 Para 3.2.3.

1013 Paras 3.2.6 and 3.2.7. What are the implications of such a requirement? Does it mean that RECs should be independent from Universities, who are often the hosts of research activities? This does not however mean that RECs cannot cooperate with various stakeholders relevant for the research (see para 3.2.8).

1014 Paras 4.2.1 – 4.2.4.

1015 Paras 4.2.1 – 4.2.4.

1016 Para 4.2.5.

1017 Para 4.3.10.

1018 Para 4.3.11.

1019 Para 4.3.12.

1020 Para 4.3.8.

1021 Para 4.3.9 read with para 4.3.10.

1022 Para 5.4.2 (a).

there may be occasions where certain research proposals may require an expedited review, the standard operating procedures (SOPs) should provide for circumstances and the type of applications requiring expedited reviews, as well as the process required for such reviews.[1023] Public health emergency may also serve as basis for an expedited review.[1024] RECs should also be transparent, which includes the publication of the RECs' summary of opinion, including its unfavourable opinion.[1025] RECs are required to adopt, and act in accordance with, standard operating procedures.[1026] RECs must further remain accountable to the authorities that appointed them.[1027]

The Association of British Pharmaceutical Industry (ABPI) Guidelines for PHASE I Clinical Trials (2018) (ABPI PHASE I Guidelines) deal with a wide variety of issues governing the conduct of health research, including how participants should be selected, more especially where children are involved;[1028] the need to adopt non-invasive procedures;[1029] approval by RECs;[1030] and the payment of incentives[1031] and compensation.[1032]

In relation to compensation for phase 1 trials, the ABPI's Clinical Trial Compensation Guidelines: Phase I Clinical Trial Compensation Guidelines (2014) (Phase I Compensation Guidelines) now make it obligatory for both healthy and patient volunteers to receive such compensation (from sponsors), which compensation may

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1023 Paras 5.5.1 and 5.5.2.

1024 Para 5.5.1.

1025 Para 5.6.1.

1026 Paras 6.4.1 and 6.4.2.

1027 Para 6.4.2.

1028 Para 10.3.2 of the ABPI Phase I Guidelines, which provides that inclusion of healthy children should where possible be avoided and that guidelines on inclusion of children in research should be followed.

1029 Para 6.7, which requires that non-invasive procedures should be preferred, and where this is unavoidable, at least those familiar with the invasive procedures should be appointed.

1030 Para 4 of the ABPI PHASE I Guidelines, which provides for the approval of phase 1 studies by a REC recognized by UKECA. RECs are also required to approve in writing the informed consent form and the information concerned before the researchers secure informed consent from the research participants (see para 10.4).

1031 Para 19.2 allows the payment of incentives for participating in research, for both healthy volunteers and patients, in the case of non-therapeutic research (in phase 1 trials). What are the side effects of this: when then do we know whether the participation is voluntary or whether it is induced by the payment? Perhaps the facts of each case will provide guidance.

1032 Para 9.1 provides for compensation for injuries as a result of participating in the study, for both healthy and patient participants, with the exclusion of oncology participants, who are expected to benefit (therapeutically) from the study. The distinction between oncology participants and other participants, for compensation purposes, does not appear justifiable here. The issue should just be whether a person was injured as a result of the participation in the study.

be reduced as a result of contributory fault on the part of the participant.[1033] The claiming participant does not have to prove negligence on the part of any other person.[1034]

On the other hand, in relation to compensation for the phase II, II and IV trials, the ABPI's Clinical Trial Compensation Guidelines: Phase II, II and IV Clinical Trials Compensation Guidelines *(*Phase II, III and IV Compensation Guidelines) recommend compensation for those whose injuries arise from the study, without making any legal commitment.[1035] The compensation does not prevent the participant from pursuing other legal remedies, but the participant cannot seek both.[1036] The Phase II, III and IV Compensation Guidelines do not apply under a number of instances, including where a placebo was used and the expected therapeutic benefits are not derived.[1037] They also do not apply where the research was initiated or sponsored by the investigators, rather than any other sponsoring company.[1038]

Instruments specifically tailored to protect children in research also exist. These include the MRC Ethics Guide: Medical Research Involving Children (2004) (the MRC Children's Guide), which is an ethical guide under the auspices of the UK's MRC. It outlines various principles around research on children, including the following: inclusion of children in research only where adults cannot be used to achieve the same result; necessity to obtain informed consent, on a continuous basis; a child's refusal, including being uncomfortable with the procedure, must always be respected; and the involvement of parents or guardians in decision-making where a child is incompetent, unless exceptional circumstances exist.[1039]

Those dealing with children are required to undergo security screening, so as to ensure children's safety.[1040] There is no specific provision dealing with research for displaced children. The general principles discussed above will therefore be adapted to cater, though inadequately, for the situation of such children.

1033 Para 1, read with para 4 (ii), of the Phase 1 Compensation Guidelines.
1034 Para 1.1.
1035 Para 1 of the Phase II, III and IV Compensation Guidelines.
1036 Paras 5.3 and 5.5.
1037 Para 3.
1038 Para 2.4.
1039 Para 1.3 of the MRC Children Guide.
1040 Para 5.4.

Though, as indicated earlier the UK does not prefer a human rights language in dealing with the protection of children, the MRC Children Guide arguably does create room for a strong protection of health research participants. It further also arguably provides for a strong bias in favour of the PLA, by providing for several measures to protect children.

The overall impression around the above ethical instruments is that although the instruments do in the main provide for the protection of health research participants, including children, the multiplicity of these codes in the UK may create confusion as to which one ought to apply at specific times.

5.4 Conclusion

The overall observation around UK law is around the following: the unwritten nature of the constitution; the system of parliamentary sovereignty; the general judicial restraint; and the cautious use of human rights language. These interdependent aspects have far-reaching impact on various other aspects of the legal system, including on the approaches to interpretation[1041] and on judicial review,[1042] amongst other aspects. This in turn has implications for health research, where protection to research participants may be reduced.

There is also the general emphasis of vertical application, rather than horizontal application, of most of the instruments.[1043] This may have the effect that private researchers might not be bound by some of the legal framework that is normally imposed on public authorities that also engage in research. Leaving private actors outside public regulation of their conduct may therefore have the effect of reducing protection to research participants in some cases.

Regarding the ethical instruments, although they do provide for the protection of research participants their multiplicity, and even fragmentation, might reduce their impact, especially if there is no clear guidance as to which of these instruments should

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1041 For example, in a parliamentary system, where the approach to interpretation is based on the intention of the legislature, it is unlikely for the courts to invalidate an undesirable legislation.

1042 As discussed above, the UK'S parliamentary system means that even in instances where courts do take into account European law, as per the HR Act, when deciding whether or not to declare a legislation incompatible with the ECHR, such declaration of incompatibility is of no practical consequence as it does not lead to the invalidation of the specific legislation.

1043 Some of the instruments taking this approach is the FOIA Act, whose obligations to process access to information is mainly on public authorities.

apply in case of conflict. As indicated earlier, the issue of multiplicity and fragmentation of instruments is equally applicable to UK legislations.

About children, although various legislations and ethical instruments protecting them do exist the problem of fragmented, rather than coherent, approach in this regard will also undermine the protection of children partaking in research. So is the cautious approach of the UK law on human rights questions: it may reduce the protection of children partaking in research. The absence of direct reference in UK legislation to the protection of displaced children partaking in research could add another dimension to diminished protection of children partaking in research.

The next chapter (chapter six) looks at the American law and its other regulatory framework.

CHAPTER SIX: THE POSITION IN THE UNITED STATES OF AMERICA

6.1 Introduction

Chapter five dealt with the legal position and other regulatory frameworks in the UK. The background to US law was discussed in chapters one and two, and such background is therefore, unless the context requires otherwise, not further touched on here. This chapter looks at the US legal position and other regulatory frameworks. It starts off by looking, in brief, at the US's general legal framework. The chapter then looks at the various laws relevant to health research or more generally, biomedical matters. The chapter ends with the ethical instruments relevant to health research, followed by chapter conclusion.

6.2 Legal framework of the United States of America

In the analysis of the US's general legal framework, one must consider the US's unique situation. It is a federal, rather than a unitary, state with a vast number of states, totalling 50.[1044] These states have their own laws and courts. The US further uses a presidential system, which vests the president with certain powers, including the powers to issue executive orders[1045] and memorandums.[1046] Some executive powers, the executive orders in particular, though intended to be instruments of implementing legislation and policy, have themselves the force of law.[1047] The executive orders should not contradict the law in terms of which they have been made, otherwise they could be challenged as invalid in a court of law.[1048]

1044 How many states are in the United States? https://worldpopulationreview.com/state-rankings/how-many-states (Accessed 13 May 2021).

1045 These are often consecutively numbered 'directives' from the US president dealing with operational issues of the federal government (see American Bar Association "What is an executive order'' (2021). https://www.americanbar.org/groups/public_education/pubications/teaching-legal-docs/what-is-an-executice-order-/ (Accessed 13 May 2021). One however uses the concept 'directives' cautiously here because the concept when used in the context of 'presidential directives' is sometimes used to mean something different from executive orders (see for example, Encyclopedia.com "Executive orders and presidential directives''. https://www.encyclopedia.com/politics/encyclopedias-almaniacs-transcripts-and-maps/executive-orders-and-presidential-directives (Accessed 13 May 2021).

1046 Law Shelf "The power of the president: the roles of executive orders in American government''. https://lawshelf.com/shortvideoscontentview/the-power-of-the-president-the-roles-of-executive-orders-in-american-government/ (Accessed 13 May 2021).

1047 Law shelf https://lawshelf.com/shortvideoscontentview/the-power-of-the-president-the-roles-of-executive-orders-in-american-government/ (Accessed 13 May 2021).

1048 Law shelf

A full appreciation of the American legal framework requires that its main sources be reflected on. The US's main sources of law include the US Constitution;[1049] legislation (at federal and state level); case law;[1050] treaties[1051] and administrative law (under which administrative regulations by agencies are enacted).[1052] Of these sources the US Constitution is the most critical, being the highest law of the land.[1053]

The US Constitution of 1787, including its subsequent Amendments (some of which introduced the Bill of Rights into the constitutional framework in 1791), is the foundation of the country's approach to constitutionalism.[1054] The US Constitution therefore enjoys constitutional supremacy in that country.[1055] Some of the constitutional principles, as appear below, have been developed by the courts.

The US Constitution consists mainly of first generation rights namely political and civil rights, which are often aimed at limiting government action, and mostly stated in negative form.[1056] It therefore does not expressly provide for second and third generation rights, which often place positive obligations on the state to do something.[1057] So as to affirm the view that the US Constitution, in the main, does not

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https://lawshelf.com/shortvideoscontentview/the-power-of-the-president-the-roles-of-executive-orders-in-american-government/ (Accessed 13 May 2021).

1049 Apart from the US Constitution, there are also state constitutions which, at state level, apply in addition to the US Constitution (also see Advisory Commission on Intergovernmental Relations State Constitutions in the Federal System: Selected Issues and Opportunities for State Initiatives (1989). https://digital.library.unt.edu/ark;/67531/metadc1442/m1/9/ (Accessed 16 June 2021).

1050 Which also, in the main, restates the common law.

1051 This is particularly constitutionalized in articles III and VI of the US Constitution.

1052 See What are the four main sources of American law? https://www.reference.com/four-main-sources-of-american-law-5cb95cca5a59a856 (Accessed 14 May 2021). Also see Law shelf ''Sources of law in the United States". https://lawshelf.com/shortvideoscontentview/sources-of-law-in-the-united-states/ (Accessed 14 May 2021).

1053 See art VI of the US Constitution.

1054 The American Declaration of Independence (1776), which is one of the important documents outlining the declaration of intent by American States that called for independence from Britain, could be said to have laid the foundation on what was later outlined in the US Constitution. The right to equality, liberty and life were, for example, first expressed in this instrument (see The Declaration of Independence. https://www.ushistory.org/declaration//document/index.html (Accessed 29 June 2021).

1055 See art VI of the US Constitution. Also note that the article also places 'the laws of the United States which shall be made in pursuance' of the US Constitution, at the apex. And so are 'all treaties made, or which shall be made, under the authority of the United States...' (Art VI). This article therefore arguably does clarify, though on a limited basis, the question of primacy or hierarchy of laws in the US.

1056 Kende MS *Constitutional rights in two worlds: South Africa and the United States* (Cambridge University Press New York 2009) 6.

1057 Kende *Constitutional rights in two words* 6 -7.

tend towards the imposition of positive duties the court in *DeShaney v Winnebago County Department of Social Services* 489 U.S. 189 (1989), referring to the Due Process Clause in the Constitution, says the following:

> The Clause is phrased as a limitation on the state's power to act, not as a guarantee of certain minimal levels of safety and security. It forbids the state itself to deprive the individuals of life, liberty, or property without 'due process of law,' but its language cannot fairly be extended to impose an affirmative obligation on the State to ensure that those interests do not come to harm through other means. Nor does history support such an expansive reading of the constitutional text.[1058]

The US Constitution also does not have an express provision guaranteeing the right to dignity.[1059] This does not however, as appears in the discussion below, mean that other provisions of the Constitution may not be read to give effect to this right. The US Constitution further does not expressly make provision for justified partiality i.e. allowing certain forms of discrimination in order to cure some injustice.[1060] The US Constitution also does not expressly provide for the general limitation of rights.[1061] The courts have developed principles in this respect, including the principle of proportionality, which plays a central role in the limitation analysis.[1062]

The US Constitution further does not have an express provision dealing with its approach to the application of international law.[1063] In the case of foreign law, not only

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1058 *DeShaney v Winnebago County Department of Social Services* 489 U.S. 189 (1989).

1059 Kende *Constitutional rights in two words* 6.

1060 However, the courts have from time-to-time, though adopting a very cautious and limited approach, allowed the use of race as factor in taking certain decisions, as long as the principle of 'strict scrutiny' is observed. This was the case in *Fisher v University of Texas* 579 U.S. (2016) (further see Cornell Law School "Affirmative Action''. https://www.law.cornell.edu/wex/affirmative-action (Accessed 16 June 2021)).

1061 For example, the Ninth Amendment, which prohibits the rights contained in the Constitution from being construed in ways that 'deny or disparage others retained by the people', could be interpreted as setting general limitation on rights. This article could of course also be interpreted to mean that the rights listed in the Constitution are not exhaustive, i.e. they do not deny the existence of other rights already 'retained by the people' (see for example, the US Supreme Court's confirmation of this position in *Grisworld v Connecticut* 381 U.S. 479 (1965) particularly at paras 21, 25 and 26, where the court also relied on this provision to found the right to privacy, which is not explicitly mentioned in the US Constitution). For other examples of limitations, see *Jacobson v Massachusetts* 197 U.S. 11 (1905) paras 7 – 8, which dealt with limitations which states' health and safety laws, including those providing for vaccination, place on a person's liberty. The court here takes what is arguably a very strong public interest approach.

1062 See Breyer S *America's Supreme Court: making democracy work* (Oxford University Press New York 2010) 162 – 164 where Breyer, a US Supreme Court justice, highlights the importance of proportionality, together with values, as tools in constitutional interpretation. On the US Courts' reliance on limitation principles in some instances, without however using the two-stage approach as SA does, further see *S v Makwanyane and Another* 1995 (3) SA 391 (CC) para 100.

1063 Though its provision for the supremacy of treaties in art VI could arguably be seen as respecting international law. At legislative level the Alien Tort Claims Act 28 U.S.C. § 1350, otherwise commonly known as Alien Tort Statute (ATS), which grants universal jurisdiction over the

does the US Constitution not expressly provide for it, but the American legal and political cultures, more in particular the latter, appear to frown upon any reference to foreign law.[1064] This could be problematic, given that other legal systems use foreign law as persuasive sources to shape their own laws.[1065] This could be important in the context of health research, where legal systems with better frameworks ought to be referred to, so as to provide guidance.

Further absent from the US Constitution is the approach to application of the Constitution. In other words, what is the scope of the Constitution's application? Does it only apply vertically, or does it apply both vertically and horizontally? There is nothing (arising from any of its provisions) suggesting that the US Constitution also applies horizontally i.e. it appears to apply only vertically. Applying vertically could imply that it only imposes obligations on the State and public authorities, while leaving private actors, however powerful they might be, beyond touch.

That the US Constitution tends towards vertical rather than horizontal application could also be gleaned from the court's attitude in *DeShaney v Winnebago County Department of Social Services* where the court, with respect to the Due Process Clause, says the following: "But nothing in the language of the Due Process Clause itself requires the State to protect the life, liberty, and property of its citizens against invasion by private actors''.[1066]

This could be problematic in the context of health research, where the most powerful of the actors are not necessarily the public actors, but the private actors like sponsors,

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commission of torts that violate international norms, could be said to be a strong confirmation of the US's respect for international, at least in the context of civil law (also see Cornell Law School "*Alien Tort Statute*''. Https://www.law.cornell.edu/wex/alien_tort_statute (Accessed 21 June 2021). Further see Britannica "Alien Tort Claims Act''. https://www.britannica.com/topic/Alien-Tort-Claims-Act (Accessed 25 January 2022). Further see The Center for Justice & Accountability "The Alien Statute Tort Statute''. https://cja.org/what-we-do-/litigation/legal-strategy/the-alien-tort-statute/ (Accessed 25 January 2022)). Further see Gowar C "The Alien Tort Claims Act and the South African litigation: is the end nigh?" 2012 *Speculum Juris* 55 – 73. The US's general reluctance to commit to some international legal instruments like the *Rome Statute of the International Criminal Court (2002)* could be seen as a drawback on its part with regard to international law (See American Bar Association ''The US – ICC Relationship'' (2021) https://www.aba-icc.org/about-the-icc/the-us-icc-relationship/ (Accessed 26 June 2021)).

1064 Kende *Constitutional rights in two words x.* Further see Jackson VC "Constitutional Dialogue and Human Dignity: States and Transitional Constitutional Discourse'' (2004). http://scholarship.law.georgetown.edu/facpub/106/ (Accessed 22 May 2021).

1065 South Africa is one of those countries that has even constitutionalised the consideration of foreign law in terms of s 39 of the Constitution.

1066 *DeShaney v Winnebago County Department of Social Services* 489 U.S. 189 (1989) para 23.

who are often big multinational pharmaceutical companies. Because of the US Constitution being arguably the oldest, this brand of constitutionalism, where the emphasis is placed on setting limits on governments rather than also on the private actors, is what has generally influenced the notion of constitutionalism.[1067]

Beyond the US Constitution itself it appears that even some laws prefer exempting private bodies from their applicability. The Federal Policy for the Protection of Human Subjects (45 CFR 46) (The Common Rule) itself only applies to those researchers funded by US government (United States Department of Health and Human Services (HHS), the Food and Drugs Administration (FDA)[1068] and other public agencies.[1069] And so is the FOI Act only applying to public authorities.[1070]

The US Constitution provides for freedom of speech.[1071] The freedom of speech is however stated in near absolute terms.[1072] This is important in health research too, given that research and other forms of scientific enquiries are by their very nature a form of expression, which requires the same protection as the rest of other forms of expressions.

What is the US's approach to legal standing? The US's approach to standing also arguably takes a public interest approach, for not only focusing on the interests of the person directly affected, but also on the interest of those within the same class.[1073] This public interest approach, if it does exist in the context raised here, is however very limited. The approach recently taken by the Supreme Court decision in *California, et al., Petitioners v Texas, et al.,* 593 U.S. (2021), dealing with the unsuccessful challenge by some states and individuals to the constitutionality of the Patient

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1067 On the meaning of constitutionalism, also see Waluchow W *"Constitutionalism" 2017 Stanford Encyclopaedia of Philosophy.* https://plato.stanford.edu/entries/constitutionalism/ (Accessed 20 February 2021).

1068 One does however take note of the fact that the FDA has not yet, at the time of writing, adopted the Revised Common Rule, which is the one currently applicable (See Stanford University "Common Rule 2019''. Https://researchcompliance.stanford.edu/panels/hs/common-rule (Accessed 16 June 2021).

1069 Chapter 14: Introduction. https://bioethicsarchive.georgetown.edu/achre/final/chapter 14_1.html (Accessed 15 May 2021).

1070 § 552a (f) of FOIA. Further see US Department of State "The Freedom of Information Act''. https://foia.state.gov/learn/foia.aspx (Accessed 15 May 2021).

1071 First Amendment to the US Constitution.

1072 First Amendment to the US Constitution. This does not however mean that there are no limitations that the courts consider in practice, but that the provision itself does not have an internal limitation or qualifier (also see Breyer *America's Supreme Court* 160).

1073 *Carey v Population Services International* 431 U.S. 678 (1977) para 1.

Protection and Affordable Care Act (124 Stat. 119) (ACA) which, restating some of its earlier decisions, emphasised that before there can be standing, plaintiffs had to have suffered some injury and that the injury must be traceable to unlawful conduct of the defendant, is even more limiting. The Court, as per Justice Breyer, said in this regard:

> For these reasons, we conclude that plaintiffs in this suit failed to show a concrete, particularized injury, fairly traceable to the defendants' conduct in enforcing the specific statutory provision they attack as unconstitutional. They have failed to show that they have standing to attack as unconstitutional the Act's minimum essential coverage provision.[1074]

The court has also considered the requirement of redressability, which enquires into the relationship between the relief sought and the injury suffered.[1075] This approach does not appear to sufficiently support a public interest approach.[1076] What happens in instances where an adult person who is not part of a particular class wants to pursue a case on public interest grounds? It would, under the above requirements, be difficult for that person to prove that he or she has suffered injury from the particular law or conduct being challenged.

What is the US's approach to the rule of law? The US does recognise the principle of the rule of law which, though preceded the US Constitution, is now incorporated in the Constitution.[1077] The American conception of the rule of law appears to be centred around the following: respect for law; the law must be promulgated publicly; everyone is equal before the law; the courts applying the law must be independent and the laws must be consistent with international human rights law.[1078]

What is the US's approach to legal interpretation? The US Constitution does not have an express and mandatory provision dealing with the interpretation of legislation and of the Constitution itself.[1079] Because of the absence of the mandatory provision

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1074 *California, et al., Petitioners v Texas, et al.,* 593 U.S. (2021) para 2.

1075 *California, et al., Petitioners v Texas, et al.,* 593 U.S. (2021) para 2.

1076 It is interesting to note that the dissenting judgement, as per Justice Alito, generally considered to be part of the conservative wing of the court, sarcastically attacked the court's refusal to invalidate ACA on the grounds stated as something the 'fans of judicial inventiveness will applaud once again' (*California, et al., Petitioners v Texas, et al.,* 593 U.S. (2021) para 32. Further see Gerstein J "Alito was just pissed': Trump's Supreme Court breaks down along surprising lines'' (2021). Https://www.politico.com/news/2021/06/17/alito-supreme-court-trump-4951212 (Accessed 20 June 2021).

1077 American Bar Association "Rule of law in American life: a long and intentional tradition'' (2019). https://www.americanbar.org/groups/public_education/resources/rule-of-law/rule-of-law-in-american-life-a-long-and-intentional-tradition/ (Accessed 28 May 2021).

1078 US Courts "Overview – rule of law''. https://www.uscourts.gov/educational-resources/educational-actities/overview-rule-law (Accessed 28 May 2021).

1079 Kende *Constitutional rights in two words* 8.

requiring judges to use a particular interpretive approach, there is no uniform approach to interpretation, resulting in some judges favouring originalism (intentionalism) while others see the Constitution as a living document.[1080] The latter has as a result, in the US context at least, been referred to as living constitutionalism.[1081] (This could arguably also be considered a contextualist or text-in-context approach.[1082])

Originalism is generally considered to use historical facts, beliefs or prevailing facts at the time of the enactment of the particular provision being interpreted.[1083] The proponents of this approach are not concerned about what the interpreter thinks about the values the Constitution has, but what the original framers of the Constitution thought about those values.[1084] The proponents of the approach claim that this approach is objective (neutral), whose objectivity the opponents of the theory question.[1085]

The proponents of the theory further claim that the theory is stable.[1086] One of the objections to originalism is that the precise content of original intentions or understandings is indeterminate, therefore forcing the interpreter to rely on other factors than those they claim to rely on.[1087] Their possible response to this objection is not plausible either, for the indeterminacy of what would have been intended. It says that they (the interpreters) may rely on what is termed 'hypothetical intent', whose focus is not on what the original framers intended, but what they would have intended.[1088]

1080 Kende *Constitutional rights in two words* 8.

1081 Waluchow W *"Constitutionalism" 2017 Stanford Encyclopaedia of Philosophy.* https://plato.stanford.edu/entries/constitutionalism/ (Accessed 20 February 2021). Also see Strauss DA "The living constitution" 2010 The University of Chicago: The Law School. https://www.law.uchicago.edu/news/living-constitution (Accessed 30 June 2022). Further see Rappaport M "Living constitutionalism on the Supreme Court's website" 2017. https://lawliberty.org/the-living-constitution-on-the-supreme-courts-website/ (Accessed 30 June 2022). Anderson BC "How the Supreme Court used three cases to inspire a 'living constitution" 2002. https://www.manhattan-institute.org/html-how-supreme-court-used-three-cases-inspire-ă€living-constitutionă€™-0917.html (Accessed 30 June 2022).

1082 Botha C *Statutory Interpretation: An introduction for students*. 5th ed (Juta Cape Town 2012) 160.

1083 Breyer *America's Supreme Court* 76.

1084 Waluchow https://plato.stanford.edu/entries/constitutionalism/ (Accessed 20 February 2021).

1085 Breyer *America's Supreme Court* 76.

1086 Waluchow https://plato.stanford.edu/entries/constitutionalism/ (Accessed 20 February 2021).

1087 Waluchow https://plato.stanford.edu/entries/constitutionalism/ (Accessed 20 February 2021).

1088 Waluchow https://plato.stanford.edu/entries/constitutionalism/ (Accessed 20 February 2021).

Another notable objection is that originalism seeks to provide the basis for future generations to be permanently bound by the intentions of past generations, despite the past generations not fully grasping what the future might look like i.e. being inflexibly past-looking rather than being forward-looking creates an undue burden on future generations who might be faced with an environment totally different from that of the past generation.[1089] A possible response to this objection is that the future generation must simply make their own laws, including the new Constitution, rather than interpreting (and therefore adapting) the Constitution for the new situation. This response is implausible, considering that constitutions, especially in relation to their fundamental rights, are often stated in broad terms, so as to discourage any need for frequent amendments when new situations arise.[1090]

Living constitutionalism approaches the Constitution as a living document adaptable to changing circumstances.[1091] One of the notable objections to living constitutionalism is that it tends to undermine the separation of powers, the rule of law and other important constitutional values.[1092] This objection is only plausible if it is understood within the context of Parliamentary sovereignty, where the framework might view the role of the courts as very limited (where the courts have to state the law as is rather than also adapting or even invalidating the law where necessary).[1093]

Another possible objection could be that the courts, by adapting the laws they interpret, are undermining the will of the majority, as expressed through Parliament.[1094] This objection would be implausible for the same reasons as indicated for the first objection above (i.e. the undermining of the separation of powers and the rule of law objection). A further response to this objection could be that the court's decisions are simply an expression of what the original makers of the Constitution, being the people, intended, rather than the intention of legislatures, who are mere agents.[1095] Breyer proposes the

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1089 Waluchow https://plato.stanford.edu/entries/constitutionalism/ (Accessed 20 February 2021).
1090 Waluchow https://plato.stanford.edu/entries/constitutionalism/ (Accessed 20 February 2021).
1091 Waluchow https://plato.stanford.edu/entries/constitutionalism/ (Accessed 20 February 2021).
1092 Waluchow https://plato.stanford.edu/entries/constitutionalism/ (Accessed 20 February 2021). Also see Botha *Statutory interpretation* 164.
1093 Botha *Statutory interpretation* 92.
1094 Botha *Statutory interpretation* 164.
1095 US Courts "Overview – rule of law''. https://www.uscourts.gov/educational-resources/educational-actities/overview-rule-law (Accessed 28 May 2021).

use of amongst other factors, the underlying values, purposes and consequences, which he calls a pragmatic approach.[1096]

What is the US's approach to public interest? Though there is no specific reference to public interest in the US Constitution, its Preamble provides for the notion of 'general welfare'. What is the relationship between this and public interest? The question whether or not this concept is related to public interest or not will depend on how the courts in the US interpret it. From the point of view of originalists, would they think that this is what the original framers had in mind when they used that concept? From the point of view of the living constitutionalists, it will depend on whether or not the interpreters consider public interest as one of the underlying values of the US Constitution, as viewed today rather than in the past.

Assuming that both the originalists and living constitutionalists answer the question in the affirmative i.e. they both conclude that the concept of general welfare did include (in case of the past-looking originalists) or the concept does include (in the case of living constitutionalists) the notion of public interest, this then leads to another related question: what is the content of that public interest? Is it for example, one underpinned by a human rights culture?

The originalist' approach to this question might create some difficulties. Because their approach is to have a historical understanding of the concept, and find out if the original framers of the Constitution would have had a particular content of public interest, it would be difficult to know in this case as at the time when the Constitution was originally drafted the Bill of Rights was not part of the Constitution, but only included through a series of Amendments later on, starting from 1791.[1097] The Living constitutionalists are likely to answer this question satisfactorily in that they need only determine whether or not this concept (public interest), as formulated through the concept of general welfare, could be said to have a human rights orientation.

1096 Breyer *America's Supreme Court* 82. One wonders if this pragmatic approach (which in principle treats the Constitution as a living document) is not the living constitutionalism espoused above.

1097 The originalists might of course counter that this is not necessarily an obstacle, because the interpreters could still find out what the original framers thought before they drafted the constitution e.g. what they thought in some of the pre-constitutional writings, like their contributions in the Federalist Papers.

What then is the general legal framework's implications for health research? From an interpretive point of view, although the US Courts have considered both originalism and living constitutionalism as principles to adopt, the absence of express provision in the Constitution mandating a purposive approach risks inconsistent approaches by the courts, and therefore is likely to undermine protection of research participants. The absence of positive obligations placed on the state to deal with socio-economic rights presents a serious drawback in so far as the protection of research participants is concerned. This means that although the US has a very strong human rights culture, the individualist orientation and strong emphasis on negative rights may shape its public law approach in ways that undermine the protection of the research participants.

6.2.1 Approach to judicial review

6.2.1.1 Common law

The US's judicial review has been mainly developed by the courts. The decision in *Marbury v Madison*,[1098] in as early as 1803, kick-started this process.[1099] In that case the court, as per Chief Justice John Marshall, ruled that an Act not in conformity with the constitution was unconstitutional.[1100] The Court, however, also ruled against the courts being involved in ruling on purely political decisions related to ambassadors, ministers and consuls.[1101]

In the main, the practice since then has been to allow the US Supreme Court to invalidate legislation that it considered unconstitutional. This power by the courts is mainly founded on the Constitution's supremacy provision.[1102] In *Marbury v*

1098 *Marbury v Madison* 5 U.S. (1 Cr.) 137 (1803).

1099 Marbury v Madison establishes judicial review. https://www.history.com.cdn.ampproject.org/v/s/www.history.com/amp/this-day-in-history/marbury-v-madison-establishes-judicial-review?amp (Accessed 16 May 2021).

1100 Cornell Law School "Judicial Review''. https://www.law.cornell.edu/wex/judicial-review (Accessed 24 February 2022). The court says in this regard: "Certainly those who have framed written constitutions contemplate them as forming the fundamental and paramount law of the nation, and consequently the theory of every such government must be, that an act of the legislature repugnant to the constitution is void" (*Marbury v Madison* para 138). Further see Jones MA *The limits of liberty: American history 1607 – 1980* (Oxford University Press Oxford 1983) 92 – 93).

1101 Britannica "Marbury v Madison" https://www.britannica.com/event/Marbury-v-Madison (Accessed 25 January 2022).

1102 See Art VI of the US Constitution. This is arguably what Chief Justice Marshall mainly relied on in *Marbury v Madison* (see Cormell Law School "Judicial Review''. https://www.law.cornell.edu/constitution-conan/article-3/section-2/clause-1/judicial-review (Accessed 21 May 2021).

Madison,[1103] further reaffirming this position, the court said: "It is emphatically the province and duty of the judicial department to say what the law is".[1104] He further says, in the same case, "the Constitution is superior to any ordinary act of the legislature".[1105]

Alexis de Tocqueville has, confirming the US courts' power to invalidate laws, described the position as follows:

> Whenever a law that the judge holds to be unconstitutional is invoked in a tribunal of the United States, he may refuse to admit it as a rule; this power is the only one peculiar to the American magistrate, but it gives rise to immense political influence.[1106] (Footnotes or commentary omitted).

6.2.1.2 Constitutional framework

The early thinking around judicial review in the US could be summed up by what James Madison, one of the early thinkers behind the US Constitution, said in the *Federalist*.[1107] He argued that if governments, which control men, were run by angels rather than men, there would be no need to place any controls on them, whether internally or externally.[1108] Madison's view here could be seen as making a case for accountability on the part of governments.

Placing the control of government decisions, including those of the Congress, under the judicial review, controversial as it was at the time, was therefore thoroughly debated and favoured by the original framers of the US Constitution.[1109] The prevention of abuse of the majority over the minority was also one of the motivations behind placing the control of government and Congress decisions under review by the

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1103 *Marbury v Madison* 5 U.S. (1 Cr.) 137 (1803).

1104 As cited in Irons P and Guitton S (eds.) *May It Please the Court*. (The New Press New York 1993) 4. Further note Justice Brennan's related position in *Baker v Carr* 369 U.S. 186 (1962), i.e. with regard to the justiciability or otherwise of whether certain functions fall within certain powers or not in terms of the doctrine of separation of powers, which resides with the courts (see Irons and Guitton *May it Please the Court* 16).

1105 As cited in Irons P and Guitton S (eds.) *May It Please the Court*. (The New Press New York 1993) 4.

1106 De Tocqueville A "Judicial power in the United States, and its influence on political society" in Griffith T (ed) *Democracy in America* (Wordsworth Classics Hertfordshire 1998) 45.

1107 Breyer *America's Supreme Court 82.*

1108 Breyer *America's Supreme Court 82.*

1109 *Breyer America's Supreme Court* 6-8.

courts.[1110] The US position on judicial review is however not clearly elaborated on in the Constitution itself.[1111]

6.2.1.3 Legislative framework

One of the main statutes regulating judicial review is the Administrative Procedures Act of 1946 (APA).[1112] The APA provides for the review of any agency action where anyone has been legally wronged, aggrieved or adversely affected by such an action.[1113] The APA provides only for those actions that are reviewable under a statute or where there is a final agency decision in respect of which there is no other adequate legal remedy in a court.[1114] The APA provides for the grounds of review as follows: arbitrariness; capriciousness; abuse of discretion; unlawfulness; unconstitutionality; absence of jurisdiction; absence of authority; absence of statutory right; improper procedure; absence of substantial evidence and that the decision is unwarranted by the facts.[1115]

What could then be drawn from the APA provisions, as key grounds of review, could be summed up as follows: arbitrariness, unlawfulness, unconstitutionality and improper procedures. Outside the APA the due process clause in the US Constitution is arguably another ground of review.[1116] Rationality has also found space in the scheme of judicial review, especially where the limitation of some rights in the Bill of Rights is concerned.[1117]

1110 Breyer *America's Supreme Court* 9.

1111 Breyer S *America's Supreme Court: Making Democracy Work* (Oxford University Press Oxford 2010) 3. However, the supremacy clause of the Constitution, which requires that 'judges in every state shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding', may be read as implying that the courts may invalidate anything not consistent with this constitutional supremacy (Art VI).

1112 U.S. Environmental Protection Agency "Summary of the Administrative Procedures Act 5 USC §551 et seq. (1946)''. https://www.epa.gov/laws-regulations/summary-administrative-procedure-act (Accessed 5 June 2021).

1113 S 10(2)(a) of the APA. No judicial review is however available where a statute excludes such, and the agency decision amounts to a discretion (see s 10(1) and (2)).

1114 S 10(2)(c) of the APA.

1115 S 10(2)(e) of the APA.

1116 Britannica "Judicial review in the United States''. https://www.britannica.com/topic/constitutional-law/judicial-review-in-the-United-States (Accessed 23 May 2021). Though used in a criminal law context, the due process provision of the US Constitution played a key role in the decision in *De Jonge v Oregon* 299 U.S. 353 (1937).

1117 See for example, *United States, Railroad Retirement Board v Fritz* 449 U.S. 166 (1980), where the court held that there was a rational basis for the differentiation by the employer's retirement fund system in its provision of benefits under the Railroad Retirement Act of 1974.

6.2.1.4 Implications for health research

The framework on judicial review does create sufficient space for the challenge of decisions. Researchers, research participants or other stakeholders in research may therefore rely on these principles to challenge decisions taken by various state bodies, including any statute they consider to be unconstitutional. The problem, however, is that these principles have not as yet been invoked in the context of health research, therefore weakening the PLA contemplated in this thesis.

6.2.2 The right to human dignity

6.2.2.1 Common law

Human dignity is recognised in US tort law.[1118] This is not so in criminal law.[1119] Given the close proximity between the right to human dignity and other rights like privacy, which are also already recognised under the common law, there is no doubt that the protection of human dignity could also come through the exercise of such other rights.

6.2.2.2 Constitutional framework

There is no specific provision with regard to human dignity in the US Constitution.[1120] This does not mean that the Constitution has not been, or cannot be, interpreted to give effect to such a right.[1121] Despite human dignity being referred to in a number of

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1118 Evans S "Dignity in non-constitutional American jurisprudence" (2018). https://delawarelaw.widener.edu/files/resources/saraevansdignityinamericanlaw.pdf (Accessed 28 May 2021). Also see cases referred to therein.

1119 Evans *Dignity in non-constitutional American jurisprudence* 2018. That human dignity is not recognised in criminal law could in this instance only mean that its violation is not treated as a crime, but it arguably cannot, as can be shown below in the context of the assessment of whether or not a death penalty is consistent with human dignity, be said that it plays no part in the adjudication of criminal cases in general.

1120 Jackson VC "Constitutional Dialogue and Human Dignity: States and Transitional Constitutional Discourse'' (2004). http://scholarship.law.georgetown.edu/facpub/106/ (Accessed 22 May 2021).

1121 *S v Makwanyane and Another* 1995 (3) SA 391 (CC) para 57, where the court, as per Chaskalson P, states that the US Supreme Court has recognized human dignity as part of the core of the Constitution's prohibition of what is 'cruel and unusual' punishment in the American Constitution. The court refers to *Gregg v Georgia* 428 U.S. 153 (1976). The Court, in *S v Makwanyane* para 328 further refers to *Furman v Georgia* 408 U.S. 238 (1972), where the US Supreme Court also endorsed the recognition of human dignity in American law. At state level *S v Makwanyane* para 91 further refers to the Californian Supreme Court decision in *People v Anderson* 493 p.2d 880 (Cal.1972), where the principle of human dignity was also emphasised. Further see Jackson VC "Constitutional Dialogue and Human dignity: States and transitional constitutional discourse'' (2004). https://scholarship.law.umt.edu/mlr/vol65/iss1/2/ (Accessed 22 May 2021).

cases in the US, the concept remains 'episodic and underdeveloped'.[1122] It should be said that at state level, there is a unique instance of the State of Montana, whose Constitution does provide for human dignity.[1123]

6.2.2.3 Legislative framework

There is currently no legislative framework at federal level specifically dealing with human dignity. However, there are, at state level, various statutes touching on 'dignity' in the context of assisting people with dying.[1124]

6.2.2.4 Implications for health research

The general reluctance to refer to human dignity in American constitutional law, which also weakens the PLA contemplated in this thesis, may have the effect of reduced protection to participants in health research, given the centrality of the principle of human dignity in the protection of research participants. This protection could even be lessened in the case of children, more particularly those displaced, due to their increased vulnerability.

6.2.3 The right to health care

6.2.3.1 Common law

There is no clearly recognised right to health care under the US common law.[1125] This does not mean that other common law principles cannot be relied on to institute claims on health-related issues. The general contractual and tort principles could for example be relied on in some instances to protect a person from health hazards or other related forms of harm.

1122 Jackson *Human dignity* 2004. The concept was for example used in a series of dissenting judgements by Justice Murphy in *In re Yamashita* 327 U.S. 1 (1946), *Korematsu v United States* 323 U.S. 214 (1944) and *Cox v United* States 332 US 442 (1947). It was further referred to by Frankfurter J in a concurring opinion in *Adamson v California* 332 U.S. 46 (1947) and by a majority decision in *Rochin v California* 342 U.S. 165 (1952) where in the latter case the use of force in securing evidence was considered as brutal and 'offensive to human dignity' (See Jackson *Human dignity* 2004 for a brief discussion of these and other cases where human dignity was referred to).

1123 Jackson *Human dignity* 2004.

1124 Death with dignity Acts. https://deathwithdignity.org/learn/deathg-with-dignity-acts/ (Accessed 28 May 2021).

1125 Perkins J "The state of health care in the United States''. https://www.americanbar.org/groups/crs/publications/human_rights_magazine_home/the-state-of-healthcare-in-the-united-states/state-of=healthcare/ (Accessed 17 May 2021).

6.2.3.2 Constitutional framework

The US Constitution does not have an express provision for the right to health care.[1126] The US's general reluctance to institutionalise the right to health care in a legal framework can arguably be gleaned from its non-ratification of the ICESCR, which requires states to take measures to deal with health care-related needs.[1127] This therefore leaves those seeking protection of their right to health care to rely on other provisions to secure health-related rights.

6.2.3.3 Legislative framework

There is arguably no legislative framework specifically dealing with the right to health care in the US, though there are some laws that provide for related rights.[1128] The US Supreme Court has in particular recognised the power of the states to enact laws within their territories to regulate health and safety issues.[1129] Various public health laws often pose constitutional challenges.[1130] In *Bolger v Youngs Drug Products Corp.* 463 U.S. 60 (1983) the Supreme Court affirmed the Federal District Court's declaration of a law outlawing the unsolicited mailing of advertisements of contraceptives, unconstitutional. The basis for the declaration of unconstitutionality was in the main the law's violation of the First Amendment's freedom of speech.

1126 Perkins J "The state of health care in the United States''. https://www.americanbar.org/groups/crs/publications/human_rights_magazine_home/the-state-of-healthcare-in-the-united-states/state-of=healthcare/ (Accessed 17 May 2021). The reluctance to endorse the health care rights could also be gleaned from the court's attitude in *Webster v Reproductive Health Services* 492 U.S. 490 (1989), para 37 where the court, in relation to access to public facilities for abortion purposes, said; "Nothing in the Constitution requires states to enter or remain in the business of performing abortions. Nor, as appellees suggest, do private physicians and their patients have some kind of constitutional right of access to public facilities for the performance of abortions''.

1127 Gerisch M "Health care as a human right''. https://www.americanbar.org/groups/crsj/publications/human_rights_magazine_home/the-state-of-healthcare-in-the_united-states/health-care-as-a-human-right/ (Accessed 26 May 2021).

1128 Perkins "The state of health care". American health systems tend more towards health insurance than health care, which can also be evidenced by the passing of the *Patient Protection and Affordable Care Act* (ACA) (Also see Gerisch M "Health care as a human right''. https://www.americanbar.org/groups/crsj/publications/human_rights_magazine_home/the-state-of-healthcare-in-the_united-states/health-care-as-a-human-right/ (Accessed 26 May 2021). The ACA (sometimes informally referred to as the Obamacare Act) sought to provide some basic health care insurance (also see *California, et al., Petitioners v Texas, et al.,* 593 U.S. (2021).

1129 *Jacobson v Massachusetts* 197 U.S. 11 (1905).

1130 Note for example, the case of *Jacobson v Massachusetts* 197 U.S. 11 (1905) where the Massachusetts vaccination laws were unsuccessfully challenged for their unconstitutionality.

6.2.3.4 Implications for health research

The absence of an express provision dealing with the right to health care has the implication that research participants may not be maximally protected. Although some cases, including *Jacobson v Massachusetts* 197 U.S. 11 (1905) (at least at face value), did arguably promote a public law approach, not all have taken this route. *Jacobson v Massachusetts* could arguably also not be said to have provided a proper balance between public interest and individual rights. This might therefore not provide for the ideal PLA contemplated in this research.

6.2.4 The protection of children

6.2.4.1 Common law

The American common law, with a strong English law influence, recognises the principle of the best interests of the child.[1131] Historically, under English law, the principle of the best interest of the child mainly involved the Chancery courts having the authority "to oversee the guardians 'for the benefit of the infant'".[1132] English common law further had significant influence on American law in the area of abortion, where in the earlier years abortion done before what was considered to be 'quickening' was not considered an offence.[1133]

6.2.4.2 Constitutional framework

There is no express provision in the US Constitution dealing with the protection of children. This does not however mean that children cannot rely on other provisions of the Constitution to protect their rights. In *Carey v Population Services International* 431 U.S. 678 (1977) the Supreme Court declared a law prohibiting the distribution and advertisements of contraceptives to persons, including children, unconstitutional for violating the First and Fourteenth Amendments, dealing in the main with freedom of speech and privacy (liberty) respectively. Courts have also held that a parent does

1131 Carbone J "Legal applications of the 'Best interest of the child' standard: judicial rationalization or a measure of institutional competence" (2014). https://pediatrics.aappublications.org/content/134/Supplement_2/S111 (Accessed 26 May 2021).

1132 Carbone https://pediatrics.aappublications.org/content/134/Supplement_2/S111 (Accessed 26 May 2021).

1133 *Roe v Wade* 410 U.S. 113 (1973) para 40.

not, based on religious beliefs, have the liberty to expose children to communicable diseases or to death or ill-health.[1134]

However, one of the US's predicaments, which arguably has an impact on its approach to the protection of children, is her non-ratification of the UN Convention on the Rights of the Child, despite having signed it.[1135]

6.2.4.3 Legislative framework

Various American States have statutes providing for the best interests of the child.[1136] Though these statutes do not define what constitutes the best interest of the child, they provide for various factors that they take into account in defining what is considered to be in a child's best interest, though these factors vary as amongst the various states.[1137] Some of the factors and principles used in assessing the best interest of the child include the health, safety and in general the protection of the child.[1138] These factors and principles could be very important in the protection of children who partake in health research.

Other Acts, mainly at state level, have also dealt with issues that impact on the status of the unborn child. A notable example of such laws includes the Texas laws dealing with abortion, one of which is known as the Texas Heartbeat Act of 2021[1139] and their counter-part Missouri statutes regulating same, one of which is known as the Missouri Revised Statutes Tittle XII. Public Health and Welfare §188.010.[1140] In relation to child

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1134 *Prince v Massachusetts* 321 U.S. 158 (1944).

1135 Humanium "Signatory states and parties to the Convention on the Rights of the Child''. https://www.humanium .org/en/convention/signatory-states/ (Accessed 17 May 2021).

1136 Children's Bureau "Determining the best interests of the child'' (2020). https://www.childwelfare.gov (Accessed 26 May 2021). These various laws at state level no doubt have a significant influence on the shaping of American child law in general. Some of the states include the state of Alabama (in terms of Ala. Code §30-3-152); California (in terms of Cal. Fam. Code § 3011) and Delaware (in terms of 13 Del. C. §722) (Also see Morgan Lewis and Bockius LLP "Best interests of the child – factors in state law" (2017). https://niwaplibrary.wcl.american.edu/wp-content/uploads/Appendix-Q1/Best-Interests-of-the-Child-All-Factors.pdf (Accessed 1 July 2022).

1137 Children's Bureau "Determining the best interests of the child'' (2020). https://www.childwelfare.gov (Accessed 26 May 2021).

1138 Children's Bureau https://www.childwelfare.gov (Accessed 26 May 2021).

1139 Texas Abortion Laws. https://www.findlaw.com/state/texas-law/texas-abortion-laws.html. (Accessed 1 July 2022).
Further see *Roe v Wade* 410 U.S. 113 (1973), which dealt with the constitutionality of the Texas abortion laws.

1140 Also see Missouri Abortion Laws. https://www.findlaw.com/state/missouri-law/missouri-abortion-laws.html. (Accessed 1 July 2022). Further see *Webster*

privacy there is an Act specifically dealing with this aspect, namely the Children's Online Privacy Protection Act of 1998 (COPPA). The Act mainly protects child privacy in the context where operators of websites collect personal information belonging to children below 13, in which case the consent of the parents is required. COPPA does not however specifically deal with privacy in the context of health research. It is however not inconceivable that where the websites collect information that may be used for research purposes, COPPA may be useful in protecting the participating children.

6.2.4.4 Protection of displaced children

There is no law specifically dedicated to the protection of displaced children. Some of the general principles discussed above will however become applicable in the context of the protection of displaced children.[1141]

6.2.4.5 Implications for health research

Some principles discussed above, including the best interest of the child standard, may be very critical in the protection of participants in health research. However, while the best interests of the child standard does go some way in supporting the PLA contemplated in this thesis, the absence of an express constitutionalisation of the rights of children could be a drawback, as it may lead to inconsistencies in the interpretation of the various provisions in the Constitution with a view to applying them in the protection of children.

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v Reproductive Health Services 492 U.S. 490 (1989) where a Missouri statute, whose preamble sought to protect the health, life and well-being of unborn children beginning at conception was challenged. In this case the court, departing from *Roe v Wade*'s rigid trimester and viability requirements, noted with approval Justice White's dissenting judgement in *Thornburgh v American College of Obstetricians & Gynecologists* 476 U.S. 747(1986) that the state had legitimate or compelling interest in protecting the life of the unborn children not only after viability but also before viability, i.e. during the whole course of pregnancy. The court therefore, held that the state's choice of viability in the Missouri Act, as by implication it would have been the case if the state had chosen to intervene before the state of viability, was not unconstitutional (see *Webster v Reproductive Health* Services paras 53 – 55).

1141 Note however that some of the principles like the best interest of the child principle was held not to apply the same in other contexts. For example, in *Michael v Gerald* 491 U.S. 110 (1989), the court refused to use the best interest of the child principle to allow a challenge to the immigration rules allowing deportation of children (also see Carbone https://pediatrics.aappublications.org/content/134/Supplement_2/S111 (Accessed 26 May 2021)).

6.2.5 Approach to equality

6.2.5.1 Common law

The US's English law roots means that some common law principles of equality as applicable in the UK have also found some application in American law.[1142] In the context of common law the principle of equality is rooted within the principle of the rule of law, which requires that no one should be above the law.[1143]

6.2.5.2 Constitutional framework

The US Constitution, in its Bill of Rights, has a provision dealing with equal protection, in a more general sense.[1144] The relevant provision does not however, in the main, spell out the scope of this equality. It does not for example spell out what grounds of discrimination will be considered a violation of the equality contemplated here. Discrimination based on the more usual grounds of unfair discrimination like race, gender, sex, sexual orientation, etc. is more likely to undermine this provision.[1145] The failure to enumerate some prohibited grounds has created some uncertainty around what the equal protection clause seeks to cover.[1146]

The US Constitution further does not have a provision outlining the circumstances under which certain forms of discrimination may be justified.[1147] Another provision

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1142 Equal Protection: the common law (2021). https://jrank.org/pages/6538équal-protection-common-law.html (Accessed 10 June 2021).

1143 Equal Protection: the common law (2021). Further see *United States v. Nixon 418 U.S. 683 (1974)* para 41, where the court, in adjudicating on the permissibility of the executive privilege of immunity from producing documents subpoenaed for a criminal trial, restated the court's 'historic commitment to the rule of law', which Implied, though not so loudly, that the president should not be granted immunity in an impermissible manner so as to undermine equality before the law. https://jrank.org/pages/6538équal-protection-common-law.html (Accessed 10 June 2021).

1144 S 1 of the Fourteenth Amendment prohibits states from denying 'any person within its jurisdiction the equal protection of the laws'.

1145 Note however the limited context in which some grounds of prohibited discrimination are mentioned, mainly the context of voting or the holding of political office (see the Fifteenth Amendment (prohibiting discrimination on the ground of race, colour and servitude); Nineteenth Amendment (prohibiting discrimination on the ground of sex) and the Twenty-Sixth Amendment (prohibiting discrimination on the ground of age).

1146 For example, although the court in *Romer v Evans* 517 U.S 620 (1996) ruled as unconstitutional the Colorado laws removing existing legal protection to homosexuals, the mere fact that there was a very strong dissenting opinion to this judgement could show the uncertainty surrounding the equal protection clause.

1147 But, as indicated earlier, the courts may sometimes recognize the consideration of race in taking some decisions, within the confines of what has been dubbed 'strict scrutiny' (see *Fisher v University of Texas* 579 U.S. (2016) (further see Cornell Law School "Affirmative Action''. https://www.law.cornell.edu/wex/affirmative-action (Accessed 16 June 2021).

more relevant to questions of discrimination is s 1 of the Thirteenth Amendment, which prohibits slavery and servitude, except where these serve as forms of punishment for duly convicted persons.

6.2.5.3 Legislative framework

Various laws deal with equality issues in the US, including the Civil Rights Act of 1964; the Pregnancy Discrimination Act of 1978; the Equal Pay Act of 1963; Tittle I of the Americans with Disabilities Act of 1990; Civil Rights Act of 1991; the Genetic Information Non-discrimination Act of 2008 and the Rehabilitation Act of 1973.[1148] There is also the proposed Equality Act, not yet finalised at the time of writing, which will also deal with equality issues.[1149]

6.2.5.4 Implications for health research

None of these laws directly deal with health research issues. This does not, however, mean that the generic principles stated therein may not be applied in a research context. There is no available evidence that the courts have used any of these principles in a health research context as yet, therefore weakening the PLA contemplated in this thesis.

6.2.6 Approach to remedies

6.2.6.1 Common law

The US recognises in the main the remedies of damages and a declaratory relief.[1150] An injunctive relief is also sometimes resorted to, whether successfully or without success.[1151] One important area of the law that impacts on the shaping of remedies is

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1148 U.S. Equal Employment Opportunity Commission "Laws enforced by EEOC''. https://www.eeoc.gov/statutes/laws-enforced-eeoc (Accessed 31 May 2021). Further note the proposed Equality Act, which will further improve on some of the existing equality laws, more particularly the Civil Rights Act of 1964, more especially with regard to sexual orientation and other related grounds of discrimination (see Center for American Progress "What you need to know about the Equality Act'' (2021). https://www.americanprogress.org/issues/lgbtg-rights/reports/2021/03/15/497158/need-know-equality-act/ (Accessed 16 June 2021).

1149 White House "Fact Sheet: The Equality Act will provide long overdue civil rights protections for millions of Americans''. (2021) https://www.whitehouse.gov/briefing-room/statements-releases/2021/06/25/fact-sheet-the-equality-act-will-provide-long-overdue-civil-rights-protections-for-millions-of-americans/ (Accessed 26 June 2021).

1150 Cornell Law School "Remedy''. https://www.law.cornell.edu/wex/remedy (Accessed 21 May 2021).

1151 *Doe v Bolton* 410 U.S. 179 (1973), where both a declaratory relief and injunctive relief were asked for, but the court declining the latter. Also see *Roe v Wade* 410 U.S. 113 (1973).

the law of equity, which makes it possible for the courts to offer equitable remedies where existing remedies are not sufficient.[1152]

One area impacting on remedies, which has also been influenced by equity principles, is the aspect dealing with limitation of liability, including exemptions from liability, which impacts on the freedom of contract. American courts have been confronted with this issue, which was particularly the case in *Henningsen v Bloomfield Motors Inc*,[1153] where the court considered the principle of freedom of contract as not immutable.[1154] The principles of justice, equity and fairness were instead considered very important.[1155] Warranties limiting a manufacturer's liability were also considered to be contrary to public policy.[1156]

6.2.6.2 Constitutional framework

In addition to the common law framework, the US Constitution creates scope for equitable remedies, as it provides for judicial power to "extend to all cases, in law and equity,...''.[1157] So as to give effect to various provisions in the US Constitution various remedies, including declaratory and injunctive reliefs, have been awarded by the courts.[1158] The courts have also recognized constitutional damages arising mainly from the violation of the US Constitution by federal officials.[1159]

6.2.6.3 Legislative framework

1152 Cornell Law School "Equity''. https://www.law.cornell.edu/wex/equity (Accessed 12 June 2021). Further see Britannica "Equity: law''. https://www.britannica.com/topic/equity (Accessed 12 June 2021).

1153 *Henningsen v Bloomfield Motors Inc.* 32 N.J. 358 (1960).

1154 Dworkin R *Taking Rights Seriously* (Bloomsbury London 2013) 40.

1155 Dworkin Taking Rights Seriously 40 and 43.

1156 *Henningsen v Bloomfield*. https://www.casebriefs.com/blog/law/commercial-law-keyed-to-lopuck/performance/henningsen-v-bloomfield-motors/ (Accessed 20 May 2021).

1157 Art III (2) of the US Constitution.

1158 See *Doe v Bolton* 410 U.S. 179 (1973), where both a declaratory relief and injunctive relief were asked for, though the court declined the latter. Also see *Roe v Wade* 410 U.S. 113 (1973).

1159 One of the leading decisions in this regard is the case of *Bivens v Six Unknown Named Agents* 403 U.S. 388 (1971). This case related mainly to the violation of the Fourth Amendment. The defence of absolute immunity (from these types of claims) however exists in the case of the US President and those performing adjudicatory functions, as per the decisions in *Nixon v Fitzgerald* 457 U.S. 731 (1982) and *Butz v Economou* 438 U.S. 478 (1978), respectively. A further defence of qualified immunity exists in the case of those performing discretionary functions (See Lawyer Zone "Bivens Action (Constitutional Torts: All you need to know)'' (2021). https://lawyer.zone/bivens-action/ (Accessed 18 January 2022). Further see Cornell Law School "Bivens Actions''. https://www.law.cornell.edu/wex/biens_actions (Accessed 18 January 2022).

Some remedies are specifically provided for in terms of specific legislation. Some statutes provide for the remedies of the writs of prohibition and mandamus, for certain types of disputes.[1160] Title VII of the Civil Rights Act of 1964 provides for an injunctive relief in certain forms of discrimination.[1161] With regard to constitutional damages, the Civil Rights Act of 1871 (section 1983 actions) makes provision for such damages, including punitive damages, at state level.[1162] With regard to liability for various types of official misconduct, some of which the section 1983 actions (which are only limited to constitutional torts) do not cover, the Federal Tort Claims Act of 1946 (FTCA) makes provision for.[1163] With regard to exemption clauses or limitation of liability, there is the Uniform Commercial Code of 1952 (UCC), a code reflecting on, and harmonizing, commercial laws that have been adopted by American states.[1164]

§ 2-718 (1) of the UCC prohibits the fixing of unreasonable liquidated damages as a penalty. Despite that the UCC permits the limitation or exclusion of consequential damages, it prohibits such limitation if the limitation or exclusion is unconscionable.[1165] Where the limitation of consequential damages is in respect of personal injury, the limitation is *prima facie* unconscionable.[1166] Where any clause in contract is unconscionable a court may refuse to enforce such a contract, or only enforce that part of the contract that is not unconscionable, or limits the application of the unconscionable portion of the contract in ways that avoid the unconscionable result.[1167]

1160 See Cornell Law School "Rule 21. Writs of Mandamus and Prohibition, and other extraordinary writs''. https://www.law.cornell.edu/rules/frap/rule_21 (Accessed 31 May 2021). Further see Cornell Law School "28 U.S. Code § 1651 – Writs". https://www.law.cornell.edu/uscode/text/28/1651 (Accessed 20 February 2022).

1161 Library of Congress "The Civil Rights Act of 1964: A long struggle for freedom''. https://www.loc.gov/exhibits/civil-rights-act/epilogue.html (Accessed 16 June 2021).

1162 The relief under this Act has come to be known as the section 1983 actions because of the section where it is located in the Civil Rights Act of 1871 (also see Love JC "Damage: a remedy for the violation of constitutional rights'' 1979 *California Law Review* 1242 - 1285).

1163 For a discussion of the differences between the section 1983 actions and the actions under the FTCA, see Love JC "Damage: a remedy for the violation of constitutional rights'' 1979 *California Law Review* 1242.

1164 See Tembe HC "Problems regarding exemption clauses in consumer contracts: the search for equitable jurisprudence in the South African constitutional realm" (LLD thesis University of Pretoria 2017) 299.

1165 § 2 - 219(3) of the UCC. Also see Tembe *Exemption clauses* 299. Further see § 2 - 316(1) of the UCC dealing with related provisions on the exclusion or modification of warranties.

1166 § 2 - 219(3) of the UCC.

1167 § 2 - 302(1), read with (2), of the UCC.

6.2.6.4 Implications for health research

The equitable remedies under both the common law and the US Constitution could be very useful in the protection of participants in health research. So will the provisions of the UCC regulating the limitation or exclusion of liability or certain remedies be also useful. The possibility that constitutional damages could be granted under certain circumstances could also prove useful in the protection of health research participants, therefore potentially supportive of the PLA framework contemplated in this thesis. Current evidence does not however suggest that these principles have yet been used in the context of health research, which may therefore weaken the PLA.

6.2.7 Promotion of access and protection of information

6.2.7.1 The Common law

Privacy is recognised under the law of torts.[1168] Warren and Brandeis also argues that the common law also recognised the right to be let alone (which is a simplified attempt to describe the right to privacy).[1169] That the right to privacy exists under the common law can also be evidenced by the court's attitude in *Grisworld v Connecticut*,[1170] where the court said:

> We deal with a right of privacy older than the Bill of Rights older than our political parties, older than our school system. Marriage is a coming together for better or for worse, hopefully enduring, and intimate to the degree of being sacred.[1171]

6.2.7.2 Constitutional framework

The US Constitution has no express provision providing for the general right to privacy.[1172] It does however expressly provide for certain types of privacy. For example, the Fourth Amendment provides for privacy in the context of 'searches and

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1168 Haydel "Privacy'' (2009) https://www.mtsu.edu/first-amendment/article/1141/privacy (Accessed 17 May 2021).

1169 Haydel *Privacy* (2009). Further see Irons and Guitton *May it please the Court* 339. Also see Van Der Merwe DP (ed), Roos A, Pistorius T, Eiselen GTS and Nel SS *Information and Communications Technology law* 2nd ed (LexisNexis Durban 2016) 370. The expression of the right 'to be let alone' was of course, not Warren and Brandeis' own invention, but apparently that of Judge Cooley (see Warren SD and Brandeis LD "The Right to privacy'' 1890 *Harvard Law Review* 195).

1170 *Grisworld v Connecticut* 381 U.S. 479 (1965).

1171 *Grisworld v Connecticut* 381 U.S. 479 (1965) para 18.

1172 Haydel ''Privacy'' (2009) https://www.mtsu.edu/first-amendment/article/1141/privacy (Accessed 17 May 2021).

seisures'.[1173] Other less specific provisions may also be used. These include the provisions dealing with the protection of liberty.[1174] In one of the leading cases, *Roe v Wade,*[1175] a pregnant woman successfully relied on the liberty provision to challenge the constitutionality of a Texas statute that prohibited the termination of pregnancy unless the woman's life is in danger.[1176] In *Grisworld v Connecticut* 381 U.S. 479 (1965) a Connecticut law that prohibited married persons from using, amongst other things, contraceptives, was in the main declared invalid on privacy grounds.[1177]

6.2.7.3 Legislative framework

One of the main legislative frameworks in the US governing the protection of personal information is the Privacy Act of 1974 (the Privacy Act). It specifically protects the personal information of individuals[1178] held by an agency.[1179] Although the definition of agency in the Privacy Act does not necessarily make it clear whether the concept includes institutions other than public institutions (linked to government), or whether it

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1173 The right to privacy. http://law2.umkc.edu/faculty/projects/ftrials/conlaw/rightofprivacy.html (Accessed 16 May 2021).

1174 See Fifth Amendment. Liberty is, in general, even highly cherished in the US, as may be evidenced by specific reference to it in the Preamble to the US Constitution.

1175 *Roe v Wade* 410 U.S. 113 (1973). Further see Irons and Guitton *May it please the Court* 343.

1176 Note however *Skinner v Oklahama* 316 U.S. 535 (1942) where issues that arguably interfere with personal liberties were decided under the Fourteenth Amendment's equal protection clause. In this case an Oklahoma law permitting the sterilization of those convicted for at least two times for crimes of felonies was declared invalid (also see American Bar Association "Parental rights cases to know'' (2016). https:/www.americanbar.org/groups/public_interest/child_law/resources/child_law_practiceonline/child_law_practice/vol-35/February-2016/parental-rights-cases-to-know/ (Accessed 24 May 2021). Further see Gur-Arie R "Skinner v Oklahoma (1942)'' (2016). https://embryo.asu.edu/pages/skinner-v-oklahoma-1942 (Accessed 12 June 2021). Further see The Embryo Project Encyclopedia "Skinner v. Oklahama (1942)''. https://embryo.asu.edu/pages/skinner-v-oklahama-1942# (Accessed 25 January 2022).

1177 American Bar Association *Parental Rights Cases* (2005). In a like manner in *Eisenstadt v Baird* 405 U.S. 438 (1972) a Massachusetts law was declared invalid for prohibiting "the distribution of contraceptives to unmarried persons' (see American Bar Association *Parental Rights Cases* (2005). Contrast this with the earlier decision in *Buck v Bell* 274 U.S. 200 (1927), where the privacy argument did not even arise. In that case a Virginia law authorizing a feeble-minded woman to be sterilized ostensibly to protect the patient's health and societal interests was affirmed by the Supreme Court.

1178 § 552a (a)(2) confines the concept of 'individual' to the US citizens and immigrants who hold lawful permanent residence status. This creates a problem in that those who are in the US on a temporary basis, or who are there illegally, are not afforded protection. This should be contrasted with the frameworks in SA and the UK, which do not make direct reference to citizenship or permanent resident status as the basis for the protection of personal information.

1179 § 552a (a)(4), read with § 552a (b), of the Privacy Act.

is confined to public institutions, the context of the usage suggests that the concept is only confined to a public institution.

If this conception of an agency is adopted, the implications are that the obligations to respect an individual's personal information are only placed on public authorities, with private persons only serving as the rights' recipients.[1180] Except where provided otherwise, an agency is not permitted to disclose personal information of an individual to another person or agency without the request or the prior consent, in writing, of the person to whom the information relates.[1181]

Although the Privacy Act does provide for circumstances under which an individual's personal information may be supplied to another person or agency, without breaching the Act's provisions, such circumstances do not specifically include research purposes. What comes closer to research purposes is where the agency to whom a disclosure has been made has provided 'advance adequate written assurance' about the record being used 'solely as a statistical research or reporting record'.[1182] A further condition to the preceding circumstance is that the record must take 'a form that is not individually identifiable'.[1183] Given that this condition is only confined to statistical research, it is arguably not relevant to health research, which this study is concerned with.

Another condition justifying the disclosure, which could be relevant to health research, is where information has been disclosed to another person or agency as a result of 'compelling circumstances' impacting on an individual's health or safety, provided that, after disclosure, a notification is sent to that's individual's last known address.[1184] This circumstance appears to mean an instance where an agency is of the view that the disclosure of information to another person might be to the benefit of the data subject, in that the information could be used for the data subject's health or safety.[1185]

1180 This approach is consistent with the US constitution's philosophical outlook, which mainly views public authorities as holders of obligations, and private persons as rights' holders (this philosophical outlook should also be viewed in the context of what the court said in *DeShaney v Winnebago County Department of Social Services* para 23 which, as pointed out earlier, implied that there is less focus on private actors, other than in instances where they are rights' holders.

1181 § 552a (b) of the Privacy Act.

1182 § 552a (b)(5).

1183 § 552a (b)(5).

1184 § 552a (b)(8).

1185 In the context of health research this could arguably be relevant in instances where co-

The Privacy Act further requires that the information kept by an agency must remain accurate in terms of the date, nature and purpose of the disclosure of the information as well the name and address of the person to whom the information was disclosed.[1186] It further requires that the accounting records be kept for about five years or for 'the life of the record', depending on which of the two periods is longer, from the date of the disclosure in respect of which the accounting was made.[1187]

The Privacy Act further provides for access to information by the data subject.[1188] This right includes the right of the individual to be permitted to review and even copy the records held by an agency.[1189] It further includes the right to correct the information held by an agency, and to have the decision to refuse an individual's request to correct the information reviewed.[1190] However access to information is not permitted where the request for access is in anticipation of court (civil) proceedings.[1191]

The Privacy Act also provides for the circumstances under which information is to be kept, which includes the fact that information must only be kept if it is relevant and necessary for the execution of the agency's purpose in terms of the law.[1192] Where the information is likely to adversely impact on the assessment of an individual's rights, benefits, privileges or other related interests provided under the Federal Programs, the agency must do as best as is possible to collect the information directly from the individual concerned.[1193]

The Privacy Act provides also for the agency collecting information to inform the data subject about specific aspects, including the legal basis for the collection of the information and whether or not it is voluntary to disclose the information;[1194] the intended principal or other purposes for the collection ('the routine uses');[1195] the

researchers who are physicians may be informed about an adverse event during the conduct of research, so that the participants involved can be taken care of.

1186 § 552a (c)(1) of the Privacy Act.
1187 § 552a (c)(2).
1188 § 552a (d).
1189 § 552a (d)(1).
1190 § 552a (d)(2) and (3).
1191 § 552a (d)(5).
1192 § 552a (e)(1).
1193 § 552a (e)(2).
1194 § 552a (e)(3).
1195 § 552a (e)(3)(B).

extent of the collection's compatibility with the original purpose of the collection[1196] and the effect on the individual if the information is not supplied.[1197]

It further requires that where an agency maintains a system of records, the agency must place a notification in the Federal Register about the existence and character of such a system of record.[1198] The information kept by an agency for the purposes of making determinations about an individual must be as accurate, relevant, timely and complete as it may be necessary to ensure that such determinations be fair.[1199] An agency collecting information should also maintain the necessary safeguards to ensure the security and confidentiality of a data subject's information.[1200]

The Privacy Act provides for a number of civil remedies against an agency's failure to comply with various provisions of the Act.[1201] These remedies may include, where this is applicable, the court's ordering of the agency to emend an individual's record as per the individual's request, or in any other manner as the court may deem fit.[1202] Where applicable, the remedies may also include the court enjoining the agency not to withhold the relevant records, and ordering the agency to produce 'the agency records' the agency improperly withheld from the complainant.[1203]

Where in the case of the agency's non-compliance with § 552a (g)(1)(C)[1204] or (D)[1205] the court determines that the actions of the agency were 'intentional or wilful', the court may order the payment of actual damages suffered, which may not be less than $1000.[1206] The remedies in the preceding discussion may include the court's ordering of reasonable attorney fees, and other litigation costs against the United States.[1207]

1196 § 552a (e)(3)(C).

1197 § 552a (e)(3)(D).

1198 § 552a (e)(4). The notice referred to in the section has to include certain details, as prescribed from § 552a (e)(4)(A) - (I) of the Privacy Act.

1199 § 552a (e)(5).

1200 § 552a (e)(10).

1201 § 552a (g)(1).

1202 § 552a (g)(2)(A).

1203 § 552a (g)(3)(A).

1204 § 552a (g)(1)(C) contemplates a civil action in case of a failure to ensure that the records kept are accurate, relevant, timely and complete, as may be necessary to the determination of an individual's rights, benefits or related interests, and whose failure results in a determination that adversely affects an individual's rights, benefits or related interests. This therefore leads to the civil remedies contemplated in § 552a (g)(4) of the Privacy Act.

1205 § 552a (g)(1)(D) contemplates a civil action in the case of failure to comply with any other provision of this Act or its regulations, whose failure results in an adverse determination of an individual's rights, benefits or related interests.

1206 § 552a (g)(4)(A).

1207 See § 552a (g)(2)(B), (3)(B) and (4)(B).

The Privacy Act makes it an offence for the commission of some acts not in compliance with this Act, including where an employee or official of an agency wilfully discloses to another person or agency any information that the Act or its regulations prohibit from disclosure.[1208]

The Privacy Act further provides for both general and specific exemptions from the application of some of its provisions, neither of which are relevant, at least directly, to the conduct of health research.[1209] Where any legal act were to be performed by an individual in terms of § 552, but such an individual is incompetent to perform such an act, the act may then be performed by such an individual's parent or legal guardian, on behalf of that individual.[1210]

Another relevant legal instrument is the Privacy Shield. As indicated in chapters one and two, this is a framework entered into between the US and the EU, so as to regulate the protection of personal data flowing from the EU to the US. The Privacy Shield is legally binding to those (in the US) who self-certify to participate in the framework.[1211] The Privacy Shield defines personal data (personal information) as 'data about an identified or identifiable individual …'.[1212]

In the main the Privacy Shield provides for the giving of notice to individuals about a number of activities, including (by implication) the fact that their information is being processed; that the organisation processing the information is a participant in the Privacy Shield; the list of the participants in the Privacy Shield or the link or web address to the Privacy Shield list; the type of information being processed; the persons to whom the information is to be transferred; complaints or enquiry mechanisms and

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1208 § 552a (i)(1). It should be noted here that the punishment is directed not against the agency, but the employees or officials. (Does it then mean that the principle of vicarious liability is not applicable here? It is however unnecessary here to dwell much into the applicability or otherwise of the principle of vicarious liability in this context).

1209 § 552a (j) and (k).

1210 § 552a (h).

1211 See also para I of the Privacy Shield.

1212 See para I (8) of the Privacy Shield. It should be noted that it does not indicate whether the person should be living or not, therefore implying that it could cover personal information about persons no longer alive. A further question related to this would therefore be as to after how long the protection will cease, in the case of persons no longer alive? One could also infer here that the word 'individual' is limited to natural, rather than juristic, persons.

channels; etc.[1213] The notice given to the relevant individuals must be couched in a clear language.[1214]

The Privacy Shield then makes provision for the individuals to choose whether or not to opt-out of the request for their information to be transferred to third parties.[1215] An opt-out mechanism is available in the case where the data collector wants to use previously collected information for a purpose materially different from the purpose the information was originally collected for.[1216] There is however an exception to the rule that when transfer of data is made to third parties the data subject must be given an opportunity to-opt out. Such an opportunity is not available if the transfer is made to a person who acts as an agent for the organisation collecting the information.[1217]

Where the information to be transferred to a third party is sensitive personal information, the consent must be affirmative i.e. it must be in the form of opt-in (sensitive personal information includes information about the data subject's medical or health conditions and a person's sex life).[1218] The opt-in requirement equally applies where there is a change of original purpose of collection of the information.[1219] Where the data collector receives information from a third party, and the third party treats that information as sensitive information, the data collector must also treat such information as sensitive.[1220]

The opt-in requirement in relation to the procession of sensitive personal data does not apply under the following instances: where the information collection is vital for the

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1213 Para II (1)(a).
1214 Para II (1)(b).
1215 Para II (2)(a).
1216 See para II (2)(a). An opt-out, as opposed to an opt-in mechanism, could be problematic in most instances. What the former means substantially is that if you don't object to a particular request, you are deemed to have consented. In other words, the adage 'silence means consent' becomes applicable. This could be complicated by the fact that in the case of a change of purpose of collection, it may not always be clear to an individual whose information is being collected whether the new purpose is materially different from the original purpose of collection. In the case of health research for example, because of the complexity of some studies, understanding the difference between the original purpose of collection and the new purpose of collection might be a challenge (This could of course be mitigated by the fact that the required notice pointed out above, which includes notices about the transfers to third parties and their purposes as well as, in general, the purpose of collections, must be in a clear language).
1217 Para II (2)(b).
1218 Para II (2)(c).
1219 Para II (2)(c).
1220 Para II (2)(c).

interests of the data subject[1221] or those of another person;[1222] the information collection enables a person to establish a claim or a defence; the information collection is for the purposes of medical diagnosis or care;[1223] the information collection is necessary to carry out the data collector's obligations under employment law;[1224] the information was placed in the public domain by the data subject and where the information is collected by religious organisations, trade unions; political organisations, philosophical organisations and other non-profit organisations as part of the legitimate activities of these organisations, provided that the information collection relates only to their members or persons in constant contact with these organisations in relation to their purposes, and is not transferred to third parties without the consent of the data subjects.[1225] Are there any research-specific exceptions? There does not appear to be any, but the above exceptions could arguably be adapted for research contexts.

The Privacy Shield, subject to several limitations, makes provision for access by the data subjects to their information. This includes knowing whether an organisation has the data subject's information, and the right to have the information forwarded to the data subject, to enable the data subject to verify, correct, amend or delete the information.[1226]

Regarding the more research-specific information, the Privacy Shield provides for the data subjects to be informed about the possible future use of their information in research, in line with the notice and choice requirements discussed above.[1227] Where information is used in research while there is no previous consent on such new usage, consent is again required for the new purpose i.e. where the new purpose is not consistent with the original general research purpose of collection.[1228]

The Privacy Shield appears to, in principle, allow future new uses that were not unanticipated at the time of original consent, but data collectors in such cases must

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1221 Care should here be taken, in handling this, to avoid the danger of being over paternalistic.

1222 It is unclear what will qualify as vital interests here. It is not clear if, for example, the fact that the research participant will benefit from such a research will qualify as such a vital interest.

1223 Will health research qualify here, apparently not?

1224 What about obligations under other laws? This sounds unnecessarily restrictive.

1225 para III (1)(a).

1226 Para 8(a)(i). Para 8 further makes provisions for a number of restrictions, under certain circumstances defined in the paragraph, to the access of personal information by the data subject.

1227 Para 14(b)(ii).

1228 Para 14(b)(ii).

have indicated, in the notices discussed above, that the data subjects must anticipate such unforeseen uses, provided that the new uses are not inconsistent with the general research purpose for which consent was originally obtained.[1229]

Participants in research have the freedom of withdrawal from the study, or they may be asked to do so.[1230] However, any personal information collected before the withdrawal may continue to be used, provided that this was initially indicated to the data subject in the notice discussed above.[1231] Participants in blinded studies do not have to be provided with all the information, if this would undermine the integrity of the study and the participants were informed about this limitation at the beginning of the research.[1232] Participants may however access the information at the end of the research and after analysis of the results.[1233]

Regarding access to information, the US's FOI Act generally provides for access to information held by public authorities.[1234] FOI Act specifically requires each agency to state separately and publish certain information about the agency's procedures and workings in the Federal Register, to serve as guidance to the public.[1235] FOI Act further requires each agency to make specified information available for inspection and copying.[1236] The information so to be made available may include the agency's final opinions and orders;[1237] the agency's adopted statements of policy and interpretations not published in the Federal Register[1238] and the agency's manual and communication to staff which have an impact on the public.[1239]

Unless certain exceptions described in § 552 (a)(3) apply, each agency must, upon request that it provides a reasonable description and other relevant details of the requested records, promptly supply the requested information to the requester.[1240] Where a request is made to an agency, the agency must do what is reasonably

1229 Para 14(b)(ii).
1230 Para 14(c)(i).
1231 Para 14(c)(i).
1232 Para 14(e)(i).
1233 Para 14(b)(ii).
1234 See § 552(f) of the FOI Act, whose definition of agency is confined to institutions which could be considered public authorities.
1235 § 552 (a)(1).
1236 § 552 (a)(2).
1237 § 552 (a)(2).
1238 § 552 (a)(2)(B).
1239 § 552 (a)(2)(C).
1240 § 552 (a)(3)(A).

possible to search, 'in electronic form or format', for the requested information.[1241] The agency however need not comply with the search requirement if this would hinder the smooth operation of the agency's automated system in a significant way.[1242]

So as to comply with the provisions of FOI Act, each agency must publish regulations providing for the schedule of fees payable, and the circumstances under which the payment of the fees may or may not be applicable, or may be payable at a reduced rate.[1243] The published regulations shall, in the case of requests for commercial use, limit the fees to the 'standard reasonable charges' for the search, duplication and review of documents.[1244]

Where the request is for non-commercial purposes, and made by an educational or non-commercial scientific organisation for research purposes, or by news media representative, the regulations shall limit the fees to the 'standard reasonable charges' for document duplication.[1245] Where the purpose of the request is neither for a commercial use or, in the case of a non-commercial use, is not made by the institutions provided in the relevant subsection described in the preceding discussion, the regulations shall limit the fees to the 'standard reasonable charges' for document search and duplication.[1246]

Where the disclosure of the information is in the public interest, in that it is likely to significantly contribute to better understanding of the government's operations, the supply of the requested information could be free or at a reduced rate.[1247] The fees to be charged in relation to the § 552 request activities are those that relate only to the direct costs of the search, duplication and review of the document.[1248]

No agency may charge advance fees for requests, except where the requestor previously failed to pay on time or where the fees exceed $250.[1249] It is permissible

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1241 § 552 (a)(3)(C).
1242 § 552 (a)(3)(C).
1243 § 552 (a)(4)(A)(i).
1244 § 552 (a)(4)(A)(ii) (II).
1245 § 552 (a)(4)(A)(ii) (II).
1246 § 552 (a)(4)(A)(ii) (III).
1247 § 552 (a)(4)(A)(iii). Note that the usage of the concept of public interest here appears very limited and appears not to include requests for research purposes, in respect of which charges, as indicated earlier, are limited to the 'standard reasonable charges' for document duplication.
1248 § 552 (a)(4)(A)(iv).
1249 § 552 (a)(4)(A)(v).

for a statute to set a certain level of fees for certain categories of records.[1250] An agency shall be prohibited from assessing search, and where applicable duplication, fees if it has failed to comply with the timelines as determined in § 552(a)(6) of the FOI Act.[1251]

The FOI Act also provides for timelines within which requests, and appeals to such requests if applicable, should be processed.[1252] Such timelines may be extended if 'unusual circumstances' exist.[1253] The FOI Act further provides, where this is possible, for the aggregation of multiple requests, whether from one requester or multiple requesters, into a single request, provided such requests comprise related matters.[1254] Where exceptional circumstances exist and the agency has exercised due diligence, the court may allow the agency additional time within which it has to complete its processing of requests.[1255] The FOI Act further makes provision for the expedited processing of requests, if a compelling need exists or as determined by the agency.[1256]

The FOI Act further makes provision for a number of exemptions from the obligations to release information to requesters, upon request.[1257] While none of these exemptions directly speaks to research, some could arguably be relevant to research contexts (In fact some exemptions might have implications for the conduct of research). The FOI Act in particular provides for the exemption from disclosure of 'personnel and medical and similar files', if such disclosure could lead to the unjustified violation of privacy.[1258] Because health research will often involve the use of medical files, this exemption will be important in the protection of research participants.[1259]

6.2.7.4 Implications for health research

The legal instruments providing for privacy, more in particular the Privacy Shield, do go some way in protecting health research participants, especially its opt-in provisions in respect of sensitive information. The Privacy Shield's application is however limited,

1250 § 552 (a)(4)(A)(vi).
1251 § 552 (a)(4)(A)(vii).
1252 § 552 (a)(6)(A)(i) and (ii).
1253 § 552 (a)(6)(B).
1254 § 552 (a)(6)(B)(iv).
1255 § 552 (a)(6)(C)(i).
1256 § 552 (a)(6)(E)(i) (I) and (II).
1257 § 552 (b).
1258 § 552 (b)(6).
1259 Because it is the agencies here that would be relying on these provisions, this provision could therefore be relied on by them in their capacities as researchers, or funders of research.

in that it only applies to those who have volunteered (self-certified) to be bound by the Privacy Shield. A related shortcoming also exists in the case of both the Privacy Act and the FOI Act, in that they mainly place obligations on government and other public institutions.[1260] This leaves private actors with a free hand to abuse research participants. None of the three instruments gives special attention to the protection of children.

6.2.8 Approach to research oversight

Various laws, both general and specific in nature, provide for, or have implications for, the oversight of health research. These include the US Constitution; the common law and legislation, in particular the National Research Act of 1974[1261] and the Common Rule.

6.2.8.1 Common law

The general common law principles, including those under the law of contract, the law of equity; breach of fiduciary duties and the law of torts remain applicable in the context of the regulation of the conduct of health research. One of the leading cases, though not decided at Supreme Court level, dealing with health research is the case of *Abney et al v Amgen, Inc* 443 F.3d 540 (6th Cir. 2006) (Abney case)**.**

In this case the claimants (research participants) sued sponsors of a clinical trial (research) for failing to provide them with drugs for treatment as agreed in the informed consent form. The District Court rejected their preliminary application for injunction, and on appeal, the appeal court still rejected their claim. The appeal court reasoned that there was no contractual relationship between the sponsors and the claimants. It further reasoned that there was no agency relationship between the sponsors and the investigators (or their university). The court further held that there was no fiduciary relationship between the sponsors and the claimants, as a fiduciary relationship implies that one party (the fiduciary) should act only in the interests of another, which was not the case here.[1262]

1260 This is however not substantially consistent with the PLA framework contemplated in this research.

1261 See the discussion of the National Research Act in chapter 1.

1262 As to the nature of a fiduciary relationship, see *Suthers v Amgen, Inc.,* 372 F.Supp. 2d 416

It also followed then that there could be no reliance on estoppel as claimed by the research participants. The court however said, without deciding the point, that if the claimants had sued the investigators and IRBs (RECs), they perhaps would have succeeded. The *obiter dictum* has therefore left the matter open as to whether the relationship that the claimants had with the investigators, through informed consent arrangement, constituted a contract or some other relationship, for example a public law relationship not predicated on contracts. It then follows that the *obiter dictum* has equally left open the question of what sort of obligations arise from that type of relationship.

Again, the court's rejection of the existence of an agency relationship between the investigators and sponsors was premised on a flawed grounding. It reasoned that because there was no control element by the sponsors over the investigators this implied lack of an agency relationship. This reasoning is erroneous in that not all agency relationships, at least in the South African jurisprudence, require the presence of a control element. A control element is only required in some forms of agency, e.g. employment relationship, but not in all agency relationships. This case has therefore created a need for further investigation into the plausibility of public law approaches to the determination of the nature of the relationships and obligations by the key stakeholders in research. The courts, including, as appears below, the South African courts, have not yet explored this approach in the context of health research.

In *Grimes v Kennedy Krieger Institute, Inc.,* 728 A 2d 807 (Md. 2001), also referred to in the Abney case, the court dealt with non-therapeutic research involving children. In

(S.D.N.Y. 2005), where the court, at least in the context of New York law, reasoned against finding that a sponsor could be a fiduciary, as this would be in conflict with the need for the investigator to remain independent from sponsors, i.e. if the sponsor were to be a fiduciary in relation to research participants, this would mean that the sponsor would be the one answerable to the IRB, and by implication the research participants, rather than the investigator being so answerable. The judgement could further be read as ruling out the fiduciary principle in general from also applying to the field of clinical trials. The court says in this regard: "Furthermore, the importation of an ill-defined fiduciary duty into the field of clinical drug trials would raise other concerns. For example, in a double-blind placebo study, such as was conducted in this case, the supposed fiduciary would be charged with knowledge that some of the persons to whom it owed this duty were not receiving a beneficial drug. The fiduciary would be required to reassess the best interests of a study participant based upon preliminary and incomplete results. Necessarily it would be guided by the interests of each individual participant and not by the search for truth about the safety and efficacy of the drug. This would likely undermine the reliability of research results which, in turn, could undermine drug safety".
Perhaps it is confining the answerability question to the fiduciary relationship and other related principles, rather than also using public law obligations, that creates a problem here.

this case parents with children had been placed in houses that had lead paint, so as to test the effect of such paint on them, when compared with those without such paint. The children then developed 'elevated levels of lead dust'.[1263] The research participants sued the researchers for negligence. The trial court found that there was no contract between the parties, and therefore no legal duty arose. It further found that there was no special relationship between the parties, giving rise to any obligations.

On appeal the appeal court found that there was a legal duty on the part of the researcher to warn the participants about the dust and lead. The reasoning was based in the main on the following: the existence of a contract created by the informed consent arrangement (at least in this case) and the existence of a special relationship. Breaching these duties therefore gave rise to negligence. Although the claimants were successful in this case, what is to be noted is that public law approaches were also neglected.

In conclusion regarding case law, one common thread here is that the focus of the legal questions to be decided has mainly been on common law obligations arising from contracts, torts and fiduciary duties.[1264] Not much attention has been placed on public law obligations.

6.2.8.2 Constitutional framework

The US Constitution does not expressly provide for principles dealing with health research. However, some of the more generic principles in the Constitution remain

1263 Grimes v Kennedy Krieger Institute. www.columbia.edu/itc/hs/pubhealth/p9740/readings/grimes-krieger.pdf (Accessed 23 June 2021).

1264 Note however isolated instances where there were challenges to health regulations dealing with consent to participation in nontherapeutic' research posing greater than minimal risk by those incapable of proving consent, including children, and the court declared the regulations invalid for lack of statutory authority to enact such regulations. This was the case in *T.D. et al. v New York State Office of Mental Health* 165 Misc.2d 62, 626 N.Y.S.2d 1015 (1995) (for a summary of the case and other relevant cases, see Campbell AT "State regulation of medical research with children and adolescents: An overview and analysis" (2004). https://www.ncbi.nlm.nih.gov/books/NBK25556/ (Accessed 01 July 2021). Further see Findlaw "T.D. et al., Appellants v. New York State Office of Mental Health''. https://caselaw.findlaw.com/my-court-of-appeals/1178770.html. (Accessed 2 July 2021). One is also however aware of the recent tendency towards the broadening of the scope of causes of action by litigants who sue based on research atrocities (See in this regard Shaul RZ, Birenbaumm S and Evans M "Legal liabilities in research: early lessons from North America''. https://bmcmedethics.biomedcentral.com/articles/10.1186/1472-6939-64 (Accessed 01 July 2021)).

relevant to the context of health research. These include provisions dealing with the equality protection; liberty; prohibition of slavery; due processes, etc.

6.2.8.3 Legislative framework

The Federal Policy for the Protection of Human Subjects (45 CFR 46 Subpart A), commonly known as the Common Rule, is one of the main regulatory frameworks dealing with health research in the US.[1265] Unless the context indicates otherwise, the concept of Common Rule shall be used in this chapter and the rest of the thesis, to refer to this framework.

The Common Rule applies to research funded by any of the federal departments or the federal government's agencies, if the departments or agencies take the necessary steps to make the regulations applicable.[1266] It also applies to research conducted outside the federal government, if the federal government funds the research.[1267] The final decision as to whether or not the Common Rule applies remains with the head of the relevant federal department or agency.[1268] In exercising their decision as to whether the Common Rule applies, the relevant heads must act in accordance with the principles in the Belmont Report.[1269] For the researchers to be fully compliant with the Common Rule they must comply with the relevant federal laws and regulations providing for added protections to research participants.[1270]

The Common Rule gives recognition to existing laws at state, local or tribal level that provide better protection to research participants than the Common Rule.[1271] The Common Rule gives similar recognition to foreign laws that provide added protections to the research participants.[1272] In case a foreign law where the federally-funded research is conducted prescribes procedures that are different from, but at the least

1265 HHS *Federal Policy for the Protection of Human Subjects ('Common Rule')*. Https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html (Accessed 14 June 2021).
1266 §46.101(a) of 45 CFR 46 Subpart A.
1267 §46.101(a).
1268 §46.101(c).
1269 §46.101(c).
1270 §46.101(e).
1271 §46.101(f).
1272 §46.101(g).

equivalent to, the procedures in the Common Rule the relevant departmental or agency head may allow the research to be conducted under that foreign law.[1273]

The relevant departmental or agency head may also waive the need for research to follow the procedures in the Common Rule, if the alternative procedures are at least consistent with the principles of the Belmont Report.[1274] In the event of such a waiver, the relevant departmental or agency head must submit 'advance notices' about the intended actions to the Office for Human Research Protections, Department of Health and Human Services or the successor thereof, or to any other equivalent office and must further publish such notices in the Federal Register or other appropriate platforms.[1275] Such a waiver notice must also detail the conditions of its application as well as its justification, which should include the way the decision is consistent with the Belmont Report principles.[1276]

For any research that has to be done in terms of the Common Rule, and federally-supported, the researcher must submit a written assurance of compliance with the Common Rule to the departmental or agency head.[1277] The researcher shall further provide certification to the effect that the proposed study has been approved by an IRB (REC).[1278] One of the criteria the IRB should consider in the approval of the research is the equitability of the selection of the research participants.[1279] The IRB should in particular consider the extent of vulnerability from 'coercion or undue influence' of the categories of persons so participating, including 'children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons'.[1280] In such a situation additional protective measures should be made to protect such participants.[1281] These provisions could play an important role in the protection of children, including those displaced, from being unduly influenced by, for example, excessive payments, into partaking in research.

1273 §46.101(h). One takes note of the ambiguity of the words 'by the institution', which may not make sense if not referring to the foreign system, but the definition of institution in the common rule does not suggest this.
1274 §46.101(i).
1275 §46.101(i).
1276 §46.101(i).
1277 §46.103(a).
1278 §46.103(a) and (d).
1279 § 46.111.
1280 § 46.111(a)(3).
1281 § 46.111(b).

The Common Rule makes provision for a broadly representative IRB, with at least a minimum number of five members.[1282] At least one member of the IRB must be from a scientific background, while at least another one must be from a non-scientific background.[1283] At least one member of the IRB shall not be directly linked, nor shall a member be a family member of a person directly linked, to the institution (conducting the research).[1284] A conflicted person may not, other than merely providing requested information, partake in IRB activities.[1285] Where necessary, IRBs may invite specialist persons to assist in specific areas where the IRB does not have expertise, but such persons may not vote.[1286]

The Common Rule further makes provision for informed consent by research participants.[1287] In this regard the Common Rule further prohibits provisions in informed consent arrangements which exempt the investigator from liability.[1288] The informed consent arrangement must also include certain information, including a statement describing that the project is about research; the purposes of the research and the duration of such research.[1289] The Common Rule further provides for the waiver of consent or alteration of such consent under certain circumstances, including in instances where the research serves public benefit purposes.[1290]

The Common Rule provides for some exemptions from the application of this framework for certain categories of research.[1291] Most of the exempted categories of research are those conducted in educational settings involving 'normal educational

1282 §46.107(a).

1283 §46.10 (b). Does this requirement suggest that the IRB in the US also engages in the review of the science, as opposed to, for example, the UK position where some frameworks like the UK Governance Arrangements specifically prohibit the review of the science by the IRB equivalents i.e. the REC (See para 5.4.2 (a) of the UK Governance Arrangements).

1284 §46.107(c). What are the implications of this 'family affiliation' rule, more so if the 'institution' could be a university, making it difficult to use the family rule? Perhaps this could be unduly restrictive where the family member operates in a different environment, even if working for the same institution. Further note that in the UK Governance Arrangements the prohibition of affiliation was for all members of the REC, rather than being confined to only one member.

1285 §46.107(d).

1286 §46.107(e).

1287 § 46.116.

1288 § 46.116(a)(6).

1289 § 46.116(b).

1290 § 46.116(e). This flexibility does arguably go some way in promoting a PLA framework.

1291 § 46.104(a).

practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction'.[1292]

It further exempts research including 'interactions' in the form of interview procedures; survey procedures; educational tests and observation of human behaviour provided that the identity of the research participants is protected;[1293] any disclosure of responses or other information by research participants does not place the research participants at risk, including criminal and civil risks[1294] and where any information obtained may be readily ascertained, limited review by an IRB is conducted.[1295] Other exempted research, with some necessary provisos, include brief, harmless, painless and physically non-invasive behavioural interventions[1296] and 'taste and food quality evaluation and consumer acceptance studies'.[1297]

The 45 CFR 46 Subpart D – Additional Protections for children involved as subjects in research (the 45 CFR 46 Subpart D) provides for the protection of children in research supported by the Department of Health and Human Services.[1298] The 45 CFR 46 Subpart D categorises research into those posing no greater than minimal risk (minimal risk research); research posing greater than minimal risk but presenting the prospect of direct benefit to the individual research participants (risky but directly beneficial research); research posing greater than minimal risk but presenting no direct benefit to individual research participants, which may produce generalisable knowledge about the subject's problem or condition (research producing generalisable knowledge) and research which would otherwise not be approvable but which provides an opportunity for the understanding, prevention or alleviation of a serious condition concerning the health or welfare of children (research for the health and welfare of children).

1292 § 46.104(d)(1).

1293 § 46.104(d)(2)(i).

1294 § 46.104(d)(2)(ii).

1295 § 46.104(d)(2)(iii). That information obtained leads to the identity of the human subjects being revealed is only permissible if an IRB has a limited review is the most sensible interpretation one can attach to this sub-paragraph, otherwise it would not make sense, and it would appear contradictory to the earlier proviso in § 46.104 (d) (2) (i). Even with this limited review by an IRB, it is worrying that such a compromise of research participants' identities is allowed.

1296 § 46.104(d)(3).

1297 § 46.104(d)(6).

1298 § 46.401 of the 45 CFR 46 Subpart D. For other instruments relating to the protection of children partaking in research, see 45 CFR 46 Subpart B – Additional Protections for Pregnant Women, Human Fetuses and Neonates involved in research.

For the conduct and funding of a minimal risk research, an IRB must find that adequate provision is made for securing the assent of children, and the permission of parents or guardians.[1299] In addition to the soliciting of the assent of children and permission of parents or guardians, for the conduct or funding of a risky but directly beneficial research an IRB must find that the anticipated benefits to the subjects justify the risk and the anticipated benefits to the subjects are comparably more beneficial than those presented by an alternative approach.[1300]

For the research producing generalisable knowledge the conduct or funding of research shall only take place if the risk presents 'a minor increase over minimal risk'; the experiences presented to the subjects by the interventions or procedures are reasonably consistent with those experienced in medical, social, psychological, dental or educational settings; the intervention or procedure must lead to generalisable knowledge about the research participant's problem or condition and adequate provision is made for securing the assent of children and the permissions of parents or guardians.[1301]

The conduct or funding of research for the health or welfare of children, which would otherwise not be approvable under the above categories could still be allowed if the research presents an opportunity to understand, prevent or alleviate a serious condition concerning children's health and welfare; where the secretary after consultation with a panel of experts otherwise finds that the research in fact meets the conditions in §46.404, §46.405 or §46.406, or that the research meets the following conditions: provides a reasonable opportunity for the further understanding, prevention or alleviation of a serious condition concerning children's health or welfare; that the conduct of the research will guided by sound ethical principles or that an adequate provision is made for the securing of assent of children and permission of their parents or guardians.[1302]

6.2.8.4 Implications for health research

1299 § 46.404.
1300 § 46.404.
1301 § 46.406.
1302 § 46.407.

The Common Rule and the 45 CFR 46 Subpart D go some way in the protection of participants in health research. The 45 CFR 46 Subpart D in particular does go a long way in the protection of children partaking in health research. The approval of participation of children in research even in those instances where there might be no direct benefits but where there is generalisable knowledge or where there is an opportunity to prevent, understand or alleviate a serious condition concerning the health or welfare of children also goes a long way in promoting taking a public interest approach, and therefore the PLA contemplated in this thesis. And so is the possibility of the approval of research, without informed consent, in those circumstances where the research serves public benefit.[1303]

As indicated earlier, the provision in the Common Rule for additional safeguards for vulnerable persons exposed to coercion or undue influence also plays an important role in the protection of children.[1304] It would have however been more valuable if both the Common Rule and the 45 CFR 46 Subpart D could have been explicit on the question of how the issue of payments to children partaking in research should be handled.

6.3 Ethical instruments having implications on health research

6.3.1. The existing ethical instruments

There are various ethical instruments providing for, or at least relevant to, health research. These include the American Medical Association Principles of Medical Ethics (the AMA Principles of Medical Ethics) and Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the Belmont Report).

The AMA Principles of Medical Ethics is one of the key ethical instruments relevant to health research, or at least bioethics. The AMA Principles of Medical Ethics was first developed in the 1800s but has been revised several times since then.[1305] AMA

1303 § 46.116(e).

1304 § 46.111(a)(3).

1305 AMA "History of the Code". https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/ethics/ama-code-ethics-history.pdf (Accessed 14 June 2021). Also see AMA "Code of Medical ethics overview''. https://www.ama-assn.org/delivering-care/ethics/code-medical-ethics-overview (Accessed 14 June 2021). Further see AMA "AMA History". https://www.ama-assn.org/about/ama-history# (Accessed 14 June 2021).

Principles of Medical Ethics mainly applies in the context of doctor-patient relationship, and therefore does not specifically deal with health research. Most of the principles in the AMA Principles of Medical Ethics are however applicable in the context of health research, more so when the researcher is a physician, and the research participant is a patient of that physician.

A further ethical instrument is the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the Belmont Report). The Belmont Report is, as indicated in the earlier Chapters, an instrument developed by the US Department of Health, Education and Welfare, as it then was.[1306] The Report has arguably been triggered by the scandals of the earlier years.[1307] It identifies three principles for the ethical conduct of research involving human subjects, namely the principle of respect for persons;[1308] beneficence[1309] and justice.[1310]

The Belmont Report conceptualises the respect for persons in two senses: respect for the autonomy of those who have the capacity to take their decisions and protecting those who do not have the capacity to take their own decisions from being harmed or being coerced into decisions.[1311] Those who might not be in the position to take their own decisions might include children, persons with mental incapacity or persons who are seriously ill.[1312] Where the potential research participants fall under the latter category i.e. those who have diminished capacity to take decisions on their own, a third party shall take the decisions on their behalves, including both consenting and, where necessary, withdrawing from the study, if it is in the participant's best interest that such a decision be taken.[1313]

1306 HHS *The Belmont Report: ethical principles and guidelines for the protection of human subjects of research.* https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html (Accessed 13 June 2021).

1307 Although the Belmont Report does refer to the Nazi Atrocities, as part of its background, it hardly refers to any scandals that occurred outside Germany, some of which occurred in the US. (The general background to the Belmont Report was briefly reflected on in the earlier chapters and need not be repeated here.)

1308 The Belmont Report.

1309 The Belmont Report.

1310 The Belmont Report.

1311 The Belmont Report.

1312 The Belmont Report.

1313 The Belmont Report. One should notice here that there is an emphasis on the best interest of the participants, with nothing being said about public interest. Does it mean that there could be no situation where certain decisions are taken on the basis of public interest? (Note however the Belmont Report's conception of beneficence, which also does include the benefits to society. And so, does the Belmont Report consider the risks as also including risks to society.

The Belmont Report, apart from requiring such a person to be 'in a position to understand the incompetent participant's situation and act in their best interest', unfortunately provides no guidance as to who this third party should be i.e. whether it should be a legally authorised representative or just any third party.[1314] To leave such a crucial issue open-ended creates a risk for the abuse of such appointments.

In the context of participation in research this principle entails that the participation in research be voluntary and be preceded by an informed consent.[1315] Informed consent entails that whatever the research participants agree on should be preceded by detailed information;[1316] sufficient opportunity to explore various options in responding to the questions;[1317] full understanding of the details about the study[1318] and continuous information about the study as the circumstances require, as the study carries along.[1319]

The principle of beneficence in the main means doing good, including doing no harm, to others.[1320] If operationalised in the context of research it means a balanced assessment of risks and benefits.[1321] The expected benefits may include benefits to society.[1322] With regard to the principle of justice the Belmont Report considers it to include the fair or balanced distribution of benefits and burdens of research.[1323] This may include the fair selection of research participants, avoidance of over-inclusion of certain communities (who might not even benefit from the research) and under-inclusion of others.[1324] The Belmont Report further requires the continuous monitoring of the selection process, so as to ensure that there is no abuse of the process e.g.

The inclusion of risks and benefit to society is arguably not hostile to public interest, though the general orientation of the Belmont Report appears to take a more individualist approach, and that individual being the research participant).

1314 The Belmont Report.
1315 The Belmont Report.
1316 The Belmont Report.
1317 The Belmont Report.
1318 The Belmont Report.
1319 The Belmont Report.
1320 The Belmont Report.
1321 The Belmont Report.
1322 The Belmont Report. This may be relevant for the consideration of any public interest angle of the Belmont Report.
1323 The Belmont Report.
1324 The Belmont Report.

selecting certain communities merely because they are easy to get, even if that population is not relevant to the problem of the study.[1325]

6.3.2 Implications for health research

At the minimum the ethical codes discussed above do provide for the protection of research participants. Although the Belmont Report does in a general sense deal with the issues of informed consent in the case of those with diminished capacity, which may include children, it does not have dedicated provisions dealing with the protection of children. Nor do the AMA Principles of Medical Ethics provide for principles specifically dedicated to children. This may therefore diminish the level of protection required for children, more particularly those displaced. This may therefore arguably weaken the PLA framework contemplated in this research.

6.4 Conclusion

This chapter had to examine the US legal position and other related regulatory framework. It started off by examining the general, overarching US legal position, including the constitutional framework. The defining character of its overarching legal framework, reflected mainly in its constitutional framework, is its tendency away from the protection of socio-economic rights, with therefore potential negative effects on the protection of research participants. And so is the US legal framework's tendency towards a vertical, rather than a horizontal, approach to the protection of rights. This means that despite that some of the US legal frameworks, more especially the constitutional framework, provide for public law obligations, these are not necessarily the type of public law obligations as contemplated in this thesis.

A further gap in its framework is its cautious approach to deviation from formal equality, i.e. where certain formal principles of equality could be relaxed so as to accommodate those disadvantaged by certain established practices. Also cautious is the US's approach to international law, more especially in the context of multilateral framework, which can be evidenced from the country's reluctance to ratify some international legal instruments, including the Rome Statute.[1326] The absence of express reference, in its Constitution, to respect for foreign law was also found to be problematic.

1325 The Belmont Report.

1326 American Bar Association "The US – ICC Relationship'' (2021).

As to legal interpretation a mixed approach was found, where both originalism and living constitutionalism have some space. It was however found that the absence of a direct reference in the Constitution to a particular approach means that there will generally be inconsistencies in the interpretative framework. This may have a negative impact on the protection of research participants. The US's judicial review framework, though generally good, has not yet found some application in health research context. The absence of a direct constitutional provision relating to health care was also found to be a deficiency that may negatively affect the protection of health research participants.

The absence of a direct reference to human dignity in the US Constitution was also found to be a serious shortcoming in the protection of health research participants. Though various remedies, including those limiting exemption clauses, were found to be likely to go some way in the protection of health research participants, these have not yet found some application in health research contexts. There are also very good privacy and access to information laws, including the Privacy Act and FOIA, but these mainly, if not only, place obligations on the state and other public institutions, rather than on the private actors, therefore leaving private institutions with more power to abuse research participants.

The various instruments directly dealing with health research, including the 45 CFR 46, were found to go some way in the protection of health research participants. These however mainly place obligations on institutions funded by the US Government, therefore leaving those not so funded at liberty to do as they wish. This means that, as partly alluded to earlier, although these instruments arguably take a public law approach, this is not one contemplated in this thesis, where horizontality of the placement of obligations, i.e. also requiring private actors to have certain obligations, should not be ruled out. The ethical frameworks like the Belmont Report and the AMA Principles of Medical Ethics also go some way towards the protection of health research participants, though their failure to directly provide for the protection of children could be a drawback, and therefore weaken the PLA framework contemplated in this research.

https://www.aba-icc.org/about-the-icc/the-us-icc-relationship/ (Accessed 26 June 2021).

The next chapter provides a comparative analysis of the laws of the three jurisdictions discussed from chapters 4 to 6, namely South African law, UK law and American law.

CHAPTER SEVEN: SUMMARY OF COMPARATIVE ANALYSIS

7.1 Introduction

Chapter six examined the American legal position. This was preceded by the examination of the South African and UK legal positions in chapters four and five respectively. This chapter summarises the comparative conclusions observed in the three preceding chapters to, as close as possible, reflect the best comparative features of the three countries. These include the general legal theory of each country; the protection of children, including displaced children; judicial review; approaches to equality; approaches to the protection of human dignity; approaches to the protection of personal information and access to information; approaches to the right to health care; approaches to remedies and approaches to health research oversight. The implications of these approaches to health research and the promotion of the PLA framework contended for in this research are also reflected on.

7.2 The general legal theory of the countries

The three countries are, in the main, part of the common law family. Both South African and American laws have greatly been influenced by English law, with both countries once colonised by the British. This shared history could however be misleading. The US, upon independence, broke away from the English Parliamentary system of government,[1327] which placed parliament at the apex, i.e. which recognised parliamentary supremacy, while also still retaining the role of a monarchy, as head of state, where the monarchy's role is arguably largely more symbolical than substantive.[1328] On the contrary, the idea of recognising a monarchy, even at a ceremonial level, is unheard of in the US. If anything, the idea is even detested.[1329] The US has therefore established a constitutional government, underpinned by the supremacy of the Constitution. South African law was not only influenced by English

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1327 It should be noted that there was a time in history, mainly in the early 1600s, when parliamentary sovereignty was not at the apex of English law (see Jones B, Gray A, Kavanagh D, Moran M, Norton P and Seldom A *Politics* 2nd edition (Harvester Wheatsheaf London 1994) 488.

1328 The role of the Monarchy. https://www.royal.uk/role-mornarchy (Accessed 28 October 2021).

1329 The tone of the American Declaration of Independence (1776), which preceded the US Constitution, tells it all that the idea of a monarchy was detested, based on the harsh experiences the anti-colonists went through under the British monarchy (see A Declaration of Independence: a Transcription. Https://www.archives.gov/founding-docs/declaration-transcript (Accessed 2 August 2021).

law, but also by Roman-Dutch law. The influence of the Roman-Dutch law was a result of South Africa being colonised by the Dutch, who themselves had also inherited some aspects of Roman law. While South Africa after 1910 initially adopted a parliamentary system of government, though tainted with apartheid ideology, this changed in 1994 when a new constitutional framework was adopted, which founded a constitutional system of government based on constitutional supremacy. To this extent therefore, both the US and South African laws have something in common, in that they are both constitutional states.

These are not however constitutional states of the same kind. One of the differences is that the US Constitutionalism tends to be more formalist and process-oriented,[1330] while the South African one is more substantive.[1331] These marked approaches could be a result of the SA Constitution's express provision for constitutional values,[1332] some of which must be considered in interpreting the Bill of Rights,[1333] therefore forcing a more flexible approach to the shaping of the content of the Constitution.

The two countries' common laws also differ, in that one (US's) is underpinned only, or perhaps mainly, by the English common law while the South African one is underpinned by both the English common law and the Roman-Dutch law. The American constitutional state is further located within a federal framework, while the South African state is located within a unitary state framework.[1334] British Unionism[1335]

1330 This can partly be gleaned from some cases, including a recent case, namely *Dobbs v. Jackson Women's Health Organization 597 U.S. (2022)*, where the concurring judgement of Thomas J emphasized the need for a relook at the notion of substantive due process, which the Justice thought was misplaced. On the whole the majority judgement, in deciding to uphold the Mississippi Gestational Age Act (which outlaws abortion to some extent), in over-emphasizing that abortion rights were not rooted in the Nation's tradition and history, took a formalist approach. The US's approach on issues of race, which emphasizes the notion of 'strict scrutiny', also arguably takes a formalist direction (also see *Fisher v University of Texas* 579 U.S. (2016) (further see Cornell Law School "Affirmative Action''. https://www.law.cornell.edu/wex/affirmative-action (Accessed 16 June 2021).

1331 This could particularly be observed in *Abet Inspection Engineering (Pty) Ltd v The Petroleum Oil and Gas Corporation of South Africa (A280/2017) [2018] ZAWHC 7 (1 February 2018)* paras 7 and 24, where the court upheld the decision to award a tender, opining that it would have done so even if there were irregularities in awarding it, if the irregularities were immaterial. Also see *Allpay Consolidated Investment Holdings (Pty) Ltd and Others v Chief Executive Officer of the South African Social Security Agency and Others 2014 (1) SA 604 (CC).*

1332 S 1 of the Constitution makes provision for these values.

1333 S 39(1) of the Constitution.

1334 This is not unimportant, as the federal framework could create some incoherence, if not fragmentation, in respect of approaches to certain aspects, while the unitary framework could be comparatively more coherent, where you don't have so many state-based legislations and court decisions dealing with the same issue.

1335 Although some writers treat the UK, with its unionism, as though it is a unitary state, in this

appears no better either, as the courts of the various unions could have conflicting positions, which continue to exist until dealt with by the UK Supreme Court. In the case of matters coming from Scotland, the UK Supreme Court's intervention is even more limited.[1336]

What then are the implications of federalism; unionism and unitarism for the law? Federalism, partly alluded to earlier, in the main creates room for fragmentation of the law. In other words, unless a matter is finally resolved at federal level by the Supreme Court, the law around an aspect could remain unsettled even when the highest court in a particular state has pronounced on the matter. Unionism could lead to a similar state of affairs. This problem is mitigated in a unitary state. In the case of South Africa in particular the highest court has even affirmed 'unitarism' in the law by pronouncing that there are not many laws, but one law in South Africa, guided by the Constitution.[1337] The principle of supremacy of the Constitution, often also reflected in provisions militating against 'inconsistency with the constitution or the Bill of Rights' (or put differently, providing for 'consistency with the Constitution or the Bill of Rights'),[1338] is also a unifying principle militating against parallelism in South African law. South African law is therefore required to unite under one law, being the Constitution.

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thesis unionism and unitarism are treated separately (although one does acknowledge that unionism could arguably be a form of weak unitarism, while the SA version of unitarism could be viewed as a stronger version) (for example, Jackson RJ and Jackson D *An Introduction to Political Science: Comparative and World Politics* 4th ed (Prentice Hall Toronto 2003) 211, treats the UK as a unitary state)). This is so because under the British Unionism, the constituent parts of the Union usually have comparatively stronger independence than you will find in a typical unitary state like SA. For example, some of the constituent parts of the British Union have their own courts. There are basically three separate legal systems in the UK, namely one for England and Wales, another for Scotland and yet another for Northern Ireland (see The Judicial System and the Constitution (2021). https://www.judiciary.uk/about-the-judiciary/the-judiciary-the-government-and-theconstitution/jud-acc-ind/justice-sys-and-constitution/ (Accessed 12 August 2021).

1336 Supreme Court "The Jurisdiction of the Supreme Court of the United Kingdom in Scottish Appeals: Human rights, the Scotland Act 2012 and the Courts Reform (Scotland) Act 2014". https://www.supremecourt.uk/docs/jurisdiction-of-the-supreme-court-in-scottish-appeals-human-rights-the-scotland-act-2012-and-the-courts-reform-scotland-act-2014.pdf (Accessed 28 October 2021).

1337 *Pharmaceutical Manufacturers Association of South Africa and Another: In re Ex Parte President of the Republic of South Africa and Others* 2000 (2) SA 674 (CC) para 44.

1338 Note s 31 (2), for example, requiring that the rights in that section not be exercised *'in a manner inconsistent with any provision of the Bill of Rights'.* Further see a related provision in s 30. Further note s 211(1), subjecting the recognition of the institution, role and status of traditional leadership to meeting the Constitutional requirements.

The affirmation above by the court also clarifies the issue of parallelism in legal systems where, within one country, there exists parallel and sometimes not mutually coexisting principles. This position is not well-articulated in the other two jurisdictions. It is even less articulated in the UK, where the common law and law of equity arguably exist along parallel lines, rather than as part of one system of thought (i.e. they provide for two different categories of remedies).[1339] The SA law, where there is some risk of a parallel application or development of laws, addresses this through the principle of subsidiarity.[1340] In *Minister of Health and Another v New Clicks South Africa (Pty) Ltd and Others* Chaskalson CJ said:

> A litigant cannot avoid the provisions of PAJA by going behind it and seeking to rely on section 33(1) of the Constitution or the Common law. That would defeat the purpose of the Constitution in requiring the rights contained in section 33 of the Constitution to be given effect by national legislation.[1341]

1339 As observed in chapter 5, in the case of application of UK law versus European law, the doctrine of the margin of appreciation at least assists in minimizing parallelism.

1340 This, in the main, entails that a more specific legislation or forum not be bypassed in favour of a more general law or forum. In the case of a legislation, a litigant must first challenge the constitutionality of the more specific legislation before relying on the more general one (see *SANDU v Minister of Defence and Others* 2007 (5) SA 400 (CC) para 52). A phenomenon related to the principle of subsidiarity is the principle of constitutional avoidance, which means that where a legal issue is capable of resolution without reliance on the constitution, this should be done (see in this regard *S v Mhlungu and Others* 1995 (3) SA 867 (CC) para 59. Also see Zvekare TR "*The applicability of the doctrine of constitutional avoidance to constitutional adjudication in Zimbabwe*'' (LLM Thesis Midlands State University 2018) 11. The commonalities between constitutional avoidance and subsidiarity, at least in the South African context, could arguably lie in the fact that because constitutional avoidance is about the avoidance of constitutional questions, which would often be more general than reliance on specific legislation, it could be seen as one part of subsidiarity principle, but only in some instances. There is however no need in this research to go deeper into the issue of constitutional avoidance, more especially from a comparative point of view).

1341 *Minister of Health and Another v New Clicks South Africa (Pty) Ltd and Others* 2006 (2) SA 311 (CC) paras 96 – 97 and paras 433 – 437. As earlier indicated, the principle is further reflected on in *SANDU v Minister of Defence and Others* paras 51 – 54. Also see *Bato Star Fishing (Pty) Ltd v Minister of Environmental Affairs and Tourism and Others* 2004 (4) SA 490 (CC) paras 21 – 26. Further see *MEC for Education, Kwazulu-Natal and Others v Pillay* 2008 (1) SA 474 (CC) para 40. Also see *Mazibuko and Others v City of Johannesburg and Others* 2010 (4) SA 1 (CC) paras 73 – 74, where the court raised the principle in passing, though it found it not applicable on the facts. The Western Cape High Court in *NAPTOSA and Others v Minister of Education, Western Cape Government* 2001 (2) SA 112 (C), cautioned against bypassing the more specific legislation in favour of the more general, s 23 of the Constitution in that case. The court in *NEHAWU v University of Cape Town and Others* 2003 (3) SA 1 (CC) paras 16 – 17, also very briefly touched on the problem of development of parallel legal systems, as articulated in *NAPTOSA and Others v Minister of Education, Western Cape Government*, but considered that case distinguishable. The issue was further considered and relied on in *Ingledew v Financial Services Board* 2003 (4) SA 584 (CC) para 23 – 24, where an applicant sought to rely on s 32 of the Constitution (dealing with access to information) without challenging the constitutionality of the more specific rule of court, namely rule 35, which allows for discovery during certain stages of a trial. Though the SCA in *State Information Technology Agency Soc Ltd v Gijima Holdings (Pty) Ltd* 2017 (2) SA 63 (SCA) para 44 also ruled against the by-passing of PAJA in favour of the more general constitutional principle of legality, on appeal the

Although the principle of subsidiarity is not a uniquely South African legal principle, it has been better articulated in South Africa than it has been in the other two jurisdictions. This goes some way in minimising the uncertainty that may arise from the proliferation of causes of action; remedies and dispute resolution forums, amongst other problems.[1342]

Constitutional Court reversed the decision (though not in relation to the principle of subsidiarity itself), and then ruled that PAJA was inapplicable where an organ of state sought to review its own decision. In other words, the principle of subsidiarity became irrelevant on the facts, as PAJA was no longer considered applicable (see *State Information Technology Agency Soc Limited v Gijima Holdings (Pty) Limited* 2018 (2) SA 23 (CC) paras 35 – 42). The principle of subsidiarity is further well-articulated in the minority judgement in *My Vote Counts NPC v Speaker of the National Assembly and Others* [2015] ZACC 31 (30 September 2015*)* paras 44 – 66, as per Cameron J.

1342 One does however take note of the fact that even within South Africa the principle has not been applied consistently. For example the court ignored the principle in *Albutt v Centre for the Study of Violence and Reconciliation and Others* 2010 (3) SA 293 (CC) (Albutt) but invoked the principle in *Minister of Defence and Military Veterans v Motau and Others* 2014 (5) SA 69 (CC) (Motau) without making reference to the Albutt decision (see Hoexter C "South African Administrative law at a Crossroads: The PAJA and the principle of legality'' (2017) (https://adminlawblog.org/2017/04/28/cora-hoexter-south-african-administrative-law-at-a-crossroads-the-paja-and-the-principle-of-legality (Accessed 1 November 2021). Hoexter further observes that in *State Information Technology Agency Soc Ltd v Gijima Holdings (Pty) Ltd* 2017 (2) SA 63 (SCA) the SCA, while affirming the principle of subsidiarity, also made no reference to *Albutt* and *Motau* cases (Hoexter *South African Administrative Law at a crossroads* (2017)). This therefore poses the risk of continued inconsistent application of the principle (further see Murcott M and Van Der Westhuizen W "The Ebb and flow of the Application of the principle of subsidiarity – Critical Reflections on Motau and My Vote Counts" 2015 *Constitutional Court Review* 43 – 67. The constitutional court decisions in *Fredericks and Others v MEC for Education and Training, Eastern Cape and Others* 2002 (2) SA 693 (CC) (*Fredericks*); *Chirwa v Transnet Limited and Others* 2008 (4) SA 367 (CC) (*Chirwa*) and *Gcaba v Minister for Safety and Security and Others* 2010 (1) SA 238 (CC) (*Gcaba*), all dealing with labour matters, may have also deepened this perception of lack of coherence in the court's approach to forum shopping, which the principle of subsidiarity partly seeks to address. In *Fredericks* for example, the court allowed a litigant to by-pass more specific legislations and forums in favour of the more general, while in *Chirwa* the court adopted a different attitude, which tended more towards the principle of subsidiarity (see in particular paras 41 – 44) (Langa CJ's minority judgement held however that jurisdiction should be assumed based on pleadings, therefore in substance undermining the principle of subsidiarity (see para 168). Langa CJ also took pains to allay the fears that this approach could lead to incoherence in the application of the law. See para 178 in this regard)). In *Gcaba* the court, which ostensibly tried to reconcile *Fredericks* and *Chirwa*, did not make things clearer. It, for example, endorsed Langa CJ's minority position in *Chirwa* that jurisdiction should be decided based on pleadings, yet rejecting Gcaba's insistence that his claim was a challenge to the employer's administrative action (Also see *Baloyi v Public Protector and Others [2020] ZACC 27* para 33). The court held instead that Gcaba's action was 'essentially rooted in the LRA' (see *Gcaba* paras 75 - 76). The high court in *Minister of Home Affairs and Another v Public Protector of the Republic of South Africa and Another* 2017 (2) SA 597(GP) accepted the decision of the Public Protector, a Chapter 9 institution under the South African Constitution, to deal with what was essentially a labour matter that ought to have been handled in terms of the procedures under the LRA. The court (para 57), in rejecting the argument by the applicant that the Public Protector did not have jurisdiction, more especially taking into account the decision in *Gcaba*, held that *Gcaba* was irrelevant as it dealt in the main with the comparison of jurisdiction between the Labour Court and the High Court, and the Public Protector is not a court. The court further held that the powers of the Public Protector were sourced from the Constitution itself and given effect to by

Another area of interest in the three jurisdictions is the extent to which the systems tend towards governmentalism, i.e. where the primary area of focus in placing obligations is on government and other public institutions. Within this framework private actors are generally left unscathed. Both the US and the UK tend towards strong governmentalism while SA, though arguably also placing more obligations on the state[1343] than the private actors, also has a horizontal focus, which springs principally from its Constitution.[1344] South Africa's version of governmentalism can therefore be said to be relatively weak from this angle. The notion of governmentalism, whether in its strong or weak form (as expressed here) should not be divorced from the general theoretical (ideological) outlook that these three jurisdictions tend towards. The US's arguably strong libertarian ethos does play a role in its tendency to place more obligations on the public institutions than it does on the private actors. The US's libertarian ethos could be discerned from the emphasis its constitution, including its Preamble, and the American Declaration of Independence (1776) place on liberty.

The UK's governmentalist state also arguably stems from its liberal ethos, or perhaps liberal-welfarist ethos.[1345] The South African's arguably hybrid (or even pluralist)

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the Public Protector Act. This decision was, on appeal, further confirmed by the SCA in *Minister of Home Affairs and Another v Public Protector of the Republic of South Africa* 2018 (3) SA 380 (SCA) para 44, rejecting the arguments by appellants that both *Gcaba* and *Chirwa* were applicable. The court in addition held that there was nothing in the SA Constitution and the Public Protector Act ousting the jurisdiction of the Public Protector. This approach has made it difficult to extract the court's clear and coherent position on the principle of subsidiarity.

1343 This stem, in the main, from the Constitution's requirement for the state to 'respect, protect, promote and fulfil the rights in the Bill of Rights' (s 7(2) of the Constitution)). Though, as further shown below, the Constitution also places obligations on private actors, there is no equivalent provision in the Constitution calling upon the private actors to 'respect, protect, promote and fulfil the rights in the Bill of Rights'. One further instance of the Constitution's placement of more obligations on the state than other actors is that a requestor of access to information held by the state does not need to justify his or her request, while a requestor of information held by a private actor needs to show that the requestor needs the information for the protection or exercise of 'any rights' (s 32(1) of the Constitution)). This constitutional provision has been given effect to by PAIA, which also makes a related distinction between access to information held by a public body and that held by a private body (see s 11(1) and (3), read with s 50(1), of PAIA)). PAIA goes a step further and requires that where a public body requests access to information from a private body, the public body must show that such a request is in the public interest. Another example of a governmentalist approach stems from s 33 of the Constitution, given effect to by PAJA in a language that in the main places obligations to have a lawful, procedurally fair and reasonable administrative action on the state or, in the case of natural and juristic persons, those exercising public power or performing public function in terms of an empowering provision (see definition of an administrative action in s 1 of PAJA).

1344 S 8(2) of the Constitution also places obligations on natural and juristic persons where the nature of the obligations so allows. S 8(1) of the Constitution also makes the Bill of Rights applicable 'to all law', which arguably includes private law. S 9(3) and (4) places obligations not to unfairly discriminate, on both the state and private actors, respectively.

1345 Lumen "History of the Welfare State''.

stance, placing obligations on both the public and private actors, could stem from its social democratic ethos (or controversially, egalitarian ethos).[1346] The more libertarian orientation of the US further has the implication that its rights conception also takes a more individualist orientation.[1347] South Africa's arguably more social democratic orientation also has some implication on the direction its rights conception takes which, for lack of a better concept, is a more egalitarian position. As indicated earlier, this could be partly gleaned from the strong component of socio-economic rights in its constitution, which seek to redress social inequalities. In the UK case, despite its weak rights conception (or at least less explicit rights conception), its liberal-welfarist tradition is arguably also reflected in this limited rights' conception where a lot is, for example, done not necessarily along rights lines, but along welfare lines.[1348]

The next point is the question of the three jurisdictions' approach to foreign law. As indicated in chapter four, SA's approach to foreign law is given tooth in the Constitution itself, where the courts may consider foreign law.[1349] The courts have also in practice used foreign law.[1350] On the other hand the US Constitution does not have a corresponding provision encouraging the use of foreign law.[1351] Nor have the courts, more in particular the US Supreme Court, tended towards the use of foreign law in

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https://courses.lumenlearning.com/boundless-politicalscience/chapter/the-welfare-state/ (Accessed 28 October 2021). Though it is difficult to pigeon-hole any phenomenon into any clear-cut social category, one here uses the term 'liberal-welfare' to denote the tendency in a liberal state to also have strong social welfare programmes. The term 'reform liberalism' has also been used in other literature to denote substantially the same, or something related to the same, thing, often in contrast to classical liberalism (see Jackson and Jackson *An introduction to political science* 181).

1346 The hybrid (or pluralist) nature of the rights provision in the SA Constitution stems from the fact that the Constitution provides not only for civil and political rights, but also socio-economic rights (more particularly those in ss 26 and 27). Its application both vertically and horizontally also adds to this hybridity. One however uses the concept of social democracy very cautiously and mainly for convenience due to lack of a better term. See Klare KE "Legal culture and Transformative Constitutionalism'' 1998 *SAJHR* 151, where he avoids the concept of 'social democratic' in favour of the concept of 'postliberal' to describe SA constitutional orientation. One does not however find the concept of 'postliberal' appropriate here, for its ambiguity.

1347 As observed in chapter six, the US's rights framework is mainly confined to civil and political rights, mainly providing for negative rather than positive rights. These rights are more individualist in orientation.

1348 This could be gleaned from several instruments, discussed below, enacted to protect children and other research participants, without necessarily resorting to the rights' language.

1349 S 39(1)(c) of the Constitution.

1350 Note how this was extensively canvassed in *S v Makwanyane and Another* 1995 (3) SA 391 (CC).

1351 This does not mean that other instruments do not provide for recognition of foreign law. The *Federal Policy for the Protection of Human Subjects* (45 CFR 46 Subpart A) (the Common Rule), for example, provides for the recognition of foreign law protecting human participants, if such foreign law is equivalent to the Common Rule (see §46.101 (g) of 45 CFR 46 Subpart A).

adjudication of cases.[1352] With the UK not having a written constitution, this principle is also not articulated in any of its key instruments, nor is it well articulated in case law.[1353] These two jurisdictions have in fact been accused of having 'a strong self-referencing and sovereigntist tendency', when it comes to the citation of foreign law.[1354]

Related to the issue of the three jurisdictions' approaches to foreign law is their approach to international law. As indicated in chapter four South Africa's consideration of international law, which is mandatory, is specifically provided for in the Constitution itself which the courts, tribunals and forums must take into account when interpreting the Bill of Rights.[1355] The US on the other hand does not, except for reference to the supremacy of treaties in art VI of its Constitution, have a constitutionally-mandated position on consideration of international law.

The US's non-ratification of some important international legal instruments, notably the UN Convention on the Rights of the Child and the Rome Statute, could also be viewed as defining its attitude to international law.[1356] The UK, though not having a written constitution, does give respect to international law through some

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1352 Kwai Hang NG and Jocobson B "How Global is the Common law? A comparative study of Asian Common law systems – Hong Kong, Malaysia, and Singapore'' 2017 *Asian Journal of Comparative Law* 209 – 232.

1353 Kwai Hand and Jacobson 2017 *Asian Journal of Comparative Law* 210.

1354 Kwai Hand and Jacobson 2017 *Asian Journal of Comparative Law* 210.

1355 S 39(1). S 232 further specifically makes customary international law part of South African law, unless the customary international law rules are inconsistent with the Constitution or an Act of Parliament. S 233 further mandates courts, when interpreting legislation, to prefer a 'reasonable interpretation' that is consistent with international law to an interpretation that is inconsistent with international law. S 37(4), authorizing some derogations by law from the protection of some rights during states of emergencies requires that, amongst other requirements, such derogations be consistent with South Africa's obligations under international law. For a discussion of the various contexts in which international law may be invoked in South African courts also see Du Plessis M and Scott S "The world's law and South African domestic courts: the role of international law in public interest litigation" in Brickhill J (ed) *Public interest litigation in South Africa* (Juta Cape Town 2018) 48 – 92.

1356 Humanium "Signatory states and parties to the Convention on the Rights of the Child''. https://www.humanium .org/en/convention/signatory-states/ (Accessed 17 May 2021). Also see American Bar Association "The US – ICC Relationship'' (2021). https://www.aba-icc.org/about-the-icc/the-us-icc-relationship/ (Accessed 26 June 2021). Further see Human Rights Watch "United States Ratification of International Human Rights Treaties'' (2009). https://www.hrw.org/news/2009/07/24/united-states-ratification-international-human-rights-treaties (Accessed 19 October 2021).

legislations.[1357] Some of the common law presumptions dealing with interpretation of statutes also tend to support the UK's international obligations.[1358]

Another area of importance is the approach of the different jurisdictions to legal standing. South Africa's approach to legal standing, at least in so far as the enforcement of the Bill of Rights is concerned, is broad and flexible.[1359] The breadth and flexibility of this framework ensure that even those who act in the interest of, or as members of, a particular class,[1360] or in the public interest,[1361] are able to institute legal proceedings, if a right in the Bill of Rights has been infringed or threatened. Where a litigant does not rely on a direct infringement of the Bill of Rights, the more restrictive common law rules of standing are applicable. These rules require that a litigant should have a direct and sufficient interest in the matter, therefore disqualifying a person who seeks to rely on public interest.[1362]

The US's approach to standing is not coherent, if clear at all, apparently taking a public interest approach in some instance,[1363] and moving away from that in some cases.[1364] As to the UK Law, as observed in chapter five, a person will have standing if the person can show that he or she is a victim of the unlawful act complained of.[1365]

1357 The Children Act 2004 ("2004 CA") for example specifically requires commissioners to consider the *UN Convention on the Rights of the Child* when assessing what would be in the best interests of the child. The UK further gives effect to the ECHR through the Human Rights Act 1998. One does however consider the limitations that the UK's adherence to the ECHR have, given that UK law will remain applicable in case of incompatibility with the ECHR.

1358 Devenish GE *Interpretation of Statutes* (Juta Cape Town 1992) 214.

1359 S 38 of the Constitution. Further see *Ferreira v Levin NO and Others* 1996 (1) SA 984 (CC) para 229. Also see Hoexter *Administrative Law in South Africa* 491.

1360 S 38(c).

1361 S 38(d).

1362 Hoexter *Administrative Law in South Africa* 488. This narrow approach to standing also means that even a close family member cannot have legal standing in matters affecting the family (see *Carelse and Another v Standard Bank of South Africa Limited* (12443/07) [2021] ZAWCHC 211 (22 October 2021) para 20.

1363 *Carey v Population Services International* 431 U.S. 678 (1977) para 1.

1364 The Supreme Court in *California, et al., Petitioners v Texas, et al., 593 U.S.* (2021) para 2, took a very narrow approach to legal standing, where it required that plaintiffs had to have suffered traceable injury for them to be able to sue.

1365 S 7(1)(b) of the HR Act, read with art 34 of the ECHR. This approach is arguably very limiting too and does not appear substantially different from the common law position in South Africa, and the US position adopted in *California, et al., Petitioners v Texas, et al.,* 593 U.S. (2021). Persons who therefore seek to pursue actions based on research atrocities might not succeed if they were to solely act in the public interest. While there is provision for persons to act in a representative capacity in the UK, the position regarding class actions is very unclear and the position appears to be more away from, rather than towards, such actions. For a discussion of collective actions in general in the UK, see *Lloyd v Google* LLC [2021] UKSC 50 paras 3 and 24 – 83.

Another critical aspect is the approach of the three jurisdictions on the question of limitation of rights. As indicated in chapter four, the South African Constitution has a general limitation clause under s 36. When South African courts do a limitation analysis they follow a two-stage process namely first determining whether a right in the Bill of Rights has been infringed, and secondly (in the event that the rights have infringed) determining whether such infringement may be justified under the general limitation clause. South Africa's version of the principle of proportionality has mainly been shaped out of the various elements within the limitation clause. The US Constitution does not have a general limitation clause.[1366] The courts in the US have therefore had to interpret the rights narrowly to find limitations within the rights themselves.[1367] The UK does not have a constitutionalised general limitation clause, perhaps principally because of the country's lack of a written constitution. The country instead, because of the Human Rights Act's incorporation of the ECHR,[1368] relies on the internal limitations or qualifiers provided for in various provisions of the ECHR.[1369]

Next is the approach the different jurisdictions take about interpretation. As discussed in chapter four, the SA Constitution adopts a purposive approach to interpretation.[1370] The US Constitution does not specifically deal with the approach to be adopted when interpreting both the Constitution and legislation. This has therefore been left to the courts to craft the correct approach to interpretation. This has therefore created a divided approach, with some judges preferring originalism, which uses the original intention of the framers of the Constitution as the starting point, and those preferring living constitutionalism, which is adaptive to changing circumstances.[1371]

1366 *S v Makwanyane* para 100.

1367 *S v Makwanyane* para 100. The court here shows how although in some instances the two-stage approach in SA and the one-stage approach in the US may lead to the same result, they may sometimes produce a different result. *Gregg v Georgia* 428 U.S. 153 (1976), cited in this case, therefore shows that (in the US) the premises for proving the limitations are totally different from those in South Africa, where the issue is not about whether the decision was wrong, but about whether it was reasonable and justifiable based on the requirements of s 36. These marked differences could therefore also mean that the approaches of the two jurisdictions to questions of proportionality will not necessarily be the same, as SA's proportionality assessment is mainly linked to the criteria in s 36, while the US position will most certainly not be based on a similar framework.

1368 The Preamble to the HR Act.

1369 Some of the internal limitations could be found in arts 2(2); 5(1); 8(2); 9(2) and 11(2) of the ECHR.

1370 This is mandated by s 39 of the Constitution.

1371 Waluchow W *"Constitutionalism" 2017 Stanford Encyclopaedia of Philosophy.* https://plato.stanford.edu/entries/constitutionalism/ (Accessed 20 February 2021). The problem

The position of the UK is quite different. There being no written constitution clarifying the approach to be adopted and being the only one of the three using a system of parliamentary supremacy, the courts have over the years mainly adopted the literal approach to interpretation, with the intention of the legislature being the starting point.[1372]

Concluding the general legal theory of the three jurisdictions, it needs to be stated that this has implications for health research, some of which are therefore highlighted here. The extent to which countries respect international law is very critical in the context of health research. Such importance stems from the fact that a significant number of health research laws and guidelines are also provided for in international instruments, whose observance is important. Where a country does not abide by these international instruments this will rob research participants from these countries of adequate protection.

Whether or not a country's constitution or other key legal framework promotes a vertical or horizontal approach in its application is also very critical. The promotion of both horizontal and vertical application in South Africa's key legal frameworks is therefore very useful in the protection of health research participants, while the two other jurisdictions' tendency to focus on vertical application weakens the protection regime, in that private actors may go unpunished. The approach in the two jurisdictions may therefore undermine the PLA contemplated in this thesis.

7.3 Approaches to the protection of children

As observed in chapter four, South Africa's position regarding the protection of children is specifically provided for in s 28 of the Constitution, and further given effect to in the CA. These frameworks are in addition to what already exists under the common law. To fortify its position South Africa has also ratified the UN Convention on the Rights of the Child (CRC). The common thread in these instruments is the best interest of the child standard, used when deciding on issues concerning a child.[1373] The principle of

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with this approach is therefore that the question as to which approach will be followed arguably becomes dependent on 'which faction' dominates the bench at the time when a matter is decided on.

1372 However, the UK's use of literal approach has not been absolute, a point recognized by Sachs J in *S v Mhlungu* (See *S v Mhlungu* paras 122 – 123).

1373 S 28(2) of the Constitution. Also see s 9 of the CA.

child participation is also provided for.[1374] Some of these principles have been incorporated into health research frameworks.[1375]

The US on the other hand does not have a specific provision in the Constitution dedicated to children. Children, or those seeking to protect them, therefore have to rely on the more generic constitutional provision for protection.[1376] As indicated in chapter six, the common law in the US does recognise the best interest of the child standard.[1377] As observed above, the US has not ratified the UN Convention on the Rights of the Child.[1378] As indicated in chapter five the UK, with no written constitution, has some legislation specifically dealing with the protection of children, including the 1989 CA and the 2004 CA. The UK has also ratified the UN Convention on the Rights of the Child. None of the three countries have any specific legal framework dealing with displaced children, therefore leaving these children to rely on the instruments applicable to children in general (and in the case of the US, they have to rely on the more general laws, including other more general provisions in the Constitution).

The legal framework dealing with children has some implications for health research. The general[1379] legal framework protecting children, as provided for in the South African context could, if correctly applied, go some way in protecting children who participate in health research. Equally capable of protecting children who participate in health research is the general framework provided for in UK law. The ratification of the UN Convention on the Rights of the Child (CRC) by both SA and the UK goes a long way in ensuring that the rights of children who partake in research are

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1374 S 10 of the CA.

1375 Para 3.2.2 of the *2015 Ethics in Research,* where the concept of the interest of the minor is used. As indicated in Chapter Four, the principle of assent by a child provided for in most health research instruments could be derived from this broader principle of child participation.

1376 Also see cases like *Prince v Massachusetts* 321 U.S. 158 (1944) and *Carey v Population Services International* 431 U.S. 678 (1977), where issues involving children were, amongst other issues, also invoked.

1377 Carbone J "Legal applications of the 'Best interest of the child' standard: judicial rationalization or a measure of institutional competence" (2014). https://pediatrics.aappublications.org/content/134/Supplement_2/S111 (Accessed 26 May 2021). Also note *Quilloin v Walcott* 434 US 246 (1978), as cited in *Fraser v Children's Court, Pretoria North and Others* 1997 (2) SA 261 (CC) para 31, where the standard of best interests of the child was relied on in the context of adoption.

1378 Humanium "Signatory states and parties to the Convention on the Rights of the Child''. https://www.humanium.org/en/convention/signatory-states/ (Accessed 17 May 2021).

1379 One uses the word 'general' or its derivative concept 'generic' in the context of this discussion to mean that the framework, though specifically dealing with children, does not specifically deal with health research.

protected.[1380] With the US not specifically dealing with the rights of children in its Constitution, or in any legislation, its failure to also ratify the UN Convention on the Rights of the Child weakens its protection regime towards children.[1381] That all the three countries do not have specific laws protecting displaced children significantly weakness the protection of this category of vulnerable children in the three jurisdictions. In general, however the three jurisdictions do go some way in using a PLA to address the issue of the protection of children.[1382]

7.4 Approaches to judicial review

All the three jurisdictions make provision for judicial review. Though the common law is still applicable, South Africa's judicial review is provided for mainly in legislation and the Constitution. Generally, the South African judicial review is provided for in s 33 of the Constitution. Apart from the judicial review provided for in specialised legislation, s 33 is then further given effect to by PAJA. As observed in chapter 4, where the exercise of (public) power or performance of public function being challenged cannot be challenged under s 33 and PAJA, the person challenging the exercise of public power or performance of public function may rely on the principle of legality, which has been described by the courts as the incidence of the rule of law, provided for in the Constitution.[1383]

As observed in chapter six the US sources its judicial review power mainly from its Constitution, case law[1384] and legislation, including one specifically dedicated to the matter. Though questions have arisen as to whether the US Constitution itself provides

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1380 The negative effect of the UK's reluctance to use the rights language in protecting children is arguably mitigated by the UK's express recognition of this international instrument.

1381 One does however recognise that the US, as discussed under research oversight below, does have specific regulations dealing with health research, including those covering children, but the absence of other more generic frameworks dealing with children could weaken the country's protection regime. This is even more so because the regulations discussed below do not apply to all research (they do not for example cover research not supported, funded or regulated by the federal government or federal agencies).

1382 The SA leaning towards the PLA mainly stems from its legislative, common law and constitutional framework, and its ratification of the CRC, while the UK's leaning, weak though it may be, stems in the main from its ratification of the CRC and its legislative framework. The US PLA leaning, weak though it may be, stems in the main from its common law recognition of the best interest of the child standard, as highlighted above.

1383 See *Law Society of South Africa v President of the Republic of South Africa and Others* 2019 (3) SA 30 (CC) para 30, read with *Affordable Medicines Trust v Minister of Health* 2006 (3) SA 247 (CC) para 49. Also see Freedman W and Mzolo N "The principle of legality and the requirements of lawfulness and procedural rationality: Law Society of South Africa v President of the RSA (2019 (3) SA 30 (CC))" 2021 *OBITER* 421 – 430.

1384 *Marbury v Madison 5* U.S. (1 Cr.) 137 (1803).

for judicial review, the supremacy clause therein, and the way the courts have interpreted the Constitution,[1385] suggest that the Constitution does make provision for the issue. One of the legislations providing for judicial review is the APA, which provides for the review of any agency action by any person who has been legally wronged, aggrieved or adversely affected by the agency's action.[1386]

The UK's judicial review principles are mainly sourced from the common law, whose main ground is the doctrine of *ultra vires.* There is no special legislation dedicated to judicial review. Judicial review is however provided for in some legislation not specifically dedicated to it, including the CPR;[1387] the SC Act;[1388] the 2007[1389] TCEA and the HR Act. In particular, the HR Act, which gives effect to the ECHR, provides for the review of decisions not in compliance with the ECHR.[1390] Most importantly, while s 6 of the HR Act provides for the control of power exercised by public authorities, parliament is not subject to such control.[1391] This exclusion appears to be influenced by the UK's adherence to the principle of parliamentary supremacy.

The general observation on the three jurisdictions' approach to judicial review is that while there is apparently no great divergence in terms of the grounds of review, the principle of legality as used in SA is more unique and better spelt out than in the other two jurisdictions (where its existence is not even clearly spelt out). Differences possibly also exist, more especially as between South Africa and US on the one hand, and the UK on the other, on the extent to which each jurisdiction defer to other decision-makers, due to the system of constitutional supremacy *vis-à-vis* parliamentary supremacy, as used by SA and US on the one hand, and the UK on the other, respectively. In the UK judicial deference could arguably be the default position, while the other two jurisdictions, more especially South Africa, arguably use deference as an exception.

1385 As for example observed above in the case of *Marbury v Madison* 5 U.S. (1 Cr.) 137 (1803).
1386 S 10(2)(a) of the APA.
1387 Rule 54 of the CPR.
1388 Ss 31 and 31A of the SC Act.
1389 S 15 of the TCEA.
1390 LawTeacher "Judicial Review in the United Kingdom" (2019). https://www.lawteacher.net/free-law-essays/constitutional-law/judicial-review-in-united-kingdom-law-essays.php. (Accessed 30 April 2021). See also s 7(1) and (4) of the HR Act.
1391 S 6(3)(b), read with s 6(6).

The way judicial review is approached in different countries could have some implications for health research. The principles around judicial review could be very useful to health research participants if they were to be applied. However, as observed in chapters 4 – 6, these principles have hardly been invoked in any of the countries in the health research context, therefore weakening the PLA contemplated in this thesis. The utilisation of these principles could go some way in fostering the PLA framework.

7.5 Approaches to human dignity

As indicated in chapter four, South African law provides for respect for human dignity at various levels namely at common law (as part of the law of delict),[1392] at legislative level in terms of PEPUDA[1393] and at the level of the Constitution. The Constitution not only makes human dignity a right,[1394] but also one of the constitutional values.[1395] As observed in chapter four, the right to human dignity has been considered by the courts to be one of the pillars of most of the other rights in the Bill of Rights.[1396]

The US also recognises human dignity as part of its tort law, under the common law. The violation of human dignity is however not recognised as a crime under American law,[1397] though various cases show that the concept has been used as part of deciding some cases, including criminal cases.[1398] The US Constitution also does not expressly provide for the right to human dignity. This does not however, as observed in chapter

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1392 It should be noted that violating human dignity does not only constitute a delict, but it may also be a crime under the common law (see Burchell J "Protecting dignity under the common law and the Constitution: The significance of *crimen injuria* in South African criminal law''. https://open.uct.ac.za/bitstream/handle/11427/21163/Burchell_protecting_dignity_under_2014.pdf?sequence=1 (Accessed 1 November 2021).

1393 S 2(b)(iv), read together with para (b)(ii) of the definition of prohibited grounds in s 1, of PEPUDA.

1394 S 10.

1395 S 1(a) of the Constitution. This elevation to the status of a constitutional value also has the effect that human dignity becomes one of the rudders to be used in several contexts, including during interpretation of the Bill of Rights in terms of s 39 and the assessment of the reasonableness and justifiability of the limitations in terms of s 36.

1396 This position was affirmed in *S v Makwanyane* 1995 (3) SA 391 (CC) paras 144 and 328.

1397 Evans *Dignity in non-constitutional American jurisprudence* 2018.

1398 See a series of cases where the concept was used, including dissenting judgements by Justice Murphy in *In re Yamashita* 327 U.S. 1 (1946), *Korematsu v United States* 323 U.S. 214 (1944) and *Cox v United States* 332 US 442 (1947). The concept was further referred to by Frankfurter J in a concurring opinion in *Adamson v California* 332 U.S. 46 (1947). It was further referred to by a majority decision in *Rochin v California* 342 U.S. 165 (1952) in which the court considered the use of force in securing evidence as brutal and 'offensive to human dignity' (Also see Jackson *Human dignity* 2004 for a brief reflection on these and other cases where the concept was used).

six, mean that other provisions in the US Constitution are not capable of being interpreted in ways that support respect for human dignity.[1399]

The UK does not (at least clearly) recognise human dignity as part of its common law, legislative[1400] and (the unwritten) constitutional framework.[1401] Just like was said in the case of the US above, the absence of express provision for human dignity does not mean that respect for human dignity is not recognised at all.[1402] Because of the UK's incorporation of the ECHR in its domestic law, through the HR Act, various provisions of the ECHR, which itself also does not expressly provide for human dignity, may be interpreted in ways that support respect for human dignity. Further, as observed in chapter five, the UK litigants could rely on the CFREU, which does expressly provide for human dignity.[1403]

Just like the approaches to various aspects discussed above, the three jurisdictions' approaches to the question of human dignity has some far-reaching implications for health research. South Africa's express provision for human dignity at various levels of its sources of law, and not only in its ethical instruments, is important in the protection of health research participants. On the contrary, the absence of express provision for, or recognition of, human dignity in the US's public law framework weakens the extent to which its framework protects health research participants. The same goes for the absence of express provisions for, or recognition of, human dignity

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1399 As observed in chapter six, the right to human dignity has been recognised in the context of what could be a 'cruel and unusual' punishment in terms of the Constitution. Cases of *Gregg v Georgia* 428 U.S. 153 (1976) and *Furman v Georgia* 408 U.S. 238 (1972) are some of the cases where human dignity was used in this context (see *S v Makwanyane* paras 57 and 328).

1400 Cooper J "Dignity, the right to life and the Coronavirus'' Oxford Human Rights Hub (2020). http://Ohrh.law.ox.ac.uk/dignity-the-right-to-life-and-the-coronavirus/ (Accessed 30 April 2021).

1401 Perhaps one could safely say the UK does not as yet use the language (vocabulary) of human dignity in its legal thought. Also see Duprė C "What does dignity mean in a legal context'' (2011) https://www.theguardian,com/commentisfree/libertycentral/2011/mar/24/dignity-uk-europe-human-rights (Accessed 28 April 2021). One is however aware of the UK's use of the language of dignity in some of its ethical instruments (see, for example, para 3.7.1 of UKRIO's Code of Good Practice for Research: Promoting good practice and preventing misconduct (2009) (UKRIO's Code of Good Practice). Further see paras 3.2.1 and 3.2.2 of Health Departments' Governance Arrangements for Research Ethics Committees: 2020 edition (2020) (the UK Governance Arrangements).

1402 For some reference to human dignity, see for example *Campbell v MGN Ltd* [2004] UKHL 22*;* [2004] 2 AC 457 para 50, as cited in *Lloyd v Google* LLC [2021] UKSC 50 para 97.

1403 One says this very reservedly, as one does take account of the UK's withdrawal from the European Union. As observed in chapter five, the European Union (Withdrawal) Act 2018 (EUWA), however, does make provision for the retention of some of the principles which are considered to exist 'irrespective of the Charter' (see in particular s 5 (4) and (5), read together with s 6, of EUWA. Also see ss 19 and 20. Further see Sch 1 to EUWA)).

in the UK's legal framework. While the PLA framework is strengthened in the SA law, it is weakened in the other two jurisdictions. Despite SA's express provision for human dignity however, the framework has not yet been relied on in health research cases.

7.6 Approaches to equality

South Africa's equality protection is sourced mainly from both legislation and the Constitution. Section 9 of the Constitution provides for equality and non-discrimination. The prohibition of discrimination is based on a variety of grounds, including race, gender, sex and sexual orientation.[1404] Under exceptional cases, certain forms of discrimination could be justified if they are consistent with affirmative action measures,[1405] or they are established to be fair.[1406] As observed in chapter four PEPUDA gives effect to s 9 of the Constitution, and gives further details around equality and non-discrimination issues.

As observed in chapter six the US law does provide for equality protection in terms of the common law; US Constitution[1407] and legislation.[1408] The problem with the US's equality framework is that it does not, in the main, have a provision that lists the prohibited grounds of discrimination, therefore creating uncertainty as to which grounds may or may not be prohibited grounds of discrimination.[1409] The US Constitution also does not spell out instances where discrimination may be justified.

The UK also does have an equality protection framework, which it sources mainly from the common law,[1410] legislation[1411] and continental obligations. In the case of

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1404 S 9(3 and (4) of the Constitution.

1405 S 9(3).

1406 S 9(5). The importance of this provision is that not all discrimination is prohibited, but only unfair discrimination is. This position has further been elaborated on in several cases, including *Harksen v Lane and Others* 1998 (1) SA 300 (CC) para 44.

1407 As observed in chapter six, the equality provision is more particularly stated in s 1 of the Fourteenth Amendment.

1408 These legislations include the Pregnancy Discrimination Act; the Equal Pay Act of 1963; Civil Rights Act of 1964; Tittle I of the Americans with Disabilities Act of 1990; Civil Rights Act of 1991; the Genetic Information Non-discrimination Act of 2008 and the Rehabilitation Act of 1973 (Also see U.S. Equal Employment Opportunity Commission ''Laws enforced by EEOC''. https://www.eeoc.gov/statutes/laws-enforced-eeoc (Accessed 31 May 2021)).

1409 See chapter six for the few, isolated instances where prohibited grounds of discrimination are stated.

1410 Dicey's conception of English law, which allegedly subjects everyone equally before the law, points to the common law as one of the sources of equality law (see Schreiner *Contribution of English Law* 77).

1411 As observed in chapter five, one of the main legislations dealing with equality issues in the UK

continental obligations, this means that the UK litigants may rely on the ECHR which, as pointed out earlier, was given effect to by the HR Act. The ECHR does enumerate a wider variety of grounds than the Equality Act 2010 (EA).[1412] The pitfall with reliance on the ECHR is however that where there is a conflict between the ECHR and domestic legislation, the declaration of incompatibility, if made, does not invalidate domestic legislation.[1413]

The three jurisdictions' approach to equality issues has some implications for health research. SA's equality framework, if used appropriately, has the potential to protect health research participants. The framework can foster the PLA contemplated in this research. The framework has however to-date not been used in the context of litigation involving health research. The UK and US frameworks limited though they are in their provision for equality issues may also, when used appropriately, be useful in the protection of health research participants and be capable of promoting the PLA contemplated in this thesis. They too are yet to be used in the context of litigation involving health research.

7.7 Approaches to health care

The South African law governing health care may be sourced from the common law,[1414] legislation and the Constitution. In case of legislation the NHA, as observed in chapter four, assumes a central role. As indicated in chapter four, the NHA gives effect to the right to health as provided for in ss 27 and 28(1)(c) of the Constitution.[1415] S 27 provides, amongst other things, for everyone to access health care services within the state's available means.[1416] It further deals with the right to emergency medical treatment.[1417] S 12(2)(c) of Constitution, further dealt with under research oversight below, provides for the right of everyone 'not to be subjected to medical or scientific

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is the Equality Act 2010 (EA). The EA provides for several prohibited grounds of discrimination, including race, gender and sexual orientation. Unfortunately, the EA provides for a closed list of prohibited grounds, meaning that those relying on those grounds not enumerated, including health-related grounds, might not find protection.

1412 See art 14 of the ECHR for these grounds.

1413 S 4(4) of the HR Act.

1414 This could for example arise from contractual obligations; duty of care; and arguably from the fiduciary obligations of the provider of the services.

1415 S 2(c) of the NHA, read with the Preamble to the Act. It should be noted that s 28(1)(c) deals, amongst other things, with children's right to health care services.

1416 S 27(1) and (2).

1417 S 27(3).

experiments' unless they provide informed consent. Case law has had to deal with the various provisions related to the right to health, especially s 27. These cases include *Soobramoney v Minister of Health*[1418] and *Minister of Health v Treatment Action Campaign and Others* (No.2).[1419]

The US does not have a clearly recognisable right to health care under both its common law[1420] and the Constitution.[1421] As observed in chapter five there is also arguably no legislative framework specifically dedicated to the right to health care.[1422] Health-related rights issues have therefore mainly come to the courts through challenges to public health laws.[1423] The UK equally does not have a clearly recognisable right to health care under the common law,[1424] nor does it have any under the legislative framework. This right is also not clearly provided for in the ECHR, which the HR Act gives effect to. This therefore leaves litigants to rely on other related rights like the right to privacy;[1425] non-discrimination;[1426] etc., which the ECHR provides for.

1418 *Soobramoney v Minister of Health (Kwazulu-Natal)* 1998 (1) SA 765 (CC). This case dealt with s 27(3) of the Constitution, where the Constitutional Court held however that Soobramoney's requested treatment did not qualify as an emergency treatment as contemplated in the provision (see *Soobramoney v Minister of Health* paras 13 and 21).

1419 *Minister of Health and Others* v *Treatment Action Campaign and Others (No 2)* 2002 (5) SA 721 (CC). In this case the government had to be forced to provide nevirapine to HIV positive mothers in public health facilities, so as to prevent mother-to-child transmission.

1420 Perkins J "The state of health care in the United States''. https://www.americanbar.org/groups/crs/publications/human_rights_magazine_home/the-state-of-healthcare-in-the-united-states/state-of=healthcare/ (Accessed 17 May 2021). This does not however mean that health-related issues cannot be handled under fields like contract and tort laws.

1421 Perkins J "The state of health care in the United States''. https://www.americanbar.org/groups/crs/publications/human_rights_magazine_home/the-state-of-healthcare-in-the-united-states/state-of=healthcare/ (Accessed 17 May 2021). Further see the court's attitude towards this direction in *Webster v Reproductive Health Services 492* U.S. 490 (1989), para 37. As observed in chapter five, the US's reluctance to ratify the International Covenant on Economic, Social and Cultural Rights (ICESCR), which provides for health-related rights in art 12, could further support the position that the US does not have, and is not in favour of, the right to health care. The absence of an express right to health care does not however mean that other provisions cannot be relied on to pursue the same ends.

1422 Perkins J "The state of health care in the United States''. https://www.americanbar.org/groups/crs/publications/human_rights_magazine_home/the-state-of-healthcare-in-the-united-states/state-of=healthcare/ (Accessed 17 May 2021). Also note challenges to the Patient Protection and Affordable Care Act (ACA), sometimes informally referred to as the Obamacare Act, which sought to provide some basic health care insurance, in *California, et al., Petitioners v Texas, et al.,* 593 U.S. (2021).

1423 See for example *Jacobson v Massachusetts* 197 U.S. 11 (1905), where the vaccination laws were, however, unsuccessfully challenged.

1424 Litigants may of course still raise health-related issues under contract and tort law.

1425 Art 2(1) of the ECHR.

1426 Art 14 of the ECHR.

This therefore places litigants who want to vindicate their health-rights in a very weak position.

The approach of the three jurisdictions to the regulation of questions of access to health care, just like the approaches to the aspects discussed above, has some implications for the conduct of health research. The South African framework dealing with access to health care arguably does go some way in protecting health research participants, if applied appropriately. The framework also does promote the PLA contemplated in this research. Unfortunately, these principles have not yet been relied on in litigation pursued in the context of health research. The US's lack of express provision for the right to health care weakens the protection to be afforded to health research participants.[1427] The UK is in the same position. Its framework is not likely to adequately protect health research participants.[1428] Its main reliance on the ECHR is not sufficient to cure this deficiency given that, as indicated earlier, any conflict between the ECHR and the UK's domestic laws will not result in the invalidation of the defective domestic laws.[1429]

7.8 Approaches to remedies

As observed in chapters 4 to 6, courts have from time to time to apply remedies so as to meet the request of an aggrieved litigant.[1430] It was observed that all the three countries under discussion have frameworks within which the appropriate remedies could be applied. In South Africa considerations based on a sense of justice; equity and fairness[1431] have shaped the thinking in the application of the remedies. These are, in the main, sourced from the Constitution,[1432] the CPA and case law. The US

1427 As indicated earlier, the fact that the US does have regulations specifically dealing with health Research participants does not allay these fears, given the limited application of these regulations (see the discussion of the regulations, more in particular the Common Rule, under health research oversight below).

1428 One is however aware of the more specific legislations dealing with the protection of health research participants below which might mitigate against this shortcoming.

1429 S 4(6) of the HR Act.

1430 See chapter four for the various cases that have dealt with this and related issues in the South African context.

1431 These principles may come in different forms: where a conduct is considered unfair; unjust; unreasonable and unconscionable as contemplated in s 52 (1) and (3) of the CPA. In addition to these principles, some decisions have also invoked the value (or principle in this context) of ubuntu (See *Beadica 231 CC and Others v Trustees for the time being of the Oregon Trust and Others* 2020 (5) SA 247 (CC) para 72).

1432 As observed in chapter four, the Constitutional provisions includes s 34 (entitling everyone to have his or her dispute adjudicated in a fair hearing); s 38 (entitling those with legal standing to apply for an appropriate relief) and s 172 (1) (providing for a just and equitable remedy).

law, including the Constitution,[1433] legislation[1434] and case law,[1435] also make provision for the consideration of equity issues. The sense of justice, equity and fairness is therefore considered using, just like in SA law, different concepts to signify this.[1436]

What appears to be the common thread here is that both SA and US law, apart from using the same concepts, do not apply principles of equity independently from the rest of their other laws. The reason for this is arguably that these principles are directly provided for in the two countries' supreme constitutions. However, in SA law, there could be some difference in the courts' reasoning in support for these principles. Although these principles are, just like in the US, often contrasted with the freedom of contract, in the South African case the importance of freedom is directly (in the sense of being expressly provided for) sourced from the Constitution, being one of the constitutional values in s 1 of the Constitution.[1437] Being such a constitutional value means that it must be taken into account in the interpretation of the Bill of Rights, and in the assessment of limitations in terms of s 36 of the Constitution.

In the UK equity was developed as a curing mechanism for the defects in the common law. It therefore applies when the common law in a particular situation cannot provide an effective remedy.[1438] As to its authority, equity is sourced mainly from case law[1439] and legislation.[1440] As to the general approach to contracts in general the UK, England

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1433 See Art III (2) which makes provision for judicial authority to 'extend to all cases, in law and equity,…'.

1434 See § 2-718(1) of the Uniform Commercial Code (UCC). Also see Tembe HC "Problems regarding exemption clauses in consumer contracts: the search for equitable jurisprudence in the South African constitutional realm" (LLD thesis University of Pretoria 2017) 299. Further see § 2 - 316 (1) of the UCC.

1435 Henningsen *v Bloomfield Motors Inc.* 32 N.J. 358 (1960). *Further see* Dworkin R *Taking Rights Seriously* (Bloomsbury London 2013) 40 and 43.

1436 Concepts like 'unreasonable' and 'unconscionable' are also used in the US context (See § 2-718(1); § 2 - 219(3) and § 2 - 302(1), read with (2), of the UCC.

1437 See how the link between sanctity of contracts and the constitution is built in *Pop-up Trading 39 (Pty) Ltd and Others v Super Group Holdings (Pty) Limited and Another* (14544/2020) [2021] ZAGPJHC 575 (20 October 2021) para 22. Further see *Beadica 231 CC and Others v Trustees for the time being of the Oregon Trust and Others* 2020 (5) SA 247 (CC) paras 83 – 87). The Court in this case decided in favour of enforcing the contract, as it could not be shown that its enforcement would be contrary to public policy (see para 102).

1438 The implication of this could be that the common law's application is the default position, while equity law applies as a matter of exception.

1439 Equity law has historically been developed by the Court of Chancery (see Martin J *The English legal system* 6th ed (Hodder Education London 2010) 18.

1440 The notion of equity, just like is the position in the case of the US and SA law situations, comes in different shapes, more particularly using the concept of fairness and reasonableness (see ss 6 (1A) and 7 (1A) and (4) of the Unfair Contract Terms Act (UCTA). Further see s 11 and Schedule 2 of UCTA. See s 62 of the Consumer Rights Act 2015 (CR Act). Also see Part 1 of Schedule 2 to the CR Act. Further see s 71 of the CR Act. S 8 (1) of the HR Act grants a court

and Wales in particular, have been said not to have a general duty of good faith, but have instead approached the issue on a piecemeal basis in their attempt to arrive at fairness.[1441]

Unlike in the US and SA law situation, the application of equity in the UK creates parallelism, as both the common law and equity law may develop separately. UK law however tries to reconcile the possible conflict between two sources of law by making equity law applicable in case of conflict between the two systems.[1442] The UK's adherence to the system of parliamentary sovereignty also implies that the courts there will be more cautious not to apply equity principles in ways that encroach into the terrain of the other branches.

As observed in chapter four, South Africa has also considered what is termed constitutional damages in principle, although in most cases the courts have been reluctant to grant them holding that they are, on the facts of a specific case, not appropriate, especially where the common law delictual remedies are already available to vindicate the right.[1443] As observed in chapter four, the US has also considered constitutional damages under both the legislative framework (in particular the section 1983 actions) and under the US Constitution (the Bivens actions).[1444]

The approach to the remedies has important implications for research too. The consideration of flexible principles like equity, fairness and justice in the three jurisdictions will go a long way in protecting the rights of health research participants. The conception of these principles in the three jurisdictions will not necessarily be the

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powers to make a relief that is 'just and appropriate'. Though as a general rule an award for damages under the HR Act is not permitted, the court may allow it under certain circumstances if it considers such an award to be affording a 'just' satisfaction to the beneficiary of the award (see s 8(3) of the HR Act).

1441 *Beadica 231 CC and Others v Trustees for the time being of the Oregon Trust and Others* 2020 (5) SA 247 (CC*)* paras 64 – 66.

1442 Martin J *The English legal System* 6th ed (Hodder Education London 2010) 18.

1443 *Residents of Industry House, 5 Davies Street, New Doorfontein, Johannesburg and Others v Minister of Police and Others* [CCT 136/20) [2021] ZACC 37 (22 October 2021) paras 91 - 92 and 97. The position appears to be that the remedy could be available but is seldom available where common law remedies are already available to vindicate the right concerned. Further see this line of reasoning in *Thubakgale and Others v Ekurhuleni Metropolitan Municipality and Others* (CCT 157/20) [2021] ZACC 45 (7 December 2021) paras 121; 157 – 158; 169; 175 – 176 and 196 – 197.

1444 Section 1983 actions are so named because of the section they were based on in terms of the Civil Rights Act of 1871, while Bivens actions are so named because they were first developed in *Bivens v Six Unknown Named Agents* 403 U.S. 388 (1971). As observed in chapter four, the *Federal Torts Claims Act* also provides for liability for some official misconduct.

same, given the broader frameworks within which these principles have to be applied, especially when these principles have to be juxtaposed with the principle of freedom of contract.[1445] On the whole, the approach of the three jurisdictions on the issue of remedies do tend towards the PLA contemplated in this research. These principles have however not yet been applied by courts in the context of health research. Were the South African courts to be more willing rather than, as appears from case law, hesitant to grant constitutional damages in addition to the common law remedies (and not only when common law remedies are not available), this would go a long way in strengthening protection for health research participants. The latter would also be significant in promoting the PLA contemplated in this study.

7.9 Approaches to access to information and the protection of personal information

As observed in chapter four, SA's privacy law is sourced mainly from the common law;[1446] legislation[1447] and the Constitution.[1448] Grounds of justification exist in case of the violation of privacy. Under the common law the grounds mainly include consent to the act and public interest.[1449] Under POPIA the grounds of justification,[1450] though not so coherent, depend on the context of the violation of the personal information. These

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1445 These principles will, for example, be assessed differently in jurisdictions following the system of parliamentary supremacy and those following a system of constitutional supremacy. Even in the countries following the system of constitutional supremacy, as SA and the US do, there could be differences in approach. As indicated earlier, South Africa's constitutional values, which are not necessarily the same as those of the US (which does not have any express provision for such), might influence the way the principles above are given effect to. South Africa's additional reliance on Ubuntu principles may create an added dimension to its approach to the principles above.

1446 In terms of the common law the violation of privacy constitutes both a *delict* and a crime.

1447 POPIA is one of the main legislations dealing with the protection of personal information.

1448 S 14 of the Constitution is one of the key provisions dealing with privacy.

1449 Neethling J and Potgieter JM *Neethling – Potgieter – Visser Law of delict* 6th ed (LexisNexis Durban 2010) 348. Also see Milo D and Stein P *A practical guide to media law*. (LexisNexis Durban 2013) 57 (Although Milo and Stein discuss this in the context of media law, these defences remain central even in other contexts).

1450 One should note that these grounds of justification also appear in the Act as exclusions and exemptions, in addition to appearing as exceptions. Apart from, as appears below, those grounds that are more specific to research purposes and public interest, there are those that could also imply public interest without explicitly saying so. For example, the justification arising from compliance with an obligation imposed by law, as contemplated in s 11(1)(c) of POPIA might, or might not, be said to be a justification based on public interest, depending on the issue forming the subject matter of compliance. It could be interesting to enquire whether, for example, the subpoenas and related processes contemplated in ss 179, 186, 187, 188, 189 and 205 of the Criminal Procedure Act 51 of 1977, which could ideally also apply to researchers who are in possession of information relevant to the resolution of a particular case, could be said to be in the public interest or not. It is however here unnecessary to take this matter any further, save to say it will depend on the facts of each case.

grounds include public interest, though these might be labelled differently under different provisions.[1451]

The question of access to information is mainly regulated by PAIA and the Constitution.[1452] As indicated in chapter four, though PAIA mainly deals with the promotion of access to information, it also provides for the protection of privacy under certain circumstances.[1453] Most importantly, PAIA does also make provision for mandatory disclosure of personal information in the public interest.[1454] It is also important to note that PAIA applies to both private and public bodies.[1455]

As observed in chapter six, the US's privacy law is mainly sourced from the common law of torts;[1456] legislation[1457] and indirectly from the Constitution. Regarding access to information, this is regulated by the US's FOI Act. As noted in chapter six of the FOI Act, just like the Privacy Act, applies mainly to public authorities (in the sense of placing obligations mainly on these authorities).[1458] While the FOI Act in the main does not focus on research issues, some of the principles could be applicable to research contexts.[1459] With regard to fees charged for requests for accessing documents, the

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1451 For example, processing for research purposes is one of the grounds, and this is certainly a public interest issue (and it is in fact sometimes included when what is considered public interest is elaborated on, as in s 37(1) and (2)(e) of POPIA. Note however ss 27(1)(d) and 35 (1)(d), which have been phrased in such a way that they do contemplate that there could be processing for research purposes that might not be in the public interest)).

1452 S 32 is one of the key provisions dealing with the promotion of access to information. Due to the tension between access to information and the protection of personal information, the discussion of the two topics is done together.

1453 Note ss 34 and 63 of PAIA.

1454 Ss 46 and 70 of PAIA.

1455 S 3 of PAIA.

1456 Haydel JA "Privacy'' (2009) https://www.mtsu.edu/first-amendment/article/1141/privacy (Accessed 17 May 2021).

1457 One of the main legislations dealing with privacy in the US is the Privacy Act of 1974. Though not expressly stated, the contextual reading of the Act suggests that it applies only to (in the sense of binding) public authorities. The Privacy Act does not clearly and expressly provide for a public interest defence, nor does it expressly apply to health research. As observed in Chapter Six, apart from the Privacy Act there is the EU-US Privacy Shield, which applies to those in the US who self-certify to abide by it. One of the important provisions of the EU-US Privacy Shield is that its definition of personal data suggests that it does not only apply to the protection of personal information about a living individual, therefore implying that information about dead persons could also be protected (see para 1(8) of the EU-US Privacy Shield. It should be noted that participants in blinded studies do not have to be provided with the information if providing same will undermine the integrity of the study, provided the participants were informed about the limitation before the commencement of the study (See para 14(e)(1)). Participants however retain the right to access the information after the completion of the study and results analysis (see para 14(b)(i)).

1458 See US Department of Justice "Overview of the Privacy Act of 1974''. https://www.justice.gov/archives/opcl/definitions (Accessed 25 October 2021).

1459 For example, FOIA provides for some exemptions from the application of the Act, including

FOI Act distinguishes fees charged for requests of access for commercial purposes and those for non-commercial purposes, if made by educational and non-commercial scientific organisations for research purposes.[1460] The fees in the former case are limited to 'reasonable standard charges for search, duplication and review of the documents, while in the latter case they are limited to the 'standard reasonable charges' for duplication.[1461] Where there is public interest in the disclosure of the requested information because such disclosure is likely to lead to a better understanding of the government's operations, the access could be free or at a reduced rate.[1462]

The UK law also does have some privacy framework, which is mainly sourced from legislation and European law.[1463] As observed in chapter four, the English common law does not recognise a general right to privacy, more particularly in the context of tort law.[1464] English law does however recognise the protection of information through the law of confidence.[1465] As discussed in chapter four, the main legislation dealing with the protection of personal information in the UK is the DPA 2018 which in the main provides for personal information to be processed fairly and lawfully, with the data subject's informed consent.[1466] It further provides for data subject participation,

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where medical records and files are requested. Requests for access could therefore be refused on privacy grounds, where privacy could be unjustifiably violated (see § 552(b)(6)).

1460 § 552(a)(4)(A)(ii)(II).

1461 § 552(a)(4)(A)(ii)(II)).

1462 § 552 (a)(4)(A)(iii). It is unclear what categories of disclosure will be in the public interest. What is clear however is that in the context of the provision it will not include requests for access for research purposes (this contrasts with the conception, though incoherent too, of public interest in POPIA. The conception of public interest in s 37(1) and (2) (e) of POPIA, as indicated earlier, is one that also includes processing for research purposes, while that in ss 27(1)(d) and 35(1)(d) suggest that not all instances of processing for research purposes will engage public interest).

1463 As pointed out in chapter five, the privacy provision in art 8 of the ECHR will also be applicable to the UK.

1464 Library of Congress "Online privacy law: United Kingdom' https://www.loc.gov/law/help/online-privacy-law/2012/uk.php# (Accessed 30 April 2021).

1465 Bently L and Sherman B *Intellectual Property Law*. 2nd ed (Oxford University Press New York 2004) 995 – 998. As discussed in chapter four, there are defences to the alleged breach of confidence, which include public interest, compliance with a statutory obligation, compliance with a court order and giving effect to some equity-based defences (Bently and Sherman *Intellectual Property Law* 1039 – 1046).

1466 S 2(1)(a). What should further be noted is that the protection is about the personal data of an 'identifiable living individual', therefore ruling out the protection of the personal data of a deceased person or that of a juristic person (see s 3(2) and (3)). This is in contrast to the formulation in both PAIA (which does contemplate the protection of the data of deceased persons in s 34 (1)) and POPIA, which also covers information of juristic persons under certain circumstances. In other words, both PAIA and POPIA are also contradictory in this regard as POPIA, just like the DPA, does not appear to cover personal information of deceased persons as, apart from juristic persons, it also talks of an identifiable 'living' person (see s34 (1) of PAIA

which includes accessing information by the subject and correcting it where necessary.[1467] As indicated in chapter four, the DPA gives effect to the EU's GDPR. The DPA also recognises the processing of personal information in the public interest.[1468] The DPA further recognises the processing of personal information for research or scientific study purposes.[1469]

On the question of access to information, the UK law sources this mainly from legislation. As highlighted in chapter five, one of the main legislations in this regard is the FOI Act. The FOI Act however only applies to access to information held by public authorities.[1470] The FOI Act also provides for public interest to be considered in the determination of whether or not to confirm or deny the existence of certain information by a public authority.[1471] The requirements dealing with access to information are also inapplicable where the FOI Act provides for absolute exemptions.[1472] Amongst the various exemptions the FOI Act provides for are the disclosures that could endanger the health and safety of individuals,[1473] the protection of trade secrets or commercial interests[1474] and where the information to be accessed was supplied by another person in confidence.[1475]

The general observation arising from the above is that all the three jurisdictions do refer to public interest, but it is not clear from the key instruments as to whether processing for research purpose is inherently (in itself) a public interest issue, whether it has to have certain qualities to be able to qualify as serving public interests or whether, at least in the FOI Act case, the provision for public interest as contemplated there could also apply in research contexts.[1476] What is important is that all the three

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and s 1 of POPIA). These contradictions between POPIA and PAIA remain despite that the definition of 'personal information' in s 1 of PAIA has now been replaced by POPIA's definition of personal information as s 34 (1), which refers to the protection of personal information relating to a deceased individual, has not been repealed (see Schedule to POPIA).

1467 S 2(1)(b).

1468 For example, public interest may be considered in the making of regulations setting the conditions dealing with the necessity or otherwise of transfer of personal data to other countries or international organizations (see s 18).

1469 S 19(1)(b) of the DPA, read with Part 1 of Schedule 1 to the DPA.

1470 S 1(1) read with s 1(3) and (5) of FOI Act. This may therefore leave private researchers relatively free to do as they wish.

1471 S 2(1).

1472 S 2(3) of the FOI Act, which provides for the sections that the Act considers conferring absolute exemption.

1473 S 38(1).

1474 S 43(1) and (2).

1475 S 41(1)(a) and (b).

1476 FOIA's usage of the concept is even more problematic, and very unlikely to contemplate

jurisdictions do recognise the need for public interest considerations when dealing with issues of access to information as well as privacy. Another observation is that while the SA's main framework, namely POPIA, also covers information belonging to juristic persons, the two other jurisdictions' framework do not cover such, or at least do not clearly do so.[1477]

A related observation is that generally the instruments in the three countries do not protect information belonging to deceased persons, although as observed earlier SA's PAIA, which in the main deals with privacy issues, does cover personal information relating to deceased persons. In terms of s 3(2)(a) of POPIA, where there is inconsistency between POPIA and any other legislation in respect of the protection of personal information, POPIA is applicable.[1478] A further notable observation is that SA's privacy and access to information laws not only apply vertically but also horizontally, while those in both the US and the UK mainly, if not only, apply vertically, i.e. as between subjects and the state (in the form of public authorities or agencies). This has far-reaching implications in that private actors in the US and the UK might comparatively have the liberty to do as they wish, therefore reducing the protection afforded to research participants.

The above frameworks have far-reaching implications for health research. The mainly vertical application of the key instruments in the US and UK could have the effect of reducing protection to research participants attached to research conducted by private actors. The fact that the three jurisdictions do not, on the whole, clearly provide for the protection of personal information belonging to deceased persons is likely to undermine protection in the case of personal information belonging to deceased persons.[1479] The limited provision for privacy in the US Constitution (in the sense of

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inclusion of access to information for research purposes. For example, § 552(a)(4)(A)(iii) provides for disclosure of information at a reduced or free rate if the disclosure is in the public interest, but in the sense of being likely to improve understanding of government's operations.

1477 But in the case of the protection of confidentiality juristic persons are most certainly covered. In the case of the UK, see, for example, S 41(1)(a) of FOI Act which implies that this is the case.

1478 This is however subject to the proviso that if any other legislation provides for more 'extensive conditions for lawful processing, the extensive conditions shall apply (s 3(2)(b)). Because this proviso only applies when the other legislation provides for 'extensive conditions'' and not necessarily better protection, this still makes it unclear as to whether it should be PAIA or POPIA that should reign supreme in this case. But if one were to read this provision together with s 2 (the objects of the Act), 'extensive conditions' should in one's view be read as 'better protective conditions. Read this way, PAIA would then apply as it provides for better protection (than POPIA) in the case of personal information belonging to deceased persons.

1479 One does note however, as indicated earlier, the possible application of PAIA if the

absence of direct provision) and limited recognition of same in the UK common law deprive research participants of clarity as to whether and when privacy will or will not be protected. This therefore limits the PLA contemplated in this research. The SA position does, however, to some extent support the PLA contemplated here. The provisions have however yet to find application in the context of health research litigation.

7.10 Approaches to research oversight under various laws

7.10.1 Approaches under case law

7.10.1.1 South African law

In South African law only two cases have come before the courts as yet, both involving the same parties. As one was an appeal against the other only the appeal case, being *Venter v Roche Products (Pty) Ltd* (A11/2014) [2014] ZAWCHC 157 (22 October 2014), whose details have already been reflected on in chapter four, is reflected on here. As highlighted in chapter four the appellant, who was injured during an oncology research, sued the respondents based on contract (tacit agreement). The appellant also alternatively grounded his claim on *stipulatio alteri* and delict.[1480] The claim failed. It appears that the over-reliance on private law causes of action, rather than also resorting to public law causes of action, contributed to the failure of appellants' claim. The issue of the development of the common law, as contemplated in s 39 of the Constitution, was also not considered.[1481]

7.10.1.2 United Kingdom case law

Just like South Africa, the UK has not had many cases directly dealing with health research. Except for *Morton James Wylie v Dr Donald Grosset, Greater Glasgow Health Board* [2011] COSH 89, hardly any case directly dealing with health research could therefore be found.[1482] As observed in chapter six, the litigant in this case mainly

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interpretation one assigns to s 3 of POPIA above is to be found plausible.

1480 *Venter v Roche Products (Pty) Ltd* para [2].

1481 S 39(2) of the Constitution provides for the development of the common law, so as to give effect to the spirit, objects and purport of the Bill of Rights.

1482 It should also be noted that this was not decided by the UK Supreme Court, the highest in that country, but by a Scottish Court, located within one of the Unions forming part of the UK. The case however remains relevant to provide some directions as to how other courts in the rest of the UK would have approached it.

relied on private law, namely the unilateral obligation and alternatively contract, to ground his action. Although the court accepted the existence of a contractual relationship between the claimant and defendants (being the investigators and institutions to which they belonged),[1483] the court opined, though in passing, that there was no such a relationship between the claimant and the sponsors (which were in any way not joined in the action). It is therefore unclear how this case would have been decided had the claimant also relied on public law obligations to pursue his case. One argues that it is likely to have yielded a different outcome.

7.10.1.3 United States case law

As observed in chapter six several cases dealing directly with health research came before the courts in various states of the US. These include *Abney et al v Amgen, Inc* 443 F.3d 540 (6th Cir. 2006) (Abney);[1484] *Suthers v Amgen*, Inc., 372 F.Supp. 2d 416 (S.D.N.Y. 2005)[1485] *and Grimes v Kennedy Krieger Institute, Inc.,* 728 A 2d 807 (Md. 2001).[1486] Claimants in these cases generally tended towards reliance on private law obligations, and there was therefore hardly any reliance on public law obligations.[1487] The narrow approach to defining obligations in these cases therefore also, in the main,

1483 The court, though, still dismissed the action on the basis that the terms of the contract, which relied on the *ABPI Guidelines*, did not create an enforceable obligation to pay compensation.

1484 As observed in chapter six, the claimants in this case, who were suing the sponsors of the research unsuccessfully grounded their action mainly on contract, fiduciary relationship and estoppel, all principally located within the private law sphere. The Court's *obiter dictum* however, that had the claimants sued the investigators or the IRBs they perhaps would have succeeded, has left the issue open as to how the case would have been resolved had the investigators been sued.

1485 The claim here was also based on the notion of fiduciary relationship on the part of, or with, the sponsors, which the court rejected.

1486 Although the claimants in this case, whose children had suffered as a result of the lead paint they had contacted while part of the research, were successful on appeal, the practice of reliance on private law obligations, rather than also on public law obligations, was evident (contract and the existence of a special relationship were amongst the grounds relied on).

1487 This does not however mean that there are no isolated instances where reliance was placed on causes of action with a public law leaning. In the case of *T.D. et al. v New York State Office of Mental Health* 165 Misc.2d 62, 626 N.Y.S.2d 1015 (1995), for example, there was some challenge to some regulations. (For a further discussion of the case and other relevant cases, see Campbell AT "State regulation of medical research with children and adolescents: An overview and analysis''. https://www.ncbi.nlm.nih.gov/books/NBK25556/ (Accessed 01 July 2021). Further see Findlaw "*T.D. et al., Appellants v. New York State Office of Mental Health''*. https://caselaw.findlaw.com/my-court-of-appeals/1178770.html. (Accessed 2 July 2021)). As indicated in chapter 6 there are further instances of the recent tendency towards the broadening of the scope of causes of action by claimants, whose actions are based on research atrocities (Also see in this regard Shaul RZ, Birenbaumm S and Evans M "Legal liabilities in research: early lessons from North America''. https://bmcmedethics.biomedcentral.com/articles/10.1186/1472-6939-64 (Accessed 01 July 2021)).

ensured that sponsors remained unscathed by any allegations of impropriety.[1488] However, none of these cases came before the US Supreme Court, therefore leaving the issue as yet uncertain as to how the highest court would approach the same matters in the future. These cases however remain of value. The thread that cuts across all the cases consulted (in so far as the regulation of health research is concerned) is that they, except for isolated instances of challenges to regulations, tended to use private law as a starting point. The claims of the litigants were mainly grounded on contracts, torts, fiduciary obligations, special relationships and estoppel. Hardly any of these cases relied on public law obligations. It therefore remains uncertain how the cases would have been decided had they also relied on public law obligations.

7.10.2 Approaches to research oversight under legislation and related instruments[1489]

7.10.2.1 South African law

Apart from the more generic provisions discussed earlier, the South African Constitution does have a provision that directly speaks to health research, but only in the context of informed consent.[1490] What follows below is a discussion of the relevant legislative and related instruments directly touching on health research issues. One of the leading legislative frameworks dealing with health research is the NHA. The NHA, in the main, protects those who partake in health research, more specifically children. Where the research concerns children, the NHA makes a distinction between therapeutic[1491] and non-therapeutic research,[1492] where in the latter case a ministerial

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1488 For the discussion of *Abney* and another case, *Kernke v The Menninger Clinic, 173 F.Supp.2d 1117 (D. Kan. 2001)* also see Lohman KG "The legal duties of clinical trial sponsors". https://www.lexology.com/library/detail.aspx?g=ff102251-552b-40f1-844f-8b9e35ebc3ff (Accessed 26 January 2022).

1489 Though neither the South African Constitution nor the US Constitution are legislations in the strict sense, this subheading covers them too (hence the addition of the concept of 'related instruments', so as to remove any doubt about the relevance of their inclusion here).

1490 As observed in chapter four, s 12 (2) (c) of the Constitution provides for the right of everyone 'not to be subjected to medical or scientific experiments' unless the person gives his or her consent.

1491 S 71(2).

1492 S 71(3).

consent is required. As observed in chapter four, the NHA further provides for institutional oversight mechanisms, which include the NHREC[1493] and the RECs.[1494]

As observed in chapter four of the 2014 Health Research Regulations have been enacted in terms of the NHA. The Health Research Regulations outline several principles which, though appearing many at first sight, are substantially similar to those provided for in other legal instruments discussed below.[1495] The Health Research Regulations further provide for the protection of vulnerable participants, including children.[1496]

Another important legislation relevant to health research is the MSA), which creates SAHPRA.[1497] The MSA requires that medicines be registered with SAHPRA.[1498]

7.10.2.2 United States law

The main legal instrument in the US, the US Constitution, does not make express provision for the regulation of the conduct of research. This therefore leaves the potential litigants to rely on other provisions of the Constitution, including equality provision; liberty provision and due process provision. The absence of direct provision in the Constitution no doubt weakens the protection to be afforded to research participants, as it may not always be clear whether a particular constitutional provision is or is not applicable to research contents. However, as observed in chapter six, more specific legislation dealing with health research does exist.

In the US health research is, in addition to the National Research Act,[1499] mainly regulated under the Federal Policy for the Protection of Human Subjects (45 CFR 46 Subpart A) (the Common Rule).[1500] The Common Rule is applicable to research conducted, regulated or supported by a federal agency or federal department, or the federal agency or federal department takes steps to make the framework

1493 As observed in chapter four the NHREC deals with, amongst other things, the adjudication of complaints against RECs.
1494 RECs must be registered with the NHREC (see s 73(1) of the NHA).
1495 See Regulation 2 for these principles, some of which are outlined in chapter four.
1496 See Regulations 4.1 – 4.4.
1497 SAHPRA replaces the Medicines Control Council (MCC).
1498 S 15 of MSA.
1499 See the discussion of the National Research Act in chapter 1.
1500 HHS *Federal Policy for the Protection of Human Subjects ('Common Rule')*. Https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html (Accessed 14 June 2021).

applicable.[1501] The Common Rule is further equally applicable where the research is conducted outside the US government but funded by the government.[1502] Where participants are more vulnerable, the Common Rule requires that there be additional protections.[1503] The Common Rule does also provide for a waiver or alteration of consent under certain instances, including instances where the research serves public benefit purposes.[1504] Most importantly, as indicated in chapter six, the Common Rule prohibits an informed consent arrangement that exempts the investigator from liability.[1505]

In addition to the Common Rule the 45 CFR 46 Subpart D – Additional Protections for children involved as subjects in research (the 45 CFR 46 Subpart D) makes provision for added protections to children.[1506] In the main the 45 CFR 46 Subpart D grades the various types of research involving children, in terms of the level of risk involved to the child, in relation to the benefits expected to the child, production of generalisable knowledge and the understanding, prevention or alleviation of a serious condition involving the health and welfare of children.[1507] The greater the risk, the more stringent the requirements are.

In the case of a more than minimal risk research with direct benefits to the child, in particular, the anticipated benefits to the subject must justify the risks undertaken when compared to the benefits to accrue from the use of an alternative approach.[1508] It is important to note that in the various categories of the grading of these risks and benefits, the assent of the child to the research is required.[1509]

7.10.2.3 United Kingdom law

1501 §46.101(a) of 45 CFR 46 Subpart A.
1502 §46.101(a) of 45 CFR 46 Subpart A.
1503 § 46.111(a) (3). This provision could play an important role in the protection of children, including displaced children.
1504 § 46.116(e).
1505 § 46.116(a) (6).
1506 § 46.401 of the 45 CFR 46 Subpart D. For other instruments protecting children, see 45 CFR 46 Subpart B – Additional Protections for Pregnant Women, Human Fetuses and Neonates involved in research.
1507 See the discussion around the grading of these risks and benefits in chapter six.
1508 § 46.405.
1509 § 46.404; § 46.405(c); § 46.406(d) and § 46.407(b)(2)(iii).

The UK's relevant legislative framework includes the Care Act;[1510] the MCA;[1511] the Medicines for Human Use (Clinical Trial) Regulations (2004) (UK Clinical Trial Regulations)[1512] and the HTA.[1513]

7.10.3 General observation from the research oversight laws

The general observation to be gleaned from the research oversight legal frameworks from the three jurisdictions is that of the three jurisdictions only South Africa provides for more specific provision on health research issues and only in the case of informed consent, in its supreme law.[1514] In relation to case law, all the three jurisdictions have to date had limited litigations in the area of health research oversight, therefore not having sufficient case law to serve as precedent for future decision-making.[1515] In all the three jurisdictions, none of these cases have been decided at the highest level in each country's judiciary.[1516] In all the three jurisdictions these cases have, except for a few instances highlighted in the US case above, tended to use private law as a starting point, with very little reference to public law obligations.

The frameworks in the three jurisdictions provide for the protection of children participating in health research and do acknowledge the need for greater justification, and in some instances additional requirements, for the inclusion of children in research, depending on the risks and benefits expected.[1517] The issue of informed

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1510 The Act creates an institutional mechanism, including *the Health Research Authority (HRA),* one of whose functions is to facilitate the safe and ethical conduct of research (see s 110(2)(a) and (b)). This further includes ensuring that RECs do their work as required by the relevant policies (See s 112(3)(a) and (b)).

1511 The Act provides for the protection of persons who lack decision-making power. In the context of research it specifically prohibits intrusive research on persons who lack decision-making capacity, except where the intrusive research is conducted as part of an approved research project in terms of ss 31, 32, and 33 of the MCA (see s 30(1)(a) and (b)).

1512 The UK Clinical Trial Regulations, in the main, provide for an institutional oversight framework for health research, including the United Kingdom Ethics Committees Authority (UKECA), whose principal role is the establishment, recognition and monitoring of ethics committees (Regulation 5 (1) of the UK Clinical Trial Regulations). In particular, the UK Clinical Trial Regulations also set out, amongst other things, the conditions under which research involving minors should take place (Part 4 of Schedule 1 to the UK Clinical Trial Regulations).

1513 This Act regulates the use and storage and removal for use of human material and material of deceased persons, which must be done with appropriate consent (see s 1 of HTA).

1514 This point is certainly more relevant for South Africa and US, which have supreme laws, rather than the UK, which does not have a supreme constitution.

1515 Though the US has comparatively more cases than South Africa and the UK, none of the cases have yet reached the US Supreme Court.

1516 As earlier indicated none have reached, in the US case, its Supreme Court and in the South African and UK cases, the Constitutional Court and UK Supreme Court respectively.

1517 The NHA for example deals with this aspect by distinguishing between participation of children

consent is provided for in the three jurisdictions. In the three jurisdictions there is significant involvement of the RECs (IRBs) in overseeing the conduct of health research. None of the three jurisdictions make express provision for displaced children, therefore leaving such children to rely on the provisions applying to all children, and those applying to vulnerable persons in general.

Despite these apparent similarities within the legislative frameworks themselves, this does not mean that the application of the principles in the three jurisdictions will be the same. The application will be dependent on the other general legal principles discussed earlier, which themselves diverge. The question of who will be bound to apply these legislative frameworks may also create a basis for divergent application in different jurisdictions. In the US the application of the Common Rule, for example, is guided by whether the research was supported, funded or regulated by federal government or its agencies. This may leave a significant section of research participants unprotected. This means that some research might fall outside these frameworks. Though this is not the approach followed in SA, in the case of the UK it was observed in chapter 2 that when UKECA was established, it had its own standard operating procedures applicable (mainly if not only) to the NHS research, and reviewed by the NHS RECs.

Except for South Africa, which makes some provision for it in the Health Research Regulations,[1518] the issue of compensation for injuries during research is not clearly provided for in the legislation of the two other jurisdictions.[1519] Equally not clear is the issue of post-research benefits, i.e. to what extent is the researcher, or sponsor,

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In therapeutic research and in non-therapeutic research, and therefore setting additional requirements (in the form of Ministerial consent), for such participation (see s 71(3)(a)(ii), read with s 71(3)(b)). One should note here that one of the factors to be considered in granting such a consent includes where the reasons for agreement to the research by the parents or guardian or the child, if applicable, is contrary to public policy (see s 71(3)(b)(iii)). Absence of scientific understanding of the condition of the minor, which would result in the potential benefit to the minor or other minors, is also another factor to be considered (see s 71(3)(b)(ii)). One does also take note of MRC Children Guide (applicable to the UK), which discourages the use, in relation to research, of the concepts of 'therapeutic' and 'non-therapeutic' because of the overlapping nature of the research in both instances (see para 4.2 of MRC Children's Guide). Despite these concerns, one however still considers the concepts useful to provide clarity on the levels of justification needed, more especially in legal, rather than merely ethical, documents.

1518 See Regulation 2 (i) of the Health Research Regulations. Even in the case of South Africa, such a provision is only necessary in the case of more than minimal risk research.

1519 This aspect appears to have been left mainly to the ethical guidelines (at least for some jurisdictions).

obliged to provide benefits to those who partook in the research? On the payment of incentives for partaking in research, the UK law is clear on this,[1520] while the position in both the US and SA is not that clear (in their legislation).

On the implications of the above frameworks on the PLA, it has been observed that case law in the three countries provides very little guidance on the question of protection of research participants, more especially from the point of a public law approach. This, overall, weakens the PLA contemplated in this research. In relation to legislative and other related frameworks, the express provision for informed consent in the SA Constitution does go some way in fostering the PLA contemplated here. Though in general the legislative and related frameworks in the three countries do go some way in protecting health research participants, the absence of some health research-related provisions in the main frameworks (in the constitution in the US case, and in the ECHR in the UK case) weakens the PLA contemplated in this thesis. There is however no specific framework or provision dealing with the protection of displaced children partaking in research in the three countries. This therefore further weakens the PLA contemplated in this research.

7.11. Oversight under various ethical instruments

Apart from the legal framework above there are also instruments that do not necessarily have legal force but which have significant influence in shaping the direction of health research. In South Africa these include the SAMRC Guidelines; some guidelines of the HPCSA; the 2020 Clinical Trial Guidelines[1521] and the 2015 Ethics in Research.

As observed in chapter four, the SAMRC Guidelines provide for shared responsibility between researchers and RECs.[1522] The SAMRC Guidelines further provide for communication of the results to stakeholders.[1523] The SAMRC Guidelines further require engagement with communities where the research is conducted.[1524] The

1520 The UK Clinical Trial Regulations specifically prohibit payments to children as incentives, but do allow such if it is meant to compensate a person for loss or injury (see item 8 of Part 4 of Schedule 1 to the UK Clinical Trial Regulations).

1521 As stated in chapter 4, one does take note of the fact that compliance with the 2020 Clinical Trial Guidelines is stated to be compulsory, therefore implying its having legal force. Its inclusion under ethical guidelines is not considered to cause any damage to the discussion.

1522 Para 6.1 of SAMRC Guidelines.

1523 Para 5.5.7.

1524 Para 5.5.8.

SAMRC Guidelines could therefore be said to, in the main, foster the culture of transparency and community engagement. As indicated earlier, various guidelines from the Health Profession Council of South Africa (HPCSA) also exist.

The HPCSA's General Ethical Guidelines for Health Researchers (Booklet 13) (HPCSA's Booklet 13) provides for respect for the environment.[1525] It further provides for payment for injuries suffered during research;[1526] post-research treatment[1527] and insurance cover.[1528] Though discouraging payments as incentive for participating in research the HPCSA's Booklet 13 allows compensation for expenses or lost income.[1529] Another guideline, the HPCSA's Confidentiality: Protecting and Providing information (Booklet 5) (HCPSA's Booklet 5) in the main prohibits disclosure of information.[1530] Another ethical framework, the 2015 Ethics in Research, in the main, restates the four established bioethical principles.[1531]

As indicated earlier, another ethical instrument guiding health research is the 2020 Clinical Trial Guidelines. In addition to a number of principles that are, on the whole, similar to principles stated in the instruments above, the 2020 Clinical Trial Guidelines provide for the transparency[1532] and the continuous monitoring of the study.[1533] The 2020 Clinical Trial Guidelines further make provision for the payment of incentives to partake in research provided amongst other things that they do not unduly induce participants to partake.[1534] As observed in Chapter four the 2020 Clinical Trial Guidelines make provision for the payment of compensation for injuries during research only indirectly, by way of requiring insurance coverage by sponsors.[1535] The

1525 Para 12 of HPCSA's Booklet 13.
1526 Para 6.1.11 of the HPCSA's Booklet 13.
1527 Para 6.1.13 of the HPCSA's Booklet 13.
1528 Para 6.1.11 of the HPCSA's Booklet 13.
1529 Paras 6.1.12 and Para 6.1.10 of the HPCSA's Booklet 13.
1530 Disclosure may however be made under certain circumstances, including where there is public interest (see para 1.2 read with paras 3.1, 3.2, 3.2.3 and 8.2.2.5 of HPCSA's Booklet 5).
1531 Para 2.1 of the 2015 Ethics in Research. Most notably, the 2015 Ethics in Research provides a conception of respect for persons that includes not only respect for autonomy but also dignity (see Para 2.1 of 2015 Ethics in Research). This is the conception that the Clinical Trial Guidelines also follow.
1532 As indicated in Chapter Four this will mainly be through the publication, as well as release and reporting, of trial results (see paras 6.15 and 6.16 of the 2020 Clinical Trial Guidelines).
1533 Para 6.11 of the 2020 Clinical Trials Guidelines.
1534 Para 2.7 of the 2020 Clinical Trials Guidelines.
1535 Para 10.2 of the 2020 Clinical Trial Guidelines.

guidelines further make provision for the assent of children who partake in research.[1536]

Apart from the AMA Principles of Medical Ethics, which applies mainly to the doctor-patient relationship rather than specifically to health research contexts, the main ethical framework, short of legal status,[1537] is the Belmont Report. The principles from the *Belmont Report* are mainly respect for persons; justice and beneficence. These principles have influenced various other legal instruments, both in the US[1538] and elsewhere. These principles, overall, do protect health research participants. Informed consent is, for example, a key aspect of respect for persons; fair selection of research participants is a key aspect of the principle of justice and the management of risks and benefits is a key aspect of the principle of beneficence.

Regarding the UK, one of the critical instruments governing the ethics of research is the UK Governance Arrangements. The UK Governance Arrangements provide in the main for the independence of the RECs, including their composition.[1539] REC members are in particular required to maintain confidentiality.[1540] Members of the RECs must be indemnified from liability for the work they do.[1541] The UK Governance Arrangements further provide that the interests of the patients should not be subsumed by those of science and society as a whole.[1542] An REC does not have to review the

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1536 Para 3.2.5.2 of the 2020 Clinical Trials Guidelines.

1537 One does not however claim that the principles in the Belmont Report have not been given legal teeth, whether in the US or elsewhere, but merely that the Report itself is not a product of a legislative framework, at least in a direct sense (indirectly it does have some roots in the *National Research Act of 1974*, which made provision for the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research that produced the report) (see Schindelholz K ''How the National Research Act of 1974 Enhanced Trial Safety'' (2019) https://www-imarcresearch-com.cdn.ampproject.org/v/s/www.imarcresearch.com/blog/the-national-research-act-1974?am (Accessed 1 November 2021). Also see HHS ''The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research''. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html (Accessed 1 November 2021).

1538 For example, the Common Rule discussed above does also provide for instances where a research might not follow the procedures in the Common Rule, but that such alternative procedures must at least be consistent with the principles in the Belmont Report (see §46.101 (i) of the 45 CFR 46).

1539 Paras 3.2.6, 3.2.7 and 4.2.1 – 4.2.4.

1540 Para 4.3.11.

1541 Para 4.3.12.

1542 Paras 3.2.1 and 3.2.2.

science of the study.[1543] Public health could serve as the basis for an expedited review of a study.[1544]

As observed in chapter 5, the PHASE I Guidelines is another important instrument dealing with the ethics of research in the UK. Apart from the standard provisions dealing with approvals by RECs, it also provides for guidelines on the payment of compensation for injuries during research.[1545] It also provides for the payment of incentives for partaking in research.[1546] Most notably it excludes oncology patients from the payment of compensation for injuries during research.[1547] As further observed in chapter five there are, with respect to Phase 1 trials, also compensation guidelines, namely Phase 1 Compensation Guidelines. Under the Phase 1 Compensation Guidelines sponsors are obliged to compensate both healthy and patient volunteers, without the claimant having to prove negligence.[1548] Compensation guidelines further exist for the other phases of the clinical trials, namely the Phase II, III and IV Compensation Guidelines, which in the main merely recommend, without legal commitment, the payment of compensation for injuries arising from the study.[1549]

A further ethical instrument applicable to the UK is the MRC Children's Guide, published under the UK's Medical Research Council. Apart from the more common provisions dealing with health research, the MRC Children's Guide provides for the security screening of those who work with children.[1550] It further provides for the need to obtain informed consent on a continuous basis.[1551]

The general observation from the various ethical instruments above is that the guidelines in the three jurisdictions do at least provide for the established biomedical principles like beneficence; non-maleficence; justice and respect for persons, even if formulated in different styles. The three jurisdictions also make clear provision regarding oversight by RECs (IRBs). Both SA and the UK have provision for payment of compensation for injuries during research.[1552] This position is however not clear in

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1543 Para 5.4.2 (a).
1544 Para 5.5.1.
1545 Para 19.1.
1546 Para 19.2.
1547 Para 19.1 of ABPI PHASE 1 Guidelines.
1548 Para 1 of the Phase 1 Compensation Guidelines.
1549 Para 1 of the Phase II, III and IV Compensation Guidelines.
1550 Para 5.4 of the MRC Children Guide.
1551 Para 1.3 of the MRC Children Guide.
1552 Under the 2020 Clinical Trial Guidelines this is done only indirectly through the provision of

the US frameworks. Some instruments in both the UK and SA do clarify the issue of payment as incentive for partaking in research, while the US instruments are silent on this.

None of the instruments, in the main, clearly provide for post-research benefits.[1553] Although the various instruments in the three jurisdictions do provide for consent of another person with capacity in case of a research participant who lacks capacity, the Belmont Report simply speaks of the consent of a third party in such a situation, without clarifying who will qualify to be such a consenting third party. This could create room for abuse.

Lastly, none of the instruments in the three jurisdictions make express provision for the protection of displaced children, therefore leaving these children to rely on other more general provisions protection vulnerable persons.

The various instruments have some implication for PLA framework contemplated in this research. While these various ethical instruments do go some way in providing protecting for health research participants, including children, the absence of post-research benefits provision could undermine the PLA contemplated in this thesis. Equally likely to undermine the PLA framework is the absence of express provision for the protection of displaced children who participate in health research.

The emphasis in some instruments, including the UK Governance Arrangements that the interests of the patient are above those of science and society could be problematic in some instances, most especially where research has to be conducted during pandemics, where the interests of science and society could sometimes be more important than those of the individual research participant. The UK Governance Arrangements' provision, however, that public health could serve as the basis for an expedited review[1554] is very critical in supporting the PLA contemplated in this research.

7.12 Conclusion

insurance cover (see Para 10.2 of the 2020 Clinical Trial Guidelines).

1553 One is however aware of an isolated talk of 'post-research treatment' in the HPCSA's Booklet 13, which could broadly be interpreted to be part of post-research benefits (see Para 6.1.13 of the HPCSA's Booklet 13).

1554 Para 5.5.1.

This chapter had to provide a comparative analysis of the approaches adopted by the countries subject of comparison in this research, namely SA, the UK and the US. As indicated in the introduction, the key areas of comparison include the general legal theory of each country; the approaches to the protection of children; approaches to human dignity; approaches to equality protection; approaches to judicial review; approaches to remedies; approaches to health care; approaches to privacy and access to information and approaches to health research oversight, both under the legal and ethical frameworks.

The general observation, regarding the general legal framework, is that the three countries have fundamental differences, and these differences could inform the way the rest of the laws are applied. South Africa, it was observed, is a unitary state founded on constitutional supremacy while the US, though also founded on a constitutional supremacy, is a federal state. The UK though sometimes referred to as a unitary state,[1555] is a union founded mainly on parliamentary supremacy. Being unitary could, bar other factors, encourage uniformity in the legal system, while being a federal state could create fragmentation within the system. British unionism could arguably have the same problem of fragmentation as in federalism. The most fundamental aspect, with far-reaching implications for the implementation of the rest of the laws is however the contrast between parliamentary supremacy and constitutional supremacy. This has an impact on the nature of the judicial review that each country has, with countries adopting a system of constitutional supremacy more likely to invalidate legislations and other decisions of the other branches of government while those adopting, as the UK does, the system of parliamentary sovereignty more likely to show deference (respect) towards the other branches. These overarching differences may further influence the way the rest of the laws are interpreted.

South Africa's inclusion of socio-economic rights in its constitution has also been highlighted, and such inclusion strengthens the protection of health research participants, and the PLA framework contended for in this thesis. On the contrary, the non-inclusion of a socio-economic rights focus in the US Constitutional project may weaken protection to health research participants. It may further weaken the PLA framework proposed in this research. The UK's ambiguous approach on these

1555 Jackson and Jackson *An Introduction to Political Science* 211.

questions, partly due to lack of a written constitution, will not assist in advancing protection to health research participants and the PLA framework contended for in the thesis.

It has also been shown that South Africa's key legal frameworks, including both the Constitution and some legislation,[1556] apply both vertically and horizontally. Frameworks in both the US and the UK tend to place obligations principally on the state and other public authorities.[1557] Further, while South Africa expressly provides for human dignity in both its constitution[1558] and some legislation,[1559] the UK and US do not have any provision for that in their main laws (though, as discussed earlier, the US does recognize it under torts in its common law).[1560] Given the centrality of human dignity in health research, this approach by the UK,[1561] and to some extent the US, significantly weakens the protection of health research participants and the PLA framework pursued in this research.

As regards legal standing, it has been observed that while SA allows a public interest approach to litigation when rights in the Bill of Rights have been threatened, it still retains the more limiting common law approach where no allegation of infringement of rights is pleaded (the latter approach means that the affected individual is the one mainly to pursue the matter).[1562] The US also takes a mixed approach, where public interest has been allowed in some cases but disallowed in others.[1563] The UK's approach to standing is also mainly centred around the victim of the alleged unlawful act, and therefore not public interest-based.[1564] This means that, on the whole, the

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1556 PAIA is one such example.

1557 As indicated above, both the Privacy Act and the FOI Act, in the US and UK respectively, mainly apply to public authorities.

1558 S 10.

1559 As indicated above, PEPUDA is one of the legislations also recognizing human dignity.

1560 As indicated above, this does not mean that there are no instances where human dignity may be relied on. As discussed above, the US has also used human dignity based on other provisions in its Constitution.

1561 As indicated earlier, this does not mean that there is no casual reference to human dignity at all. For some reference to human dignity, also see *Campbell v MGN Ltd* [2004] UKHL 22*;* [2004] 2 AC 457 para 50, as cited in *Lloyd v Google* LLC [2021] UKSC 50 para 97.

1562 Hoexter *Administrative Law in South Africa* 488.

1563 *Carey v Population Services International* 431 U.S. 678 (1977) para 1 and *California, et al., Petitioners v Texas, et al.,* 593 U.S. (2021) para 2, where in the latter case claimant was required to have a traceable injury to be able to pursue the matter.

1564 S 7(1)(b) of the HR Act, read with art 34 of the ECHR. As indicated earlier, though there is room for representative actions in UK law, the position regarding class actions is by no means clear. For a discussion of collective actions see *Lloyd v Google* LLC [2021] UKSC 50 paras 3 and 24 – 83.

three jurisdictions, with the exception of SA in the case of alleged infringements of rights in the Bill of Rights, still retain a very limited approach to legal standing and therefore weakening the PLA framework contended for in this research.

As observed above, although both SA and the UK have clear frameworks dealing with the protection of children, the UK does not use a rights language in this regard. The absence of a rights' language could weaken the protection for children and the PLA framework proposed in this thesis. The US position is even more problematic, as the country does not have any express provision protecting children in the Constitution, nor does it have a dedicated legislation on this. The three countries do not have any clearly defined framework providing for the displaced children. This weakens the protection to be afforded to children as well undermining the PLA framework proposed in this research.

It has also been observed that not enough cases have been decided in the three countries, dealing with health research issues. Of these very few decided cases none of them, except for some isolated instances indicated above, focused on public law. None of these cases were decided at the highest level of each of the country's judiciary. The preoccupation with private law approach undermines the PLA framework proposed in this research. The legislative and other related frameworks have however been found to go some way in protecting health research participants. This however depends on whether and how they will be used in practice.

Lastly, it can be concluded from the above discussion that the three countries, South Africa in particular, do have some laws capable of protecting health research participants if properly applied. Some of the laws do foster the PLA framework pursued here. However, none of these laws have yet to be applied in a litigation involving health research context. The next chapter examines international and regional laws governing health research.

CHAPTER EIGHT: INTERNATIONAL LEGAL POSITION

8.1 Introduction

Chapter seven dealt with the overall analysis of the comparison between SA, the UK and US legal positions. This chapter looks at the international legal position, including the regional legal positions[1565] covering the African, European and the Inter-American positions.[1566] Both the general and specific laws impacting on health research are reflected on. It starts off by reflecting on the general theory of international law. It then looks at the approaches of both the regional and international positions towards specific areas relevant to health research. The general observation arising from the approaches of various instruments towards an aspect relevant for health research is then made, followed by the reflection on the implication, for health research, of the approaches by the various instruments. The approach of the various instruments, legal and ethical, towards research oversight is then reflected on. This is followed by the overall chapter conclusion. Although international law proper generally does not include international ethical instruments entered into with no intention to give them legal force, this chapter does also cover such instruments.

8.2 International law's general theory and framework

In the discussion of the various laws of the three countries under comparison, in chapters four to six, the general legal framework of the three countries had to be examined as a starting point. This approach is equally fitting in the case of the discussion of international law, where its general framework needs some brief reflection. This general framework will be useful in the understanding of the possible place of international law in the regulation of health research.

One of the most important principles of international law is the freedom of contract, as expressed through a number of principles, including free consent, good faith and the principle of *pacta sunt servanda*, as used in relation to treaties.[1567] Related to the

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1565 Though international law also includes regional legal positions, for the sake of clarity one here, unless the context indicates otherwise, uses the concept of international law to mean intercontinental law, while using regional law to mean continental law.

1566 Unless the context indicates otherwise, the discussion of the international instruments in this chapter generally focuses on those instruments that were created after the World War II.

1567 Art 26 of, and the preamble to, the Vienna Convention on the law of treaties (1969)

freedom of contract is international law's approach to interpretation. About interpretation, international law interpreters have to take context, object and purpose into account when interpreting treaties.[1568]

Another area of critical interest of international law is the general approach to limitations of rights in the various international instruments.[1569] The general approach of various international legal instruments is to infuse the limitations within specific articles (internal qualifiers), rather than a one-size-fits-all approach where a single limitations clause applies to various provisions.[1570] However, despite the various provisions having their own internal limitations, these criteria (or conditions) for the limitations share some similarities.[1571] This approach (of having only internal qualifiers) creates some problems in that where there is no general limitation clause and some provisions do not have any express internal limitations, it makes it unclear whether or not such provisions should be treated as absolute.[1572]

(The 1969 Vienna Convention). Further see art 26 of, and the preamble to, the as yet to come into force, Vienna Convention on the law of treaties between States and International organizations or between international organizations (1986) (the 1986 Vienna Convention).

1568 Art 31 of the Vienna Convention on the Law of Treaties (1969) (The 1969 Vienna Convention). Also see art 31 of the 1986 Vienna Convention. Further interpretative framework is also given in the various international instruments not specifically dedicated to questions of interpretation. For example, art 29 of the American Convention on Human Rights (ACHR) prohibits interpretations that unduly restrict the enjoyment of the rights in the Convention or in the American Declaration for the Rights and Duties of man (1948).

1569 It should be noted that human rights talk has been the central feature of the post-World War II international law, so the focus on the limitations here already assumes this centrality of human rights (also see Dugard J *International law: A South African perspective* 2nd ed (Juta Cape Town 2000) 234.

1570 However, while ICCPR takes this approach, the ICESCR takes a slightly different approach, where it provides for the general limitation clause, with only some isolated internal qualifiers. Art 4, for example, provides for the general limitation clause whose conditions are that there must be a law, the limitations must be compatible with the nature of the rights being limited and that the limitations must solely promote general welfare in a democratic society. In the case of the internal qualifier, one isolated provision for that is in art 8(2), which provides for restrictions in the context of strikes. Further see the UN Convention on the Rights of the Child (CRC), which also uses internal qualifiers (art 10(2) of the CRC provides for such limitations).

1571 The common thread in these limitations is that the limitation must be in terms of a law; must be necessary in a democratic society; must be in the interest of national security; must be for the promotion of public health; must be in the interest of public safety; must be in the interest of public order; must be in the interest of the maintenance of morals; and must be for protection of the rights and freedoms of others. See, for example, also arts 11 and 12(b) of ACHPR, which have related justifying conditions. Also see the American Declaration of the Rights and Duties of Man (American Declaration) which, with a general limitations clause, provides for justifying conditions such as compatibility with the rights of others; assurance of security for all; promotion of general welfare and the promotion of democracy (see art xxviii). Some of these limitations, when read with art xxix, which emphasizes the duty towards others when exercising one's rights, could arguably be said to promote the PLA framework contemplated in this thesis.

1572 Arts 2 and 3 of the ICCPR (both touching on equality issues), for example, do not have internal

A further aspect requiring critical focus is the general approach of international law on issues of public interest. In the case of regional instruments, the ACHPR provides for common interest and the principle of solidarity in the exercise of individual rights in that the rights of others, collective security and common interest must be considered in the exercise.[1573] In the case of the Inter-American region the Charter of Organisation of American States (COAS) refers to the 'common welfare and prosperity of the peoples of the continent' as one of the objects of economic cooperation.[1574] In the case of the European Continent, and European Union in particular, some of the rights in the CFREU are built around the principle of solidarity, an aspect important in the consideration of public interest.[1575] Even in the case of other international legal instruments, the nature of the justifying conditions, at least in relation to some rights as not all provisions have some limitations, do to some extent take a public interest angle.[1576]

The general observation about international law's general legal framework or theory is that although it does respect a strong focus on individual rights, this is also counterbalanced by the consideration of common interests.[1577] If approached this way in practice, it may enhance protection of the participants in health research.

8.3 The approach to the protection of children

8.3.1 Regional instruments

limitations while arts 12; 19, 21 and 22, for example, have such limitations. It sounds absurd to think that there would be no instances where arts 2 and 3 could be limited, i.e. that there could be no justified partiality offending these provisions under certain circumstances.

1573 Art 27(2) of the ACHPR. Also see art 29(4), which also provides for 'social and national solidarity'. Further see Art 31(c) of the ACRWC, which provides for a child to foster 'social and national solidarity'.

1574 Art 3(k) of COAS. Further see art 3(j), which provides for social security and social justice as the basis for lasting peace. This approach arguably tends more towards public interest. Further note that in the case of the limitations under CFREU, these may only be made if they 'are necessary and genuinely meet objectives of general interest recognized by the Union…' (art 52(1)). Further see art xxix of the American Declaration, which provides for every individual to have duties towards society.

1575 Chapter IV of CFREU, covering arts 27 to 38, which is headed 'solidarity'.

1576 For example, the limitation clause in art 4 of the ICESCR, which provides for rights to be limited only for the promotion of 'the general welfare in a democratic society', could be interpreted as supporting the notion of public interest.

1577 This, as observed earlier, is mainly evidenced by the rights limitation's framework provided by various international instruments, and the language used in some instruments (including the usage of concepts of solidarity, general welfare, etc., as earlier reflected on). This balancing approach is consistent with the PLA framework contended for in this dissertation.

On the Inter-American front the American Declaration provides for the protection, care and aid to children.[1578] The ACHR makes provision for the special protection of children, guided by a child's condition as a minor.[1579] For the African front the ACHPR also makes provision for the protection of children, alongside women.[1580] The AU Displaced Persons Convention also requires states parties to provide special protection to displaced persons, especially children and mothers of young children.[1581]

An instrument more dedicated to children's rights on the African continent is the ACRWC). The ACRWC in the main emphasises the principle of best interest of the child.[1582] The ACRWC further emphasises the principle of child participation in decisions concerning the child which will, depending on the context in which his or her views are sought, mainly be in the form of the child's assent.[1583] The ACRWC also makes provision for the special protection of handicapped children, which takes account of their special needs.[1584] The ACRWC also makes provision for the prohibition against torture and child abuse.[1585] The ARCWC further protects a child against harmful social and cultural practices, including those endangering a child's health or life and those that are discriminatory.[1586] It further makes provision for the protection of refugee children and those internally displaced, who must receive appropriate humanitarian assistance, based on the rules of international humanitarian law.[1587] The ACRWC further provides for every child to have 'the best attainable state of physical, mental and spiritual health'.[1588]

1578 Art vii, read with art xxx, of the American Declaration. Although this is more of a moral than a legal framework, it has been generally referred to in other instruments of a legal nature, therefore warranting some inclusion here (see, for example, the reference to it in the Preamble to the Anti-Racism Convention). One should also note the provision for the protection of those who seek asylum, which could arguably be useful in the protection of displaced children (see art xxvii).

1579 Art 19. Also note art 3, which grants juridical personality to all persons, i.e. to be treated as persons before the law. It is unclear whether this should start at conception, or whether before that. Further note art 4 and its implications in the context of the rights of unborn children, as the article only protects the right to life at conception.

1580 Art 18(3) of the ACHPR.

1581 Art IX (2)(c).

1582 Art 4(1) of ACRWC.

1583 Art 4(2).

1584 Art 13(1).

1585 Art 16(1).

1586 Art 21(1)(a) and (b).

1587 Art 23(1) and (4), read with art 22(1).

1588 Art 14(1) read with art 14(2).

On the European front CFREU provides for the protection and care of children.[1589] CFREU further provides for child participation in decisions concerning a child, including the right of the child to express his or her views freely.[1590] CFREU also provides for the consideration of the best interest of the child principle, whether by public authorities or private institutions.[1591]

8.3.2 International instruments

The UDHR provides for the giving of special care and assistance to children and mothers and, in the case of children, without regard to whether or not a child was born out of a wedlock.[1592] The ICCPR also makes provision for the protection of children, taking into account their level of minority, without discrimination based on a number of factors, including race, sex and property status.[1593]

Another instrument, the ICESCR provides for the special protection of children against social and economic exploitation.[1594] The ICESCR further provides for states parties to take steps necessary to reduce the stillbirth rate and infant mortality and those necessary for a child's healthy and better development.[1595] Another instrument, the CEDAW, provides for equality between men and women, and provides for the same rights and responsibilities for men and women as parents, in relation their children, irrespective of their marital status.[1596] In all such instances the best interests of the children are paramount.[1597] The UNGIDP makes provision for the special consideration of displaced children and displaced mothers with young children, who need special protection and assistance.[1598]

An international instrument wholly dedicated to the protection of children is the UN CRC. The CRC restates the consideration of importance of the best interest of the child principle in all matters involving the treatment of the child.[1599] The CRC makes provision for child participation in decision-making concerning the child, which will

1589 Art 24(1).
1590 Art 24(1).
1591 Art 24(2).
1592 Art 25(2) of the UDHR.
1593 Art 24 (1).
1594 Art 10(3) of ICESCR.
1595 Art 12(2)(a).
1596 Art 16(1)(d) of CEDAW.
1597 Art 16(1)(d).
1598 Art 4(2).
1599 Art 3(1). Also see art 18(1).

often be in the form of child assent.[1600] The CRC further protects the child against all forms of violence and abuse.[1601] The CRC also provides for humanitarian assistance or protection to a child refugee or those seeking a refugee status, and such assistance or protection should be in accordance with international human rights law or international humanitarian law.[1602] The CRC also provides for special protection for disabled children.[1603]

8.3.3 General observations

All the three regions discussed have some general framework dealing with the protection of children, with the African continent having a special convention dedicated to children, though not specifically dealing with health research issues.[1604] These instruments, in particular the European and African regional instruments, provide for the consideration of the best interest of the child, as well as child participation when dealing with issues concerning a child.[1605] At inter-continental level the CRC also does make provision for the consideration of the best interest of the child. Although the African continent is the only one with a more specific instrument dealing with displaced persons[1606] the European and Inter-American regions do have provisions related to refugees, whose principles are adaptable to situations of displaced children. At international level there is also a specific framework dedicated to displaced persons, though not directly dealing with health research issues.[1607]

8.3.4 Implications for health research

Although principles like 'the best interest of the child' standard are generic in nature, they will be useful in the protection of children partaking in health research. Equally important is the principle dealing with child participation. Principles around the protection of displaced persons, including those calling for the use of international

1600 Art 12(1).
1601 Art 19(1). Also see arts 34 and 36, protecting a child from various forms of exploitation. Further see art 37, protecting a child against torture and inhuman, cruel or degrading treatment.
1602 Art 22(1).
1603 Art 23.
1604 One does however also take note of the more specific PANDRH's Paediatric Guide, which applies on the inter-American continent and is reflected on under research oversight below.
1605 Note art 24(1) of CFREU and art 4(2) of ACRWC.
1606 Namely the AU Displaced Persons Convention.
1607 The UGIDP.

human rights law or international humanitarian law, will also be useful in the protection of displaced children partaking in health research.[1608]

8.4 Approach to human dignity

8.4.1 Regional instruments

On the inter-American front, the ACHR provides for respect for human dignity.[1609] The American Declaration also refers to human dignity in its Preamble. Another instrument, the Inter-American Convention Against Racism, Racial Discrimination and Related Forms of Intolerance (Anti-Racism Convention), though dedicated to issues of racial discrimination, also does provide for human dignity in the context of discrimination.[1610]

On the African continent the ACHPR also makes provision for respect for human dignity, including prohibition against torture and inhuman, cruel or degrading treatment or punishment.[1611] The African Women's Protocol also provides for women's right to human dignity.[1612] In addition to the right to life, the African Women's Protocol also provides for the right to security and integrity of a person, including the right not to be treated or punished in an inhuman, degrading or cruel manner.[1613] This framework further includes the prohibition of the conduct of medical or scientific experiments without a woman's (data subject's) consent.[1614]

In relation to displaced persons the AU Displaced Persons Convention[1615] also provides for respect of their human dignity, alongside the principle of humanity.[1616] On

1608 Also see art 22(1) of the CRC and art 23(1) and (4), read with art 22(1), of the ACRWC.

1609 Art 5(2) of the ACHR. This should be read with art 11 which, though specifically dedicated to privacy does also touch on human dignity. This is evidence of the inherent connection between privacy and human dignity. For the provision for human dignity, further see art 45(a) of COAS.

1610 See the Preamble to the Anti-Racism Convention, which reaffirms the importance of human dignity as provided for in other international instruments. Further see the Preamble to the Inter-American Convention to Prevent and Punish Torture, which also reaffirms the relationship between prevention of torture and respect for human dignity.

1611 Art 5 of the ACHPR. Further see the Preamble to, and art 21 of, the ACRWC, which also recognize respect for human dignity.

1612 Art III of the African Women's Protocol.

1613 Art IV.

1614 Art IV(2)(h).

1615 Although the Convention is sometimes referred to as the Kampala Convention, the concept of AU Displaced Persons Convention will be used here.

1616 Art III(1)(c). Also see art IX(2)(a).

the European front CFREU also provides for respect for human dignity, which it considers 'inviolable'.[1617]

8.4.2 International instruments

On questions of human dignity, the CUN sets the tone in its preamble, which expressly provides for respect for the 'dignity and worth of the human person'. The UDHR also makes provision for the respect for human dignity.[1618] Another international instrument, the ICCPR, also provides for respect for human dignity and humanity in the treatment of those whose liberty has been deprived.[1619] The ICCPR, in the context of health research, prohibits the conduct of medical or scientific experiments without a data subject's 'free consent'.[1620] The UNGIDP also provides for the respect of human dignity when persons are internally displaced.[1621] The ICERD, though mainly dedicated to issues of racial discrimination, also does touch on respect for human dignity.[1622]

8.4.3 General observations

The common thread above is that that all the three regions have frameworks providing for human dignity. So is the inter-continental framework. Some instruments like the African Women's Protocol and the ICCPR even go to the extent of linking this human dignity (or related provisions) to the context of health research.[1623]

8.4.4 Implications for health research

1617 Art 1 of CFREU. Also see art 3, which deals with respect for the integrity of a person. Further see art 4, which deals with the prohibition against torture and inhuman or degrading treatment or punishment.

1618 Art 1 of, and the Preamble to, the UDHR. Further see art 5, which deals with the related issue of prohibition of torture and inhuman and degrading treatment or punishment. Also see the CRC, which also makes provision for human dignity (see the Preamble to the CRC). Further see the UN Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (1984), which also refers to human dignity in its Preamble.

1619 Art 10(1). Further see the Preamble to the ICCPR which further restates the position of the UN Charter regarding the importance of human dignity, which it considers inherent.

1620 Art 7 of the ICCPR.

1621 Para 8 of UNGIDP. Further see para 11(1) and (2)(a). To fortify respect for human dignity, UNGIDP further provides for informed consent to be sought from those displaced, in case there is displacement other than during emergencies, armed conflict or disasters (para 7(3)(c)). Further see provision for a related principle, the principle of humanity, as provided for in para 24(1).

1622 See the Preamble to ICERD. This is an approach CEDAW also takes (see the Preamble).

1623 Art IV(2)(h) of the African Women's Protocol and art 7 of the ICCPR.

Because of the centrality of human dignity in health research, the provision for it in various instruments will be critical in enhancing the protection of health research participants. This equally goes some way in promoting the PLA contemplated in this research. The problem though is that, as observed in chapters 4 to 6, these principles have not been relied on in case law dealing with health research.

8.5 Approach to equality

8.5.1 Regional instruments

On the Inter-American front the COAS prohibits discrimination on the basis of race, creed, sex and nationality.[1624] Another instrument, the American Declaration, also provides for the prohibition of discrimination on a number of grounds, including race, creed, sex, language, and 'any other factor'.[1625]

The ACHR places obligations on states parties to treat all persons equally based on race, sex, social condition, economic status and other related factors.[1626] An instrument more dedicated to non-discrimination issues on the Inter-American continent is the Anti-Racism Convention.[1627] Most importantly, the Anti-Racism Convention prohibits the conduct of research, or application of research findings, in ways that undermine human rights and dignity and discriminate on the basis of genetic characteristics.[1628]

Another related instrument, the American Anti-Discrimination Convention, does not only focus on racial discrimination but also on other categories of discrimination. The American Anti-Discrimination Convention prohibits discrimination on several grounds, including sexual orientation; refugee status; internal displacement status; stateless status; generic traits and health condition.[1629]

1624 Art 3(l) of COAS. Also see art 45(a) of COAS.

1625 Art II of the American Declaration.

1626 Art 1, read with art 24.

1627 Art 1(1) of Anti-Racism Convention.

1628 Art 4(XIII).

1629 Art 1(1) of the American Anti-Discrimination Convention. The breath of these grounds of prohibition represents a departure from the narrow approach followed in most instruments, both at domestic and international level. The specific prohibition of discrimination against internally displaced persons is also unique in instruments not specifically dedicated to displaced persons (also see Nogueira MB "New OAS Conventions protecting IDPs against racism and discrimination'' (2014) *FMR Online*. https://www.fmreview.org/crisis/nogueira (Accessed 10 November 2021). Just like the Anti-Racism Convention, the American Anti-Discrimination

As observed in chapter five, on the European front the ECHR also prohibits discrimination on several factors, including race, colour, language and property status.[1630] CFREU also provides for equality and non-discrimination.[1631]

On the African continent the ACHPR prohibits a discrimination on a number of factors, including race, colour, ethnic group and sex.[1632] The African Women's Protocol takes the ACHPR's vision with regard to the protection of women further. The African Women's Protocol provides, in the main, for the elimination of all forms of discrimination against women in all spheres of life, including social, political and cultural spheres.[1633] Women should also be treated equally with men under laws protecting refugees, including giving them full protection as provided for under international refugee law.[1634] Women in armed conflict situations, including internally displaced persons, must also be protected against violence and sexual exploitation.[1635] Women must also be protected against harmful practices, including social and cultural practices.[1636] In the context of displaced persons the AU Displaced

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Convention also prohibits the conduct of research or application of research findings in ways that are discriminatory based on genetic characteristics and that undermine human rights and human dignity (see art xiii). The American Anti-Discrimination Convention, just like the Anti-Racism Convention, further provides for justified partiality, in the form of affirmative action measures, provided the measures do not create separate categories of rights and are discontinued once their stated purpose has been served (Art 1(4). For affirmative measures under the Anti-Racism Convention, see art 1 (5) of the Anti-Racism Convention)).

1630 Art 14. It is interesting to note that this provision's formulation is not substantially different from the formulation in the ICCPR. One should further note here that sexual orientation is not listed as one of the prohibited grounds of discrimination, nor is it in any provision in the ICCPR.

1631 Arts 20, 21 and 23. What is notable in the list of prohibited grounds of discrimination in art 21 is the inclusion of the ground of sexual orientation, which is generally absent in other major instruments. Further notable is the inclusion of 'genetic features' as one of the prohibited grounds of discrimination, a ground also generally absent in most other key instruments.

1632 Art 2 of the ACHPR. Discrimination based on sexual orientation is however not expressly included. Given that some countries in Africa, including Uganda, are notably opposed to the protection of homosexuals, one cannot easily think that such inclusion could be implied (see for example, Uganda Report of Violations based on Gender Identity and Sexual Orientation (2015). https://outrightinternational.org/sites/default/files/15_02_22_lgbt_violations_report_2015_final.pdf (Accessed 25 November 2021). (As to general prejudice on this even in other continents, also see the Preamble to the American Anti-Discrimination Convention which provides, 'alarmed by the surge in hate crimes motivated by gender, religion, sexual orientation, disability and other social conditions…'). Further see arts 3, 18(3), 19 and 28 of the ACHPR. Further note the African Charter on the Rights and Welfare of the Child (1990) (ACRWC), which also provides for prohibition of discrimination on similar or related grounds as those in the ACHPR, but in this case mainly in relation to the children's parents or legal guardians (see art 3 of the ACRWC).

1633 Also see art II of the African Women's Protocol. Further see art VIII, read with IX.

1634 Art IV (2)(k).

1635 Art XI (3).

1636 Art V, read with art II (2), of the African Women's Protocol.

Persons Convention also provides for non-discrimination and equality before the law.[1637]

8.5.2 International instruments

As observed in chapter one, the more generic CUN provides the starting point on questions of non-discrimination and equality.[1638] Another instrument, which also deals with the issue of non-discrimination is the UDHR, which prohibits discrimination on the basis of some factors, including race, language, sex and property status.[1639] It further provides for equality before the law.[1640]

As briefly highlighted in chapter one, the ICCPR requires states parties to it to ensure the protection of persons within their jurisdiction, without discrimination based on a number of grounds, including race, colour, nationality and sex.[1641] Another instrument, the ICESCR takes a similar line and prohibits discrimination on a number of prohibited grounds including race, sex and property status.[1642] The ICESCR further provides for equality between men and women.[1643]

Another instrument, the CRC, prohibits discrimination against a child based on certain characteristics related to the child's parents or legal guardians, including race, colour, sex, property status, expressed opinion, etc.[1644]

An international instrument mainly dedicated to the provision of discrimination is ICERD, but which mainly focuses on racial discrimination. The instrument's prohibition of racial discrimination includes the prohibition of the propagation of ideas or theories based on racial stereotypes.[1645] ICERD's framework includes prohibition of discrimination in the provision of the enjoyment of rights, including the right to public health and medical care.[1646] ICERD makes provision for justified partiality, through the

1637 Art III (1)(d). Also see arts IV (4)(a), V (1) and IX (1)(a) and (2)(a).
1638 Preamble to, and art 1(2) and (3) of, the CUN.
1639 Art 2 of the UDHR. Further see art 4, dealing with the prohibition of slavery.
1640 Art 7.
1641 Art 2(1) of the ICCPR. Further see art 3, which provides for the equality of men and women. Further see art 14 (1) which provides for the equality of all persons before the courts or tribunals. Further see arts 24 (which prohibits discrimination in relation to children), 25 and 26.
1642 Art 2(2) of ICESCR.
1643 Art 3.
1644 Art 2(1) and (2) of the CRC. Also see art 30.
1645 Art 4 of ICERD.
1646 Art 5(e)(iv).

provision for affirmative measures, provided the measures do not create separate categories of rights (for different groups) and the measures are discontinued once their stated objectives have been achieved.[1647] Another related instrument, CEDAW, promotes non-discrimination against women, and for their equality with men, in various spheres of life including the political, cultural, economic, social and civil spheres.[1648]

In the context of displacements, the UNGIDP prohibits discrimination against displaced persons.[1649] The UNGIDP places the inclusion of women in decision-making at the centre.[1650]

8.5.3 General observations

Discrimination is prohibited in all the three regions, and at inter-continental level. Instruments in the Inter-American[1651] and European[1652] continents further provide for the prohibition of discrimination based on sexual orientation. However, outside the Inter-American and European continents the general trend appears to be to avoid express prohibition of discrimination based on sexual orientation, in both the regional[1653] and intercontinental instruments.[1654]

8.5.4 Implications for health research

While the general provision for prohibition of discrimination in all the three regions and at inter-continental level does go a long way in protecting health research participants,[1655] including displaced children,[1656] the general absence in these

1647 Arts 1(4) and 2(2). This is an approach CEDAW also adopts (see art 4(1)).

1648 Arts 1, 2 and 3 of CEDAW.

1649 See para 18(2), which prohibits discrimination in the provision of some basic services. Further see para 19(1), which prohibits discrimination in the provision of medical care on grounds other than medical grounds. Further see para 24, providing for humanitarian assistance to be provided in due consideration to the principles of impartiality and humanity and without discrimination. Further see para 22. Also see para 4(1), which prohibits discrimination on a variety of grounds, including race, property status and sex.[1649]

1650 Para 18(3).

1651 Art 1(1) of the American Anti-Discrimination Convention.

1652 Art 21(1) of CFREU. Also see the prohibition of the processing of special personal data, including information about sexual orientation, in the context of the protection of personal data in terms of art 9(1) of the GDPR.

1653 Not even the African Women's Protocol, dedicated to women issues, makes express provision for it.

1654 Not even CEDAW, at least more dedicated to women's issues, makes provision for it.

1655 And to this extent leaning more towards the PLA contemplated in this thesis.

1656 As observed above, some Inter-American instruments even go to the extent of including internal displacement as a prohibited category of discrimination (see Art 1(1) of the American Anti-Discrimination Convention).

instruments of protection based on sexual orientation may have far-reaching negative implications for the protection of health research participants. Even these principles, however, have as yet to find application in case law dealing with health research.[1657]

8.6 Approach to health care

8.6.1. Regional instruments

One of the instruments providing for the right to health care is the ACHPR, which provides amongst other things for the enjoyment by anyone of the 'best attainable state of physical and mental health'.[1658] The African Women's Protocol further provides for the rights to health, including reproductive rights.[1659] The AU Displaced Persons Convention also requires states parties to provide humanitarian assistance, which includes provision of medical care and related health care services.[1660]

On the European front the CFREU provides for access to preventative health care and to medical treatment.[1661] On the Inter-American continent the American Declaration provides for access to health, which is achievable through a variety of mechanisms, including by way of access to sanitation, clothing, housing, medical care and food, within the permissibility of the available 'public and community resources'.[1662]

8.6.2 International instruments

The UDHR provides for everyone to be entitled to a standard of living sufficient for advancing the person's health and wellbeing or that of his or her family, including the provision of medical care.[1663] Another international instrument, the ICESCR, requires states parties to come up with measures to provide to everyone the highest possible standard of health, which includes creating conditions for the provision of medical service and attention in case of sickness.[1664] A further instrument, CEDAW, also requires states to prohibit discrimination against women in the provision of health care and related services.[1665] In the context of children another instrument, the CRC, also

1657 This could be observed from the case law discussed in chapters 4 to 6.
1658 Art 16(1) of the ACHPR.
1659 Art XIV (1), read with art XIV (2), of the African Women's Protocol.
1660 Art IX (2)(b) of the AU Displaced Persons Convention.
1661 Art 35 of CFREU.
1662 Art XI of American Declaration.
1663 Art 25(1) of the UDHR.
1664 Art 12(1) and (2) (d).
1665 Art 13(1) of CEDAW. Also see 14(2)(b).

makes provision for a child to enjoy 'the highest attainable standard of health' as well as access to facilities appropriate for the treatment of diseases and rehabilitation of health.[1666] In the context of displacements, UNGIDP requires authorities to undertake displacements with due consideration to proper conditions of health, safety, hygiene and nutrition.[1667]

8.6.3 General observations

All the regions have instruments providing for access to health care. The international instruments also provide for same. This provision by the various instruments, though, is outside the research context.

8.6.4 Implications for health research

Because of arguably a close relationship between the provision of health care and the participation in health research, the general provision for health care remains important in ensuring that hearth research participants are adequately protected.[1668] These provisions have however not yet been relied on in health research litigation.

8.7 Approach to judicial review and remedies

Persons aggrieved should not be left without a remedy. Various regional and international instruments, discussed below, therefore provide for remedies in the event any person's rights are violated. As most of these remedies will often be sought through judicial and related authorities, this discussion has been combined with the discussion, though brief, on judicial review.[1669]

1666 Art 24(1), read with art 24(2) – (4), of the CRC. Also see art 25.

1667 Para 7(2) of UNGIDP. Further see para 18(2)(d) which requires medical services and sanitation to be provided, at the minimum. Further see para 19. Women should be allowed full participation in the distribution and supply of these goods, which are considered basic (see para 18(3)). Further see para 19(2), which provides for special attention to be paid to women in the provision of the right to health care.

1668 For example, the right to health care could be very important in ensuring that post-research benefits are provided to communities from which the participants come, including access to benefits by those who may not necessarily have partaken in the research. The right to provision of health care is no doubt a provision leaning towards a PLA framework, more in line with the PLA framework contemplated in this thesis.

1669 Though in the discussion of national legal frameworks judicial review may require some extensive focus, one considers it unnecessary in the international law context, where the focus should just be on the need for member states to have basic national mechanism to allow the courts and related institutions to do their work without undue interference, often through the guarantee of judicial independence. Note should however be taken of the fact that in the case of enforcement or monitoring of human rights at international level, various instruments further

8.7.1 Regional instruments

On the Inter-American front the ACHR provides for everyone to have protection in a competent court or tribunal from conduct that violates a person's fundamental rights as provided for in the Convention.[1670] Such protection may also be provided even if the perpetrator was acting in an official capacity.[1671] The competent authorities should not only have the power to develop 'the possibilities of' judicial remedies, but also to enforce them.[1672] The American Anti-Discrimination Convention provides for those aggrieved to have equal access to justice; to have their disputes resolved effectively and expeditiously and to be compensated fairly.[1673]

On the African continent the ACHPR is less explicit on the issue of judicial remedies (at least outside criminal law context). What it does however is the provision for the guarantee of the independence of the courts and the creation or improvement of appropriate national institutions tasked with the advancement and protection of the rights under the Charter.[1674] The African Women's Protocol (which is the protocol to the ACHPR) is however clearer on this, and provides for effective remedies by competent judicial, administrative or legal authorities in case women's rights provided for in the framework have been violated.[1675] The AU Displaced Persons Convention also requires states parties to provide for effective remedies, which may include just and fair compensation, for aggrieved displaced persons.[1676]

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create mechanism for either enforcement or mere monitoring, through various institutions including, for example, the Human Rights Committee in the case of the ICCPR (also see Cassese A *International law* 2nd ed (Oxford University Press 2005) 386 - 387. Further see Sieghart P *The International law of Human Rights* (Clarendon Press Oxford 1983) 14 – 16 and 379 – 443. Also see art 28 of the ICCPR, which provides for the Human Rights Committee)). At regional level also note art 30, read with art 45, of the ACHPR, which makes provision for the African Commission on Human and People's Rights, to promote and ensure the protection of human rights in Africa. Further note art 33, read with art 41, of the ACHR, which establishes the Inter-American Commission on Human Rights and the Inter-American Court of Human Rights, with a view to promoting and defending human rights on the Inter-American region. At European level one could take note of institutions like the European Commission and the Court of Justice of the European Union, which play a key role in the enforcement of Union law in Europe (see art 13, read with art 17, of the Consolidated Version of the Treaty on European Union (2016)).

1670 Art 25(1) of ACHR.

1671 Art 25(1).

1672 Art 25(2).

1673 Art 10 of the American Anti-Discrimination Convention.

1674 Art 26. Though this provision does create space for judicial review, it does not sufficiently provide a clear indication about the remedies to expect.

1675 Art 25 of the African Women's Protocol.

1676 Art 12 of the AU Displaced Persons Convention.

On the European continent the ECHR also provides for an effective remedy for persons whose rights under the framework have been violated.[1677] It is immaterial that the wrongdoer was acting in an official capacity.[1678] The CFREU also provides for a right to good administration from institutions and bodies of the European Union, which entails that an individual's affairs be handled fairly, impartially and without undue delay.[1679] The CFREU further provides for a recourse to tribunals in case any rights provided therein have been violated.[1680]

8.7.2 International instruments

In relation to remedies the UDHR provides for aggrieved parties to be granted effective remedies by competent authorities at national level, as provided for in the law or the constitution.[1681] The ICCPR also provides for the competent authorities to grant effective remedies for the violation of the rights in the Covenant.[1682] The ICCPR further provides for judicial administrative, legislative and other competent authorities to determine the rights for the persons claiming the remedies and where possible, develop 'the possibilities of judicial remedy'.[1683] The ICCPR also provides for the competent authorities to enforce the remedies.[1684] The Convention Against Torture does also make some provision for remedies.[1685]

UNGIDP provides for those displaced in circumstances other than during armed conflicts, emergencies and disasters to seek an effective remedy, including the right to review decisions by judicial authorities.[1686] ICERD also provides for effective

1677 Art 13 of the ECHR.
1678 Art 13.
1679 Art 41(1) of CFREU. The right may include the right to be heard before an adverse decision is taken; the right to access his or her file and the right to be given reasons for the decision (see art 41(2)). Compensation is possible for any person who has suffered damages as a result of his or her rights being violated (see art 41(3)).
1680 Art 47.
1681 Art 8. Further see art 10, which entitles everyone to a fair and public hearing before an independent and impartial tribunal for the determination of his or her rights and obligations.
1682 Art 2(3)(a). This is so irrespective of whether the person violating the rights acted in an official capacity.
1683 Art 2(3)(b). However, it is unclear as to what developing 'the possibilities of judicial remedy' means here. It is not clear whether it means developing new remedies beyond those provided within the existing legal system of a state, or whether it means creating remedies capable of being adjudicated by the courts.
1684 Art 2(3)(c).
1685 Art 14(1) for example requires states parties to provide for an enforceable right to a fair and adequate compensation, 'including the means for as full rehabilitation as possible'.
1686 Para 7(3)(f). Also see para 7(3)(e), which requires the competent authorities to take the

remedies by competent national authorities and other relevant institutions for those whose rights are violated through discrimination.[1687] The remedies could include just and adequate reparations or 'satisfaction' in case any damage has been suffered.[1688] CEDAW also provides for the 'effective protection' of women by competent national tribunals or other institutions against acts of discrimination.[1689]

8.7.3 General observations

All the three regions have instruments providing for effective remedies if a person's rights provided for in the specific instrument have been violated. Same is also provided for in the international instruments. What is important is that some of these instruments provide for remedies even against persons who were acting in an official capacity at the time of violating the rights.[1690] In the case of human rights violations, the tendency at both regional and inter-continental levels has been to create institutions that promote and defend human rights at the respective levels.

8*.7.4 Implications for health research*

The provision for effective remedies in case of violation of rights could be useful in the protection of health research participants. Most, if any at all, of these instruments have however to-date not been relied on in case law.[1691]

8.8 Approaches to access[1692] to information and privacy

8.8.1 Regional instruments

On the inter-American front the American Declaration provides for the protection of a person's privacy.[1693] The ACHR also provides for the right to privacy.[1694] Although

necessary measures to enforce the UNGIDP. Further see para 7(3)(b), which provides for compensation and relocation where necessary.

1687 Art 6 of ICERD.

1688 Art 6.

1689 Art 2(c) of CEDAW.

1690 Note art 13 of the ECHR and art 2(3)(a) of the ICCPR.

1691 Note the cases discussed in chapters four to six, which do not use any of these instruments, with their associated remedies, as their starting point.

1692 Under regional and intercontinental instruments, the discussion of access to information is only touched on very casually as and when it becomes relevant in the context of the discussion of privacy (e.g. in the context of correction of data by a data subject, and related activities). There is generally not much, for the purposes of this study, to be discussed under access to information, at regional and intercontinental levels, outside this context.

1693 Arts V and X, read with art IX, of the American Declaration.

1694 Art 11.

there is no Convention on the Inter-American front specifically dedicated to privacy and related issues, the Inter-American States have adopted a statement of principles, the OAS Privacy Principles, which deal with the same issues. The OAS Privacy Principles provide for, in the main, twelve data protection principles. These include lawful and fair purposes;[1695] clarity and consent;[1696] necessity and relevance;[1697] limited use and retention;[1698] confidentiality;[1699] data protection and security;[1700] data accuracy;[1701] data access and correction;[1702] special protection of sensitive personal data;[1703] accountability;[1704]accountability for trans-border flow of data[1705] and lastly the disclosure exceptions to the OAS Privacy Principles.[1706]

1695 See First Principle, which in the main provides for personal data to be processed for lawful purposes, through lawful and fair means.

1696 See Second Principle, which provides in the main that the purpose of the collection of the data should be specified at the time of the collection of the data and that the data subject should consent to the collection. The data subject should also be able to withdraw the consent if he or she so wishes.

1697 See the Third Principle, which in the main requires that data be necessary for, and relevant to, the purpose of collection. Proportionality plays an important role in this regard as a balancing mechanism, more so where public interests have to be weighed against privacy interests.

1698 See the Fourth Principle, providing for data to be used in a lawful manner compatible with the original purpose of collection and not to be kept longer than is necessary.

1699 See the Fifth Principle, which provides for protection of the confidentiality of personal data unless the data subject consents, or the disclosure is required by law. Although the principle also includes the fact that there could be disclosure 'with the knowledge of' the data subject, it is unclear what this means in this context: does this differ substantially from that the disclosure be with the consent of the data subject? A mere knowledge without consenting might, in one's view, not make sense at all in the context of the exception.

1700 See Sixth Principle, which in the main provides for the reasonable and appropriate protection and safeguards of the data against, for example, unauthorized access; loss and destruction, except with the data subject's 'knowledge or consent or other lawful authority'.

1701 See Seventh Principle which, in the main, requires data to be kept up-to-date and accurate for the purposes of the data's use.

1702 See Eighth Principle, which provides for the data subject to access, and where necessary, correct, amend or delete, his or her data. Restrictions to such access should be done in terms of domestic law.

1703 See Ninth Principle, which provides for more sensitive personal information including, for example, information about a person's health and sexual preferences, to be given additional protection.

1704 See Tenth Principle, which requires amongst other things that data controllers adhere to the privacy principles and goals, including ensuring that they be held responsible for ensuring that those to whom data is transferred also comply with the principles.

1705 See the Eleventh Principle, which provides for data controllers operating in more than one jurisdiction to be also accountable to the protection of personal data.

1706 See the Twelfth Principle, which in the main requires that whenever governments seek to introduce exceptions to the OAS Privacy Principles, such exceptions should be made known by way of legislation. This is certainly meant to discourage arbitrary approaches to the development of exceptions. The OAS Privacy Principles therefore do not themselves list any specific exceptions to the framework, although they hint that national security; public order (public safety); administration of justice; regulatory compliance 'or other essential public policy prerogatives could necessitate exceptions. It is therefore not clear if the conduct of health research will be one of the exceptions.

In Europe CFREU also provides for respect for privacy.[1707] CFREU further, though separately from privacy, provides for the protection of personal data.[1708] There must be a fair procession of personal data for specific purposes and on the basis of a data subject's consent or some other legitimate grounds recognized by law.[1709] CFREU also provides for access to this data, by the data subject, for the purposes of correction of the data.[1710]

An instrument more dedicated to privacy and related issues at European level is the GDPR). As indicated in chapters one, two and five, the GDPR is a data protection framework of the European Union, having replaced the Directive 95/46/EC.[1711]

The GDPR provides for the definition of personal data, which means 'any information relating to an identified or identifiable natural person…'[1712] The GDPR then proceeds to list examples of reference points and factors with which the (identifiable) person may be identified.[1713] What is important from this definition is to note that the protected data is that of a natural person.[1714] The definition is however silent on the question of whether or not the person whose data is to be protected should only be a living person, or whether or not the data of a deceased person could be protected and, if protected, for how long after the death of the person.[1715] The GDPR further provides for the definition of consent, which reads as:

> Any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her.[1716]

1707 Art 7 of CFREU.
1708 Art 8(1).
1709 Art 8(2).
1710 Art 8(2).
1711 See art 94, read with art 99, of the GDPR.
1712 Art 4(1).
1713 Art 4(1).
1714 Note the definition in s 1 of POPIA, which does cater for juristic persons under certain circumstances.
1715 Recital 158 of the GDPR appears to provide some hint in this regard, namely that the regulations do not apply to personal information belonging to diseased persons. In the South African context previously, before the relevant provisions were amended and/or repealed by POPIA, some instruments like PAIA, the NHA (through reference to the PAIA definition of personal information in terms of s 15(2) of the NHA) and the ECTA provided for the protection of personal information of persons who have been dead for not more than 20 years. Such protection, in one's view, remains necessary and the PAIA definition ought to have been retained in this regard.
1716 Art 4(11).

The GDPR makes provision for certain generic principles relating to the processing of personal data.[1717] These include the principle of lawfulness, fairness and transparency;[1718] the principle of data minimization;[1719] the principle of purpose limitation;[1720] the principle of accuracy;[1721] the principle of confidentiality and integrity;[1722] the principle of storage limitation[1723] and the principle of accountability.[1724]

Art 6 of the GDPR then sets out conditions under which the principle of lawfulness may be said to exist. These include the data subject's consent;[1725] necessity for performance of a contract;[1726] necessity for compliance with a legal obligation to which the data controller is subject;[1727] necessity for satisfying the vital interests of the data subject or those of another person;[1728] necessity for performance of a task performed in the public interest or in the controller's exercise of official authority;[1729] and for the pursuit of the data controller's legitimate interests or those of the third party, except where the exercise of these interests undermine the fundamental rights of the data subject, particularly those of a child.[1730] The last condition for lawful processing i.e. art

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1717 Art 5.

1718 Art 5(1)(a), provides for the data subject's data to be processed in a fair, lawful and transparent manner.

1719 Art 5(1)(c), requires the personal data processed to be relevant, adequate and limited to what is necessary for the purpose for which the information was collected and processed.

1720 Art 5(1)(b), limits further procession of information to ways that are not incompatible with the specific, explicit and legitimate purpose for which the information was originally collected and processed. The sub-article however allows for further procession of data for (historical) research, statistical or scientific purposes or where such further procession is for archiving purposes in the public interest. However, such further processing for these purposes must be in accordance with art 89.

1721 Art 5(1)(d), provides for personal data to be kept accurate by, amongst other things, being kept up to-date.

1722 Art 5(1)(f), requires that personal data, while being collected and processed, be secured against unauthorised or illegal access and against loss, damage and destruction, using technical measures appropriate for this purpose.

1723 Art 5(1)(e), requires that personal data not be kept longer than necessary for the purposes for which they were collected. Where the information is kept exclusively for (historical) research, statistical or scientific purposes and for the purposes of archiving in the public interest in accordance with art 89, such information may be kept longer, provided there are 'technical and organisational measures contemplated in the Regulations, set up to protect the rights of the data subject.

1724 Art 5(2), requires that the data controller takes responsibility for compliance with the principles stated in art 5(1).

1725 Art 6(1)(a).

1726 Art 6(1)(b).

1727 Art 6(1)(c).

1728 Art 6(1)(d).

1729 Art 6(1)(e).

1730 Art 6(1)(f).

6(1)(f), does not however apply where the procession of the data is done by public authorities.[1731]

Art 7 of the GDPR provides for conditions for consent. This include the fact that where consent was given in a document which also contains other matters, the document must be clearly distinguishable from those other matters, otherwise no legal consequences arise from any part of the document that is not in compliance with the GDPR.[1732] A data subject has the right to withdraw his or her consent, and the process of doing so must be simple.[1733] Anything done before the withdrawal of the consent however remains valid.[1734]

Regarding transfer of data to third parties the GDPR first deals with the general rules, where it requires that countries to which personal information is transferred should have an adequate level of protection.[1735] Where such countries do not have such level of protection, the controllers or processors must have adequate safeguards, which can be contained in instruments like binding agreements, corporate rules, etc.[1736] Where no adequate safeguards exist, further exceptions to this exist, including the fact that the data subject has consented to the transfer; where the transfer gives effect to conclusion or performance of a contract, etc.[1737] In the absence of the preceding deviation (derogation) requirements, transfers may still be allowed subject to further appropriate safeguards.[1738] Personal information under processing or to be processed after transfer may only be transferred to a third country or international organisation, or from that third country or international organisations onward to another country or international organisations if the conditions set out in the GDPR are complied with.[1739]

On the African content the ACRWC also provides against unlawful or arbitrary interference with a child's home, privacy, family and correspondence.[1740] Equally prohibited is an unlawful or arbitrary interference with a child's honour or reputation.[1741]

1731 Art 6(1)(f).
1732 Art 7(2).
1733 Art 7(3).
1734 Art 7(3).
1735 Art 45(1) read with art 45(3).
1736 Art 46.
1737 Art 49(1)
1738 Also see Art 49(1).
1739 Art 44, read with arts 45, 46 and 49.
1740 Art 10 of ACRWC.
1741 Art 10.

An instrument however more dedicated to privacy and related issues on the African continent is the AU Data Protection Convention. Unlike most regional and international instruments, it covers cyber security, ecommerce and data protection issues in one document. Unless the context requires otherwise, for the purposes of the discussion here the focus is mainly on data protection issues.

The AU Data Protection Convention, just like other data protection instruments, whether nationally or internationally, starts off by defining personal data, which consists of 'information relating to identified or identifiable natural person by which this person can be identified, directly or indirectly in particular by reference to…'.[1742] The reference to a natural person here suggests that legal persons may not rely on the AU Data Protection Convention for protection, if the claim is that their 'personal' information has been illegally accessed. To this extent therefore, despite its specific reference to a natural person, the definition appears similar to those of other national and regional instruments, though the others in the main refer to an 'individual', which however arguably means the same thing. However, other instruments further specifically refer to a 'living' individual,[1743] which the AU Data Protection Convention does not refer to.[1744]

The AU Data Protection Convention further provides for prior authorisation[1745] by a national protection authority,[1746] for the procession of certain activities.[1747] The activities requiring prior authorisation include procession of information relating to health research or involving genetic information.[1748] What are the implications of requiring such prior authorisation for the conduct of health research? Does it mean that all research involving the processing of personal information, which most research does, must be preceded by a prior authorisation from the national protection authority? This would make sense if it was restricted to the processing of specific type of

1742 Art 1 of the AU Data Protection Convention.
1743 See, for example, s 3(2) of the UK's DPA 2018 which takes this approach.
1744 Does it mean therefore the AU Data Protection Convention also protects non-living individuals i.e. those who have died. If so, after what period, if any, does the protection expire?
1745 Art 10(4).
1746 Also see art 12(2)(j), providing for the duties of the national protection authorities, which Include advising bodies or persons engaged in 'carrying out tests and experiments likely to result in data processing'. Further see art 12(2)(k) relating to the duty of the national protection authority to authorize cross-border transfer of personal information.
1747 Art 10(4).
1748 Art 10(4)(a).

information.[1749] Similar restrictions exist for the procession of biometric data.[1750] It further provides for restrictions in the case of public interest processions, more particularly for statistical, historical and scientific purposes.[1751] Art 10 further restricts procession, and hence requiring (prior) authorisation in the case of the procession of data in relation to the commission of offences, to convictions or to security issues.[1752]

The AU Data Protection Convention identifies six principles of personal processing, namely the principle of consent and legitimacy;[1753] the principle of confidentiality and

1749 POPIA (in South Africa) has a related provision requiring prior authorization from the Information Regulator (which one assumes is the national protection authority contemplated in arts 11 and 12 of the AU Data Protection Convention) (see s 57 of POPIA, which however does not cover research purpose procession as a category, though processing for research purposes could still trigger the section in other contexts, for example, where there is transfer of special personal information or information related to children, to third parties in a foreign country not having an adequate level of protection).

1750 Art 10(4)(d).

1751 Art 10(4)(e). One should take note of the interchange of usage of the words 'research' and 'scientific': In art 10 the word 'scientific' is used but principle 3 of art 13 uses the word 'research' in almost the same or related context. One should further note here that processing 'in the public interest' is conceived as including processing for scientific (research) purposes while the wording in the GDPR does not convey the same message (see art 9 (2) (j), read with art 89, of the GDPR)).

1752 Art 10(4)(b).

1753 Art 13. Stated as principle 1, it considers data procession as legitimate only where the data subject has given consent. There are however circumstances where this requirement may be waived. Note the near striking similarities between these derogations and those provided for in the GDPR, as also discussed in this chapter. One notable difference is the justifiable condition that the procession could be permissible if necessary, for the vital interest of another person, which appears in the case of the GDPR, but does not appear in the case of the AU Data Protection Convention. The latter only confines this justifiable condition to the interests of the data subject. Equally the AU Data Protection Convention does not have the justifiable condition that procession may be permissible if necessary, for the protection of the legitimate interests of the data controller or a third party (see art 6(1)(f) of the GDPR, which provides for this)).

security;[1754] principle of transparency;[1755] the principle of lawfulness and fairness;[1756] the principle of purpose, relevance and storage[1757] and the principle of accuracy.[1758]

The AU Data Protection Convention prohibits the procession of sensitive data,[1759] which it categorises as information relating to a data subject's sex life; political opinions; trade union membership; race; health condition; ethnic origin; regional origin;[1760] parental filiation; genetic make-up; religious beliefs; and philosophical beliefs.[1761] The AU Data Protection Convention however provides for exceptions to the preceding 'specific'[1762] prohibitions to the procession of sensitive data.[1763] The exceptions include written consent by the data subject;[1764] protection of vital interests of the data subject or another person, in case the data subject is incapable of legally giving consent;[1765] if the data subject 'manifestly' makes the data public;[1766] where the procession is 'necessary in the public interest', more particularly for scientific, historical and statistical purposes;[1767]and if the procession of data, including genetic data, is for

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1754 Art 13. Stated as principle 6, it requires data controllers to maintain confidentiality when processing personal data. It further requires both the data controller and the processor to maximize compliance with the security requirements provided for in the AU Data Protection Convention.

1755 Art 13. Stated as principle 5, it requires that the data controller may be compelled to disclose personal data (under what conditions may this happen, without violating other principles of data processing? The provision ought to set the parameters within which these mandatory disclosures may be made, and what the justifiable conditions for deviation might be).

1756 Art 13. Stated as principle 2, it requires that various activities involving interaction with data, including collection, storage, procession, recording and transmission be conducted lawfully, fairly and without fraud.

1757 Art 13. Stated as principle 3, the principle requires data procession not to veer off the specific and explicitly stated purpose of collection or further procession. It further requires the data to be adequate and relevant, rather than excessive in relation to the purpose of collection. It further requires that data storage not be longer than is necessary, except where the storage is only for research, historical and statistical purposes 'under the law' (It is unclear what this qualification 'under the law' means in this context, more so that it does not appear in other provisions of the Convention dealing with the same or related issues (see for example arts 14(2)(f) and 10(4)(e). One assumes that the phrase is meant to emphasize the point that the rest of the law must, despite these relevant provisions, still be respected).

1758 Art 13. Stated as principle 4, it requires that data be accurate and up to date in relation to the purpose of collection or further processing, and that reasonable measures be taken to erase or rectify any inaccuracies.

1759 Art 14(1).

1760 Not many instruments include this. The ground could be very important in the case of the protection of displaced children, who may be from a different region from the one they are currently based.

1761 Art 14(1).

1762 One here uses the concept of 'specific' only for convenience, to distinguish this from any other more general prohibitions.

1763 Art 14(2).

1764 Art 14(2).

1765 Art 14(2)(c).

1766 Art 14(2)(b).

1767 Art 14(2)(f).

the purposes of defending a legal claim.[1768] The procession of data for artistic, research and literary (and journalistic) activities, are also allowed (even if they make use of sensitive data) if they are solely aimed at research, journalistic, literary and artistic activities.[1769] These activities must be conducted in line with the code of conduct of the relevant professions.[1770]

The AU Data Protection Convention also creates specific obligations for the data controller in relation to the procession of personal data, including storage obligations;[1771] security obligations;[1772] sustainability obligations[1773] and confidentiality obligations.[1774]

8.8.2 International instruments

In relation to personal information protection the UDHR provides for non-interference with a person's privacy, correspondence, home or family, without justification.[1775] The ICCPR also has provision specifically dealing with the protection of privacy.[1776] Another instrument protecting privacy is the CRC, which provides against unlawful and arbitrary interference with a person's privacy; correspondence; home or family.[1777]

A further international instrument also touching on privacy is WHO's IHR, which provides for the personal data from another state party or WHO, if such information refers to an identifiable or identified person, to be treated with the necessary

1768 Art 14(2)(d).
1769 Art 14(3).
1770 Art 14(3). It is unclear, in so far as research is concerned, how this provision differs from other provisions providing for research purpose activities. What will 'in accordance with the code of conduct of these professions' mean in the context of research? While the language could be clear in the case of processing for journalistic and related purposes (which other legal frameworks, including national frameworks like POPIA do provide for), it would be very ideal for the drafters to have clarified the link between this provision and other provisions dealing with research purpose exceptions (also see s 7(2) of POPIA for a related provision in the case of processions for journalistic and related purposes, which however does not expressly cover research purposes).
1771 Providing for the data not to be kept longer than necessary for the purpose of original collection or procession (see art 22).
1772 To ensure that the data is not altered, destroyed or illegally accessed (see art 21).
1773 Providing that data must still be usable irrespective of the technical device used to process the data (See art 23).
1774 Art 20.
1775 Art 12 of the UDHR.
1776 Art 17. Further see art 9(1) dealing with 'the right to liberty and security of person'.
1777 Art 16(1) of the CRC. While internal qualifiers exist in respect of some rights, this right does not provide for any internal qualifiers. Does it then mean that this right is unlimited? This sounds absurd.

confidentiality and anonymity as required in terms of the national law of the state concerned.[1778] State parties or WHO may deviate from this principle if the processing of the information is essential for assessment and management of a public health risk.[1779] An individual may, upon request, be given access to the information by WHO, without unnecessary delay or expense.[1780] An individual should also, where necessary, be given an opportunity to correct his or her information.[1781]

Some further international instruments, though not having general coverage, namely UNAIDS Guidelines on protecting confidentiality and security of HIV information: Proceedings from a workshop (2007) (UNAIDS Interim Guidelines)[1782] and the Organisation for Economic Cooperation and Development (OECD) Guidelines on the Protection of Privacy and trans-border flows of personal data (2013) (OECD Privacy Principles)[1783] are worth noting for guidance in the aspects and principles they espouse, which are adaptable to other contexts.

8.8.3 General observations

The common thread running across the various instruments, at regional and international levels[1784] is the provision for conditions, stated as principles, under which processing of personal data could be done lawfully. A further common thread, at least amongst the regional instruments, is that in the case of sensitive personal information there is, in the main, provision for added protections. A further observation is that, at least within the regional framework, there is provision for deviation from the general

1778 Art 45(1) of IHR.

1779 Art 45(2). However, state parties or WHO must still, in such a case, ensure that the information is processed fairly and lawfully and not be further processed in ways not compatible with the original purpose of collection (being for the assessment and management of a public health risk); the information must be 'adequate, relevant and not excessive in relation to that purpose' and the information must remain accurate and if necessary be kept up to date, and reasonable steps be taken to ensure that inaccurate or incomplete information be removed or corrected (art 45(2)(a) – (c)). The information must also not be kept longer than is necessary for the purpose of processing (art 45(2)(d)).

1780 Art 45(3).

1781 Art 45(3).

1782 As the name suggests, the UNAIDS Interim Guidelines only apply to HIV/AIDS-related contexts.

1783 Although also going beyond a continent, the OECD Privacy Guidelines only cover a limited number of countries party to the OECD, which are mainly developed countries.

1784 One is however cognizant of the limited application of those instruments applying at inter-continental level, where there is no single instrument dedicated to privacy issues, with a wider coverage.

principles under certain defined circumstances and, except for the Inter-American continent,[1785] processing for research purposes is one of those defined circumstances.

8.8.4 Implications for health research

The provision for the framework within which processing of personal data should occur lawfully will no doubt go a long way in enhancing the protection of personal data belonging to health research participants. The added protection in the case of the processing of sensitive (special) personal information will also enhance the protection of health research participants.[1786] As indicated earlier at international level the CRC makes provision for the protection of a child's privacy.[1787] So is the position on the African continent[1788] and Europe.[1789]

8.9 The regulation of research oversight under both legal and ethical instruments

8.9.1 Regional instruments

One of the instruments regulating research is the EU Clinical Trial Regulations, which provide for a variety of principles to be observed around the conduct of clinical trials

1785 As indicated in the discussion earlier, the OAS Privacy Principles do not expressly provide for processing for research purposes as one of the exceptions to the general principles around the lawful processing of personal data. One is however of the opinion that research purpose procession is likely to qualify as one of those exceptions, as part of 'other essential public policy prerogatives' (see the Twelfth Principle. One should also note here that the exceptions under the OAS Privacy Principles are grouped together under the Twelfth Principle).

1786 Although art 9(2)(j) the GDPR makes provision for the deviations, in the case of processions for research purposes, from the prohibition on the protection of special categories of personal information such processing, apart from being necessary for such purpose, must 'be proportionate to the aim pursued', as well as respecting 'the essence of the right to data protection' and provide for appropriate measures to protect the data's subject's rights. Art 89 of the GDPR should in such a case further be complied with. As for the African continent, art 14 (2)(f) of the AU Data Protection Convention, providing for related exceptions in the case of research purpose procession, does not provide for an oversight (safeguard) mechanism, therefore creating room for abuse. As for the Inter-American continent the Ninth Principle dealing with protection of sensitive personal information does not provide for an exception directly dealing with research purpose exception (even if the Twelfth Principle exceptions were to be read as covering research purpose exception, those exceptions are to all the principles, rather than specifically directed at procession of sensitive data). Whether these deviations, where they include processions for research purposes, enhance or hinder the protection of health research participants is a debatable question that is for the purposes of this thesis parked, except to say for now that the presence or otherwise of protection will be dependent on the interpretation of these provisions as well as the facts of each case.

1787 Art 16(1).

1788 Art 10 of ACRWC.

1789 Although art 8 of the GDPR deals with a child's consent in relation to 'information society services', the principles outlined therein in relation to children could, with some necessary adaptations, equally be applicable in respect of a child's consent in research situations.

for members of the EU. The EU Clinical Trial Regulations specifically provide for a distinction to be made between a clinical trial and a clinical study, the latter being broad enough not only to include a clinical trial, but also includes a non-interventional study.[1790] The EU Clinical Trial Regulations do not apply to non-interventional studies, but only to clinical trials.[1791] The EU Clinical Trial Regulations in the main provide for the dignity, safety, well-being and (other) rights of research participants to be respected.[1792]

Most importantly, the EU Clinical Trial Regulations provide for the interests of research participants to always receive 'priority over all other interests'.[1793] The EU Clinical Trial Regulations further provide for research, in the case of clinical study, to be only conducted if it is likely to produce reliable data.[1794] The EU Clinical Trial Regulations further provide for clinical trials to be preceded by authorization.[1795] The authorization envisaged here includes the ethical and scientific review of the study by the relevant committees, in particular the RECs.[1796] In the case of a change of the principal investigator or a change of the clinical trial site, the change must be authorized as provided in the EU Clinical Trial Regulations.[1797]

The EU Clinical Trial Regulations set out further general requirements for participation in research. These requirements (or conditions) include the following: the expected benefits both to the research participant and public health must justify the expected risks for participation in the study[1798] and the participants, or their legally authorized representatives, must be duly informed or have given informed consent, in accordance with art 29 of the EU Clinical Trial Regulations.[1799]

The EU Clinical Trial Regulations further, as earlier indicated, provide for the written informed consent, which it specifically requires to be signed and dated by the

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1790 Para 3 of the Preamble to the EU Clinical Trial Regulations.
1791 Art 1 of the EU Clinical Trial Regulations.
1792 Para 1 of the Preamble to the EU Clinical Trial Regulations. Also see art 3 of the EU Clinical Trial Regulations.
1793 Para 1 of the Preamble to the EU Clinical Trial Regulations. Also see art 3 of the EU Clinical Trial Regulations. What does this mean in relation to the notion of public interests? This implies that public interests here could take a back seat, more so if the provision is not qualified.
1794 Art 3 of the EU Clinical Trial Regulations.
1795 Para 2 of the Preamble to the EU Clinical Trial Regulations.
1796 Art 4.
1797 Art 15.
1798 Art 28(1)(a).
1799 Art 28(1)(b), read with art 28(1)(c).

interviewer and the research participant.[1800] Where the research participant lacks the capacity a legally designated representative may consent.[1801] Where the research participant is unable to read and write, the consent given orally must be recorded through other alternative means, attested to by another witness.[1802]

The EU Clinical Trial Regulations further provide framework for the conduct of research involving minors. Research on minors must be preceded by informed consent from a legally authorised representative.[1803] Information presented to minors should be adapted in accordance with the age and maturity of the minors.[1804] Where the minor concerned is capable of understanding, the minor should be informed to express an opinion on his or her participation, including the decision to withdraw, and such opinion must be respected.[1805] Incentives for a minor's participation in the study are not allowed except where the incentives are a compensation for the expenses or loss in earnings as a result of the time spent in the study.[1806] The study may further be conducted on minors where the study investigates a medical condition existing in minors, or where the study is essential to validate a study already conducted on adults.[1807]

A further requirement for the inclusion of minors is that the study relates to the medical condition which that minor is suffering from or where the study is one that can only be conducted on minors.[1808] The minor may only also participate where there are scientific grounds to believe that the minor will benefit directly from the study,[1809] or where the population of the minor will benefit, provided in the latter case that there is only a minimal risk or burden imposed on the minor, when compared to the standard treatment the minor is entitled to.[1810] In the event that a minor attains the age of

1800 Art 29(1).
1801 Art 29(1).
1802 Art 29(1).
1803 Art 32(1)(a).
1804 Art 32(1)(b), read with art 32(2).
1805 Art 32(1)(c).
1806 Art 32(1)(d).
1807 Art 32(1)(e).
1808 Art 32(1)(f).
1809 Art 32(1)(g)(i).
1810 Art 32(1)(g)(ii).

majority while already participating in a study, the minor's continued participation in the study is subject to the minor's informed consent.[1811]

The EU Clinical Trial Regulations further regulate the participation of incapacitated minors in research.[1812] The requirements for the participation of an incapacitated person are like those discussed with regard to minors above, subject to the changes as required by the context.[1813]

Another instrument regulating health research is the Oviedo Convention, which is a European regional instrument under the auspices of the COE and deals with human rights issues around biomedical issues.[1814]

The Oviedo Convention in the main provides for the respect for human dignity, identity; non-discrimination; a person's integrity and other fundamental rights.[1815] The Oviedo Convention further provides for the interests of 'the human being' to be placed above the 'sole' interests of science or society.[1816] The Oviedo Convention further requires parties to provide for equitable access to appropriate and quality health care.[1817] The Oviedo Convention further provides for any interventions in the health fields, health research included, to comply with professional standards and obligations.[1818]

Only freely given consent is permissible.[1819] Appropriate information, including the nature, purpose, risks and consequences of the research, shall therefore be provided to the data subject, so that the latter could take an informed decision.[1820] The data subject is permitted to withdraw his or consent.[1821]

1811 Art 32(3).

1812 The framework for the participation of incapacitated persons in research is set out in art 31(1) – (3) of the EU Clinical Trial Regulations.

1813 Art 31(1) – (3).

1814 The instrument was entered into in Oviedo, hence the 'Oviedo Convention'. It should be noted that although the instrument was entered into under the auspices of the Council of Europe, non-member states of the COE may by invitation be allowed to be party to the Convention (see art 34, read with the Preamble).

1815 Art 1, read with art 11, of the Oviedo Convention. Art 11 specifically prohibits discrimination based on genetic heritage.

1816 Art 2. 'The human being' in this instance appears to refer to the person under consideration, rather than human beings in general.

1817 Art 3.

1818 Art 4.

1819 Art 5.

1820 Art 5.

1821 Art 5. Although the Oviedo Convention is silent on what happens to what had already been done before the consent was withdrawn i.e. whether what has already been done can be reversed, it has become standard practice that what has been done before the withdrawal of

Extra-protective measures (by way of conditions) are provided for those who cannot give consent due to lack of capacity.[1822] In the case of a minor for example, the minor's representative, or body or a person having the power to authorise in terms of the law, must authorise the study.[1823] The child's opinion must however still be taken into account when giving the authorisation.[1824] A related approach is adopted in the case of a person who lacks capacity to consent due to mental disability and related disabilities, in which case the research participant's representative, or a body or person authorised by law, must provide the authorisation.[1825] The research participant still, to the extent that this is possible, partakes in the authorisation processes.[1826]

Another protective mechanism for both a minor and other persons lacking capacity to consent is the requirement that research done on these persons may only be conducted if they benefit directly from the research.[1827] Persons required to give consent on behalf minors or other persons without capacity as outlined above, must also be provided with the same information as would be provided to the research participants themselves if they were not assisted.[1828] These persons are also allowed to withdraw their consent if it is in the best interest of the data subjects to do so.[1829]

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the consent remains valid.

1822 Arts 6 and 7.

1823 Art 6(2).

1824 It is unclear whether considering the minor's opinion means that the minor must assent, or whether it is something less than that. One is of the view that considering a minor's opinion in this case does not translate into an assent, as an assent implies that the minor must agree, not merely that his or her views must be taken into account.

1825 Art 6(3).

1826 Art 6(3). It is however unclear what form this participation should take, i.e. whether this is in the form of assent or not. One is of the view that here, unlike in the case of a minor above (where only the opinion needed to be taken into account), the participation takes the form of an assent, in that the research participant is allowed, if not required, to partake in the authorization process, rather than merely having his or her opinion considered.

1827 Art 6(1). Also see art 6(7), which further protects those with serious mental disorder, by requiring that the intervention be necessary to prevent harm to their health i.e. without the treatment intervention, their health would be adversely affected.

1828 Art 6(4).

1829 Art 6(5). Though the provision is a bit ambiguous in the sense that it refers to the interest of the 'person concerned', making it unclear whether it refers to the interest of the data subject or the interest of the person who had provided authorization, the context suggests that it is the interest of the persons for whom authorization was given, rather than the interest of the authorizers themselves, given that it is the data subjects themselves whose interests are likely to be negatively affected by the research. Art 6(8) also provides protection to persons in emergency situations who cannot provide consent. Such persons may only partake in the intervention without consent if the intervention is in the interest of the individual (participant) concerned.

The Oviedo Convention further directly regulates biomedical research, which should be conducted freely and in compliance with the Convention and other relevant legal provisions.[1830] The Oviedo Convention then provides for justifiable conditions for the conduct of scientific research involving human persons and these conditions include informed consent of the data subject, which can be withdrawn at any time; the research cannot be effectively conducted on non-humans; the risks to be suffered by the research participant are not disproportionate to the likely benefits; the research has been approved by an independent, multidisciplinary and competent body, after assessing the research's scientific merit, including the research's aims and the data subject has been informed about the appropriate safeguards and rights required by law.[1831] Where the research participant does not have the capacity to consent, apart from complying with the other provisions of the Convention further protective conditions are prescribed, including the fact that the research has to produce 'real and direct'' benefit to the person's health;[1832] the fact that the research could not be effectively conducted on any other persons capable of giving consent[1833] and that the research participant does not object.[1834]

Except as provided for in art 26(2), deviations from the provisions of the Convention are permissible, as prescribed by law and as are necessary in a democratic society, for reasons of public health, prevention of crime, for public safety; for the protection of the rights of others, etc.[1835]

States parties to the Oviedo Convention are required to enact laws providing for judicial protections in their own countries to stop existing or impending violations, in case of violation of the provisions of the Oviedo Convention.[1836]

1830 Art 15.

1831 Art 16.

1832 Art 17(1)(ii). However, where the research does not have the potential to produce real and direct benefit to the research participant, the research may, apart from complying with the other provisions of the Oviedo Convention, still be allowed under additional grounds, including the fact that the research may lead to a better understanding of the individual's condition or disease, which may eventually benefit the person or other persons of the same age or others with the same conditions; and further that the risk for participating in that research is minimal (Art 17(2)(i) and (ii). This approach arguably takes the PLA tone argued for in this thesis.

1833 Art 17(1)(iii).

1834 Art 17(1)(v)

1835 Art 26(1). The provisions, provided for in art 26(2), in respect of which there may be no deviation include those relating to consent (arts 11 and 17) and the provision prohibiting the selection of a child's future sex unless justified to avoid a hereditary disease (art 14).

1836 Art 23.

Lastly on the regulation of health research on the European Continent, one needs to briefly reflect on the research related aspects of the GDPR, though the rest of its principles were earlier discussed under the topic dealing with protection of personal information and information access. The GDPR requires that processing for historical research, statistical or scientific purposes, alongside that for archiving purposes in the public interest, be done subject to appropriate safeguards.[1837] These appropriate safeguards include having technical and organizational measures in place to ensure data minimization, which may entail pseudonymisation, if the purposes of these activities can still be achieved this way.[1838] The GDPR further provides for Union or Member state law to provide, where this is necessary for the fulfilment of the stated research purposes and subject to appropriate safeguards contemplated in art 89(1), for deviations from the rights in arts 15, 16, 18 and 21.[1839]

On the Inter-American continent there are also various research-related guidelines, some of which were recently developed as a specific response to COVID-19.[1840] One of the instruments dealing with health research in that region is the Pan American Health Organisation (PAHO) Good Clinical Practices: Document of the Americas (PAHO GCP). The PAHO GCP reaffirms the need for compliance with Helsinki Declaration and the established principles of respect for persons, justice and beneficence, which 'permeate all the GCP principles' outlined in the PAHO GCP.[1841] The rest of the principles are, in the main, respect for the primacy of the interests of the trial subjects;[1842] that the anticipated benefits should outweigh the anticipated risks;[1843] the protocol must have beforehand been approved by, or received a favourable opinion from, an REC;[1844] the research must be scientifically sound and

1837 Art 89(1).

1838 Art 89(1).

1839 Art 89(2). However, where the processing also serves any other purpose than historical research, statistical or scientific purposes the deviations will not extend to that other purpose (art 89(4)).

1840 Some of the Guidelines developed in response to COVID-19 include PAHO Guidance and Strategies to streamline ethics review and oversight of COVID-19-related research (2020); PAHO Ethics Guidance on issues raised by the novel coronavirus disease (COVID-19) pandemic (2020) and PAHO Template and operational guidance for the ethics review and oversight of COVID-19-related research (2020).

1841 Para 2 of PAHO GCP.

1842 Para 2.2. This paragraph should be read with para 3.1.2, which emphasizes the principle of dignity, and that the pursuit of research goals should not undermine the interests of the trial subjects. These provisions do not however, or at least in one's view should not be interpreted to, necessarily mean that the interests of society and science should not be considered at all.

1843 Para 2.1

1844 Para 2.3. The RECs must be independent (see para 3.1.4). The RECs must also be

based on adequate non-clinical, and where applicable clinical, information;[1845] medical care and medical decisions should be taken care of by qualified physicians or where applicable dentists;[1846] securing data subject's prior informed consent;[1847] proper handling, recording and storage of trial information;[1848] respect for confidentiality and privacy;[1849] the manufacturing, handling and storage of investigational products in accordance with the relevant good manufacturing practice (GMP) and approved protocol[1850] and the implementation of quality assurance systems.[1851]

Another instrument relevant to health research on the Inter-American content is the Pan American Network on Drug Regulatory Harmonisation (PANDRH) Guide for conducting clinical studies in paediatric populations (2008) (PANDRH's Paediatric Guide). PANDRH's Paediatric Guide, as the name implies, in the main deals with the conduct of research involving children, including the ethical dimension of such studies. One of the objectives of PANDRH's Paediatric Guide is to ensure that the development of clinical studies involving children in the inter-American region takes place in 'a rigorous, scientific and safe manner'.[1852] Children represent vulnerable populations and therefore require special measures to protect them and minimise their exposure to possible risks.[1853] Research participants should, unless special circumstances exist, benefit from the clinical research they participate in.[1854]

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multidisciplinary in their composition. Where they regularly review studies involving vulnerable populations like children, they must also include a person who is an expert in matters affecting the targeted population (see paras 3.2.2 and 3.2.10).

1845 Paras 2.4 and 2.5. It should be noted that RECs are also required to evaluate the scientific aspects of the research (see also para 3.2.1).

1846 Paras 2.7 and 2.8.

1847 Para 2.6. The trial subject, or the legally authorized representative, should therefore not be coerced or unduly influenced into consenting, nor should the trial subject or legally authorized representative be required to waive his or her rights or release anyone from liability for negligence arising from the research (see paras 4.3.7 and 4.3.8). Where payments to research participants are involved, RECs must review both the 'amount and method of payment' and ensure such payments, which must have been included in the informed consent form, are not based on whether the person completes his or her participation in the study (paras 3.1.10 and 3.1.11). In the case of children who are not able to consent but are able to understand, they should be informed about the study so that they sign it (para 4.3.17) (it is not clear whether this is a form of assent or not. One assumes it is meant to be).

1848 Para 2.9.

1849 Para 2.10.

1850 Para 2.11.

1851 Para 2.12.

1852 Para 1.1 of PANDRH's Paediatric Guide.

1853 Para 2.1.

1854 Para 2.1.

Where an REC reviewing a study involving children does not have persons with expertise in children's affairs on the committee, external consultants with relevant expertise may be sought.[1855] There should further be no inducements to attract participation into the research.[1856] As children are generally not capable of giving informed consent, it is the guardians or other legally authorised representatives who must give consent.[1857] The investigator is further required to take steps to reduce any known risks[1858] and discomfort to the participating children.[1859] An REC must continuously monitor any study it has approved.[1860]

On the African front there is currently no dedicated instrument on clinical research. As observed above, the AU Data Protection Convention and the African Women's Protocol do touch on this, though very briefly. The general principles covered by these two instruments, which require no repetition here, are however very critical in the context of health research too. A few things need be said again about the AU Data Protection Convention namely that it, just like its counterparts in the other two regions under discussion, provides for general principles for the lawful[1861] processing of personal information. As observed above, in the case of the processing of personal information for research purposes, without regard to the category of personal information processed, there must be prior authorization from the relevant national protection authority.[1862]

Although the AU Data Protection Convention generally provides for additional protection in the case of the protection of sensitive personal information, by prohibiting such procession, the prohibition does not apply in the case of procession for research

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1855 Para 2.5.1. Also see para 3.2.10 of PAHO GCP.

1856 Para 2.5.2.

1857 Para 2.5.3. As discussed under the PAHO GCP, where the child has reached a certain level of maturity to understand the study, the child must be informed of the study, and must sign a 'written informed consent' form, made separately from the informed consent (signed by the legally authorized representative). The language could be confusing here: it could be better if the 'written informed consent' signed by the child should simply be referred to as an assent form.

1858 Para 2.5.4.

1859 Para 2.5.5.

1860 Para 2.5.6.

1861 Though 'lawfulness', when used in a narrow sense (as has been the case in other parts of this thesis), is also one of the requirements for the processing of personal data, one uses the concept here in a broader sense to mean permissible procession under a specific instrument prescribing the conditions for the procession.

1862 Art 10(4)(e), read with (4)(a) and (4)(d), of the AU Data Protection Convention (this should not be confused with requirements in other instruments that research be approved by an REC).

purposes.[1863] The AU Data Protection Convention further requires non-member states to which data is transferred to have an adequate level of protection of privacy and other fundamental rights of the data subject, before data can be transferred to such a state.[1864]

8.9.2 International instruments

As indicated in the earlier chapters the Helsinki Declaration [1865] is one of the more specific international instruments regulating health research. It is an ethical rather than a legal instrument.[1866] The Helsinki Declaration in the main provides for the protection of research participants, with their interests being considered primary, or even to supersede any other interests.[1867] It further provides for the special consideration of categories of research participants that are considered vulnerable.[1868] These may be persons who are not in a position to either give or refuse consent on their own.[1869] Further included in the category of vulnerable persons could be persons who are likely to be subjected to coercive conduct or undue influence.[1870]

It further provides for researchers to observe their applicable national ethical, legal and other regulatory framework.[1871] It further provides for the researchers to observe the applicable international framework.[1872] Neither the national nor the international framework may 'reduce or eliminate any of the protections for research subjects' as

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1863 Art 14(2)(f). This provision must obviously be read with art 10(4)(e) which, as earlier indicated, requires prior authorization for the processing of personal information for research purposes.

1864 Art 14(6)(a). The prohibition of such transfer does not however apply where there is a prior authorization for such transfer by the national protection authority (see art 14(6)(b), read with art 12(2)(k)).

1865 This is, as at the time of writing, the latest version as amended by the 64th General Assembly of the World Medical Association (WMA) in Fortaleza, Brazil, in October 2013. See World Medical Association "WMA Declaration of Helsinki – Ethical principles for medical research involving human subjects''. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ (Accessed 21 November 2021).

1866 Para 1 of the Helsinki Declaration.

1867 See para 4. But also see para 20, which though arguably capable of being interpreted either way, i.e. in favour of individual interests or public interests, still weighs towards the individual interest (though the interests in this case are those of a group or community partaking in the research the approach is still narrower, focusing on the interests of the participating group, rather than generally on those of the rest of the community).

1868 Para 19. Also see paras 20 and 27.

1869 Also see para 27.

1870 Also see para 27.

1871 Para 10.

1872 Para 10.

provided for in the Helsinki Declaration.[1873] The Helsinki Declaration further requires that medical research where human participants are engaged should meet the generally accepted scientific standards.[1874]

The Helsinki Declaration further provides for the study to be accompanied by a detailed research protocol, clearly descripting various aspects, including the design and performance of the study; a statement about the ethical consideration and indications about how the principles outlined in this Declaration have been considered and addressed.[1875] The Helsinki Declaration further requires the inclusion in the protocol of details about funding; sponsorships; institutional affiliations; any other possible conflict of interests; any incentives to research participants for partaking in the research; treatment or compensation for research-related injuries and provision for 'post-trial' arrangements.[1876]

The Helsinki Declaration provides for the oversight mechanism, namely through an independent REC, to which a research protocol must be submitted for the latter to consider, provide guidance and approve before the commencement of a study.[1877] The REC further has the power to monitor studies on an on-going basis.[1878] The researcher is also required to submit 'monitoring information' to the REC, more

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1873 Para 10.

1874 Para 21. This means that the science of the study must be acceptable. In other words, as has often been said by ethicists, bad science may raise ethical questions (also see 2002 CIOMS Guidelines, which say in this regard: 'Moreover, because scientifically invalid research is unethical in that it exposes research subjects to risks without possible benefit, investigators and sponsors must ensure that proposed studies involving human subjects conform to generally acceptable principles...' (2002 CIOMS Guidelines); further see Guideline 1 of the 2016 CIOMS Guidelines. See also Principle 5, read with Principles 1 and 2, of WHO Handbook for Good Clinical Research Practice: Guidance for Implementation (2005). Further see Standard 7(1) of WHO Standards and Operational Guidance for Ethics Review for Health-Related Research with Human Participants (2011) (WHO's Standards and Procedures). Further see para 8.4 of the Nuffield Council on Bioethics The Ethics of Research related to Healthcare in Developing Countries (2002) (note however the concerns as to whether both the ethical and scientific issues, assuming that the REC can raise both, should still be dealt with 'in a single ethics committee', i.e. whether as part of a single process or separate processes, or whether they should be handled separately in a separate committee (see para 8.5)). On the relationship between scientific validity and ethical acceptability, further see Guidance point 4 of the UNAIDS and WHO Ethical Considerations in HIV Prevention Trials (2021).

1875 Para 22.

1876 Para 22. The post-trial arrangements or provisions contemplated here could include, but are not necessarily limited to, the post-trial care or benefits (The concept of 'post-study' access to 'care or benefits' was used in para 14 of the 2008 Edition of the Helsinki Declaration. Though no longer appearing in the 2013 edition of the Helsinki Declaration, one is of the view that the substance has been retained).

1877 Para 23.

1878 Para 23.

particularly as it relates to serious adverse events.[1879] The REC must also consider, comment on, and approve, any change to the protocol.[1880] The REC is expected to, when performing its functions, consider the applicable national and international framework, provided that that framework does not provide for protection standards that are lower than those provided for in the Helsinki Declaration.[1881] Researchers are also required to submit to the REC, at the end of the study, a summary of the findings and conclusions of the study.[1882]

The researchers must do a risk and benefit analysis before conducting the study.[1883] The Helsinki Declaration further provides for the registration of clinical trials in databases before the commencement of the recruitment processes for research participants.[1884] It further provides for the protection of the privacy of the research participants as well as the confidentiality of the research participants' personal information.[1885]

The Helsinki Declaration further provides for voluntary consent, which consent should preferably be in writing.[1886] In the event that the consent may not be given in writing, the oral consent must then be documented, and be attested to by a witness.[1887] There are also instances where informed consent may not be properly secured from the research participant himself or herself, because the research participant is incapable of giving such,[1888] or the informed consent cannot be administered by the researcher himself or herself, due to a number of factors, including duress and undue influence.[1889] In case of a dependent relationship between the researcher and the research participant or where duress is a possibility, another suitably qualified independent person should be sought to administer such a consent process.[1890] It may also arise that the subject of research is not competent to, or is incapable of giving,

1879 Para 23.
1880 Para 23.
1881 Para 23.
1882 Para 23. Although this requirement arguably promotes transparency and accountability on the part of researchers, it could arguably create an unnecessary administrative burden for RECs.
1883 See Paras 16, 17 and 18.
1884 Para 35.
1885 Para 24.
1886 Paras 25 and 26.
1887 Para 26.
1888 See para 28.
1889 See, for example, para 27.
1890 Para 27.

consent to the research, in which case the consent is obtainable from a legally authorized representative.[1891] Those incompetent to give, or incapable of giving, consent must not be included as subjects of study unless the study is potentially beneficial to the health needs of the population from which the subject of the study is selected; the study may not be conducted on competent or capable persons and the study does not pose more than a minimal risk and burden.[1892]

Where a person incompetent or incapable to give informed consent is instead competent or capable to give assent that person must, in addition to the informed consent by a legally authorized representative, be given an opportunity to give the assent, in which case that person's dissent should be respected.[1893] In case of persons incompetent to give, or incapable of giving, an informed consent due, for example, to mental or physical conditions they can only be subjects of study 'if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group'.[1894]

While it is required that in case a person incapable of giving informed consent participates in the research an informed consent from a legally authorized representative must be obtained, this requirement may be dispensed with if the representative is not available, and the study cannot not be delayed.[1895] In such a case the study may continue without the informed consent, provided that the researcher has stated the reasons for the inclusion, in the study, of persons whose conditions render them incapable of giving informed consent and the relevant REC has approved of such a study.[1896] The consent must then as soon as possible thereafter be obtained from the research participant or the legally authorised representative.[1897]

1891 Para 28.
1892 Para 28.
1893 Para 29.
1894 Para 30. Though the concepts of being 'incompetent' and being 'incapable' do not necessarily mean one and the same thing (as a person could be competent to give consent by virtue of being above the required age, but still incapable due to physical and mental problems at a particular time), the concept of being incapable appears to have been used in the Declaration to cover both situations.
1895 Para 30.
1896 Para 30.
1897 Para 30.

The Helsinki Declaration further requires the researchers (authors) to publish the results of the research.[1898] The researchers must in this regard therefore comply with the generally acceptable principles of publication.[1899] This requires, amongst other things, that the researcher reports on, or makes available, the positive, negative and inconclusive findings of the study.[1900] It further prohibits reports not in accordance with the Helsinki Declaration from being published (or being accepted for publication).[1901]

The Helsinki Declaration further requires sponsors, investigators and governments to, 'in advance of a clinical trial', provide for post-trial access to interventions identified as being beneficial during the trial, for all those participants who need the intervention.[1902] As indicated under the discussion of informed consent, this information must have been included in the informed consent process.[1903]

Another instrument of international significance is the 2016 CIOMS Guidelines, developed by the Council for International Organisations of Medical Sciences in collaboration with the WHO, which replace the 2002 CIOMS Guidelines. The 2016 CIOMS Guidelines provide for a number of guidelines (principles) relating to the conduct of health-related research.[1904] These guidelines or principles include the scientific validity of the study;[1905] securing informed consent from those capable of giving such;[1906] fair distribution of burdens and benefits;[1907] assessment of potential

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1898 Para 36.

1899 Para 36.

1900 Para 36. This provision no doubt advances the principle of transparency and the important principle of public interest. This means that even if the results could put a researcher's own country in a negative situation, as it happened when scientists in South Africa discovered the existence of Omicron, a new COVID-19 variant in the country. Some countries immediately imposed a travel ban on South Africa, leading to concerns being raised by SA's Ministers of Health and International Relations and Cooperation, Joe Phaahla and Naledi Pandor respectively, as well as WHO (see Eye Witness News "Phaahla: We must inform WHO about new COVID variant for the sake of transparency'. https://ewn.co.za/2021/11/26/phaahla-we-must-inform-who-about-new-covid-variant-for-sake-of-transparency (Accessed 27 November 2021). Also see *The Citizen* "Covid variant: SA being 'punished' for 'excellent science', says Dirco''. https://www.citizen.co.za/news/covid-19/2931665/covid-variant-sa-being-punished-for-excellent-science-says-dirco/ (Accessed 27 November 2021).

1901 Para 36.

1902 Para 34.

1903 Para 34.

1904 It should be noted that the 2016 CIOMS Guidelines use the concept of 'health-related research' instead of the narrower concept of 'biomedical research' (see the Preface to the 2016 CIOMS Guidelines).

1905 Guideline 1.

1906 Guideline 9. While those not capable of giving consent should also be included in research, a legally authorized representative must consent, while the participant himself or herself should give assent, to the extent of that person's level of understanding (see Guideline 16).

1907 Guideline 3.

risks and benefits to the individual;[1908] caring for the research participants' health needs;[1909] review of the research by independent RECs;[1910] reimbursement and reasonable compensation for partaking in research;[1911] provision for treatment and compensation for research-related injuries;[1912] special protections for vulnerable groups;[1913] the use of 'privacy-protective measures' in case of the use of data obtained online[1914] and public accountability for the research.[1915]

Regarding children in particular the 2016 CIOMS Guidelines provide that children be included in health-related research unless there are scientific reasons for their exclusion.[1916] For the children to be included in health research the parents or legally authorised representatives must give informed consent. Children, if they are mature to do so, must give assent, even if that maturity is attained during the study.[1917]

Just like in the case of children, the 2016 CIOMS Guidelines require the inclusion of women unless there are scientific reasons for their exclusion.[1918] Where the study is not likely to present direct individual benefits to the participating pregnant or breast-

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1908 Guideline 4.

1909 Guideline 6.

1910 See in particular Guidelines 8 and 23.

1911 See Guideline 13. The compensation, which can also be in non-monetary forms, should not be large enough to serve as an undue inducement for participation. Provision for both reimbursement and compensation must be approved by an REC.

1912 Guideline 14. The REC must ensure that there is adequate provision for such in relevant instruments. The right to receive these benefits cannot be waived.

1913 Guideline 15. It should be noted that women and displaced persons are also specifically listed as examples of vulnerable persons or groups.

1914 Guideline 22.

1915 Guideline 24. Public accountability here also includes the fact that the results of the research must be published.

1916 Guideline 17 of the 2016 CIOMS Guidelines. This provision suggests that the inclusion of children are treated as default position, rather than an exception. This formulation appears a departure from the 2002 CIOMS Guidelines, which were cautious and generally against the inclusion of children unless certain conditions were met, including the fact that the same research could not be conducted on other persons (see Guideline 14 of the 2002 CIOMS Guidelines). However, in the case of health research that does not present direct benefits to the individual children, the condition that this must only be done if it cannot be done on adults still remains, unless the children's participation remains necessary, and the risks involved are no more than minimal risks (it may also be allowed if the social value of the research is compelling and there is only a minor increase over minimal risk, upon such being approved by the relevant REC (see Guideline 14 of the 2016 CIOMS Guidelines).

1917 Guideline 14.

1918 Guideline 18. This formulation is in contrast to formulation in the 2002 CIOMS Guidelines, which simply required that investigators and other stakeholders 'should not exclude women...' Though 'must be included' (as used in the 2016 CIOMS Guidelines) could generally be said to mean closely the same thing as 'should not exclude', this is not so in the context of the two Guidelines (the Preamble to the 2016 CIOMS Guidelines makes it clear that they attach greater moral weight to the word 'must' than they do to 'should').

feeding women, they should also be involved in the study if the risk is minimal and the study is likely to produce relevant knowledge about the health needs of pregnant or breast-feeding women or their foetuses in general.[1919] Where the social value of the study on breast-feeding or pregnant women is compelling; the study cannot be conducted on non-breastfeeding or non-pregnant women and there is a minor increase over minimal risk, the study may also be allowed if the REC approves the study.[1920]

Women of child-bearing age, who must give informed consent on their own, must be informed of the risks of harm to the foetus in the event that they become pregnant.[1921] If the participation in the health research might be hazardous to the foetus in case the participants become pregnant during the duration of the study, researchers and sponsors must guarantee these participants access to contraceptive methods, pregnancy tests and legal abortion, whether before or during the participation.[1922]

One further relevant ethical instrument is the ICH Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2) (2016) (ICH-GCP Harmonized Guideline). Though the ICH-GCP Harmonised Guideline is mainly intended to provide a unified framework for the European Union, US, Canada, Japan and Switzerland, while drawing on some practices also from other countries like Australia and the Nordic Countries as well as WHO, the framework has served as a guiding standard in many other countries.[1923] The ICH-GCP Harmonised Guideline provides for a number of principles which should serve as guidance in the conduct of clinical trials.[1924]

1919 Guideline 19.

1920 Guideline 19.

1921 Guideline 18.

1922 Guideline 18. As a rule, the guarantee for the provision of access to effective legal abortion should be the condition for involving pregnant women in research that is likely to be hazardous to the foetuses in case pregnancy is unwanted (as a requirement) for such participation (see Guideline 19 of the 2016 CIOMS Guidelines).

1923 See the introduction to the ICH-GCP Harmonised Guideline. Also see The CRA Training Institute "Countries that follow ICH-GCP Guidelines for Clinical Trials''. https://crtinstitute.org/ICH-GCPcountries.pdf (Accessed 18 November 2021). The importance here is not about its adoption as law (as the European Union has for example done), but as an ethical instrument (see also Vijayananthan A and Nawawi O "The Importance of good clinical practice guidelines and its role in clinical trials'' (2008) *Biomed Imaging Interv J* Online. https://www.ncbi.nlm.nih.gov/pwc/articles/PWC3097692/ (Accessed 18 November 2021).

1924 Para 2 of the ICH-GCP Harmonised Guideline.

In the main the ICH-GCP Harmonised Guideline provides for the conduct of clinical trials to be done in line with the Helsinki Declaration and GCP.[1925] The ICH-GCP Harmonised Guideline further provides for the assessment of risks and benefits before the commencement of a trial.[1926] The ICH-GCP Harmonised Guideline further provides for the safety, well-being and rights of the research participant to override those of science and society.[1927] The ICH-GCP Harmonised Guideline further provides for a proposed study to be supported by adequate available information, both technical and non-technical.[1928] A study must be scientifically sound and accompanied by a clear and detailed protocol, which must have been approved by, or have received a favourable opinion from, an IRB before the commencement of the study.[1929] The ICH-GCP Harmonised Guideline further provides for the study to be preceded by a free and informed consent.[1930] The ICH-GCP Harmonised Guideline contemplates that those who are incompetent to give consent should be able to give assent, if their level of understanding so permits.[1931]

The ICH-GCP Harmonised Guideline, as a general rule, prohibits non-therapeutic research on those who cannot consent on their own, except under certain circumstances, including the fact that the research cannot be conducted on those who can consent on their own; the risks are minimal; that the law does not prohibit same and that the IRB has approved the decision or given a specific favourable opinion regarding same.[1932] Where in emergency situations a research participant cannot give prior consent and the legally acceptable representative, after being requested, is not

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1925 See para 2.1. Also see the definition of 'GCP' in para 1.24, which requires in substance that the conduct of clinical trials and the reporting of results thereof maintain credibility, accuracy and respect the confidentiality, integrity and rights of data subjects.

1926 Para 2.2. For the trial to continue the anticipated benefits must outweigh the anticipated risks.

1927 Para 2.3.

1928 Para 2.4.

1929 See paras 2.5 and 2.6. For information about IRBs, including their roles, functions, procedures and composition, see para 3.

1930 Para 2.9. The ICH-GCP Harmonised Guideline also specifically prohibits the inclusion of provision in the informed consent form, for waiver of certain legal rights, or for exemptions from liability (para 4.8.4). This provision is important as it rules out even the wishes of the parties concerned, if this would eventually disadvantage the research participant. This thinking is arguably in tune with the PLA framework contended for in this thesis. Further to be noted in the case of informed consent process is that where the research participant or his or her legally acceptable (authorized) representative cannot read, there must be 'an impartial witness' present during the whole informed consent discussion (para 4.8.9).

1931 Para 4.8.12.

1932 See paras 4.8.13 and 4.8.14. In general, such a study should be conducted on persons who have the diseases or conditions which the investigational products intend to resolve, subject to strict monitoring and possible withdrawal should a need arises (see para 4.8.14).

available to do so, the research can still be conducted in line with the measures provided for in the protocol and other documents, and as required by the relevant regulations, provided that the IRB approves or gives a favourable opinion, and provided further that the legally acceptable representative gives his or her consent so soon thereafter.[1933]

The investigational products should be manufactured, handled, stored and used in line with the protocol.[1934] The ICH-GCP Harmonised Guideline further provides for respect for privacy and confidentiality.[1935] The ICH-GCP Harmonised Guideline further provides for sponsors to make provision for compensation, including indemnity covers for researchers, for injuries sustained during the conduct of the trial, except for injuries arising from negligence or malpractice.[1936]

As indicated in chapters one and two, UNESCO has had several declarations and related instruments which though not legally binding have far-reaching implications for bioethics. These declarations include the UNESCO Bioethics Declaration; Universal Declaration on the Human Genome and Human Rights (1997) (Human Genome Declaration);[1937] Recommendations on the Status of Scientific Researchers (1974) (RSSR)[1938] and the International Declaration on Human Genetic Data (2003) (Genetic Data Declaration).[1939] Only the UNESCO Bioethics Declaration, because of its generic nature and therefore coverage of some of the principles in the other UNESCO instruments, requires further elaboration in this Chapter. As indicated in Chapter One,

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1933 Para 4.8.15.

1934 Para 2.12.

1935 Para 2.11.

1936 Para 5.8.1.

1937 Which provides for, amongst other things, everyone to have his or her dignity respected irrespective of genetic characteristics (art 2(a) of the Human Genome Declaration). It further provides for the prohibition of discrimination based on genetic characteristics if that discrimination is 'intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity' (art 6). It further prohibits practices which are not consistent with human dignity, and these include reproductive cloning of human beings (art 11)). It further encourages the establishment of independent, multidisciplinary and pluralist ethics committees for the purposes of assessing the legal, ethical and social issues of research (art 16).

1938 Though, as indicated in chapter two, the RSSR mainly focuses on the protection of scientific researchers, its provisions have implications on other stakeholders in research. For example, the RSSR not only requires member states to protect researchers, but also those who are likely to be affected by the research (see art 29(a)).

1939 This requires, amongst other things, that human genetic data and related materials be collected, processed, used and stored in accordance with international human rights law (art 1(b)). It further requires that human genetic data and human proteomic data not be for discriminatory purposes with the effect of infringing human rights and human dignity or with the effect that it causes stigmatization (art 7(a)).

the UNESCO Bioethics Declaration provides for several biomedical principles. Before discussing these principles, a brief outline of its aims is necessary.

One of the aims of the UNESCO Bioethics Declaration is the promotion of respect for human dignity; ensuring respect for human life and respect for fundamental freedoms, in line with the principles of international human rights law.[1940] The UNESCO Bioethics Declaration further aims to promote a 'multidisciplinary and pluralistic dialogue' on bioethical issues, amongst the various stakeholders and within the rest of society as a whole.[1941] The UNESCO Bioethics Declaration further aims to promote and protect the interests of not only the present generations, but also of the future generations.[1942] The UNESCO Bioethics Declaration further provides for the value of biodiversity and its conservation, to humankind.[1943]

As observed in chapter one, the bioethical principles the UNESCO Bioethics Declaration provides for respect for human dignity and human rights;[1944] respect for autonomy;[1945] informed consent;[1946]respect for human vulnerability;[1947] respect for privacy and confidentiality;[1948] respect for equality, justice and equity;[1949] solidarity and cooperation;[1950] the social responsibility in health matters;[1951] the sharing of

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1940 Art 2(c).

1941 Art 2(e). This approach is arguably more communitarian, and tends towards the PLA framework argued for in this thesis.

1942 Art 2(g). This approach is also arguably more communitarian.

1943 Art 2(h).

1944 Most importantly in this regard, the UNESCO Bioethics Declaration requires that the 'interests and welfare of the individual' should be prioritized over the 'interest of science and society' (Art 3(2)). This could, depending on the context, be problematic as it is amenable to being interpreted as undermining public interest. But it might not necessarily be so if the principle is read together with the rest of the provisions in the instrument (this line of reading is also promoted by the Declaration itself in art 26).

1945 Art 5. For persons not having capacity to exercise this autonomy, special measures to protect them should be taken. This will certainly apply in the case of children (this article should be read with art 7, dealing with persons without the capacity to consent).

1946 This should be prior, express and free (and one thinks, specific) (art 6). Exceptions to this may be permitted in terms of the Declaration (more particularly in terms of art 27, which deals with permissible limitations to the provisions of the Declaration), and in terms of ethical and legal guidelines adopted by states and in line with international law. For persons with the capacity to consent, see art 7, which also provides for the possibility of assent (art 7(a)).

1947 This provides for the consideration of the vulnerability of human beings in general and the vulnerability of specific groups (art 8). This provision could be valuable to the protection of children, including displaced children.

1948 Art 9.

1949 Art 10. Also see art 11, which deals with non-discrimination and non-stigmatization. This should broadly be treated as part of equality, justice and equity. And so is art 12, which deals with respect for cultural diversity.

1950 Art 13.

1951 Art 14. This basically requires governments to place health promotion at the centre of their

benefits;[1952] the protection of future generations;[1953] and protection of the environment and the rest of the biosphere.[1954]

8.9.3 General observations

In general, the instruments from two of the regions namely the Inter-American and European continents, as well as at intercontinental level require oversight of research by an REC.[1955] These RECs must be independent and often multidisciplinary.[1956] This oversight therefore fosters the principle of accountability. Another critical issue arising from some of the instruments is the principle of transparency.[1957] The review of the science of the study, by the RECs, is treated as important by various instruments, including the Helsinki Declaration[1958] and the 2016 CIOMS Guidelines.[1959]

Some of the instruments also emphasise the primacy of the interests of a data subject, as opposed to the interests of science and society.[1960] Another common thread is the various instruments' approach to the issue of informed consent: the default line is that informed consent must be obtained directly from the research participant and if the

activity.

1952 This principle requires that benefits from scientific research 'should be shared with society as a whole' (art 15). However, such benefits should not become an inducement to partake in research (art 15(2)). This is an important principle more consistent with the PLA framework argued for in this thesis.

1953 Art 16.

1954 Art 17. This provision is arguably more in line with the PLA framework contemplated in this thesis.

1955 Regarding the African continent, as observed above, the region does not as yet have regional instruments specifically dealing with research issues. Those instruments like the AU Data Protection Convention and the African Women's Protocol only touch on research issues very briefly and therefore do not touch on oversight by RECs. The AU Data Protection Convention's reference to oversight by a national protection authority therefore falls short of satisfying the requirement of oversight by a REC (see art 10(4)).

1956 Also see other instruments like Standard 2 of WHO Standards and Operational Guidance for Ethics Review for Health-Related Research with Human Participants (2011) (WHO's Standards and Procedures), which requires the composition of RECs to be both 'multidisciplinary and multisectoral'. Further see para 3.2.2 of PAHO GCP. For independence of REC also see para 3.1.4 of PAHO GCP. Further see Standard 4 of WHO's Standards and Procedures for its provision for independence.

1957 This could for example arise from provision for registration of clinical trials in some instruments and the requirement that results of studies be published (the Helsinki Declaration covers both the issue of publication of results and the registration of clinical trials. Also see Guideline 24 of the 2016 CIOMS Guidelines, which also makes provision for the publication of results, which is covered as part of the public accountability guideline).

1958 Para 21.

1959 Guideline 1.

1960 See for example para 2.2 of the PAHO GCP. Also note para 3 of the Helsinki Declaration, implying that the patient's health is the primary consideration. Further see para 2.3 of the ICH – GCP Harmonized Guideline and art 3(2) of the UNESCO Bioethics Declaration.

research participant is incapable of giving such consent, an authorised representative should give the consent. A person incapable of giving consent but having a certain level of understanding should be requested to give assent, to the extent of that person's level of understanding.

The various instruments also provide for special protection for children and other vulnerable persons partaking in research by providing for amongst other things the framework within which children should participate in research, more especially if the research is non-therapeutic. Some instruments, including the 2016 CIOMS Guidelines and the Helsinki Declaration, further make provision for compensation, short of serving as an inducement, for injuries incurred during participation in research, in respect of which waivers are also prohibited. The Helsinki Declaration further makes provision for access to post-trial benefits.

8.9.4 Implications for health research

Provision for oversight by RECs no doubt enhances the protection of research participants. The provision for compensation for injuries during research is also very important in strengthening protection to health research participants. Allowing a study that is not likely to produce direct benefits to the research participants but may still lead to a better understanding of the disease or eventually beneficial to the individual or other persons with the same conditions,[1961] may be very useful in promoting public interest, and therefore the PLA contemplated in this research. Equally important, and in line with the PLA framework contemplated in this research, is the provision for post-trial access to benefits in some instruments.[1962]

8.10 Conclusion

This chapter had to examine the international legal framework, including frameworks from three regions namely the Inter-American, African and European regions. International instruments of an ethical rather than legal nature were also considered where relevant. The chapter started off by reflecting on the general international legal

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1961 As discussed, the OVIEDO Convention provides for this (see art 17 (2) (i) and (ii)). Further see Guideline 14 of the 2016 CIOMS Guidelines, in terms of which research may be allowed even if it is not directly beneficial to the participating children, if the social value of the research is compelling and there is only a minor increase over minimal risk.

1962 See for example para 34 of the Helsinki Declaration.

framework, including its approach to interpretation; rights limitations and public interest. As to the approach to interpretation international law was found to tend towards a purposive approach, at least in so far as the 1969 Vienna Convention mandates.[1963] As observed above international law further respects the freedom of contract, as between states.[1964]

As to rights limitations, although most international instruments tend to prefer internal limitations (qualifiers) rather than general limitation clauses, there is a common thread on the factors that serve as justifiable conditions for limiting rights. These factors or criteria for limitations tend to take a public interest approach, though the concept of 'public interest' might not itself be used in the process. Outside these limitations, although there is no general coherence as to public interest leaning, some instruments do have other provisions that could be viewed as at least recognising the importance of public interest. These concepts include 'common interest';[1965] 'common welfare'[1966] and 'general welfare'.[1967]

As to the approach to human dignity, various instruments at both international and regional levels were found to provide for this. The same applies to the question of equality and non-discrimination, where various instruments were also found to provide for this. Though most instruments do not expressly cover prohibition of discrimination based on sexual orientation, both the European and Inter-American regions do have instruments that expressly provide for this. The provision for human dignity and non-discrimination could play an important role in the protection of health research participants. The challenge however is that these instruments have hardly been relied on in health research-related cases, as discussed under national legal frameworks in chapters 4 to 6.

Various instruments, both regional and international, also make provision for the right of access to health care services. Various instruments also make provision for the special protection of children, therefore enhancing their protection in case of

1963 Art 31(1). Further see a corresponding provision, art 31(1) of the 1986 Vienna Convention, which provides for same.
1964 Art 26.
1965 Art 27(2) of ACHPR, which also uses the concept of solidarity. Arts 27 to 38 of CFREU are also constructed around the principle of solidarity.
1966 Art 3(k) of COAS.
1967 Art 4 of ICESCR.

participation in health research. The principles of best interest of the child and child participation (and child participation includes child assent) have been given primacy by several instruments. Though generally not much is said about displaced children, there are instruments also dealing with this, though mostly outside the context of research.[1968] These frameworks, if properly utilised, could be useful in the protection of children, including displaced children, participating in health research.

With regard to the protection of personal information and access to information various instruments at regional and international levels also provide for this, more in particular the protection of personal information.[1969] Various instruments at both regional and international levels also provide for remedies, often sought through judicial and related processes, in case some of their rights are violated. These, if relied on, are likely to enhance protection of health research participants.

A number of instruments, at regional and international levels, exist specifically focusing on research oversight.[1970] In general, the various instruments focus on the nature and role of the RECs in relation to research oversight, including the need for the RECs to be independent and multidisciplinary and the need to also focus on the science of the study. They also focus on the added protections for vulnerable participants, including those incapable of giving consent, in which case legally authorized representatives should do so, while the persons themselves may still be allowed to give assent, to the extent of their level of understanding. This goes a long way in protecting research participants.

Various instruments also provide for compensation for research-related injuries, while some also provide for post-trial access to benefits. This too could go a long way in enhancing protection for health research participants. In general, therefore, there is an abundance of international instruments regulating the conduct of research. There is

1968 UNGIDP and the AU Displaced Persons Convention are some of them. In the context of research the 2016 CIOMS Guidelines does touch on this by specifically classifying displaced persons as part of vulnerable groups, therefore requiring special protection.

1969 As to access to information, this is also covered in the instruments dealing with the protection of personal information. There are no dedicated instruments at regional and international levels focusing on access to information.

1970 The African continent however, as earlier indicated, does not have a dedicated instrument focusing on health research. Both the AU Data Protection Convention and the African Women's Protocol however touch on this very briefly.

even more of these instruments, to an extent of creating the problem of hierarchies, i.e. as to which ones should be given prominence.[1971]

To conclude therefore, while the various international instruments, both legal and ethical, do provide for a good framework for the protection of health research participants, the general tendency in the past, based on the observations from the health research cases discussed in chapters 4 to 6, has been not to rely on these instruments.[1972] On the contrary therefore, the tendency has been to rely on private law-inspired frameworks. This therefore warrants both a theoretical and pragmatic shift in the approach, towards a public law approach. The next chapter principally focuses on this aspect: the PLA.

1971 This, one thinks, could be partly handled through the application of the principle of subsidiarity, referred to in some European instruments, including the CFREU (art 51, read with the Preamble). In the European context though, there principle of subsidiarity has mainly been used to address the problem of state law versus union law, rather than the way it is understood in SA law, where it also includes the issue of a more specific norm versus a more general norm (See the discussion of this principle in Chapter Seven). Also see Follesdal A "The principle of subsidiarity as a constitutional principle in international law'' *Jean Monnet Working Paper* 12/2011. https://jeanmonnetprogram.org/wp-content/uploads/2014/12/JMWP12follesdal.pdf (Accessed 22 November 2021).

1972 The existence of an abundance of laudable instruments amounts to nothing if they cannot be relied on in practice.

CHAPTER NINE: THE PROPOSED PUBLIC LAW APPROACH TOWARDS HEALTH RESEARCH

9.1 Introduction

In the previous chapters, more particularly chapters one and three, the adequacy of the existing legal and ethical frameworks was reflected on. The discussion found, in the main, that although an abundance of frameworks having a public law content exists, these frameworks have rarely been applied in the context of health research. A private law approach, dominated by the common law, has instead been relied on with far-reaching negative implications for the protection of health research participants.[1973]

The inadequacy of this approach was reflected on and is again very briefly touched on here as and when it becomes necessary. Even in those instances where public law regulations could, for example, have been used this was not done in a systematic and deliberate attempt to respect the PLA, i.e. it was done without any of the decisions being consciously informed by the PLA framework, even if they may coincidentally rely on public law. An unconscious approach to the use of any framework, however laudable the framework may be, could result in inconsistencies in application.

The various chapters therefore identified a gap, both theoretically and pragmatically, in the approaches adopted when resolving health research issues. This gap is the absence of a PLA framework. This chapter therefore seeks to construct a PLA framework for the resolution of health research issues, so as to provide a theoretical account of some decisions in health research.[1974] Though the framework is intended to address mainly legal issues in the context of health research, it remains multi- and inter-disciplinary, therefore also responding to ethical questions.[1975]

1973 In the context of ethical frameworks, this has appeared in the form of undue emphasis on respect for autonomy, and sometimes the undue emphasis on the primary consideration of the interests of the research participant (examples here could be found in some instruments).

1974 This will be in attempt to answer one of the research questions posed in chapter one, being 'What is the most plausible legal and ethical approach for adequately dealing with the health research problems, and what is the nature of the obligations such an approach creates?'. Related questions arising from that chapter also revolve around the 'plausibility of using a public law approach in adequately resolving health research problems' and 'implications of a public law approach for the development of an ethical theory and theory of law as well as principles for the adequate resolution of health research problems'.

1975 This multi- and inter-disciplinary approach to the theory is intended to properly respond to the

The construction of this theory requires that one first briefly reflects on what the general requirements of a plausible moral (ethical) theory and a theory of law[1976] ought to be, and therefore reflect on whether the proposed PLA meets these requirements. The main claim of the PLA (including its key principles) are briefly looked at, followed by the possible objections to such an approach and responses to the objections. The implications of the theory on various areas relevant to health research is then analysed.

9.2 General requirements of a plausible and adequate theory

9.2.1 General requirements of a moral theory

For a moral theory to be plausible, it must meet certain general requirements. One of the requirements of a moral theory is that it must be comprehensive. This means that it must be broad enough to account for a variety of actions, dispositions or situations. This requirement could also cover generalisability and portability to a variety of contexts.[1977] Another requirement very closely related to, but distinct from, both comprehensiveness referred to above and consistency referred to below, is universalisability.[1978] This means the ability to apply the principle beyond a particular geographic community.

For a moral theory to be plausible consistency, in the sense of being compatible with other justified beliefs, is also required.[1979] A further requirement closely related to consistency, or even arguably another version of it, is coherence, in the sense of not

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multi- and inter-disciplinary nature of health research itself, more especially as it relates to the interplay between law and ethics.

1976 Unless the context indicates otherwise, one here uses the concept of a theory of law (or a theory in law) rather than a legal theory, because of the ambiguity that the concept of legal theory has, where it is sometimes conflated with the field of jurisprudence.

1977 Though generalisability and portability could, if viewed narrowly, be separate requirements of a theory, one treats them here as part of comprehensiveness. Implicit in the requirement of comprehensiveness is also the requirement of completeness of a theory.

1978 The principle is also closely related to the principle of impartiality (or external consistency), as discussed below. However, unlike impartiality, universalisability is here meant to go beyond mere fair treatment of everyone (in the sense of fair application of the rule to everyone) but covers instances where the rule applies beyond specific states, geographic spaces or other legally defined communities. Unlike the requirement of comprehensiveness, the requirement of universalisability also here goes beyond mere generalisability and flexibility but covers generalisability only in the context of going beyond legally defined communities and geographic spaces.

1979 See in this regard Jamieson D "Method and moral theory'' in Singer P (Ed.) *A Companion to Ethics* (Blackwell Publishing Oxford 1991) 482. Although he identifies two broad principles guiding theory building, namely foundationalism and coherentism, one only treats coherentism as one of the general elements in this thesis.

being internally contradictory or inconsistent. It is further required that a moral theory be impartial in application. Impartiality, in the sense of being capable of equal or fair application to all persons (and closely related to consistency), is therefore another requirement of a moral theory.[1980] A further requirement is that of comprehensibility. Comprehensibility in this context means that the theory must be understandable. This could arguably also include the theory's explanatory power. It is further required that a moral theory be based on reasons.[1981] Provision for human dignity and other rights constitutes another requirement of a moral theory.[1982] A moral theory must also provide for respect for the environment and the biosphere.[1983] A moral theory must further make provision for the respect for duties, obligations and responsibilities.[1984]

A moral theory must also provide for a mechanism to resolve conflicting rules.[1985] Lastly, a moral theory must accommodate instances of justified deviations, i.e. there must be instances where deviations from the general rule or principle are permissible.[1986] This may, in the context of the requirement of impartiality include

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1980 This could be more in the sense in which Immanuel Kant conceives it in his usage of universal law (see Rachels J & Rachels S *The Elements of Moral Philosophy* 6th ed (McGraw Hill New York 2010) 128. In this chapter however, the concept is not used in that sense. It is here used, though overlapping with Kant's usage, as something more akin to non-discrimination, absence of bias or treating everyone as an equal agent morally (see also Rachels and Rachels *Elements of philosophy* 169 and 115).

1981 Rachels and Rachels *Elements of philosophy* 174. It is not clear whether this means rationality or something else. It appears that it does (see Rachels and Rachels *Elements of philosophy* 174). Reason was also very central in Kant's theories, which viewed human beings as rational agents (also see Rachels and Rachels *Elements of philosophy* 137). Though the requirement of reason or rationality could also be viewed as equivalent to justifiability, one avoids the latter, for the confusion it might create in that all the requirements of moral theory are what justify that moral theory (for the existence of some relations between rationality and justification, see also Watson JC "Justification''. *Internet Encyclopaedia of Philosophy*. https://iep.utm.edu/epi-just/ (Accessed 7 December 2021). Though that article however touches on that relationship in the context of epistemology rather than ethics, it ought to be equally applicable here.

1982 This too was very central in Kant's ethical thought, in his principle of respect for persons (see Rachels and Rachels *Elements of philosophy* 137). One should however note that respect for human dignity and other rights as contemplated in this thesis may not necessarily be identical to Kant's conception of respect for persons, which arguably overemphasised individual autonomy.

1983 Most traditional ethical principles, including Kantian theory, did not make provision for this (also see Rachels and Rachels *Elements of philosophy* 136, where Kant saw creatures other than human beings as having value only as they served human interests.

1984 Although respect for duties, obligations and responsibilities could sometimes be inferred from the provision for human dignity and other rights, as provision for the latter implies that someone has the duties to respect them, the provision for respect for duties, obligations and responsibilities goes beyond such being a mere corollary of rights. There are duties, obligations and responsibilities that go beyond meeting expectations of rights fulfilment.

1985 In the case of law, the principle of subsidiarity could be one such example.

1986 Most ethical theories and principles, including Immanuel Kant's categorical imperative in terms

justified partiality, i.e. it must accommodate instances where deviations from the rule of impartiality should be permissible under certain circumstances. Most ethical theories do not accommodate the deviations from general rules.[1987]

9.2.2 General requirements of a legal theory

What should a conception of a legal theory here be? Because of the ambiguity that often accompanies this concept (which can be, and often is, conflated with the field of jurisprudence as a whole or a branch of law) one would for the purposes of this chapter, unless the context indicates otherwise, instead use the concept of a theory of law (or a theory in law).[1988] What then are the requirements of a theory of law? Most discussions in this area have revolved around theories around related concepts like the rule of law and of law itself, which is not what the discussion here is all about, although most of the requirements for a rule of law will coincidentally also serve as requirements for a plausible theory in law (The requirements for a rule of law and of law itself will therefore only be referred to because of, and in order to point out, this close relationship). The following requirements, some of which have been considered to be requirements of the rule of law (and perhaps of law itself), but which one considers to be also relevant for the purposes of (constructing) a theory of law, constitute key requirements for a theory of law.

A theory of law must be general in application.[1989] This means that at the time of its development, it must not be targeted against any person or an arbitrarily selected

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of which compliance with rules is absolute, do not provide for deviations, however justified they may be (see Rachels and Rachels *Elements of philosophy* 127 – 135. It is interesting to note however how Kant struggled to respond to objections to his theory in this regard, by failing to adequately respond to the imaginary case of an enquiring murderer, who if told the truth would find and kill the escaping victim). It should be stated that a principle of this nature is already motivated by public interest concerns, as most deviations from general rules, as observed in the case of international instruments discussed in chapter eight, are often aimed at addressing issues generally affecting the public, including public safety, public morals, public health, public order, etc. The inclusion of justified deviations as one of the requirements of a moral (ethical) theory is therefore one of the inevitable implications of a PLA.

1987 Scholars like Thaddeus Metz hold that African Ethics does however provide for such partiality (see Wareham CS "Partiality and distributive justice in African bioethics" (2017). https://pubmed.ncbi.nim.nih.gov/28349324/ (Accessed 16 January 2021). Virtue theory does however also provide for partiality.

1988 One will here, unless the context indicates otherwise, use the concept interchangeably with, or to also mean, a legal rule or even a rule of law (rather than the rule of law. As to the distinction between the rule of law and a rule of law (which refers to a specific legal rule), see Waldron J "The Rule of law" 2016 *Stanford Encyclopaedia of Philosophy. https://plato.stanford.edu/entries/rule-of-law/* (Accessed 5 December 2021).

1989 This is an important requirement of the rule of law too, and one of Lon Fuller's proposed

group of persons. Another requirement of a theory of law is that the theory must be publicly known.[1990] It is also one of the requirements of a theory of law that it applies prospectively.[1991] A further requirement is that the theory must be comprehensible.[1992] So that those who have to comply must know beforehand what is expected of them, it is a further requirement of a theory of law that it must be predictable.[1993] A further requirement is that a theory of law must be internally consistent.[1994] It is a further requirement of a theory in law that it must be effective in application.[1995] A further

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requirements of the 'inner morality' of law (see Waldron https://plato.stanford.edu/entries/rule-of-law/ (Accessed 5 December 2021)).

1990 This too is an important requirement of the rule of law and also one of Fuller's proposed requirements of law (see Waldron https://plato.stanford.edu/entries/rule-of-law/ (Accessed 5 December 2021)).

1991 Also, one of the requirements of the rule of law and one of Fuller's proposed requirements of law, this requirement militates against new rules being applied to what has already been done, i.e. retrospectively. Also see Waldron https://plato.stanford.edu/entries/rule-of-law/ (Accessed 5 December 2021)). For a presumption against a retrospective application of legislation see Botha C *Statutory Interpretation: An introduction for students* 5th ed (Juta Cape Town 2012) 55. That a theory must also provide for justified deviations will however allow for deviations from this principle too (in which case, retrospective (retro-effective) application may sometimes be allowed) (see for example Botha *Statutory Interpretation* 61, for exceptions to the presumptions against retrospective application of legislation. The presumption, for example, does not apply where the retro-effective application of legislation benefits the individual against whom it applies). One should however note that in the context of a constitutional review of legislation, i.e. where the constitutionality of legislation is challenged, retrospective application of the declaration of unconstitutionality is a default position, and prospective application thereof an exception. For example, the court in *Mahlangu and Another v Minister of Labour and Others* 2021 (2) SA 54 (CC) paras 124, 129 and 131, consistent with s 172(1) (b) of the Constitution, ruled that the order of declaration, as unconstitutional, of certain provisions of the Compensation for Occupational Injuries and Diseases Act 130 of 1993 (which excluded domestic workers from claiming in case of work-related injuries) should apply retrospectively. Further see s 172(1)(b)(i) of the Constitution, which provides for such a retrospective application of the declaration of invalidity as a default position, and prospective application only as an exception (In other words, the wording of s 172(b)(i) suggests that unless the court orders the declaration of invalidity not to apply retrospectively, it will by default apply retrospectively). The retrospective application of declarations of invalidity could at face value appear contradictory to the presumption against retrospective application. This is not necessarily so if one locates this broadly within the presumption against retrospective application to which, as earlier indicated, there are exceptions in case an individual benefits from the retrospective application (Firstly, declarations of invalidity are more likely to be beneficial to individuals than a disadvantage to them. Secondly, the common law presumption against retrospective application of legislation mainly applies to legislation, and not to declarations of invalidity, which take the form of court orders).

1992 Also, part of the requirements of the rule of law and one of Fuller's proposed requirements of law, this means that it must be clear and understandable (also see Waldron https://plato.stanford.edu/entries/rule-of-law/ (Accessed 5 December 2021)).

1993 One of the requirements of the rule of law and one of Fuller's proposed requirements of law, this includes the question of stability and certainty of the particular rule (also see Waldron https://plato.stanford.edu/entries/rule-of-law/ (Accessed 5 December 2021)).

1994 This requirement, stated as coherence, is one of Fuller's proposed requirements of law (also see Waldron https://plato.stanford.edu/entries/rule-of-law/ (Accessed 5 December 2021)).

1995 This is closely related to what is stated by Fuller, in relation to the requirements of law, as being 'practicable' (see Waldron https://plato.stanford.edu/entries/rule-of-law/ (Accessed 5 December 2021)).

requirement that ought to be included as a requirement for a theory of law is respect for legality.[1996] It is further proposed that a theory must respect human dignity and other rights. It is a further requirement that a theory must provide for respect for duties and obligations. Provision for respect for the environment and the biosphere is a further requirement of a theory of law. A theory of law must further provide for a framework for resolving conflicting legal principles or rules.

It is further required that a theory must be based on reason, i.e. it must be justifiable.[1997] A theory of law must further provide for enforceability.[1998] Impartiality in application is a further requirement of a theory of law. A theory of law must also provide for the appeal to, or reviewability by, higher courts or other competent judicial authorities.[1999] A theory of law must provide for finality.[2000] Lastly, a theory of law must further provide for justified deviations, including justified partiality.[2001]

9.3 The proposed 'Public Law Approach' theory

9.3.1 The theory's main claim and its key features

Before outlining the PLA's main claim it needs to be restated that it is a multi- and inter-disciplinary theory intended to serve as both a moral theory and a theory in law, depending on the contexts in which the theory is invoked.[2002] Where it is applied as a moral theory, some of the principles for a theory in law might not be applicable[2003] and

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1996 Waldron https://plato.stanford.edu/entries/rule-of-law/ (Accessed 5 December 2021). Though it is discussed in the context of the rule of law, it is not quite clear if the discussion considers this to be just an extension of the rule of law or to be a separate requirement for the rule of law. One however, for the purposes of the requirements of a theory of law, treats it as a separate requirement.

1997 However, to avoid the possible fallacy of 'circular reasoning', 'reason' is however here preferable to 'justifiable' (as all these principles are, broadly speaking, about the 'justifiability' of a theory) (for examples of fallacies, see Dowden B "Fallacies''. *Internet Encyclopaedia of Philosophy*. https://iep.utm.edu/fallacy/ (Accessed 12 December 2021).

1998 This includes provision for effective remedies.

1999 This principle is subject to the principle of finality of court decisions (also see *Thubakgale and Others v Ekurhuleni Metropolitan Municipality and Others (CCT 157/20) [2021] ZACC 45 (7 December 2021) para 181)).*

2000 Also see *Thubakgale and Others v Ekurhuleni Metropolitan Municipality and Others* paras 181 - 184.

2001 This requirement, just like in the case of the requirements for a moral theory, is an inevitable implication arising from the PLA framework.

2002 To illustrate this point, in a court case dealing with the resolution of a health research problem the usage of the theory will mainly be in a legal context, and therefore relying on the legal principles located within the theory. Where however a REC is reviewing a research protocol the theory will, unless the context requires otherwise, mainly serve as an ethical rather than a legal guidance.

2003 Principles of legality and those of prospective application of a law will, for example, certainly

the same, though rarely, will also hold true where the theory in a specific situation is only meant to apply as a theory in law, rather than a moral theory.[2004] This means that the PLA theory will move between law and ethics, depending on the context of the usage.

The PLA's main claim is that decisions (actions) in health research are right if they are based on, and actors in health research good if they are motivated by, public considerations, including public interest, common interest, general interest, Ubuntu, interests of justice, and respect for human rights. On the contrary, decisions (actions) in health research are wrong, or at least less commendable, if they are based solely on, and actors in health research are bad if they are motivated solely by, private or individualist interests, and undermine justice, Ubuntu and human rights.

The theory's key principles or elements can therefore be broken down into the following: Ubuntu;[2005] justice (including administrative justice[2006] and social justice); transparency;[2007] accountability;[2008] legality;[2009] reason (including rationality);[2010]

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not be applicable where the theory in a particular situation is invoked as a moral theory.

2004 For example, universalisability, one of the key requirements of a moral theory, will often not be an issue when the PLA is applied in legal contexts (or at least it will not apply to the same extent as it does in the moral contexts), as legal rules are often territorial, in the sense of applying mainly in specific countries. This does not however mean that there are no possibilities for broad general principles that ought to cut across various jurisdictions (a reflection on this possibility is however parked for the purposes of this thesis).

2005 This is broad enough to cover instances of beneficence and harm-avoiding.

2006 The principle of administrative justice will however, more often than not, not be an issue when justice in raised in a moral context.

2007 This principle could include requirements that results of a study be published. Though some instruments including, as observed in chapter eight, the *Helsinki Declaration*, do make provisions for the publication of results, the traditional ethical theories do not properly account for how this principle could work out. In the case of utilitarianism for example, how could it assess the best consequences if a publication of results could, for example, lead to a travel ban on the researchers' own countries, as it recently happened when a travel ban was imposed on SA after announcing its discovery of the Omicron variant? (For further information about the travel ban, see Ellis E "Travel ban threatens information sharing, weakens global solidarity''. 2021 – 12 – 04. Daily Maverick. https://www.dailymaverick.co.za/article/2021-12-04-travel-ban-threatens-information-sharing-weakens-global-solidarity/ (Accessed 12 December 2021).

2008 The principle could, in contrast to social contract theory (at least based on Hobbes's conception of the power of the sovereign), be important in ensuring that everyone, including state actors, are held accountable for atrocities. It equally addresses a related weakness, as observed in chapter 3, inherent in legal positivism arising from the unaccountability of the sovereign, being unlikely to be bound by the law, as the lawmaker.

2009 This will mainly be applicable where the theory serves mainly as a theory in law, rather than also as a moral theory.

2010 Although rationality could also be included in other principles like the principle of legality, it is here stated separately (as part of reasons) not only for emphatic purposes, but also because legality will not be relevant in the context where a research protocol is assessed in moral rather than legal contexts, while reasons or rationality (which speaks to the justifiability of the study) remains relevant.

respect for human dignity;[2011] non-discrimination;[2012] respect for fundamental human rights;[2013] use of effective public law remedies; justified balancing of conflicting rights and rules;[2014] special protection for vulnerable persons; public interest and justified limitation of rights.[2015] These principles are, in substance, aligned to both the general requirements for a moral theory and a theory in law. Most importantly, not only is the content of these principles aligned to the general requirements, but the content of the general requirements has greatly been shaped by the proposed broader paradigm shift towards a PLA.[2016]

9.3.2 What are the key features of the theory that make it more plausible than other leading theories?

The theory possesses certain distinct features making it more plausible than its leading counter parts. The theory is, unlike most other leading theories, not reducible to a single principle, but is instead based on a cluster of principles or considerations. It was observed in the discussion of theories in chapters 1 and 3 that some, if not most, major theories tend to be reductionist in their approach.[2017] One other distinct but related

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2011 Though human dignity is also, broadly viewed, another type of human rights, it is here stated separately due to its significance, and also as the foundation of most of the other rights (also see Riley S and Bos G "Human Dignity''. *Internet Encyclopaedia of Philosophy*. https://iep.utm.edu/hum-dign/ (Accessed 7 December 2021).

2012 Although this generally forms part of other human rights, it is here only stated separately because of its significance.

2013 This covers other rights like respect for autonomy and freedom. Because there may be tension between freedom (which may often take individualist forms, as happens in contracts) and public interest considerations, a balancing approach needs to be adopted where this arises. Where freedom of contract, for example, undermines public policy considerations (as often happens when a person is required to waive his or her rights, or to exempt the other party from liability), the latter (public policy considerations) should take precedence. The same approach should be adopted where tensions exist between respect for autonomy and public interest. A similar approach could be adopted where tension between privacy and public interest arises where, for example, demands of disclosure of research participant's personal information by law enforcement authorities, for prosecution purposes, could create such a tension. In the context of health research participants who might be displaced children, respect for human rights here would also include respect for international human rights law and principles of international humanitarian assistance.

2014 In a legal context this may arguably include subsidiarity rules (the latter was discussed in Chapter Seven).

2015 This principle in the main includes provision for justified deviations, including justified partiality in the case of general rules about equality or impartiality. This may also include other principles like rationality, proportionality, reasonableness and necessity.

2016 For example, the proposed inclusion of respect for human dignity; respect for the environment and the biosphere and accommodation of justified deviations in the general requirements for both a moral theory and a theory of law is already influenced by the proposed shift in thinking towards a PLA.

2017 Utilitarianism, a version of consequentialism, tends to reduce the rightness and wrongness of

feature about the theory is that it is not only action-defining nor only character-defining.[2018] The theory is based on the assessment of both actions and characters, and is also not closed to any other considerations beyond this.[2019] The PLA theory therefore does not face the problem of incompleteness, i.e. not adequately accounting for a variety of situations that health research actors might be faced with. Another plausible aspect of the theory is that it serves as a better guidance for action than theories like virtue ethics and deontology.[2020] The flexibility that comes with a framework which consists of a cluster of principles also creates a balancing approach that places the PLA theory, if applied correctly, in a better position to avoid the risk of historical tendencies of protectionism (in the sense of over-protectionism); hard paternalism and *laissez fairism* observed in chapter 2.

The theory's explicit multi- and inter-disciplinary focus is very useful in the context of the multi-and inter-disciplinary nature of health research,[2021] where there is often an

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actions to consequences. Virtue ethics tends to reduce the goodness and badness of actors to their character. Kantianism arguably reduces everything to duty and reason (see also Rachels and Rachels *Elements of philosophy* 128 and 133).

2018 The other leading theories namely deontology, consequentialism and virtue ethics are grounded on a false dilemma fallacy, where they should either be action-based or character-based. Both deontology and consequentialism are for example only action-defining, while virtue ethics is only character-defining.

2019 There could, for example, be considerations that may not easily be pigeonholed into either actions or characters, but which may have an impact on the conduct of stakeholders in health research. A general state of affairs, conditions, dispositions or a particular environment, not definable in terms of actions or characters, could still impact on the conduct of stakeholders in health research. A general tendency in society to stigmatise the presence of certain conditions in people could, for example, undermine the protection of such people if researchers were to be also trapped in that attitude. The fear of certain policy positions or reactions by states, as it happened when many states imposed a travel ban on SA after discovery by SA scientists of the Omicron variant in SA, could influence the way researchers approach the issue of transparency. The resultant attitude of the researchers cannot be easily defined in terms of assessing the individual actions or character of a researcher, but of the totality of the environment that threatens transparency. The PLA theory's possible accommodation of these other considerations is therefore important in enhancing protection for health research participants.

2020 Though utilitarianism could also be said to be provide a good guide for action compared to the other two major theories when used as a moral guide, this may not necessarily be the case when the principle is used in legal contexts.

2021 To this multi- and inter-disciplinary nature of health research one could add the international (cross-territorial) nature of health research, where legal rules alone, which are often bound by national or regional borders, might not be enough to respond to problems in health research. The ethical dimension of the PLA theory, given the borderless nature of the application of ethical principles, will therefore try and mitigate against some of the limitations in the way the law applies (even international law already has limits in its application, and therefore cannot cure this deficiency unless also supported by ethical principles). Other traditional theories, which tend to focus on ethics alone and only used in legal context through complex adaptation, are therefore also deficient for not accounting for those instances where legal clarity might instead be required for the purposes of resolution in a litigation context.

interplay amongst various fields, more in particular between law and ethics. The theory's provision for the mechanism for resolving conflicting rules, rights and principles is another plausible factor.[2022] A further plausible feature of the theory is its provision for justifiable deviations from general rules under certain circumstances.[2023] The theory also properly accounts for the rights' framework, something that other traditional theories like virtue ethics and utilitarianism cannot properly account for.[2024]

9.3.3 What the 'Public Law Approach' theory is not about

Having discussed what a PLA theory is about, it is necessary to also in brief indicate what the PLA is not about, so that if any objections are raised, they are properly directed to the right issues. The PLA is not about the displacement of private law but about an equal consideration of public law in health research. It is therefore about creating space for the equal or equivalent use of public law frameworks where the resolution of the case requires this. It is also about the use of PLA as an alternative to private law approaches in those instances where private law is unsuited, i.e. ineffective.[2025] Even where private law is found necessary (suitable) but not sufficient, this may also require its correction or supplementation by public law approaches, without the need to take an either/or approach.[2026] The PLA framework argued for here therefore mainly serves as an anti-thesis against the dominant use of private law, with the ultimate thesis being the co-existence of the two approaches, from a position of equality. Whether this should be done through an integrated, or parallel process will

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2022 This is not a feature of most, if any, of the major traditional theories (one however, as observed in chapter three, does take note of Utilitarianism's ability to resolve conflicting rules, arguably because of its simplicity).

2023 This is also not a feature of most of the leading theories. Note however virtue ethics' recognition of justified partiality (see Rachels and Rachels *Elements of philosophy* 169).

2024 Although utilitarianism does not rule out rights protection completely, its methodology often presents a risk to the rights framework (also see Rachels and Rachels *Elements of philosophy* 113). For possibilities that utilitarianism could also use a rights language, see Sinnott-Amstrong W "Consequentialism'' 2019 *Stanford Encyclopaedia of Philosophy.* https://plato.stanford.edu/entries/consequentialism/ (Accessed 6 August 2020). Further see Bilchitz D, Metz T and Oyowe O *Jurisprudence in an African context* (Oxford University Press Cape Town 2017) 137 – 140.

2025 Effectiveness is an important element of the concept of appropriateness, as provided in s 38 of the SA Constitution (see *Thubakgale and Others v Ekurhuleni Metropolitan Municipality and Others* (CCT 157/20) [2021] ZACC 45 (7 December 2021) para 47).

2026 This may for example be the case through the development of the common law to reflect other public law-oriented considerations (though s 39 of the SA Constitution already provides for this, this has not yet been invoked in the context of health research litigation).

depend on the context. Both private law and public law approaches therefore remain relevant in areas traditionally suited for them.

9.3.4 Possible objections to the theory and responses to the objections

One of the major objections to the theory could be that the theory, though in principle also accommodating the assessment of character rather than only actions, most of the principles it is founded on are modelled around the language of actions' assessment rather than character assessment. It is therefore, it could be argued, not clear as to when it will be suitable to base an assessment on actions, rather than on character, and vice versa. Closely related to the earlier objection, it may also be raised as an objection that the theory's non-reducibility to a single phenomenon (or characteristic) may make it difficult to predict beforehand which principles fall under its framework. Because of these shortcomings, the advantages that often come with virtue ethics' assessment of character, one of them being moral motivation, become weaker for the PLA theory.

The possible response to this argument is that virtue ethics' combination with other action-based assessment principles cannot fundamentally affect its motivational power as a moral theory. If it does have some effect, this will be in the direction of enhancing, rather than reducing its power. In a legal sense, it might not be necessary to be unduly concerned about the combination of action-based and character-based theories, as this is often the case in legal instruments regulating the conduct of professions, where the instruments often focus on both the conduct and the character of the professionals.

One of the further notable objections likely to be raised is whether a PLA theory does accommodate individual rights, and if it does, whether this does not create an internal contradiction (in terms), therefore undermining the requirement of coherence that all theories in law are expected to satisfy. In other words, this objection could go, it is a contradiction in terms to claim that a public law approach could protect individual rights, which are mainly the domain of private law claims.[2027] Closely related to this

[2027] Put differently, it would be an absurdity to deny that the PLA does not come into conflict with individual human rights, when its language already implies such a conflict.

objection is also the uncertainty around the nature of the proposed relations between private law and public law.

The possible response to these objections is that, in relation to whether the PLA protects individual rights, and the possible contradiction if it does, yes it does protect individual rights, but without promoting individualism. In other words, under the PLA respect for human rights, including individual rights, is viewed as part of the promotion of general interest, depending on the context in which such rights are protected. If the rights, for example, are pursued to the disadvantage of the general public, this might not be acceptable under the PLA. In the context of contractual arrangements for example, the parties' freedom to contract is respected, but if it may transpire that the parties did not conclude the contract from a position of equal strength, it could be in the public interest that the weaker party be protected despite having agreed to the unfair terms (the prohibition against exemption clauses and other forms of limitation of liability, as discussed mainly in chapters 4 to 8, may be seen as promoting a PLA framework when viewed from this angle).

What should further be noted, and this responds also to the related objection to the uncertainty about the proposed relations between private law and public law is that the theory, as partly alluded to earlier, is not intended to do away with private law, but merely to ensure that public law applies equally alongside it and where appropriate serves as its alternative,[2028] or merely cure its deficiencies where the context demands this.[2029]

Lastly on objections, it could be objected that although the PLA's proposed principles include the mechanism for resolving conflicting rules and principles, it still lacks specificity in that it is not clear as to how these principles will be ranked in case such

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2028 This may be the case where (in the case of serving as an alternative) a private law basis is totally unsuited to resolve a particular problem. Both private law and public law approaches should however still serve as default positions in their 'traditional areas', where they are most suited. In contractual claims for example, a private law approach should still assume a default position, and the PLA only coming in to cure its deficiencies. Where a person claims to vindicate his or her constitutional rights, public law should ideally serve as a default position, without however ruling out the applicability of private law where the context requires. The PLA therefore does not seek to create an either/or situation, where it is either private law approach or public law approach, or nothing.

2029 Public law will in such a case be playing a supplementary role. As partly alluded to earlier, this could be the case where the common law has to be developed so as to reflect certain public law-oriented values, as contemplated in s 39(2) of the Constitution.

a conflict arises, i.e. in other words, if the principle of public interest conflicts with that of individual rights, we should be able to know in advance as to which principle will reign supreme. The response to this is that, it might be difficult to do that in advance, as it might not be ascertainable (in advance) as to what the basis of the conflict is.[2030] If a person were to be asked to participate in an experiment where the risk of death is very high, while the benefits to the person are very low, it might not be inconceivable that individual rights might reign supreme, after taking into account other relevant factors (including the potential or otherwise of the study to save many other lives if successful). In other words, it is consistent with the PLA framework not to reduce the conflict resolution framework to a single principle.

9.3.5 Justifiable conditions for the use of the 'Public Law Approach' framework

All law arguably sets some limits on people's freedoms. An approach with a public law orientation is no exception. It arguably even sets more limits than would a law with a private law orientation, making the tension between individual rights and some of the principles under the PLA framework inevitable.[2031] The PLA framework's inevitable restriction on individual human rights therefore requires some justification and this will be the case where the restriction on human rights is of serious nature. This therefore requires that the justifiable conditions for such limitation be set out.[2032] Though it is not possible to set out a closed list for such conditions, the following conditions, some of which should be read in combination, are considered important: proportionality; necessity; public health; in the case of law, compliance with the law; reasonableness and prevention of unjustified discrimination.[2033] Setting justifiable requirements or conditions is very important in enhancing the protection mechanism for health

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2030 Also note the reluctance to set such principles in advance by Childress JF et al "Public Health Ethics: Mapping the terrain'' in Beauchamp TL *et al* (eds) *Contemporary Issues in Bioethics* (Wardsworth Cengage Learning Belmont 2008) 634 – 635.

2031 This will often be the case where there is a conflict between public interest considerations and individual human rights.

2032 Also see a related framework by Childress *et al Contemporary Issues in Bioethics* 635, developed in the context of the tension between public health considerations and other moral considerations.

2033 Perhaps one will need to distinguish instances where the PLA will apply without posing a threat to individual rights and where it will do so. For example, to require that constitutional damages be also awarded cannot be viewed the same way as requiring that everyone be vaccinated for public health reasons. The former does not threaten individual rights, and if it does, this will only be very minimal, and therefore requiring minimal justification. Compulsory vaccinations do on the contrary limit individual rights to a significant extent, and therefore requiring greater justification to be implemented.

research participants in that it creates checks and balances. Because justifiability itself is an important feature of the PLA, setting justifiable requirements strengthens the theory.

9.3.6 The implications of the 'Public Law Approach' theory for specific areas

9.3.6.1 Implications for information protection and access

It was observed in chapters four to eight that various instruments, both nationally and internationally provide, as a default position, for the protection of personal information. Various exceptions, or exemptions in some cases, exist, including data subject consent,[2034] public interest,[2035] processing in compliance with a law and procession for research purposes.[2036] Some of these exceptions, including processing in the public interest; processing in compliance with a law and public interest are consistent with the PLA framework argued for here.[2037] With regard to access to information, prohibition of access to information is also, in the main, guided by the protection of

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2034 See for example, s 11(1)(a) of POPIA, requiring a data subject's consent or, in the case of a child, that of a competent person, for the lawful processing of persona information.

2035 See in particular, s 37(1) of POPIA. Sections 27(1)(d) and 35(1)(d) also qualify the processing of personal information for research purposes by 'public interest' (note however that s 37(2) already includes research purpose processing as part of the definition of public interest, so the qualifications (by public interest) in ss 27 and 37, which create an impression that there are research purpose processions that might not be in the public interest, therefore appear redundant).

2036 See for example s 18(4)(f)(ii) of POPIA, which provides for exception to the notification duty of the responsible party (openness condition), if the collection is for research purposes. This provision does not however expressly qualify the research purpose exception by 'public interest'. This creates inconsistencies in the way research purpose is understood in POPIA as a whole, i.e. whether it includes public interest as contemplated in s 37(2), or whether the concept may only include public interest under certain circumstances (as in ss 27(1)(d) and 35 (1)(d)). The wording of these exceptions also implies that consent of the data subject may be unnecessary once the processing is for research purposes, therefore leaving research participants less protected. This implies, for example, that personal information may be transferred to a third party in a third country or to an international organization without consent, if the provision is read this way (this line of thought can be inferred from the fact that the exception is also to s 18(1)(g), which requires the responsible party to make the data subject aware before transferring personal information to a third country or an international organization). The exception impacting on the transfer of personal information should however be read with s 57, which requires prior authorization from the Information Regulator in case of transfer of special personal information or personal information relating to children (This approach, as it relates to special personal information or personal information relating to children, is therefore arguably consistent with the PLA). Also unqualified (by public interest) is the research purpose exception to further processing limitation condition (see s 15(3)(e)). Further unqualified is the research purpose exception to the purpose specification condition (see s 14(2))

2037 Although research purpose exception is not always, or consistently, treated as a public interest issue by various instruments, including SA's POPIA, it is arguably consistent with the PLA framework contended for in this thesis (in fact, public interest is just one of the criteria for the PLA but, though the most critical, is not the only one).

personal information, or other considerations related to the protection of confidentiality. There is however also here a public interest override, in the sense that access to information may be mandatory where such public interest in such access outweighs public interest in preventing access.[2038]

This means that in both the protection of personal information and request for access to information considerations consistent with the PLA come into play, though the basis for public interest considerations is not wide enough to cover a variety of contexts. What is proposed however is more clarity and general coherence with regard to these matters, more especially in relation to the relationship between public interest and research purpose exceptions. Such clarity could enhance the protection of health research participants. It is further proposed that in relation to transfer of personal information to a third country or international organization, there should also be more stringent oversight than exists now, where there is not enough oversight in the case of transfer of personal information other than special personal information and personal information involving children.

9.3.6.2 Implications for legal standing

It was observed in chapters four to seven that the common law's approach to legal standing is mainly grounded on private law and is therefore very narrow.[2039] The approach is unsuited to dealing with public law claims.[2040] The common law rules are therefore more suited to, and in fact designed for, the resolution of disputes between two individuals, where the claims are often narrowly focused and backward looking, i.e. focusing on past events.[2041] If research participants were for various reasons not in a position to pursue cases on their own, the common law approach could therefore be defective in ensuring that their interests are protected. The PLA's public interest principle could therefore be important in grounding claims on public law bases.[2042]

2038 This outweighing of public interest will be done where the disclosure is likely to reveal a serious violation of the law or a serious or imminent environmental risk or public safety (see ss 46 and 70 of PAIA). The basis for this override is however very narrow, so though public interest is provided for, it might not necessarily cover a variety of situations.

2039 *Ferreira v Levin NO and Others* 1996 (1) SA 984 (CC) para 229. Also see Hoexter C *Administrative Law in South Africa* 2nd ed (Juta Cape Town 2012) 489.

2040 *Ferreira v Levin NO and Others* para 229.

2041 *Ferreira v Levin NO and Others* para 229.

2042 One is however aware that even the current constitutional framework, under s 38 of the Constitution, though providing for public interest litigation, does not cover instances where the person is not vindicating his or her rights under the Bill of rights. This means that where a

9.3.6.3 Implications for health care services

Provision of health care is very central in the successful conduct of health research,[2043] therefore making its adequate provision in both national and international law very important. The specific provision for health care as a right, in various national and international instruments,[2044] may therefore go a long way in ensuring that those partaking in research have adequate access to health care. Even where countries and some international instruments make provision for this right, such framework has not yet been used in the context of litigation on health research matters. There must therefore be a shift in this regard, where the rights framework is not only provided for in instruments but is also, where this is relevant in the context of health research litigation, interpreted and used consistent with the PLA theory contended for here. The PLA framework could also therefore properly account for why there is, or should be, a relationship between the right to health (as provided in some national and international instruments) and the provision of compensation for research-related injuries and the provision for post-research benefits, i.e. why the right to health could, for example, sometimes be used as the basis to claim some post-research benefits. The way the right to health care is approached, more so if it is also dealt with as a socio-economic right, as is the case in South Africa, may properly account for why researchers should not only focus on the scientific aspects of research, but also on its social value.

9.3.6.4 Implications for the protection of children

Existing framework in most instruments dealing with the protection of children provide for the best interest of the child principle. This remains important in the context of protection of health research participants. As observed in chapters 4 to 8, various national and international instruments further provide for added protections for those, including children, incapable of acting on their own. In the case of children this includes provision for child participation in decisions affecting the child. This means that even

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person is not vindicating his or her rights under the Bill of Rights, the person is still confined to the common law requirements of standing. This is not very ideal. One therefore proposes that the public interest basis be also used even when a person is not vindicating his or her rights under the Bill of Rights.

2043 Health research participants may, for example, need access to health care prior to, during and after the conduct of the health research. Those injured during research may, for example, need immediate medical attention.

2044 While, as observed in chapters four to eight, South Africa and some international instruments do make provision for the right of access to health care, the UK and the US do not have, in their instruments, provision for health care as a right.

if a parent or another legally authorized representative has given consent, the child must still be permitted to give assent, depending on the child's level of understanding. This enhances the protection of a child who participates in health research.

Participation of children in health research is also preceded by further conditions, including the fact that where the child does not directly benefit from the research, the research must only be done if it cannot be conducted on adults, unless the participation of the child is necessary and the risks to the child are no more than minimal.[2045] While some instruments, including some South African instruments and international instruments, provide for a rights-based approach to the protection of children, this approach is not expressly provided for in the UK and US. The rights-based approach, if interpreted and used consistent with a public law orientation, may also be useful in the protection of children, including displaced children, partaking in health research. To-date however, there is no evidence that this approach has been relied on in the context of health research litigation.

While this framework is consistent with the PLA theory contended for in this thesis there is yet no other theory, more especially in law, properly accounting for why the protection of children should take the shape some of the instruments already provide for. What currently exists therefore is just a set of provisions dealing with the protection of children, without a clear theoretical basis that shapes the content of these provisions. The PLA's principle of concern for the vulnerable persons can therefore properly account for why children must be given special protection. This line of thought could then be also critical in the protection of displaced children, i.e. the principle of concern for vulnerable persons will properly account for why displaced children should even be given extra protection.

It was observed in the chapters 4 to 8 that there are not enough instruments dedicated to the protection of displaced children in the context of health research. While the general framework for the protection of children, if properly interpreted, could also protect displaced children, it is however imperative that countries not only make provision for the protection of children in general, but also for the specific protection of those children who are displaced. This will ensure that these categories of children are not solely dependent on whether those interpreting the framework will be charitable

[2045] See, for example, Guideline 17 of the 2016 CIOMS Guidelines.

enough to cover their situation. The child protection framework must therefore be explicit regarding the protection of displaced children, including provision for their rights, given their added vulnerability. The rights-based approach, regarding children in general and displaced children in particular, when read together with the PLA principles, including the PLA's Ubuntu principle, will be useful for the protection of children participating in health research.

9.3.6.5 Implications for the defining of the nature of the obligations

A public law approach creates consciousness on the part of stakeholders in health research, including those adjudicating health research matters, that the relationship between, or amongst, various stakeholders is not only a private law relationship, but that it could also be a public law relationship governed by public law. A public law relationship will give rise to public law obligations and public law remedies. Parties seeking to pursue health research cases will therefore be able to ground their claims also on public law. Courts will also be able to formulate legal questions also having public law in mind. This will ensure, as further explained under approaches to judicial review and remedies below, that the remedies resulting from this are not too narrow or ineffective.[2046] From an ethical point of view, the PLA's Ubuntu principle could properly account for why, as a matter of human solidarity, the various stakeholders should cooperate and support one another, and this could motivate the provision for compensation for research-related injuries and post-research benefits.

9.3.6.6 Implications for judicial review and remedies

Remedies remain very important in the context of the resolution of health research problems. For effective remedies to be realized there must also be effective enforcement of disputes, including by way of judicial review. The role of the courts and similar institutions in this regard must therefore be guaranteed in national and international instruments. There must be a guarantee of the review of decisions on

2046 Some common law remedies, for example, under the law of delict, are not suited to deal with some claims (See *Thubakgale and Others v Ekurhuleni Metropolitan Municipality and Others* para 68, where the court (though stated in the minority judgement) indicates how the delictual remedies might not be suited to vindicate certain claims, more in particular constitutional rights. This is in contrast to the more general and forward-looking public law claims. It is therefore important to note that the impact of infringement of public law rights goes beyond those who might be litigating at a particular point in time (also see paras 43 and 49)). The limits of contract law are also self-evident, namely that if there is no contractual relationship the claimant cannot rely on a contract.

fair, lawful, reasonable, constitutional and other similar grounds generally recognized in law for this purpose.

The scope of remedies available to litigants in health research disputes must also be widened, also covering public law-based remedies.[2047] It was observed in chapter four that although South Africa does not reject the notion of constitutional damages, there has been general reluctance to award such damages. This reluctance can best be inferred from a minority judgment in *Thubakgale and Others v Ekurhuleni Metropolitan Municipality and Others*,[2048] which though it (the minority decision) supported constitutional damages in this case, still expressed caution against it. The Court said:

> Our courts rarely award constitutional damages. That is understandable. After all, relief in the form of constitutional damages ought to be considered only in those instances where it will provide the most effective relief.[2049]

The PLA argued for here contemplates that constitutional damages should also be relied on rather than using the private law, common law-based remedies as a default position.

9.3.6.7 Implications for health research oversight

2047 Both ss 38 and 172(1)(b) of the Constitution already anticipate some wider and flexible remedies, by providing for appropriate relief as well as just and equitable remedies, respectively (also see *Thubakgale and Others v Ekurhuleni Metropolitan Municipality and Others* (CCT 157/20) [2021] ZACC 45 (7 December 2021) para 76). It should however be noted here that the concept of 'appropriate relief' contemplated in s 38 is not confined to public law remedies, but may also include private law remedies (see in this regard *Law Society of South Africa v Minister of Transport* 2011 (1) SA 400 (CC) para 74; also see *Thubakgale and Others v Ekurhuleni Metropolitan Municipality and Others* para 74).

2048 *Thubakgale and Others v Ekurhuleni Metropolitan Municipality and Others* para 72.

2049 *Thubakgale and Others v Ekurhuleni Metropolitan Municipality and Others* para 72. Also see the majority position as per Jafta J (para 121), which is even more blunt, at least in so far socio-economic rights are considered, and it says: "While I agree with the first judgement that leave to appeal should be granted because a decision of this court will provide guidance on whether constitutional damages should have been granted, I disagree that such damages should have been allowed here. I accept that in an appropriate case constitutional damages may be awarded but not to enforce socio-economic rights. As a matter of principle, there is no room for constitutional damages where one is enforcing a socio-economic right".
For the court's attitude towards the awarding of constitutional damages in socio-economic rights cases, further see paras 157 – 158; 169 and 171. In general, the courts' approach towards constitutional damages is to rely on them only as a last recourse, i.e. where no other appropriate relief is available, a point which one finds problematic (see also paras 175 – 176). But also see however, Mhlantla J's concurring judgement, which does not rule out constitutional damages in case of violation of socio-economic rights, where they constitute an appropriate relief as contemplated in s 38 of the Constitution (para 196). Mhlantla J does not however substantially depart from the general attitude adopted by courts, which does not see the claim for constitutional damages as the first option (see para 197).

While some of the implications of the PLA to research oversight have partly been touched on above, e.g. those relating to the protection of children, a few other aspects relating to the implications of the theory need some consideration.

9.3.6.7.1 The role of Research Ethics Committees

The RECs play an important role in research oversight. One of the implications that a PLA theory raises is in relation to the role RECs could play in relation to the review of science, therefore placing scientific validity of research also at the centre of ethical reviews. While some instruments, as observed mainly in chapter eight, do provide for the review of science by a REC, there is no clear theoretical account from major theories on this. The PLA theory could adequately account for this: the non-review of the scientific aspects could undermine other principles espoused by the PLA. The principles likely to be threatened by the non-review of the scientific aspects of the research include the principle of transparency; accountability; non-discrimination[2050] and rationality. In the South African context, it is also doubtful if the REC, by not reviewing the scientific aspects of the study, will have complied with its statutory mandate in terms of s 73(2) of the NHA, which sets out some of the aims of the review as being the promotion of health; contribution to 'the prevention of communicable or non-communicable diseases'; contribution to the prevention of disability and contribution to the cures of 'communicable or non-communicable diseases'.[2051] The principle of impartiality could also play an important role in ensuring that RECs act independently when conducting reviews. The principles of transparency and accountability could also ensure that REC members avoid conflicts of interest, or at least disclose if any exists.

9.3.6.7.2 Payment of compensation for research-related injuries

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2050 This will, for example, speak to the fact that the aims of the study should not promote discrimination on several generally prohibited grounds of discrimination, including race, gender, sex, homosexuality, etc. As observed in chapters one and two, history is full of examples of research conducted with the aim of promoting discrimination. The research atrocities that led to the *Nuremberg Trial* immediately after the *World War II* is one such well-known example. Research solely meant to promote specific ideological positions could also be uncovered through the review of the science by RECs. For the relationship between science and ideology, see Martin EC "Science and ideology''. *Internet Encyclopaedia of Philosophy*. https://iep.utm.edu/sci-ideo/ (Accessed 8 December 2021).

2051 S 73(2)(a). This provision, which principally promotes public health, will be undermined if RECs Do not review the science of the research. This will no doubt also undermine the PLA contemplated here.

The existing dominant framework, under private law, though capable of dealing with compensation for research-related injuries, is not adequate to do so. Under contract law for example, such compensation will only be possible if provided for in a contract. If sponsors were to specifically exclude such payments in the contracts or related documents like informed consent forms, it will be difficult, if at all, for such payments to be available, unless there is a challenge to such exclusion on public policy grounds or other grounds more consistent with public law. As observed in the discussion of legal standing above, the action based on other common law grounds is also very limited and might not accommodate instances where someone must pursue the matter in the public interest. A PLA framework will not only help cure these deficiencies but will also, both legally and ethically, account for why any harm, broadly construed, occurring in the course of the research should be compensated for.[2052]

9.3.6.7.3 The provision for post-research benefits

It was observed in the previous chapters, more in particular chapter eight, that some instruments make provision for post-research benefits.[2053] This provision is often not of a legal nature, and therefore not enforceable in law.[2054] There is currently no plausible theory, at least in law, to account for the inclusion of the post-trial benefits. The existing common law will therefore not properly account for this. The PLA's principle of Ubuntu's could properly account for why sponsors and researchers, at least from an ethical point of view, should share their benefits with research participants. The PLA, which creates comparatively broader obligations, could also create space for the inclusion of the post-trial benefits in various instruments, as not only ethical but also legal obligations. If the researchers were to be employed by the state for example, and the research participants later require health-related benefits from the researchers, there could be a case to be made for the research participants to be provided with same, to the extent of the availability of resources.[2055]

2052 Though several instruments, including Guideline 14 of the 2016 CIOMS Guidelines and para 15 of the Helsinki Declaration, already make provision for compensation for research-related injuries, there is currently no plausible theory, more especially in law, that properly accounts for such provision.

2053 See for example para 22 of the Helsinki Declaration.

2054 See for example para 1 of the Helsinki Declaration, which emphasizes the Declaration's ethical status.

2055 This line of thought is also in line with the way courts have interpreted socio-economic rights in South African law, which makes their enforceability dependent on the availability of resources (also see *Thubakgale and Others v Ekurhuleni Metropolitan Municipality and Others* para 155

9.4 Conclusion

This chapter had to both address the problems identified in the earlier chapters about the dominance of private law approaches in health research and identify the gaps. The chapter therefore had to focus on the development of a plausible theory to address the gap. The chapter first outlined both the general requirements of a plausible moral theory and that of a plausible theory in law. The chapter then had to, in line with these general requirements, develop a multi- and inter-disciplinary theory, referred to as the Public Law Approach (the PLA). The multi- and inter-disciplinary focus of the theory, as alluded to above, is necessitated by the nature of the problems the theory must help resolve, which also take a multi- and inter-disciplinary form.[2056]

Apart from its multi- and inter-disciplinary form, other distinctive features of the theory, making it more distinct than other leading theories, were identified. The theory's provision for the resolution of conflicting rules or principles was identified as laudable. The theory's provision for justified deviations was also identified as laudable.

Several areas where the theory may find useful application were identified. The plausibility of the PLA, more in particular its principle of public interest, with regard to legal standing was highlighted.[2057] The PLA, if properly applied, could be very useful in the protection of personal information, including the protection of personal information in the event of transfer of personal information to third parties located in third countries or to an international organization. The PLA could therefore in this regard improve the current legal framework, at least in the SA context, dealing with the protection of personal information, which is less coherent. It may also in particular increase protection of personal information of all kinds and for everyone, in case of transfer, rather than only special personal information and personal information relating to children.

In the case of the protection of children participating in research, the PLA, through in particular the principle of Ubuntu and the principle of concern for the vulnerable

– 156 and 174. Further see *Government of the Republic South Africa and Others v Grootboom and Others* 2001 (1) SA 46 (CC) paras 41 – 46).

2056 Health research, apart from the field of medicine, heavily involves an interplay between law and ethics.

2057 This is in sharp contrast to the private law – based common law framework regarding standing, which does not accommodate instances where a person is acting in the public interest.

persons, has also been found to be potentially useful in accounting for why there should be added protective measures for such children, including those who are displaced. Though most of the instruments do provide for the special protection of children, most of the existing theories however do not properly account for why there should be such an added protection. In the case of displaced children there is also very little said about their protection, more particularly in instruments dedicated to health research.

The PLA framework has also been found to be potentially useful in defining the content of obligations and potential remedies amongst the key stakeholders in health research. The framework widens the scope of obligations and remedies to also include public law obligations and remedies (including constitutional damages), which have generally been absent in the context of health research, more especially in health research litigation. The PLA has also been found to be useful in providing a proper account for the potential relationship been the right to health and the provision of post-research benefits and compensation for health research-related injuries.

The PLA has also been found to be potentially useful in the case of not only providing for compensation for injuries during research, but also for properly accounting for its inclusion. The same goes in the case of provision of post-research benefits which the PLA, through in particular its principle of Ubuntu, can properly account for. The theory can also properly account for why RECs should review the scientific aspects of research in that the absence of such a review could undermine other PLA principles like non-discrimination if the research were, for example, to have discriminatory aims.

The overall observation from this chapter is therefore that the PLA theory, by not only relying on private law but also public law, does provide for added protection to health research participants. Because the theory does not seek to displace other existing approaches like those reliant on private law but merely to co-exist with them on an equal basis, it is not likely to face objections of being inadequate as a theory. The theory is flexible enough to cover, or adapt to, a variety of situations.[2058] This being

[2058] Without committing further to this point, as this might be a subject of another research on its own, the PLA approach could broadly be said to support a move towards what one could, for lack of a better concept, consider a progressive legal culture (or progressive legalism). The word progressive is here used in a jurisprudential rather than a political sense. A progressive legal culture could, in one's view, denote the tendency of the law and its practice to be receptive to new dynamics as well as, in a balanced and non-dogmatic manner, to be able to influence

the last chapter that must deal with one of the key aspects of the research questions, it is apt to state that the PLA is the plausible theory, asked for in the research question, to adequately deal with health research problems. The plausibility of the theory could be gleaned from what was discussed under the theory's distinct features, and under the implications of the theory for specific areas relevant for health research, including its implications on health research oversight. It is further apt to say that the PLA has, as observed, some implication on the development of both the moral theory and a theory of law, and the development and choice of various principles useful for the resolution of health research problems. Having answered the major aspects of the research questions in the various chapters, the next chapter (chapter ten) then concludes the whole of the study.

change in the direction of the most vulnerable in society. Whether (and how if it does) this conception differs from the concept of transformative constitutionalism expounded by legal scholars and other jurists is beyond the scope of this research, except to say that the conception propounded here, though consistent with the concept of transformative constitutionalism, is arguably more extensive than what is generally propounded under the latter concept, whose thinking mainly revolves around the SA Constitution, rather than the law and its practice *in* general. For various discussions around transformative constitutionalism, see Langa P "Transformative constitutionalism'' 2006 *STELL LR* 351 – 360; Mbenenge SM "Transformative constitutionalism: a judicial perspective from the Eastern Cape'' 2018 *Speculum Juris* 1 - 7; Law GupShup "Constitution Day 2019: Transformative constitutionalism and the Indian Supreme Court'' (2019). https://lawgupshup.com/2019/11/constitution-day-2019-transformative-constitutionalism-and-the-indian-supreme-court/ (Accessed 23 January 2022); Twala T and Mogadime M "Transformative adjudication and the place of administrative law in South African jurisprudence: ABSA Bank Limited v Public Protector" 2020 *PSLR* 362 – 380; Klare KE "Legal culture and Transformative Constitutionalism" 1998 *SAJHR 146 – 188;* Kibet E and Fombad C ''Transformative constitutionalism and the adjudication of constitutional rights in Africa'' 2017 *AHRLJ 340 – 366;* Burns Y and Henrico R *Administrative law* 5th ed (Lexis Nexis Durban 2020) 129 - 157 and Moseneke D *"The fourth Bram Fischer memorial lecture: transformative adjudication". 2002 SAJHR 309 – 319.*

CHAPTER TEN: CONCLUSIONS AND RECOMMENDATIONS

10.1 Conclusions

This study had to examine the existing approach to the resolution of health research problems, and whether the approach is adequate or not. The study further had to examine what the most plausible theory governing health research problems is, as well as the nature of the obligations such a theory creates. It further had to examine the plausibility of a public law approach in the resolution of health research problems. The implications of the public law approach in the development of an appropriate ethical theory, theory of law and relevant principles also had to be examined. The study also had to examine how the South African framework compares with that of other countries as well as with international law.

Answering these questions required that the historical development of various legal and ethical frameworks be examined which chapter 2, in the main, dealt with. The various tendencies, not necessarily in any particular order, that shaped this historical development were also examined. These tendencies include determinism; paternalism; *laissez fairism* and protectionism (it was important to reflect on these tendencies so as to ensure that the PLA framework proposed in chapter 9 does not get negatively affected by these tendencies. If necessary, the PLA framework has to respond to such tendencies). The period starting from the 70s, it was observed, tended more towards protectionism (at least in so far as the conduct of research was concerned).

Chapter 3 then had to examine the existing theoretical frameworks and assess their adequacy. The general observations to be made from the chapter is that most of the traditional theories tend to be reductionist. It was also observed that some theories like positivism, though not reductionist, tend to be too rigid, and therefore less likely to adequately respond to a variety of contexts. It was observed that even in those instances where the different theories possess positive features, the theories are not adequate when used in isolation.

Chapters 4 to 7 had to answer the research question about how the South African legal position compares with the position in other jurisdictions.[2059] Chapter 4 then

[2059] Chapter 4 had to examine the South African legal position while chapters 5 and 6 had to

examined the South African legal and other regulatory framework, including some ethical framework provided for in some instruments. Both the general SA legal framework and the framework relating to specific areas were looked at.[2060] The generic framework reflected in particular on the supremacy of the SA constitution; the purposive nature of interpretive framework; the inclusion of socio-economic rights in the Constitution; the horizontality of the constitution and the public interest approach to legal standing, which are the key features of the South African legal framework. The implications of any of these factors to health research and to the PLA framework were reflected on.

In respect of specific areas, the study found that there is sufficient legal framework to protect children and this framework includes the common law, the CA and the Constitution, supported by case law.[2061] The key principles governing the protection of children include the best interest of the child standard and the principle of child participation. These principles however, though very laudable and consistent with the PLA framework argued for in this thesis, have not been used in the context of health research litigation. The study also found that there is no specific legal framework dealing with the protection of displaced persons, therefore leaving them to rely on the legal framework protecting children in general.

At comparative level, the study found that although some of the principles like the child's best interest standard are applicable in the UK, there is generally no rights language in the UK legislation governing children.[2062] The rights language in the ECHR, though not specifically dealing with children, could however also be relied to protect children.[2063] As observed in chapter 6 in the US there is equally no rights

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examine the UK and US legal positions respectively. Chapter 7 then had to do a comparative analysis of the findings in chapters 4 to 6.

2060 The specific areas mainly include approaches to the protection of children; human dignity; equality; judicial review; privacy and access to information; right to health care; remedies and research oversight.

2061 Though the SA framework with regard to the protection of children is generally satisfactory, it still does not provide sufficient clarity on the protection of unborn children, therefore making such categories of children vulnerable in case they are the subjects of research.

2062 The UK's children protection framework is regulated by both the 1989 Children's Act and the 2004 Children's Act. It should further be noted that the UK also does not accord legal personality to unborn children (also see Riordan C "The legal rights of unborn babies" (2004). https://www.cambridgenetwork.co.uk/news/the-legal-rigths-of-inborn-babies. (Accessed 5 April 2021).

2063 One should however, as observed in chapter 5, note the weak impact of reliance on continental framework in the UK, arising from the UK's strong parliamentary principle, making it difficult for its own legislation to be invalidated by courts (the HR Act has solidified this by making the

language in the case of children,[2064] although the general constitutional framework can be, and has been, relied on to deal with children's issues.[2065] It was further observed that the US's reluctance to ratify the UN Convention on the Rights of the Child points towards its reluctance to endorse the rights language in the case of children.[2066]

With regard to human dignity the study observed that South African law makes provision for human dignity under the common law, legislation[2067] and the Constitution.[2068] Although the SA law's approach to human dignity was found to be consistent with the PLA framework argued for in this thesis, and useful for the protection of health research participants, the approach has yet to be relied in the context of health research litigation. At comparative level, it was observed in chapters 5 and 7 that the UK does not have any specific law expressly providing for human dignity, although there has been casual reference to it in case law. As to the US it was also observed that though human dignity is recognized under tort law, it is not the case under criminal law, i.e. its violation is not recognized as a crime.[2069] The US Constitution further does not make express provision for it.

Regarding approaches to equality, the SA legal framework expressly provides for equality in both legislation[2070] and the Constitution.[2071] Case law also fortifies SA's approach to equality issues.[2072] At comparative level, the UK does recognize equality

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declaration of incompatibility not leading to the invalidity of legislation). Another weak point relating to the reliance on continental legislation, as also observed in chapter 5, is the principle of margin of appreciation used in the European jurisprudence, which allows the courts to defer to member states in some cases.

2064 The US's non-ratification of the UN Convention on the Rights of the Child (1989) has also arguably weakened the US's rights protection framework in relation to children.

2065 See for example, *Carey v Population Services International 431 U.S. 678 (1977) where* the Supreme Court declared a law prohibiting the distribution and advertisement of contraceptives to persons, including children, unconstitutional for violating the First and Fourteenth Amendments. Further see *Prince v Massachusetts 321 U.S. 158 (1944), where the court held that a parent does not have the liberty, even if based on religious grounds, to expose children to diseases, ill-heath or death.*

2066 See Humanium "Signatory states and parties to the Convention on the Rights of the Child''. https://www.humanium.org/en/convention/signatory-states/ (Accessed 17 May 2021).

2067 It was observed in particular that PEPUDA creates a mutual link between human dignity and equality.

2068 See in particular s 10.

2069 See Evans S "Dignity in non-constitutional American jurisprudence'' (2018). https://delawarelaw.widener.edu/files/resources/saraevansdignityinamericanlaw.pdf (Accessed 28 May 2021).

2070 As observed in chapter 4, PEPUDA is one of the leading legislative frameworks providing for equality issues.

2071 In particular s 9.

2072 As observed in chapter 4, some of the leading cases include *Harksen v Lane and Others* 1998 (1) SA 300 (CC).

issues at both the common law and legislative levels. As observed in chapter 5, reliance by UK litigants can also be made on European instruments like the ECHR.[2073] The US's equality framework, as observed in chapters 6 and 7, is located in the common law, legislation and the US Constitution.[2074] As further observed, the US Constitution does not have express provision for instances where discrimination may be justified nor does it, in the main, have a list of prohibited grounds of discrimination. The equality framework has however not yet found application in the context of health research litigation in the three countries.

With regard to health care, it was observed in chapters 4 and 7 that SA provided for health care - related issues under both legislation and the Constitution as well as, though in a limited sense, the common law.[2075] The three categories of sources of law have further been fortified by case law.[2076] At comparative level, it was observed in chapters 5 and 7 that the UK does not specifically provide for access to health care as a right. As further observed not even the ECHR, which UK litigants may rely on, makes express provision for the right to health care. Though reliance on CFREU by UK litigants is uncertain the courts, as observed in chapter 5, do sometimes refer to it.[2077]

US law also does not, at least expressly, recognize a general right to health care.[2078] Not even the US Constitution makes provision for it. As observed in chapter 6, various other provisions of the US have been relied on to deal with health related issues, more especially in the context of challenges to public health laws.[2079]

2073 As observed in chapter 5, art 14 of the ECHR prohibits discrimination on a variety of grounds, including race, language, sex, colour, national or social origin, religion, political or other opinion, property, birth or other status and association with a national minority. It was observed in chapter 5 that this closed list could be disadvantageous to health research participants who might be potentially discriminated against on other grounds than those listed, including health status.

2074 In the case of the US Constitution, see s 1 of the Fourteenth Amendment.

2075 It was observed in chapter 4 that it is possible for health care - related issues to be governed by contracts. The law of delict could also become applicable under certain circumstances, more especially where injury has occurred.

2076 Note some of the leading cases in this regard namely *Soobramoney v Minister of Health (Kwazulu-Natal)* 1998 (1) SA 765 (CC) and *Minister of Health and Others* v *Treatment Action Campaign and Others (No 2)* 2002 (5) SA 721 (CC).

2077 Also see *A & Ors, R (on the application of) v East Sussex County Council & Anor* [2003] EWHC 167 (Admin) (18 February 2003), where such reference was made.

2078 As observed in chapter 6, it does not mean that other principles, including common law principles, may not be relied on to claim health - related rights.

2079 As observed in chapters 6 and 7, see for example *Jacobson v Massachusetts* 197 U.S. 11 (1905), where the vaccination laws were challenged, though unsuccessfully in this case.

Regarding judicial review it was observed in chapter 4 that SA legal framework provides for the review of decisions by the courts. Judicial review is provided for under the common law, legislation[2080] and the Constitution,[2081] supported by case law. It was observed in chapter 4 that since the aftermath of the new constitution, judicial review is now wholly shaped by the Constitution.[2082]

At comparative level the UK's judicial review, as observed in chapter 5, is mainly founded on the common law, where the principle of *ultra vires* serves as the main ground of review.[2083] The US's judicial review framework, as observed in chapter 6, is grounded on the US Constitution, legislation[2084] and the common law.[2085] The general trend in all the three jurisdictions is that the principles governing judicial review, laudable though they are and more consistent with the PLA framework in this thesis, have yet to be used in the context of health research litigation.

Regarding the approaches to remedies it was observed in chapters 4 and 7 that the SA legal framework provides for equitable remedies.[2086] As further observed SA law does not have separate courts for common law remedies and equity remedies, as is the case in the UK. With regard to constitutional damages the courts have however generally been reluctant in granting them, though accepting the possibility of granting

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2080 PAJA, which gives effect to s 33 of the Constitution, is the main legislation providing for judicial review. Review under specialized statutes is also possible, e.g. it is possible to review CCMA decisions in terms of the LRA.

2081 This will mainly be in terms of s 33 and under the principle of legality, which is an incidence of the rule of law (Also see *Fedsure Life Assurance Ltd and Others v Greater Johannesburg Transitional Metropolitan Council and Others* 1999 (1) SA 374 (CC) para 58)).

2082 Also see *Pharmaceutical Manufacturers Association of South Africa and Another: In re Ex Parte President of the Republic of South Africa and Others* para 44.

2083 Turner ID "Judicial review, irrationality, and the limits of intervention by the courts'' 2010 *Kings Law Journal* 311 – 331). Further see Law Teacher *Grounds of judicial review* (2019). https://lawteacher.net/free-law-essays/constitutional-law/grounds-of-judicial-review-constitutional-law-essay.php (Accessed 25 April 2021). As observed in chapter 5, the TCEA, SC Act, CPR and CRA do also provide for, or have provisions having an impact on, judicial review. As also observed in chapter 5 the HR Act, which gives effect to the ECHR, also has implications on judicial review.

2084 This is mainly through the APA.

2085 As observed in chapter 6, one of the early cases to kick-start the judicial review thinking in the US is the *Marbury v Madison* 5 U.S. (1 Cr.) 137 (1803). The position on judicial review is however, as observed in chapter 6, not well articulated in the US Constitution itself, though it can be inferred from other provisions like art VI.

2086 See, for example, s 172 (b) of the Constitution, which empowers the courts, when deciding on constitutional matters, to 'make any order that is just and equitable'. As observed in chapter 4, the CPA also makes provision for the courts to make a declaratory order that a particular conduct is unfair, unreasonable, unjust or unconscionable (s 52 of the CPA). Further note should be taken of the courts' rejection in some cases of exemption, limitation and similar clauses like forfeiture clauses (as was the case in *Botha and Another v Rich NO and Others*.)

same in principle.[2087] The courts have however generally been more blunt in the rejection of punitive damages.[2088]

At comparative level the UK also provides for equitable remedies.[2089] As observed in chapter 5, though the UK common law does not have general principles outlawing exemption clauses, some legislation does provide for this.[2090] US law also does make provision for equitable remedies, where existing law is not sufficient.[2091] The US law also makes provision for control of exemption clauses.[2092]

Despite that equitable remedies are provided for in the three jurisdictions, these remedies have not yet been invoked in the context of health research litigation.

Regarding privacy and access to information it was observed in chapters 4 and 7 that SA law provides for privacy under the common law, legislation[2093] and the constitution,[2094] while further augmented by case law. Access to information is mainly governed by legislation[2095] and the Constitution,[2096] while also augmented by case law.

2087 See *Fose v Minister of Safety and Security* 1997 (3) SA 786 (CC) para 67. Further see *this cautious approach in Residents of Industry House, 5 Davies Street, New Doorfontein, Johannesburg and Others v Minister of Police and Others* [CCT 136/20) [2021] ZACC 37 (22 October 2021) paras 91 - 92 and 97. The position appears to be that the remedy could be available but is seldom available where common law remedies are already available to vindicate the right concerned. Further see this line of reasoning in *Thubakgale and Others v Ekurhuleni Metropolitan Municipality and Others* (CCT 157/20) [2021] ZACC 45 (7 December 2021) paras 121; 157 – 158; 169; 175 – 176 and 196 – 197.

2088 See *Fose v Minister of Safety and Security* paras 70 and 73.

2089 As indicated above, the UK provides for equitable remedies separately from common law remedies. For further remedies see the TCEA, the SC Act and the HR Act.

2090 The Unfair Contract Terms Act 1977 (UCTA) is one such an Act (see Lawteacher "Exclusion clauses lecture" (2018) https://www.lawteacher.net/lectures/contract-law/construction/exclusion-causes (Accessed 2 April 2021). Also see the Consumer Rights Act 2015 (CR Act).

2091 Also see Cornell Law School "Equity''. https://www.law.cornell.edu/wex/equity (Accessed 12 June 2021). Equity is also provided for in art III (2) of the US Constitution. It should therefore be noted that just like SA, the US does not have separate courts dealing with equity, independently from those dealing with common law remedies. As observed in chapter 6, at legislative level Tittle VII of the Civil Rights Act of 1964 deals with injunctive relief.

2092 The Uniform Commercial Code (UCC) deals with exemption clauses. The courts have also dealt with exemption clauses (also see the case of *Henningsen v Bloomberg Motors Inc.* 32 N.J. 358 (1960)).

2093 Some of the key legislations dealing with privacy include POPIA, NHA, and PAIA.

2094 This is mainly provided for under ss 12 and 14 of the Constitution.

2095 This is mainly governed by PAIA.

2096 This is mainly provided for under s 32 of the Constitution, which PAIA gives effect to.

As observed in chapter 6, at comparative level the US does also recognize the right to privacy under the common law (mainly as part of the law of torts); legislation[2097] and the US Constitution.[2098] Regarding access to information, the US's Freedom of Information Act (FOIA) makes provision for access to information held by public authorities.

The UK, as observed in chapter 5, does not recognize a general common law right to privacy.[2099] At legislative level privacy is mainly regulated under the DPA, augmented at continental level by the GDPR. Regarding access to information the UK has the FOI Act, which makes provision for access to information held by public authorities.

As observed in chapter 7, the general observations made from the three jurisdictions is that although all the three jurisdictions do have instruments that refer to public interest, it remains unclear if public interest inherently covers research purpose processions. It was further observed that while South Africa's privacy and access to information laws mainly apply both vertically and horizontally, those in the UK and US mainly apply vertically. This could render research participants vulnerable to exploitation by private actors. It was further observed that while South Africa's POPIA also clearly protects personal information relating to juristic persons, the frameworks in the US and UK do not appear to cover such persons, or at least do not make this point clear. It was further observed that the three jurisdictions do not in the main cover personal information belonging to deceased persons.[2100] Lack of protection for deceased persons limits protection to research participants.

With regard to research oversight it was observed in chapters 4 and 7 that South Africa's legal framework provides for research oversight under the common law,[2101]

2097 The Privacy Act of 1974 and the EU – US Privacy Shield are some of the legal instruments providing for privacy in the US.

2098 Although the US Constitution does not have an express provision dealing directly with privacy, there are other provisions that indirectly do so, including provisions dealing with 'searches and seizure' as well as the liberty provisions (see Fourth Amendment and Fifth Amendment respectively).

2099 As observed in chapter 5, this does not mean that personal information cannot be protected under other existing frameworks, e.g. under contract law, property law, etc.

2100 As observed in chapters 4 and 7, although the POPIA, the main privacy law, does not make express provision for the protection of deceased persons while s 34(1) of PAIA does under certain circumstances, s 3 of POPIA could still be interpreted in such a way that the PAIA protection framework becomes applicable.

2101 Some of the common law principles were reflected in *Venter v Roche Products (Pty) Ltd* (A11/2014) [2014] ZAWCHC 157 (22 October 2014), one of the few cases, and arguably the only SA case to-date, dealing directly with health research issues.

legislation[2102] and the Constitution.[2103] It was further observed in chapters 5 and 7 that UK law provides for research oversight mainly in its common law[2104] and legislation.[2105] It was again observed that US law provides for research oversight mainly in its common law[2106] and legislation.[2107]

It was further observed, in relation to case law, that in the three jurisdictions there were, except for the US to a limited extent, no sufficient cases that dealt directly with health research issues. It was equally observed that all the cases in the three jurisdictions, except for some isolated cases highlighted in chapters 4 to 7, relied on a private law framework rather than a public law framework. It was further observed that none of the cases in the three jurisdictions were decided at the highest level, i.e. by the Supreme Courts in the US and UK, or the Constitutional Court (or at least the SCA) in South Africa.

The three jurisdictions, it was observed, provided for added protections in the case of involvement of children in research, depending on the expected levels of risks and benefits. The three jurisdictions, it was further observed, all provide for oversight by RECs. It was however, further observed that none of the three jurisdictions specifically make provision for the protection of displaced children involved in research.

2102 As discussed in chapters 4 and 7, this is mainly covered in the MSA, NHA and Health Research Regulations.

2103 S 12 of the constitution, as observed in chapters 4 and 7, requires those participating in medical or scientific experiments to first give informed consent.

2104 Some of the common law principles were discussed in *Morton James Wylie v Dr Donald Grosset, Greater Glasgow Health Board* [2011] COSH 89*, one of the few cases, if not the only UK case to-date, directly dealing with health research issues.*

2105 These include the Human Tissue Act (HTA); Care Act 2014 (Care Act); the Mental Capacity Act 2005 (MCA) and the Medicines for Human Use (Clinical Trial) Regulations (2004) (UK Clinical Trial Regulations). It was noted in chapters 5 and 7 that the ECHR does not make express provision for research related activities, although some of its general provisions could be relied on in research context. The absence of such express provision does however weaken the protection expected for research participants.

2106 This has been articulated in a number of cases including Abney et al v Amgen, Inc 443 F.3d 540 (6th Cir. 2006); Suthers v Amgen, Inc., 372 F.Supp. 2d 416 (S.D.N.Y. 2005) and *Grimes v Kennedy Krieger Institute, Inc.,* 728 A 2d 807 (Md. 2001).

2107 In addition to the National Research Act, the main legislative framework includes the *Federal* Policy for the Protection of Human Subjects (45 CFR 46 Subpart A) (the Common Rule) and the 45 CFR 46 Subpart D – Additional Protections for children involved as subjects in research (the 45 CFR 46 Subpart D). As observed in chapters 6 and 7 although the US Constitution does not make express provision for research oversight, other more general provisions could still be applicable to research context. The absence of such express provisions however weakens the level of protection expected for research participants.

The apparent similarities in the frameworks, it was pointed out, should not create an illusion that they also share the same meaning within their own respective jurisdictions. These apparent similarities should therefore be read together with other general principles applicable to the respective jurisdictions.[2108] It was further observed that except for South Africa, the two other jurisdictions do not clearly make provision for compensation for injuries during research. None of the three jurisdictions, at least in their legislation, specifically provide for post-research benefits.

Regarding ethical instruments it was observed in chapters 4 and 7 that South Africa's guidelines include the SAMRC Guidelines; HCPSA's Booklet 5; HPCSA's Booklet 13; 2020 Clinical Trial Guidelines[2109] and the 2015 Ethics in Research. The UK's ethical guidelines, it was observed in chapters 5 and 7, include the UK Governance Arrangements; ABPI PHASE 1 Guidelines; Phase 1 Compensation Guidelines; Phase II, III and IV Compensation Guidelines and MRC Children's Guide. The US's guidelines, it was observed in chapters 6 and 7, include AMA's Principles of Medical Ethics and the Belmont Report. The general conclusion made from the three jurisdictions, as observed in chapters 4 to 7, was that all the three jurisdictions had instruments that made reference, though using different formulations, to the established biomedical principles like beneficence; justice; non-maleficence and respect for persons. Instruments in the three jurisdictions also have clear provisions for research oversight by RECs. It was further observed that some instruments in both the UK and South Africa do clarify the question of payment of incentives for participation in research, while US instruments are silent on this question. Some

2108 For example, the mere fact that certain provisions will apply in a jurisdiction with a supreme constitution (as both SA and the US are) could give them a different meaning from those applying in a jurisdiction using the system of parliamentary supremacy (as the UK is). Where a particular supreme law emphasizes both vertical and horizontal application of its framework (as SA constitution does), while the frameworks in other jurisdictions mainly emphasize vertical application (as frameworks in the UK and the US appear to do), this could make another distinguishing impact on the application of principles that appear similar. Some frameworks in some jurisdictions (as the Common Rule does in the US), only apply to research that is funded, supported or regulated by federal government or its agencies. This approach is not applicable to SA and to a limited extent the UK (in the UK case, it was however observed in chapter 2 that the standard operating procedures created for research under NHS, and reviewed by the NHS RECs, could be interpreted as leaning more towards the US approach in this instance).

2109 As stated in chapters 4 and 7, one takes note of the fact that compliance with the 2020 Clinical Trial Guidelines is stated to be compulsory, therefore implying its having legal force. Its inclusion under ethical guidelines is however not considered to cause any damage to the discussion.

instruments in the UK and South Africa also do make provision for payment of compensation for injuries during research.[2110]

None of the ethical instruments consulted in the three jurisdictions make clear provision for post-research benefits.[2111] It was further observed that none of the ethical instruments consulted in the three jurisdictions make provision for the protection of displaced children partaking in research, therefore exposing these children to lesser protection.

On the international legal plane chapter 8 had to examine international law, including legal and ethical framework, at both intercontinental and regional levels.[2112] The chapter started off by examining the international law's general theory or framework. It then looked at the approach of international law towards specific areas, including research oversight, as also discussed in chapters 4 to 7. The general international framework covers in the main approaches to interpretation;[2113] public interests and rights limitations. The observation as to international law's general framework is that despite its strong respect for individual rights, this is also counterbalanced by some consideration of common interests in some cases.

Regarding the protection of children, the regional instruments, more particularly in the European and African continents, make provision for the consideration of the best interests of children and child participation. At intercontinental level, the CRC also makes provision for the consideration of the best interests of the child[2114] as well as child participation.[2115] It was further observed that the CRC makes provision for the protection of disabled children.[2116] Regarding the protection of displaced children, although there is no framework specifically dealing with displaced children, the African

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2110 As indicated earlier, in the case of SA the 2020 Clinical Trial Guidelines make provision for compensation for injuries during research only indirectly, through provision for insurance cover.

2111 One does however take note that the 'post-research treatment' referred to in Para 6.1.13 of the HPCSA's Booklet 13 could possibly be interpreted to include post-research benefits.

2112 The regions covered are the Inter-American continent; the African continent and the European continent.

2113 The 1969 Vienna Convention prefers a purposive approach to interpretation of international instruments.

2114 See art 3(1).

2115 See art 12(1).

2116 Art 23.

continent has the AU Displaced Persons Convention, which focuses on the protection of displaced persons in general. At intercontinental level there is also a general framework for displaced persons, namely UNGIDP which, though not dedicated to children, could be relevant in the protection of displaced children partaking in research. The CRC's provision for the protection of child refugees or those seeking refugee status, in line with international human rights law or international humanitarian law, could also be important in the protection of displaced children, who might also be refugees.[2117]

It was observed that the principles of best interest of the child standard and that of child participation, as also espoused in international instruments, could play an important role in the protection of participants in health research. It was further observed that the principles of international human rights law or international humanitarian law as espoused in the various instruments or frameworks could be very useful in the protection of displaced persons who partake in health research.

In relation to human dignity, it was observed that instruments at both regional and intercontinental levels make provision for respect for human dignity.[2118] Given the centrality of human dignity in health research, it was further observed, the provision for such could be very critical in the promotion of the PLA framework argued for in this thesis, and therefore enhancing the protection of health research participants.

In relation to equality it was observed that most of the instruments consulted provide, at both regional and intercontinental levels, for equality and non-discrimination. It was further observed that instruments in both European and Inter-American continents also make provision for the prohibition of discrimination based on sexual orientation while the general trend, outside the European and Inter-American levels, is to avoid making provision for the prohibition of discrimination on such a ground. While the general prohibition of discrimination in various instruments is laudable and therefore likely to protect participants in health research, the absence of express prohibition of discrimination based on sexual orientation in regional and intercontinental instruments

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2117 Art 22(1). At European level art 18 of CFREU provides for the rights of asylum seekers while, for the Inter-American continents, art xxvii of the American Declaration of the Rights and Duties of Man does the same.

2118 It was observed that some instruments like the African Women's Protocol and the ICCPR even go to the extent of providing a link between human dignity, or related provisions, to the health research context.

is a worrying issue. Such absence, which is inconsistent with the PLA framework contended for in this thesis, may likely undermine the protection of homosexuals who partake in research.[2119]

In relation to access to health care it was observed that most of the instruments at both regional and intercontinental levels make provision for health care or related needs. It was observed however that this provision is outside the research context. The principles, which are arguably consistent with the PLA framework contended for in this thesis, could however be adaptable to research contexts. Given the close relationship between health care provision and participation in health research, the provisions relating to health care could be very useful in the protection of health research participants.

In relation to judicial review and remedies at regional and intercontinental levels it was observed that most of the instruments at these levels make provision for the review of decisions by courts or other competent forums, as well as for the granting of effective remedies. Most importantly, it was observed that some of the instruments provide for effective remedies even if the perpetrators were acting in an official capacity.[2120] It was further observed that although the provision of effective remedies could be very useful in the protection of health research participants, these instruments have not yet been relied on in the context of health research litigation.

In relation to the protection of privacy, it was observed that most instruments at regional and intercontinental levels[2121] make provision for privacy. It was further observed that one of the common threads in the various regional and intercontinental instruments is the setting out of the conditions under which processing of personal information could take place. A further common thread, mainly in the regional instruments, is the provision for added protections in the case of the procession of sensitive personal information. A further common thread, also mainly amongst regional instruments, is the provision of justified deviations from the general principles

2119 In fact some may even be reluctant to participate in very useful research, for fear of victimization.

2120 This is, for example, specifically provided for in art 13 of the ECHR and art 2 (3) of the ICCPR.

2121 It was however also observed that at intercontinental level, except those whose coverage or application is limited, there is not as yet a single dedicated instrument focusing on privacy.

under certain circumstances.[2122] These provisions could go a long way in protecting health research participants.[2123]

Relating to research oversight it was observed that various instruments at regional and intercontinental levels provide for various mechanisms of oversight over research. These instruments include the EU Clinical Trial Regulations; the Oviedo Convention; the GDPR; the PAHO GCP; PANDRH's Pediatric Guide; AU Data Protection Convention; African Women's Protocol; Helsinki Declaration; 2016 CIOMS Guidelines; ICH – GCP Harmonized Guideline and the UNESCO Bioethics Declaration. As further observed the various mechanisms of research oversight in the main include provision for the approval of research by RECs;[2124] provision for the giving of informed consent by research participants (or data subjects) or their legally authorized representatives and the giving of assent by research participants incapable of giving consent if their level of understanding permits.

Some instruments also emphasize the need for the review of science by RECs.[2125] Some instruments also provide for access to post-research benefits.[2126] Other instruments also provide for reimbursements and reasonable compensation for participating in a research.[2127] Compensation for injuries arising from participating in research are also provided for in some instruments.[2128] Some instruments also provide for added protections for vulnerable groups.[2129] It was further observed that some instruments also provide for 'privacy-protective measures' in case the data used was obtained online.[2130]

2122 With the exception of the Inter-American continent, most of these deviations include processions for research purposes.

2123 It will of course be a debatable issue whether provisions for derogations or deviations (both in some national and international instruments), which in some cases include processions for research purposes, hinder or improve protection for research participants. This question is for the purposes of this thesis parked, and only responded to more generically: that it will be a matter of interpretation as to whether such provisions for derogations or deviations will hinder or enhance protection.

2124 These RECs, it was observed in chapter 8, must be independent and multidisciplinary (see Guidelines 8 and 23 of the 2016 CIOMS Guidelines. Also see art 16 of the Human Genome Declaration).

2125 See para 21 of the Helsinki Declaration and Guideline 1 of the 2016 CIOMS Guidelines.

2126 See para 34 of the Helsinki Declaration.

2127 See Guideline 13 of the 2016 CIOMS Guidelines.

2128 See Guideline 14 of the 2016 CIOMS Guidelines.

2129 Also see Guideline 15 of the 2016 CIOMS Guidelines.

2130 Guideline 22 of the 2016 CIOMS Guidelines.

These oversight mechanisms, in particular, the provision for approval by an REC; provision for assent; provision for the review of science by RECs and provision for post-research benefits are not only consistent with the PLA framework argued for here but also go a long way in protecting health research participants. The various instruments providing for these mechanisms, whether at national levels, as observed in chapters 4 to 6, or at international level as observed in chapter 8, have however yet to be relied on in the context of health research litigation. This has therefore prompted a need for a paradigm shift, both pragmatically and theoretically, towards a public law approach (PLA).

Chapter 9 had to, in answering some of the research questions, develop a public law approach towards the resolution of health research problems. The chapter, in particular, had to answer the questions as to what 'the most plausible legal and ethical approach' is for adequately resolving health research problems, and what 'the nature of the obligations such an approach' creates. The chapter further had to answer the question as to what 'the plausibility of using a public law approach' is in adequately dealing with health research problems. That chapter further had to, lastly, answer the question around the implications of a public law approach for the development of an ethical theory and theory of law as well as principles for the adequate resolution of health research problems.

The chapter, in an attempt to answer the above questions, started off by restating, as and when it becomes necessary, the dominant tendency to use private law approaches as opposed to public law approaches. The chapter further reflected on the general requirements of a plausible moral theory[2131] and of a theory of law,[2132] and then reflected on whether the proposed PLA meets these requirements (which it

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2131 As observed in chapter 9, these requirements in the main include comprehensiveness (including generalisability and portability); consistency; universalisability; impartiality; comprehensibility; provision for respect for human dignity and other rights; provision for respect for the environment and the rest of the biosphere; provision for respect for the duties, obligations and responsibilities; provision for mechanism to resolve conflicting rules; being reason-based and accommodation of justified deviations.

2132 These requirements in the main include being general in application; being publicly known; prospective application; comprehensibility; internal consistency (or coherence); effective application; respect for legality; respect for dignity and other rights; respect for duties and obligations; respect for the environment and the biosphere; provision for resolving conflict legal principles or rules; being reason-based; enforceability; impartiality in application; provision for appeallability or reviewability by higher courts or other competent forums; provision for finality and provision for justified deviations.

concluded it in substance does, as the PLA's key principles are substantially aligned to both the general requirements for a moral theory and those for a theory in law). The PLA's main claim and its distinctive features, followed by the possible objections and responses to the theory, were reflected on. The PLA's implications on various select areas of relevance to health research were then also reflected on. Without repeating the details discussed in chapter 9, it is here apt to sum up the theory's main claim and its distinctive features. Before briefly reflecting on the PLA's main claim it is, as observed in chapter 9, apt to point out that the theory is multi- and inter-disciplinary, therefore serving as both a moral theory and a theory of law, depending on the context of its usage.

As to the theory's main claim it was pointed out that the theory's claim is mainly that decisions or actions in health research are right if they are based on, and the actors in health research good if they are motivated by, public considerations, including common interests, public interests; respect for human rights; general interests; interests of justice and Ubuntu. On the contrary, it was pointed out, decisions or actions in health research are wrong, or at least less commendable, if they are based solely on, and the actors in health research bad if their actions are solely motivated by, private or individualist interest considerations and disrespect for justice; human rights and Ubuntu. The PLA's key principles can therefore be summed up as: justice; Ubuntu; transparency; reason; justified balancing of conflicting rights, principles and rules; justified limitation of rights; special protection for vulnerable persons; non-discrimination; respect for human dignity; use of effective public law remedies; public interest; legality and respect for fundamental rights.

The PLA, as observed in chapter 9, further possess certain distinctive features that arguably make it more plausible than other established theories. It was observed that, unlike most established theories, the PLA is not reducible to a single rule, principle or explanatory criterion, but to a cluster of principles or considerations. It was also observed that the theory, rather than being only action-defining or only character-defining as is the case with most traditional theories, is based on the assessment of both actions and characters. The theory, it was further observed, also does not face the problem of incompleteness, as most traditional theories do. As pointed out earlier, the theory's multi- and inter-disciplinary nature is very useful in the resolution of health research problems, which are often multi- and inter-disciplinary. Another distinctive

feature of the theory is its provision for justifiable deviations as well as provision for rights framework.

So as to clear up any misconceptions, it was also pointed out what the PLA theory is not about. It was pointed out that the theory is not about the displacement of private law approaches but an equal or equivalent consideration of public law approaches in the resolution of health research matters. The PLA theory, it was pointed out, is also about using public law approaches as an alternative where private law approaches are ineffective. It is also about the supplementation of private law approaches by public law approaches where they are found to be inadequate. The PLA theory is therefore mainly intended to serve as a counterbalancing mechanism against the dominant use of private law approaches in the resolution of health research problems. Such an approach could result in the co-existence of the frameworks, whether in an integrated form or on a parallel basis, a matter that will depend on the context.

Also requiring brief discussion are the implications of the theory in relation to various aspects or areas of research. It was observed in chapter 9 that the PLA theory has some implications in the case of the protection of personal information and access to information, in the sense of bringing some clarity and coherence to the way public interest as provided in POPIA and PAIA is approached more especially, in the case of POPIA, in the way the relationship between public interest and research purpose exceptions is approached.

It was further observed that the PLA theory has implications on the question of legal standing, whose present framework, more in particular the common law framework, does not create space for public interest litigation.[2133] The study further pointed out however the PLA could influence the way the right to health is approached, and how such a right could be used as a basis for compensation for injuries incurred during research as well as accounting for the provision for post-research benefits.

It was further observed that the PLA theory has implications for the protection of children in that the theory, through its principle of concern for the vulnerable, can properly account for why there is a need for added protections in the case of vulnerable persons like children, including displaced children. The PLA, it was further pointed out

[2133] As pointed out in chapters 4 and 7, the common law is still applicable where a litigant's claim is not founded on the infringement of rights in the Bill of Rights.

can, through the principle of Ubuntu, properly account for why displaced children should also be protected.

It was further pointed out that the PLA theory has implications on defining the nature and content of obligations, including the development of principles and formulation of causes of actions. The PLA theory, it was pointed out, creates consciousness that the relationship amongst various stakeholders is not only a private law one based on private law principles, but that it could also be a public law one governed by public law principles. The PLA therefore not only influences the content of obligations, but also the development of the principles governing them, as well as the formulation of causes of action and remedies. It was further pointed out that from an ethical point of view, the PLA's principle of Ubuntu could properly account for why stakeholders in health are obliged to compensate those who are injured during research. Ubuntu could also properly account for why stakeholders have to make provision for post-research benefits.

It was further pointed out that the PLA theory has implications for judicial review and remedies, in that the PLA's support for the use of effective public law remedies, including the granting of constitutional damages, which current case law generally does not favour, could be very critical in the protection of health research participants. The participants will not have to be confined to narrow private law-based common law remedies.

It was further pointed out that the PLA theory properly accounts for why there is a need for the review of science by RECs, as non-review of such may undermine the principles of accountability, transparency, rationality and non-discrimination, as espoused by the PLA.

10.2 Recommendations

Having examined the shortcomings of the private law approaches, and having already, in substance, covered some of the key recommendations in chapter 9 (under the proposed public law approach towards health research) the study sums up the recommendations as follows:

- There should be some legislative and other regulatory reform to specifically provide for the protection of children participating in research, more specially

those facing displacement, as they are comparatively more exposed to exploitation. This reform could, in the main, be around, though not limited to, the amendments to the CA and the NHA.

- At a more general level, there should be a theoretical and pragmatic shift from private law - based approaches to public law - based approaches in the resolution of health research problems. This reorientation should even be more important in the field of health research litigation.
- This recommended shift should in particular give primacy to the development and use of constitutional remedies in the context of health research.

The above recommendations, if implemented, could play a critical role in enhancing the protection of health research participants.

10.3 Future research

John Stuart Mill says the following about the unending nature of philosophical enquiries:

> From the dawn of philosophy, the question concerning the *summum bonum*, or, what is the same thing, concerning the foundation of morality, has been accounted the main problem in speculative thought, has occupied the most gifted intellects and divided them into sects and schools carrying on a vigorous warfare against one another. After two thousand years the same discussions continue, philosophers are still ranged under the same contending banners, and neither thinkers nor mankind at large seem nearer to being unanimous on the subject than when the youth Socrates listened to the old Protagoras and asserted (if Plato's dialogue be grounded on a real conversation) the theory of utilitarianism against the popular morality of the so-called sophist.[2134]

The above quote is as true to philosophy as it is to other systems of thought: there is no intellectual closure to most scientific questions, more especially in the field of social and legal sciences. This therefore calls for further research on the question of constitutional damages which, although it has been discussed in this study, raises far-reaching implications that require further exploration, more especially in the context of health research. Another aspect arising from this study but requiring further research is the question of the review of the scientific validity of research by an REC. Its complexity and implications, more especially given the history where science was

[2134] Curd *Argument and analysis* 112.

once used for unjustified ends, more particularly during the World War II, require further exploration.

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10. Register of abbreviations

ABPI	Association of the British Pharmaceutical Industry
ACA	Patient Protection and Affordable Care Act

ACHPR	African Charter on Human and People's Rights
ACHR	American Convention on Human Rights
ACRWC	African Convention on the Rights and Welfare of the Child
ADCS	Association of Directors of Children's Services
AHRLJ	African Human Rights Law Journal
APA	Administrative Procedures Act of 1946
AU	African Union
BCE	Era before Christ
CA	Children's Act 38 of 2005
CCR	Constitutional Court Review
CEDAW	Convention on the Elimination of All Forms of Discrimination against Women
CFR	Code of Federal Regulations / Common Rule
CFREU	Charter of Fundamental Rights of the European Union
COE	Council of Europe
COAS	Charter of the Organization of American States
CIOMS	Council for International Organisation of Medical Sciences
COPPA	Children's Online Privacy Protection Act of 1998
COREC	Central Office for Research Ethics Committees
CPA	Consumer Protection Act 68 of 2008
CPR	Civil Procedures Rules 1998
CRA	Constitutional Reform Act 2005
CR Act	Consumer Rights Act 2015
CRC	UN Convention on the Rights of the Child
CUN	Charter of the United Nations (1945)
DPA	Data Protection Act of 2018
EA	Equality Act 2010
EC	European Community

ECHR	European Convention on Human Rights
ECTA	Electronic Communications and Transactions Act 25 of 2002
ERB(s)	Ethical Review Board(s)
EU	European Union
FDA	Food and Drug Administration
FGMA	Female Genital Mutilation Act 2003
FMR	Forced Migration Review
FOI Act	Freedom of Information Act 2000
FTCA	Federal Tort Claims Act of 1946
GAFREC	Governance Arrangements for NHS RECs
GDPR	The European Union's General Data Protection Regulations of 2016
GMP	Good manufacturing practice
HA	Human Rights Act 1998
HHS	(USA) Department of Health and Human Services
HO	Hippocratic Oath
HPCSA	Health Professions Council of South Africa
HRA	Health research Authority
HTA	Human Tissue Act of 2004
ICH	International Council for Harmonising of Technical Requirements for Pharmaceuticals for Human Use
ICCPR	International Covenant on Civil and Political Rights
ICEFRD	International Convention on the Elimination of all Forms of Racial Discrimination (1996)
ICERD	International Convention on the Elimination of All Forms of Racial Discrimination
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICME	International Code of Medical Ethics
IHR	International Health Regulations

IMT	International Military Tribunal
IOMS	Council for International Organisation of Medical Sciences
IRB	Institutional Review Board
MCA	Mental Capacity Act of 2005
MCC	Medicines Control Council
MCSER	Mediterranean Center of Social and Educational Research
MSA	Medicines and Related Substances Control Act 101 of 1965
N Engl J Medicine	New England Journal of Medicine
NHA	National Health Act 61 of 2003
NHREC	National Health Research Ethics Council
NHS	National Health Service
NRA	National Research Act of 1974
NRES	National Research Ethics Service
OAS	Organization of American States
OECD	Organization for Economic Cooperation and Development
PAHO GCP	Pan American Health Organization Good Clinical Practices
PAIA	Promotion of Access to Information Act 2 of 2000
PAJA	Promotion of Administrative Justice Act 3 of 2000
PANDRH	Pan American Network on Drug Regulatory Harmonization
PELJ	Potchefstroom Electronic Law Journal
PEPUDA	Promotion of Equality and Prevention of Unfair Discrimination Act 4 of 2000
PER	*Potchefstroomse Elektroniese Regsblad*
PHS	US Public Health Service
PLA	Public law approach
POPIA	Protection of Personal Information Act 4 of 2013
PSLR	Pretoria Student Law Review

RCP	Royal College of Physicians
REC(s)	Research Ethics Committee(s)
RSSR	Recommendations on the status of scientific researchers
SA GCP	South African Good Clinical Practice
SAHPRA	South African Health Products Regulatory Authority
SAJHR	South African Journal on Human Rights
SALJ	South African Law Journal
SAMRC	South African Medical Research Council
SAMRC Act	South African Medical Research Council Act 58 of 1991
SC Act	Senior Courts Act 1981
SOP(s)	Standard operating procedure(s)
Statute L. Rev	Statute Law Review
Stell LR	Stellenbosch Law Review
TCEA	Tribunals, Courts and Enforcement Act 2007
UCC	Uniform Commercial Code of 1952
UCTA	Unfair Contract Terms Act 1977
UDHR	Universal Declaration of Human Rights
UK	United Kingdom
UK ECA	UK Ethics Committee Authority
UK MRC	UK Medical Research Council
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV and Aids
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNGID	United Nations Guiding Principles on Internal Displacement
US	United States
USA	United States of America
USSR	Union of Socialist Soviet Republics

WCRI	World Conferences on Research Integrity
WHO	World Health Organisation
WMA	World Medical Association

11. Shortened versions

American Declaration of the Rights and Duties of Man (1948) **(The American Declaration)**

American medical Association Principles of Medical Ethics **(the AMA Principles of Medical Ethics)**

Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects for Research (1979) **(The Belmont Report)**

Care Act of 2014 **(the Care Act)**

Children Act 1989 **(the 1989 CA)**

Children Act 2004 **(the 2004 CA)**

Constitution of the Republic of South Africa, 1996 **(the Constitution)**

Constitution of the United States of America **(the US Constitution)**

Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Medicine (1979) **(the Oviedo Convention)**

Declaration of Geneva: Physicians Oath 1948 **(the Physicians Oath)**

Declaration of the Rights of Women and of the (Female) Citizen **(the Women's Declaration)**

Ethical Principles for Medical Research involving Human Subjects (1964) **(The Helsinki Declaration)**

Ethics in Health research: Principles, Processes and Structures (2015) **(2015 Ethics in Research)**

EU-US Privacy Shield Framework Principles **(the Privacy Shield)**

Geneva Convention Relative to the Protection of Civilian Persons in times of War (1949) **(the Geneva War Convention)**

Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa (2006) **(the 2006 Clinical Trials Guidelines)**

Health department's Governance Arrangements for Research Ethics Committees: 2020 edition **(the UK's Governance Arrangements)**

Medical Research Council Ethic Guide: Medical Research Involving Children (2004) **(the MRC Children's Guide)**

Medicines for Human Use (Clinical trials) Regulations 2004 **(the UK Clinical Trials Regulations)**

National Research Act of 1974 **(The National Research Act)**

National Commission for Protection of Human Subjects of Biomedical and Behavioural Research **(the US National Commission)**

Privacy Act of 1974 **(the Privacy Act)**

South African Good Clinical Practice: Clinical Trial Guidelines (2020) **(the 2020 Clinical Trials Guidelines)**

The African Union Convention for the Protection as Assistance of Internally Displaced Persons (2009) **(AU Displaced Person's Convention)**

The Protocol to the African Charter on Human and People's Rights on the Rights of Women in Africa (2003) **(the Women's Rights Protocol)**

UKRIO's Code of Good Practice for Research: Promoting good practice and preventing misconduct (2009) **(UKRIO's Code of Good Practice)**

UNAIDS Guidelines on protecting confidentiality and security of HIV information: Proceedings from a workshop 2007 **(UNAIDS Interim Guidelines)**

Universal Declaration and Human Rights (2005) **(the UNESCO Bioethics Declaration)**