CHAPTER 3

ETHICAL ISSUES IN CLINICAL RESEARCH IN AFRICA: PRINCIPLES AND PRACTICE

Outline

1 INTRODUCTION

This chapter explores the origin and nature of the ethical principles deployed in the protection of research participants in clinical research. An analysis of the protection afforded by fundamental ethical principles, namely, autonomy, beneficence (including nonmaleficence), and justice, as embodied in various international and domestic documents, is presented.

The protection afforded by international documents, such as the Nuremberg Code, the International Ethical Guidelines for Biomedical Research involving Human Subjects, the Belmont Report and the Declaration of Helsinki, is scrutinised. The scope of domestic documents, such as the Medical Research Council's Guidelines on ethics for medical research and the Department of Health's Guidelines for good practice in the conduct of clinical trials in human participants in South Africa, and the objectives of the different local research ethics committees are investigated.

The chapter presents an analysis of the ethical dilemma at the centre of the controversy over the placebo-controlled trial of AZT in preventing MTCT of HIV in Uganda, and indicate problematic issues arising out of three other drug trials.

Finally, it examines ethical concerns relevant to research participants in Africa.

The purview in the chapter is broad; it focuses on clinical research relating to HIV in Africa in general, and preventive HIV vaccine efficacy trials are mentioned merely in passing.

2 THE PRINCIPLES OF CLINICAL RESEARCH ETHICS

2.1 Introduction

In deciding the 'ethical' nature of clinical research, one determines whether it conforms to the commonly considered norms of ethical research. Levine defines an ethical norm as 'a statement that actions of a certain type ought (or ought not) to be done'[1]. Certain acts are believed to be ethically 'wrong' (and should not be done), whereas others are ethically 'right' (and may be done).[2] Ethical norms have been codified as guidelines in the various international and domestic ethics documents. The following is an example:[3]

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1 Levine (1986) 19.
2 As above.
3 Art 1 World Medical Association Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research involving Human Subjects, adopted by the

> Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.

Ethical norms, such as the one quoted above, derive from three[4] ethical principles; namely, respect for persons (or respect for autonomy), beneficence (which includes nonmaleficence), and justice.[5] These ethical principles correspond to the three ethical concerns or questions in research namely, which research qualifies as both scientifically valid and necessary research, which is in the best interests of the participants, and the autonomy of the research participant.[6] In the following pages the origin of these ethical concerns and the ethical principles they involve are explored.

2.2 Conceptual framework

Beauchamp and Childress define the term 'ethics' as 'a generic term for various ways of understanding and examining the moral life'.[7] 'Ethics' has been referred to as the academic study of moral concepts and theories.[8] In departments of philosophy, 'ethics' is termed 'moral philosophy' or 'moral theory'.[9] Some writers, such as Beauchamp and Steinbock, use the terms 'ethics' and 'morality' interchangeably.[10]

However, the term 'morality' requires elucidation. Beauchamp and Childress define morality as being those norms about right and wrong human conduct that are so widely shared that they form a stable social consensus.[11] Morality thus includes standards of conduct, such as moral principles, rules, rights and virtues.[12]

A set of norms shared by all 'morally serious' persons is referred to as the 'common morality' by Beauchamp and Childress.[13] Further, morality includes moral

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18th World Medical Assembly, Helsinki, Finland, in 1964, and revised subsequently; from now on referred to as the 'Declaration of Helsinki'.

4 Writers, such as Beauchamp and Childress, refer to *four* fundamental ethical principles. They consider beneficence and nonmaleficence as two separate principles; this thesis considers the two concepts as one ethical principle; the one implying the other.

5 Levine 11; Beauchamp and Childress (2001) 12.

6 Foster (2001) 9 – 10.

7 Beauchamp and Childress (n 5 above) 1.

8 Beauchamp and Steinbock (1999) 4.

9 As above.

10 Beauchamp and Steinbock (n 8 above) 4.

11 Beauchamp and Childress (n 5 above) 2 – 3.

12 As above, 3.

13 Beauchamp and Childress 3. Such as notions that it is wrong to steal, lie, etc.

ideals (that a group readily accepts), communal norms (that bind members of a certain community), and virtues, and so on.[14]

A distinction is made between universal morality and community-specific morality,[15] in which universal morality refers to the norms in common morality, whereas community-specific morality indicates moral norms that are specific to a particular cultural, religious or institutional setting.[16]

Professional morality is the set of norms or a standard of conduct that is generally acknowledged by members of a profession who acknowledge the moral duties and responsibilities of that profession.[17] As Beauchamp and Childress point out, professional morality in the medical and related professions stems from the 'institutions, practices and traditions of medicine'.[18] Codes of medical, nursing and research ethics attempt to formalise these moral duties and responsibilities.[19]

Government agencies sometimes formulate codes that contain normative ethical guidelines,[20] and these guidelines may be legislated.[21] Such guidelines reflect public policy, for example, guidelines regulating biomedical research carried out on foetal tissue.[22] Public policies are a reflection of moral and ethical considerations,[23] and exist within 'social disagreements, uncertainties, and different interpretations of history'.[24]

Because public policies are derived in a situation of uncertainty, any set of principles and guidelines they embody is devoid of sufficient specific information so as to provide guidance in all the varying practical, political and cultural situations.[25] In the words of Beauchamp and Childress: [26]

> Principles and rules provide the moral background for policy evaluation, but a policy must also be shaped by empirical data and by information available in fields such as medicine, nursing, economics, law and psychology.

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14 As above.
15 As above. 'Morally serious' is Beauchamp and Childress' term.
16 As above. The influence of community-specific moral norms on ethical decision-making is discussed in detail in chs 4 and 5.
17 Beauchamp and Childress 5.
18 As above.
19 As above.
20 As above, 7.
21 As above. If they are legislated they acquire the force of law.
22 As above, 8.
23 As above.
24 As above.
25 As above, 9.
26 As above.

Approaches to ethics are either normative or nonnormative.[27] 'Normative ethics' is an attempt to identify the general moral norms to be used for deciding conduct that is ethically acceptable.[28] In other words, normative ethics attempts to provide a theoretical or foundational basis for how people ought to behave.[29] Various ethical theories provide ways to identify and justify these moral norms.[30]

'Nonnormative ethics', on the other hand, divides into two broad categories – descriptive ethics and metaethics. Descriptive ethics is the factual investigation of moral conduct and beliefs with the purpose of finding out how people reason and act.[31] Metaethics is a theoretical analysis of the language, concepts, and methods of reasoning in ethical discourse; [32] it investigates the meaning of ethical terms such as 'duty', 'good' and 'obligation'.[33]

Applied (also practical) ethics aims to 'implement general norms and theories for particular problems and contexts'.[34] The term 'applied' is an indication of the use of theory and analysis to examine moral problems in professions, institutions and public policy.[35] In applied ethics, theory and principles are starting points and a general guide to the development of norms of appropriate conduct.[36]

Bioethics, a discipline that is relatively recent, is a sub-field of applied ethics.[37] It has its beginnings in the late 1960s and early 1970s,[38] and, partly, was born from student demands at Anglo-Saxon universities in the 1960s for an education that was 'relevant', and, partly, as a result of advances in medical science and the novel ethical questions they raised.[39]

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27 As above, 1.

28 Beauchamp and Childress (n 5 above) 2. The concern of this thesis is limited to the approach that is normative ethics.

29 Beauchamp and Steinbock (n 8 above) 4.

30 Beauchamp and Childress 2.

31 As above.

32 As above.

33 Beauchamp and Steinbock 4.

34 As above.

35 Beauchamp and Childress 2.

36 As above.

37 The terms 'bioethics' and 'biomedical ethics' are used interchangeably in this thesis. The term 'bioethics', is preferred as it encompasses more than 'biomedical ethics'– 'bioethics' stresses that we do not limit our concern to the practice of medicine by doctors, but other disciplines are included.

38 See David Rothman's account of the history of modern bioethics in Rothman (1991) *Strangers at the bedside: A history of how law and bioethics transformed medical decision making.*

39 Beauchamp and Steinbock (n 8 above) 3. Advances in medical science include assisted reproduction, genetic testing and manipulation, and technologies to prolong life.

The concern of bioethics is with an ethics that should guide physicians and scientists. Its aim is the protection of patients and of research participants. A broad range of literature on topics in bioethics has developed to include the doctor-patient relationship; informed consent; clinical research; euthanasia; genetic testing; and reproductive choices.[40]

2.3 Philosophical background

The various ethical (or moral) theories or philosophical traditions rely on different values in deciding whether an action is right or wrong, yet each contributes something to our understanding of ethical reasoning. Beauchamp and Childress maintain that knowledge of these ethical theories is an indispensable requirement for a reflective study of bioethics.[41]

The following classical philosophical traditions are regarded as fundamental in ethical decision-making: utilitarianism, Kantianism and liberal individualism.[42] Communitarianism and the ethics of care are discussed as well, as they add significantly to an understanding of the limitations of restricting philosophical reasoning to utilitarianism; Kantianism and liberal individualism. Each tradition is summarised below (with the exception of liberal individualism, which is dealt with in detail in the next chapter).

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40 As above.

41 Beauchamp and Childress (n 5 above) 337.

42 Aristotelian virtue ethics, Utilitarianism and Kantian/Rawlsian ethics are described as traditional or classical ethical theories. Recently, these traditional ethical theories have been challenged by the proponents of a range of special interests; feminism, race, sexuality, multiculturalism and environmentalism. Traditional ethics articulates general and universal principles of right and good, from the social forces or abstracted beliefs that govern established relations between persons, races, genders and classes. The 'newer' ethical theorists pose different questions, have different goals, use different tools of analysis and, therefore, believe they are challenging the prescribed paradigm in traditional ethical discourse. They point out that in the real world, groups are divided by gender, race, poverty, sexual orientation, and that these divisions constitute the 'problem' of ethics, presenting in a non-ideal, non-ordered post-modern society. This is an attempt to unmask the ideological stereotypes and normative contradictions they claim are embodied in established systems of race, gender, sexuality and so on (Doppelt (2002) 6 *The J Ethics* 383 – 386).
This thesis, however, does not undertake a philosophical analysis of ethical theory, nor does it provide an exhaustive account of modern ethical theory. It investigates the traditional ethical theories that are the foundation of bioethical discourse. The challenges posed by the ethics of feminism and multiculturalism will be mentioned in passing, and particularly in ch 5 below.
For more on the challenges posed by modern theory, see Doppelt 'Can traditional ethical theory meet the challenges of feminism, multiculturalism, and environmentalism?' (2002) 6 *The J Ethics* 383 – 405 and Callahan 'Principlism and communitarianism' (2003) 29 *British Med J* 287 – 291.

As with all forms of generalisation, in simplifying, a summary is an inadequate representation and may even be inaccurate, however, the aim here is not to present a comprehensive or even an introductory account of the traditions, but, rather, it is to present preliminary accounts of ethical decision-making.

2.3.1 Utilitarianism

Utilitarianism is a concept developed in the writings of Jeremy Bentham (1748 – 1832) and James Mill, and refined by John Stuart Mill (1806 – 1873);[43] although its origins are much earlier.[44]

John Stuart Mill adhered to the basic principles of the utilitarian philosophy of James Mill and Bentham, the chief principle of which is that goodness is whatever produces the greatest happiness for the greatest number.[45]

Utilitarianism is considered a consequence-based theory in that it examines the consequences of actions to determine whether the actions were good or bad.[46] Utilitarianism thus holds that actions are right or wrong according to the balance of their good and bad results.[47] An action is justified for utilitarians if it produces an increase in the general welfare of a large number of people. A central aspect of utilitarianism is the principle of utility as its sole measure and, therefore, the basic principle of ethics.[48]

Utilitarians may disagree as to which values or consequences should be maximised.[49] The principle of utility may ascribe happiness, freedom and health as the ultimate good. Whereas Bentham and Mill employ the term 'pleasure' in their definition of the greatest good, more contemporary utilitarians, such as G E Moore and James Griffin, list success, friendship, beauty, knowledge, health, personal autonomy, understanding and deep personal relationships as goods that should be fostered. [50]

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43 Beauchamp and Childress (n 5 above) 341.
44 Beauchamp and Steinbock (n 8 above) 13.
45 Grayling (2003) 174.
46 Grayling 177; Beauchamp and Steinbock 13; Gillon (1994) 21.
47 Beauchamp and Childress 340.
48 As above, 341.
49 As above; Gillon (n 46 above) 21; Grayling (n 45 above) 177.
50 As above.

John Stuart Mill's refinement of utilitarianism lies in the greater emphasis on individual liberty and autonomy. Individual autonomy is to be respected, even though the person acts against her own interest:[51]

> The only purpose for which power can be rightfully exercised over any member of a civilised community, against his will, is to prevent harm to others. His own good, either physical or moral, is not sufficient warrant. He cannot rightfully be compelled to do or forbear because it will be better for him to do so, because it will make him happier, because, in the opinion of others, to do so would be wise, or even right.

To the objection levelled against utilitarian philosophy to the effect that people desire many things other than happiness, John Mill responds that they are desired for their part in bringing happiness:[52]

> Whatever is desired otherwise than a means to some end beyond itself, and ultimately to happiness, is desired as itself a part of happiness and not desired for itself until it has become so.

Utilitarians disagree as well about whether the principle of utility should apply to particular acts in particular circumstances, or to general rules that determine which acts are right or wrong.[53] Rule utilitarians examine the consequences of adopting particular rules by determining whether a particular act conforms to a particular justified rule.[54] If the rule on which the act is based is justified, then that act serves the greater good even though the outcome in a particular case may not be for the best.[55] For example, if the general rule of telling the truth is regarded as a just rule, then, though following the rule has as its result in a particular case an unjust outcome, it should still be followed.[56]

Act utilitarians, on the other hand, focus on acts and not on general rules; using the principle of utility directly.[57] Their interest is in the particular circumstances of the particular action.[58] For example, a general rule, such as telling the truth, may not, in all circumstances, produce the best outcome.[59] Therefore, the underlying circumstances should be examined to find out whether the best outcome was achieved by the rule.[60]

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51 Mill (1864) (Robson (ed) (1984)) *On liberty* 1.
52 Mill (1864) (Crisp (ed) (1998)) *Utilitarianism* 2. Also see Grayling 179.
53 Beauchamp and Childress 343.
54 As above.
55 As above, 344.
56 As above.
57 As above.
58 As above.
59 As above, 344.
60 As above.

Beauchamp and Childress base a critique of utilitarianism on the problem of individuals who have 'immoral' or 'unacceptable' preferences. Thus, it is necessary to formulate an acceptable range of individual preferences.[61] In terms of utilitarianism, in the abstract, immoral acts could be justified if they achieve a good outcome.[62]

Further, it is felt that utilitarianism is too demanding of the individual, in that, in certain circumstances, the individual may be expected to commit acts of self-sacrifice to serve the greater good.[63]

A serious criticism is that inherent to utilitarian theory is the principle that the wishes of the majority override the interests of the minority.[64]

Nevertheless, utilitarianism makes a significant contribution to bioethical thought:[65] the principle of assessing satisfaction or utility and a concern with the consequences of a course of action so that good outcomes may be maximised are at the basis of the beneficence principle in bioethics.[66]

2.3.2 Kantianism

Through the consideration of aspects of an action other than its consequences (as is the case with utilitarianism) here is a moral theory which is deontological. The Prussian philosopher Immanuel Kant (1724 – 1804) is regarded as the father of this school of thought, which is referred to as Kantianism.[67]

Kant argues that morality is grounded in the faculty of reason, rather than seeking its origin in tradition, religion, intuition or emotion.[68] Human beings, according to Kant, are rational and able to make rational decisions.[69] The morality of an individual's action consists not in its outcomes, but on the moral acceptability of the rule or maxim according to which a person acts.[70] To be morally good, a person's action must arise from the realisation of the morally correct thing to do.[71] Kant thus holds that the 'right' (moral) action is justified by a person's intrinsic

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61 As above, 345 - 346.
62 As above. For example, to achieve a good outcome such as ending a war it would be considered justifiable to torture prisoners of war.
63 As above, 346.
64 As above, 347.
65 As above, 248.
66 As above, 348.
67 Beauchamp and Childress 348 – 349; Gillon (n 46 above) 16.
68 Beauchamp and Childress 349; Gillon 16.
69 Beauchamp and Childress 349.
70 As above.
71 As above.

values: we do the right thing because we have a moral obligation to do so, not because of an extrinsic motivation.

Kant's thought is opposed to the idea of utilitarianism and its consequentialism. Kant established a notion of the 'categorical imperative' in accordance with which the morality of actions is to be judged: 'Act only according to that maxim whereby you can at the same time will that it should become a universal law'.[72] There is a voluntary choice to act in a way we would want all others in similar situations to act,[73] so that actions done out of duty alone have moral worth.[74] Feelings, such as sympathy, are not therefore a source of moral behaviour.[75]

Central to Kantian ethics is the idea that people are ends in themselves; worthy of respect and dignity[76] '[p]ersons are ... not merely subjective ends ... but are objective ends, ie, exist as ends in themselves'.[77] In expanding upon this principle, he declares:[78]

> the ground of all practical legislation lies objectively in the rule and in the form of universality, which (according to the first principle) makes the rule capable of being a law (say for example a law of nature). Subjectively, however, the ground of all practical legislation lies in the end: but according to second principle) the subject of all ends is every rational being as an end in himself. From this there now follows the third practical principle of the will as the supreme condition of the will's conformity with universal practical reason, *viz*, the will of every rational being as a will that legislates universal law.

As rational agents, people have choices and make decisions.[79] Above all, they are prized for their dignity.[80]

> [M]an as a person—that is, as the subject of a morally practical reason, is exalted above all price. For as such a one (*homo noumenon*) he is not to be valued merely as a means to the ends of other people, or even to his own ends, but is to be prized as an end in himself. This is to say, he possesses a dignity (*an absolute inner worth*) whereby he exacts the respect of all other rational beings in the world, can measure himself against each member of his species, and can esteem himself on a footing of equality with them ...

The principle of the 'absolute inner worth' of human beings is the foundation for the requirement of informed consent in bioethics.[81] Kant defines autonomy this way:[82]

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72 Kant (1785)(transl Ellignton, 1994) 30.
73 Beauchamp and Steinbock 18 – 19; Gillon (n 46 above) 16 - 17.
74 Beauchamp and Steinbock 19.
75 As above.
76 As above, 20; Gillon 16.
77 Kant (n 72 above) 36.
78 Kant 38.
79 As above.
80 Kant (n 72 above) 7. My emphasis.
81 Beauchamp and Childress 351.

> Autonomy of the will is the property that the will has of being a law to itself. [Morality] is the relation of actions to the autonomy of the will [...] That action which is compatible with the autonomy of the will is permitted; that which is not compatible is forbidden.

Several contemporary philosophers have developed a Kantian account of ethics, such as Alan Donagan, Robert Nozick, Bernard Williams and, most notably, John Rawls.[83]

Nevertheless, Beauchamp and Childress criticise Kantian theory for being too abstract to be useful in deriving the specific ethical principles that are needed by professional ethics.[84] Kant's 'rationality' and 'humanity', in this view, are empty formulations, too flimsy to be the basis upon which a set of moral norms is determined, or a set of specific obligations is derived.[85]

Yet, Kant has contributed to ethical thought the principle that ethical and moral rules cannot apply unequally to different groups to suit the occasion. A moral rule gives rise to a certain action, and all groups need to be treated in the same way in terms of that action. For example, if informed consent is required for clinical research, one cannot dispense with the requirement despite dealing with a group from whom it is impossible to obtain consent.[86]

The following two contemporary theories – communitarianism and the ethics of care - may be regarded as a reaction to, and a criticism of, the traditional ethical theories which are relied upon by Beauchamp and Childress and which are considered the basis for bioethical thought.

2.3.3 Communitarianism

Communitarianism is a term applied to a group of contemporary philosophers who are in reaction against the emphasis on the individual as autonomous moral agent in utilitarian, Kantian and liberal philosophy.[87] Communitarians include philosophers and political theorists such as Michael Sandel,[88] Charles Taylor and Alasdair

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82 Kant 44.

83 Beauchamp and Childress (n 5 above) 351 – 352. For an excellent account of some of the main tenets of Kant's philosophy, also see Häyry (2005) 31 *J Med Ethics* 645.

84 Beauchamp and Childress 355.

85 As above; Gillon (n 46 above) 17.

86 As above. For instance where one carries out research on prison populations without their consent. See also ch 5 in this regard.

87 Beauchamp and Childress 365. See ch 4 below.

88 Sandel is responsible for the work *Liberalism and the limits of justice*, published in 1982.

MacIntyre[89] whose writings refer to the thought of philosophers such as Aristotle, Hume and Hegel.[90]

Utilitarianism and Kantian theories of ethics have at the centre of their inquiry the individual.[91] As indicated in the discussion above, the utilitarian strives for the realisation of the greatest happiness for the greatest number, but does so with reference to an individual conception of happiness.[92] Kantian theory disavows that the individual should be sacrificed to community interests.[93] The primacy that has been ascribed to the individual and to personal autonomy is challenged in communitarian-based ethics.

Communitarianism asserts that the individual arrives at moral action even in traditional ethical accounts, such as utilitarianism and Kantianism, only because of her adherence to communal values, social goals, conventions, traditions and loyalties.[94] According to the communitarian, the dimension of community, neglected in utilitarian, Kantian and liberal moral thinking, should be re-established. Callahan's view is representative of this way of thinking:[95]

> Communitarianism, as I construe the term, is meant to characterise a way of thinking about ethical problems, not to provide any formulas or rigid criteria for dealing with them. It assumes that human beings are social animals, not under any circumstances isolated individuals, and whose lives are lived out within deeply penetrating social, political, and cultural institutions and practices.

Callahan further comments that communitarianism assumes that no sharp distinction can be drawn between the public and the private sphere.[96] It is important that there be a private and protected sphere, but what counts as private will be a societal decision, not something inherent in the human condition.[97]

Communitarians reject the idea that there are universal, timeless ethical truths arrived at by the application of reason, and that these truths form the basis for ethical decision-making.[98] Instead, communitarians argue that our moral thinking has its roots in the history, values and traditions of particular communities;

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89 MacIntyre's work, *After virtue: A study in moral theory*, written in 1981, criticises Beauchamp and Childress' work on the ground that it searches for a foundation for ethical theory externally – in the philosophy of Kant and others - in a domain that transcends the variabilities of space and time (see Tong in Wolf (ed) (1996) 69).

90 As above, 69.

91 Beauchamp and Childress (n 5 above) 362.

92 Beauchamp and Steinbock (n 8 above) 21.

93 As above, 21.

94 Beauchamp and Childress 362.

95 Callahan (n 42 above) 288.

96 As above.

97 As above.

communities that are composed of people who share the same traditions, beliefs and values.[99] The shared values and traditions of the community offer the starting point from which ethical problems should be solved, and are critical of a theoretical or principled approach:[100]

> As these critics [communitarians] see it, principlism[101] is what its name implies: a prescription for bioethical reasoning that favors 'top-down' reasoning (from theories to principles to rules to particular moral judgments), even if it is also capable of 'bottom-up' reasoning (from particular moral judgements to rules to principles to ethical theories).

Communitarians, like utilitarians, want to advance the common good, but, whereas the utilitarian promotes the welfare of a collection of individuals, the communitarian seeks to promote the welfare of the shared values and ideals of a community.[102] The communitarian bioethicist asks, 'What is most conducive to a good society?' and not 'Is it harmful or does it violate autonomy?'[103]

Even though members of a community may have a different concept of what the ideal of a good society is, they have certain ideals in common.[104] For example, most of society's members share the value of a belief in the benefit of educating young people. The communitarian argues that the values that advance these benefits should be pursued actively by a community. In communitarian ethics, the needs of the community may take precedence over those of the individual.[105]

MacIntyre holds the view that the practices and traditions of local communities are primary above abstract ethical theory and normative thought.[106] For example, for MacIntyre, the virtues of the medical practitioner flow not from abstract ethical theories and codes, but from 'communal and institutional care, practical wisdom, and education'.[107] In this view the history and traditions of medicine require physicians to act in a certain way.[108]

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98 Beauchamp and Steinbock (n 8 above) 21.
99 As above.
100 Tong in Wolf (n 89 above) 69.
101 'Principlism' is the term used to refer to Beauchamp and Childress' four principles-approach.
102 As above.
103 Callahan (1990) 105 - 113, quoted in Beauchamp and Childress 367.
104 Beauchamp and Childress 367.
105 As above.
106 Beauchamp and Childress 366.
107 As above.
108 As above.

Many philosophers regard the communitarian rejection of classical ethical theories as unjustified, arising out of an erroneous interpretation of these theories.[109] Beauchamp and Childress point out that the communitarian establishes two false dichotomies in a zero sum game: the first is the primacy of either the individual or the community; and, the second, is the protection of either the autonomous individual in decision-making or of a communal determination of social goals against the individual.[110] The dichotomy is a false one in that the choice does not lie in the elimination of the alternative, as Beauchamp and Childress explain: [111]

> A more accurate picture is that we inherit social roles and goals. We then critique, adjust, and attempt to improve our beliefs over time through free discussion and collective agreements. Individuals and groups alike progressively interpret, revise, and sometimes even replace traditions with new conceptions that adjust and foster community values.

2.3.4 Ethics of care

Proponents of the ethics of care (care ethics), as well as sharing communitarian questioning of the values of liberal individualism,[112] emphasise traits valued in personal relations, such as sympathy, compassion, fidelity and love:[113]

> Ethics-of-care writers argue that real people live in families and that real caring relationships are not impartial, impersonal, or equal. Instead, they embody fundamental inequalities of power, capacity, judgment, information, and responsibility. Moreover, such relationships are based on a particular connection between those involved — which implies that any one person cannot and should not care for all human beings equally. These writers argue that philosophy has ignored family life in particular, and caring in general, because it has been written mainly by men who do not fully understand, or take seriously enough, the centrality of such relationships to human experience.

The ethics of care is contrasted to an ethics of rights and obligations,[114] in such a way that it undermines a notion of a universal ethical principle, as well as that the analysis of the greater good is the consequence of impartial decision-making principles. [115]

A theorist who writes form the point of view of an ethics of care is Annette Baier. Baier finds in contemporary female philosophers a voice that is 'reflective and

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109 As above, 368.
110 As above.
111 As above.
112 As above, 369.
113 Roberts and Reich (2002) 359 *The Lancet* 1057.
114 Beauchamp and Childress 369.
115 As above, 370.

philosophical'.[116] Baier rejects the notion expressed in traditional ethical theories that emphasises universal principles and uses a Kantian contractarian model to emphasise justice, rights and law.[117] She asserts that traditional ethical theories do not take into account an ethic of love and mutual trust.[118] Baier asks,[119]

> [w]hat would be a suitable central question, principle, or concept, to structure a moral theory which might accommodate those moral insights women tend to have more readily than men, and to answer those moral questions which, it seems, worry women more than men?

Central to Baier's thought is the idea that women cannot fit their moral experience into a conception of morality based exclusively upon obligation and contract.[120] Women's life experiences are often characterized by their caring relations with those who are less powerful and highly dependent, such as relationships with children and the sick and the dying.[121] When individuals are highly dependent, their relations with others on whom they depend for care are often non-voluntary and thus they require something from their caregivers other than a contractual agreement.[122]

Classical liberal theories which rest on impartiality of judgment, thus, are challenged by these theorists, for their neglect of the partiality that care ethicists claim for our relationships with others, such as in the relations with the doctor, nurse or friend.[123]

Care ethicists argue that the liberal focus on fairness leads to the neglect of morality and that universal principles can be irrelevant and constrictive.[124] This amounts to an argument that each situation which confronts the medical practitioner or researcher calls for a response beyond generalised moral norms and principles.[125]

The ethics of care is in favour of the idea of a mutual interdependence and, therefore, emotional responsiveness. Mutually interdependent relations (such as those between a medical practitioner and patient; researcher and research participant) demand a response which does not reflect a detached respect for that person's rights, but responsibility and empathy.[126] In opposition to theories based on

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116 As above.
117 As above, 371.
118 As above.
119 Baier (1985) 19 *Nous* 55.
120 Peter and Morgan (2001) 8 *Nursing Enquiry* 5.
121 As above.
122 As above.
123 Beauchamp and Childress 371 - 372.
124 As above.
125 373.
126 As above.

reason and through the emphasis on emotion, the ethics of care points out that a moral life also has an emotional dimension alongside the cognitive, with the stress on an 'engaged and contextual moral thinking'.[127] This, they claim, other forms of ethical thinking lack because obligation rather than sympathy is central to their thought.[128]

The discussion above is but a brief account of the philosophical foundation underlying biomedical ethics. Below we turn to the principles of biomedical ethics.

2.4 Principles

Beauchamp and Childress hold that the 'common morality' expresses a set of moral norms, including principles that are basic to bioethics.[129] The principles of bioethics (responsible for the name 'principlism') were introduced by Beauchamp and Childress with the aim of reconciling the divergence between utilitarian and deontological models of thought. These principles underpin ethical theory in some form[130] and function as a guideline for bioethics.[131] They are intended to link moral decision-making to 'mid-level' principles rather than to universal rules (such as those espoused by Kant and Mill).

Although the principles are too general in quality to address the particulars of diverse circumstances, at least they can provide a starting point for moral judgement. These principles are outlined below.[132]

2.4.1 Respect for persons

By implication, respect for persons is respect for autonomy; or that people who are capable of doing so make their own decisions.[133] Clearly, individuals need the

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127 374 - 375.

128 On care ethics, also see Marian A Verkerk 'The care perspective and autonomy' (2001) 4 *Med, Health Care and Philosophy* 289.

129 Beauchamp and Childress, 12.

130 Callahan (n 103) comments that the attraction of what he calls 'principlism' (the three principles) lies in the following:
'But these theories [utilitarianism, Kantianism, etc] turned out to be too broad and cumbersome to be useful for clinical decision making or policy formation. Principlism, as a middle level approach, seemed much more helpful and more attuned to different kinds of ethical problems. It seemed to have a special appeal to physicians not too interested in ethical theory, but in need of a way of thinking through their ethical dilemmas'.

131 Beauchamp and Childress 374.

132 For a criticism of 'principlism', see ch 5 below.

133 Smith (1999) 6.

information that enables them to make informed decisions.[134] Beauchamp and Childress indicate that respect for autonomy is an acknowledgement not only of another person's right to hold views and to make choices, but also that their actions are based on personal values and beliefs.[135]

In a research environment, what this recognition means is that a participant will enter studies only after they have been provided with adequate information and have freely given their informed consent.[136] Respect for persons implies that those unable to make autonomous decisions, such as the very young, the mentally ill and others, should be protected.[137]

This principle originates in the philosophy of Kant (among others), who asserts that that respect for persons flows from a recognition that all persons have unconditional worth.[138] John Stuart Mill supports the argument that there is a moral obligation to respect the autonomy of human beings on the utilitarian grounds that such respect increases human welfare except when they do harm to others.[139] He asserts the centrality of the principle to his thinking:[140]

> The object of this Essay is to assert one very simple principle, as entitled to govern absolutely the dealings of society with the individual in the way of compulsion and control ... That principle is, that the sole end for which mankind are warranted, individually or collectively, in interfering with the liberty of action of any of their number, is self-protection. That the only purpose for which power can rightfully be exercised over and member of a civilised community, against his will, is to prevent harm to others. Hic own good, either physical or moral, is not sufficient warrant.

2.4.2 Beneficence

Beneficence (or nonmaleficence) defines an obligation to improve the state of well-being of others and to do them no harm.[141] This principle arises from the maxim '*primum non nocere*', or 'first, do no harm'.[142] Philosophers have long debated whether the obligation not to do harm is as important as the obligation to benefit or to do what is good.[143]

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134 Smith 6; Beauchamp and Childress 63.
135 As above, 63.
136 Smith (n 133 above) 6.
137 As above.
138 Beauchamp and Childress 63. See also Gillon (n 46 above) 63 – 64 where which he presents Kant's argument in favour of respecting autonomy.
139 Gillon 64 – 65.
140 Mill 'On liberty' (n 51 above).
141 Smith 7; Gillon (n 46 above) 73 – 76, 80; Beauchamp and Childress (n 5 above) 113.
142 Beauchamp and Childress 114.
143 Eg Foot, quoted by Gillon 81: 'other things being equal, the obligation not to harm people is more stringent that the obligation to benefit people'.

In a research context the principle is an assurance that the risks to the research participant do not outweigh the possible benefits gained by the research.[144] Important areas in which the principle is to be considered relate to the decision to withdraw or withhold life-sustaining treatment and to physician-assisted suicide.[145] The prohibition on the use of placebos, if an effective treatment exists, stems from this principle.[146]

2.4.3 Justice

The term 'justice' refers to the obligation to treat everyone justly, in accordance with what is that person's due, and with what is reasonable and fair.[147]

Several philosophers have proposed ways in which social goods in society, such as access to health care, should be distributed. Utilitarianism, for example, aims to maximise public utility.[148] In these proposals the term 'distributive justice' is used, and a distinction is made between formal and material principles of justice.[149]

Justice involves decision-making about the allocation of scarce medical resources.[150] In a research setting the principle of justice takes into account fair access to participation in trials, as well as the access of the research population to the benefits of research.[151]

2.5 Conclusion

Ethical discourse is about the use of terms such as 'virtue', 'obligation', 'justification', 'morality', 'permissible action', and so on. A set of ethical principles is the foundation for an individual or group to believe that they have an obligation either to do or not to do something. Such an obligation stems from a perception that it is binding upon them. Many of the terms that are used in the context in which they are used may be unfamiliar to those whose discourse is rights-based.[152]

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144 Smith (n 133 above) 7; Gillon 83 - 84.

145 As above. For a detailed discussion on these implications, see Beauchamp and Childress 113 – 157. Beauchamp and Childress also criticise the conflating of beneficence and nonmaleficence. See 114.

146 See para 4.2.2 below.

147 Smith 7; Gillon 86 – 89; Beauchamp and Childress 226.

148 Beauchamp and Childress 230.

149 See Beachamp and Childress 226 – 229 and Gillon 86 - 91.

150 For a comprehensive discussion, see Gillon 93 – 98.

151 Smith 7. See para 4.3.3 below.

152 See ch 4 for a more detailed discussion on the differences and commonalities between ethics and legal rights.

These principles of bioethics (which express essential aspects of ethical theories, including utilitarianism, Kantian ethics, liberalism) are intended to aid in the process of reasoning about bioethical problems. The process in this case is a deductive (or top-down) approach; that is, the four general principles of bioethics are applied to specific, practical problems.[153] Bioethicists apply the abstract principles to practical problems in order to arrive at an ethically 'correct' decision in a practical situation. This reliance on principles by bioethicists has led to the term 'principlism' being applied by various writers to their theory and methodology.

Beauchamp and Childress claim that the validity of the four bioethical principles is grounded in what they call 'common morality' - an undefined and quite elusive term.[154] They support a 'universal core of morality' to be distinguished from *community-specific* morality, which includes moral norms deriving from 'particular cultural, religious, and institutional sources'.[155] An important implication of the accepted universality of common morality is that Beauchamp and Childress's bioethical principles are (in theory) applicable to clinical research conducted anywhere in the world.[156]

In addition, a degree of *indeterminacy* is incorporated into Beauchamp and Childress's bioethical model: their bioethical principles are very general and abstract in nature. They express no *exact content* that may lead to *specific* moral judgments and courses of action:[157]

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153 Also responsible for the term 'applied' ethics: 'Justification occurs if and only if general principles and rules, together with the relevant facts of a situation, support an inference to the *correct or justified judgment*' (Beauchamp and Childress (n 5 above) 178). My emphasis.
The deductive model of bioethics is rivalled by the *casuistic* model. This model advocates a case-by-case evaluation of bioethical problems. It is a *bottom-up* approach that accepts that the primacy of practical decision-making is based on precedent *and* common moral judgments. Casuists maintain that the very matrix of general principles and rules (ie the conceptual framework of the deductive model) is created out of moral judgments that can only be made through an initial stage of moral reasoning over the specific, and not the general; that is, through induction, and not deduction. General moral rules can be fully understood only in terms of the paradigmatic cases which define their meaning. For an explication of the precepts and limits of casuistic model, see Beauchamp and Childress (n 5 above) 391 - 397. Also see Arras 'Getting down to cases: The revival of casuistry' in Jecker *et al* (eds) (1997) *Bioethics: An Introduction to the History, Methods, and Practice* 175 - 183.

154 See para 2.2 above; 'common morality' is defined as 'the set of norms that all morally serious persons share ... and [which] bind[s] all persons in all places' (Beauchamp and Childress 11).

155 Beauchamp and Childress 11.

156 As above.

157 Plomer (2005) 12.

> Principles may have a fairly determinate and undisputed meaning in core areas, but the precise interpretation and scope of application of the principles at the boundaries or in disputed contexts may be indeterminate and uncertain, particularly when the principle is divorced from its theoretical origins.

Bioethical principles (and the respective rules) have to be contextualised, or *specified*, and their relative weight and strengths must be *balanced* when their combined contents prove antagonistic.[158]

In the following paragraphs, the crystallisation of ethical principles into guidelines and documents will be analysed.

3 ETHICAL GUIDELINES AND DOCUMENTS

3.1 Introduction

The three fundamental ethical principles outlined above, namely, respect for persons, beneficence and justice, as the foundation of a research or bioethics, are embodied in the various international and domestic ethical guidelines and documents. In the following pages, international documents, such as the Nuremberg Code, the Council for International Organizations of Medical Sciences' International Ethical Guidelines for Biomedical Research involving Human Subjects, the Belmont Report and the Declaration of Helsinki are scrutinised; as well as domestic documents, such as the Medical Research Council's Guidelines on Ethics for Medical Research of 2004 and the objectives of research ethics review committees in South Africa. The discussion remains at a general level, laying the foundation for more details in Chapter 5 below.

3.2 International codes of ethics

3.2.1 Nuremberg Code

The Nuremberg Code, written in 1946 as the final part of the judgment in the Nuremberg trials,[159] is the first comprehensive set of guidelines on how to conduct

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158 Beauchamp and Childress 17 - 19.

159 The Nuremberg trials include the trials of the doctors responsible for some of the inhumane experiments conducted at the orders of the Nationalist Socialist German Government during World War II. The judges at the Nuremberg Tribunal provided a list of requirements for doctors conducting experimental research, now known as the Nuremberg Code. This list prescribes the conduct of physicians holding them to a minimum standard of ethical behaviour as required by universal moral, ethical and legal concepts, the violation of which would bring down upon them the condemnation of society (in this regard, see Levine (n 1 above) 425).

ethical research on humans.[160] The Nuremberg Code is a consequence of the outrage that was felt at the conduct of doctors under National Socialism in Germany, who, in the guise of science, performed cruel and inhuman medical experiments on German and non-German nationals, including Jewish and other 'asocial'[161] people during the Second World War.[162] The Nuremberg criminal trials were aimed at holding specific individuals accountable for their barbarous acts against humanity; and recording the acts committed into history.[163]

The Nuremberg Code contains ten principles.[164] The first principle is an acknowledgement that the voluntary consent of human participants is absolutely essential.[165] The Code recognises that human experimentation, if conducted ethically, is valuable in generating knowledge that cannot be obtained by any other means, but forbids research that is random and unnecessary in nature.[166] Furthermore, unnecessary risk and harm should be avoided,[167] and the risk taken should not outweigh the possible benefits of the research.[168] Investigators should be qualified to conduct the research,[169] and be prepared to terminate the research project at any time if it should become clear that harm or injury is being suffered or may be suffered by the research participant.[170] The research participant may withdraw at any time from the experiment.[171]

3.2.2 Declaration of Helsinki

The World Medical Association's (WMA)[172] Declaration of Helsinki is an international code of ethics overseeing biomedical research involving human participants that is

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160 Levine 425; Foster (n 6 above) 141. The Code deals with non-therapeutic research only (ie research that does not investigate an illness or condition from which the participants suffer).

161 For example, prisoners, Jewish people and people undergoing treatment for psychiatric illnesses.

162 As above.

163 See Taylor in Mann *et al* (eds) (1999) 284 – 285.

164 For commentary on the legal / ethical force of the Nuremberg Code, see para 4.2 of ch 5 below.

165 Nuremberg Code, reprinted in Levine (n 1 above) 425 - 426.

166 Art 2 Nuremberg Code.

167 Art 3 Nuremberg Code.

168 Art 6 Nuremberg Code.

169 Art 8 Nuremberg Code.

170 Art 10 Nuremberg Code.

171 Art 9 Nuremberg Code.

172 The WMA was created in September of 1947. It was inspired by the events at the Nuremberg trials, and consists of a large group of private physicians who gathered to establish an international association, the World Medical Association. The WMA's primary focus is on global issues confronting physicians. It was created to ensure the

framed to govern the status and behaviour pf physicians. The Declaration of Helsinki was adopted by the WMA's 18th Assembly, held in Helsinki, Finland, in 1964, and has been revised several times, most recently in October 2000.[173]

The Declaration of Helsinki represents the efforts of the WMA to develop an international consensus on the ethics of medical research involving humans, and is a guide for physicians involved in research on humans. It consists of three sections, namely, I Basic Principles; II Medical Research Combined with Professional Care; and III Non-therapeutic Biomedical Research involving human subjects (non-clinical biomedical research). Significantly, unlike the Nuremberg Code, the Declaration of Helsinki distinguishes clinical (therapeutic) from non-clinical (non-therapeutic) research.[174]

The first section, 'Basic principles', establishes that research on humans should conform to generally accepted scientific principles, and that it must be based on adequately performed animal experimentation and a thorough knowledge of the literature.[175] The research protocol should be reviewed by an independent committee;[176] the responsibility for the human participant rests with the investigator;[177] the risk and the importance of the possible benefits must be in proportion;[178] the interests of the research participant should always prevail over those of society;[179] the research participant's free informed consent should be obtained;[180] and the research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles are complied with.[181]

The second section focuses on clinical research, and states that the new method that is being tested should be more advantageous than the current

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'independence of physicians, and to work for the highest possible standards of ethical behavior and care by physicians ...' (see WMA Policy <http://www.wma.net/e/about.html> (15 December 2006). Since its inception the WMA has actively participated in the international community to protect the interests of physicians and to promote its own ideals in shaping public health policy through information gathering and dissemination in the international health arena.

173 Levine 427. 'Clarifications' have also been added to the 2000 revision, accepted in October 2002.

174 See ch 5 below.

175 Art I.1 Declaration of Helsinki.

176 Art I.2 Declaration of Helsinki.

177 Art I.3 Declaration of Helsinki.

178 Art I.4 Declaration of Helsinki.

179 Art I.5 Declaration of Helsinki.

180 Art I.9 Declaration of Helsinki.

181 Art I.12 Declaration of Helsinki.

method;[182] the control group should be assured of the best proven diagnostic and therapeutic method;[183] and the refusal of the patient to participate should never interfere with the doctor-patient relationship.[184]

The third section focuses on nonclinical research, and stresses that the researcher should remain the "protector of the health and life" of research participants;[185] participants should be volunteers;[186] the research should be discontinued if harmful;[187] and the interests of society should never take precedence over the well-being of the participant.[188]

3.2.3 Belmont Report

The American National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research[189] in 1979 published the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (Belmont Report).[190]

The National Commission felt that the Nuremberg Code and subsequent ethical codes were inadequate to cover complex situations and that they often conflicted with each other.[191] The purpose of the Belmont Report was to identify broader ethical principles to provide 'a basis on which specific rules could be formulated, criticised, and interpreted'.[192]

The Belmont Report summarises the ethical principles that are fundamental to the specific ethical rules formulated in documents such as the Nuremberg Code: respect for persons, beneficence and justice.[193] The Belmont Report is divided into three sections, namely, Section A: Boundaries between Practice and Research; B:

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182 Art II.2 Declaration of Helsinki.
183 Art II.3 Declaration of Helsinki.
184 Art II.4 Declaration of Helsinki.
185 Art III.1 Declaration of Helsinki.
186 Art III.2 Declaration of Helsinki.
187 Art III.3 Declaration of Helsinki.
188 Art III.4 Declaration of Helsinki.
189 The American National Commission was established in 1974 by the National Research Act (Levine (n 1 above) 15). The Act established the National Commission as advisory to the US Department of Health, Education and Welfare and stipulated that it was to be replaced by a long-term National Advisory Council (see Grady (1995) 41). Between 1975 and 1979 the National Commission published numerous reports, one of which was the Belmont Report (Grady 41).
190 FR Doc 79-12065 (filed 17 March 1979); <http://ohrps.osophs.dhhs.gov/humansubjects/guidance/belmont.htm> (4 March 2004).
191 Grady (n 189 above) 42.
192 As above.

Basic Ethical Principles; and C: Applications. In Section B, the Report lists and discusses the three principles that underlie ethical decision-making in research on human participants: respect for persons, beneficence, and justice, and provides a conceptual framework to these principles.[194]

3.2.4 International Ethical Guidelines for Biomedical Research involving Human Participants

The Council for International Organizations of Medical Sciences (CIOMS)[195] in conjunction with the World Medical Association (WMA) published its International Ethical Guidelines for Biomedical research involving Human Subjects (CIOMS guidelines) in 1982, and has updated these guidelines in 1993 and 2002.[196]

The 21 CIOMS guidelines are extensive in scope, and issues discussed range from the ethical justification and scientific validity of research,[197] ethical review,[198] informed consent,[199] benefits and risks of study participation,[200] vulnerable individuals and groups,[201] children and women as research participants,[202] equity regarding burdens and benefits,[203] choice of control in trials,[204] confidentiality,[205] compensation for injury,[206] strengthening of international and local capacity for ethical review,[207] and the obligations of sponsors to provide health-care service.[208]

The CIOMS guidelines are more comprehensive than the Declaration of Helsinki, and, for the first time, express an awareness of problems related to

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193 Levine 12; Smith 5; Grady 42.

194 Levine 12.

195 The Council for International Organizations of Medical Sciences (CIOMS) is an international, nongovernmental organization established by the WHO and UNESCO in 1949.
The main objectives of CIOMS are to promote international biomedical activities, serve the scientific interests of the international biomedical community, and maintain relations with the WHO and the United Nations. While CIOMS does not have the power to make binding regulations, it does have the ability report to the WHO and to influence decisions made by the WHO (see 'What is CIOMS?' <http://www.cioms.ch/frame_what_is_cioms.htm> (16 December 2006).

196 Levine (n 1 above) 12.

197 Guideline 1 CIOMS guidelines.

198 Guideline 2 & 3 CIOMS guidelines.

199 Guideline 4 – 7 CIOMS guidelines.

200 Guideline 8 & 9 CIOMS guidelines.

201 Guideline 13 CIOMS guidelines.

202 Guideline 14 – 16 CIOMS guidelines.

203 Guideline 12 CIOMS guidelines.

204 Guideline 11 CIOMS guidelines.

205 Guideline 18 CIOMS guidelines.

206 Guideline 19 CIOMS guidelines.

207 Guideline 20 CIOMS guidelines.

research in developing countries. Also, the Guidelines show a concern for the obligations of sponsors in developed countries to provide health care services to their research populations in poor, developing countries.

3.3 Domestic codes of ethics

3.3.1 Introduction

A number of codes of ethics governing biomedical research on human participants exist in South Africa.[209] These are the Medical Research Council's (MRC)[210] Guidelines on ethics for medical research, the Department of Health's Guidelines for good practice in the conduct of clinical trials in human participants in South Africa and, specifically relevant to HIV and AIDS-related research, Ethical considerations for HIV/AIDS clinical and epidemiological research, also issued by the Department of Health. These documents are outlined below, following which the nature and functions of the different research ethics committees in the country are examined.

3.3.2 MRC Guidelines on ethics for medical research

The MRC Guidelines on ethics for medical research (MRC Guidelines),[211] one of the most important codifications of research ethics in South Africa,[212] is issued in terms of section 17(1) and 17(2) of the Medical Research Council Act.[213] Section 17(1) of the Act determines that the MRC Board must regulate and control research on or experimentation upon humans. Section 17(2) empowers the Board to determine ethical directives to be followed in research and experimentation, and to take the necessary steps to enforce the ethical directives.

The MRC Guidelines govern all research carried out by or on behalf of the MRC, and research funded by the MRC, and approved by its ethics committee.[214] Ferdinand Van Oosten is of the opinion that the MRC Guidelines are to be followed

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208 Guideline 21 CIOMS guidelines.

209 Discussed in ch 4 below.

210 The South African Medical Research Council (MRC) was established in terms of two Acts of Parliament (19 of 1969 and 58 of 1991). Its most important functions were defined as promoting 'the improvement of the health and the quality of life of the population of the Republic and to perform other such functions as may be assigned to the MRC by or under this Act'. Such improvement was to be attained 'through research, development and technology transfer'. See also <http://www.mrc.ac.za/history/general.htm> (15 December 2006).

211 4th (revised) edition published in 2004, previous editions are those of 1977, 1987, and 1993.

212 Van Oosten (2000) 63 *J Contemporary Roman Dutch L* 5 7.

213 Act 58 of 1991.

also by other research institutions, if that particular body does not have its own ethical guidelines in place.[215]

The fourth edition of the MRC Guidelines was published recently. There are five books in the revised series:[216] Book 1, entitled Guidelines on Ethics for Medical Research: General Principles; Book 2, entitled Guidelines on Ethics for Medical Research: Reproductive Biology and Genetic Research; Book 3, entitled Guidelines on Ethics for Medical Research: Use of Animals in Research; Book 4, entitled Guidelines on Ethics for Medical Research: Use of Biohazards and Radiation; and, finally, Book 5, entitled, Guidelines on Ethics for Medical Research: HIV Vaccine Trials.

Book 1 of the MRC Guidelines sets out the reasons for the revised publication. In the Preface it is stressed that in the 4th edition the MRC Ethics Committee has decided that the guidelines must have a South African emphasis, and that the individual's dignity and the importance of informed consent is to be strongly highlighted, as informed consent is entrenched in the Bill of Rights.[217] The argument that developing communities must not be exploited and the view that participating communities must benefit from research done on or with them are foregrounded.[218]

Book 1 of the MRC Guidelines consists of twelve guidelines and deals with issues such as the medical justification for research;[219] the legal and moral justification for research (which includes an extensive section on consent);[220] the way in which research ought to be conducted.[221] As such, it includes a large section on research participants;[222] ethical issues in qualitative research;[223] the assessment of ethics in research;[224] the monitoring of research;[225] international collaboration in research;[226] and, finally, ethical guidelines for epidemiology.[227]

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214 Van Oosten (n 212 above) 7.

215 Van Oosten 9. He bases his opinion on the fact that the MRC is a national research institution and the fact that the MRC Guidelines have statutory authority.

216 The reason for splitting the previous single volume into five sections is explained in the Foreword the Book 1 – five different editions will make the task of future revising and updating the Guidelines considerably easier. Also, researchers with specific interests will be able to access a single volume that relates to their interests.

217 MRC Guidelines 5.

218 As above.

219 Guideline 4.

220 Guideline 5.

221 Guideline 6.

222 Guideline 7.

223 Guideline 8.

224 Guideline 9.

225 Guideline 10.

226 Guideline 11.

227 Guideline 12.

3.3.3 Guidelines for good practice in the conduct of clinical trials on human participants in South Africa

The Department of Health (DH) issued the Guidelines for good practice in the conduct of clinical trials in human participants in South Africa (Good practice guidelines) in September 2000. The Preamble to the Good practice guidelines states that they are aimed at providing 'South Africa with clearly articulated standards of good clinical practice in research that are also relevant to local realities and contexts'.[228] Although the Good practice guidelines purport to be applicable to both academic and contract research in South Africa, it is important to remember that they have no statutory power, unlike the MRC's that are issued in accordance with a statute.[229]

The Good practice guidelines are contained in nine chapters. An introduction, which discusses the reasons for and scope of the guidelines, is followed by an explanation of the role of bodies such as the ethics committee during ethical review. This, in turn, leads to an examination of the protection of study participants,[230] the responsibility of the principle investigator and participating investigators,[231] the responsibilities of the sponsor[232] and quality assurance,[233] data management and statistics,[234] multi-centre studies[235] and ethics committees.[236] Guideline 9 is of particular importance to the current study, as it focuses on ethical considerations for HIV/AIDS clinical and epidemiological research. This guideline is discussed in detail below.

3.3.4 Ethical considerations for HIV/AIDS clinical and epidemiological research

Ethical considerations for HIV/AIDS clinical and epidemiological research (HIV/AIDS research guidelines) was issued by the DH in 2002, with the view to complementing the MRC guidelines with respect to research related to HIV and AIDS.[237] It is

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228 Preamble, Good practice guidelines.
229 See 3.2.2 above.
230 Guideline 2.
231 Guideline 3.
232 Guideline 4.
233 Guideline 5.
234 Guideline 6.
235 Guideline 7.
236 Guideline 8.
237 Preamble, HIV/AIDS research guidelines.

published as guideline 9 of the Department's Good practice guidelines.[238] According to the introduction, the HIV/AIDS research guidelines emanate out of a series of consultations held by the Task Group on Ethical Guidelines for HIV research.[239] The HIV/AIDS research guidelines do not deal specifically with HIV vaccine trials, as the challenges posed by this type of research are to be dealt with in a later document.[240]

After providing a brief background which emphasises that South Africa is a middle income country reflecting severe economic disparities and that the majority of its population is of a low socio-economic status, the authors of the HIV/AIDS research guidelines explain why conditions in South Africa are so favourable for conducting HIV and AIDS-related clinical research. Apart from the rapid proliferation of an HIV/AIDS epidemic, South Africa offers clinical and scientific expertise, academic institutions of good standing, good laboratory and clinical facilities and an industrial country's infrastructure. It also has high standards in communications and other relevant technologies.[241] The authors further reiterate the importance of conducting HIV and AIDS-related clinical research, because the information that is gained could have critical implications for South Africa and the rest of the world.

The HIV/AIDS research guidelines highlight ethical issues in HIV and AIDS-related clinical research in South Africa. Among the issues elaborated are that research should be appropriate to South Africa,[242] high research and ethical standards should be applied when research is conducted in vulnerable and non-vulnerable communities,[243] during HIV-related drug trials there should be a consciousness that trials are often the only way in which HIV positive persons are able to access expensive antiretroviral medication and this could compromise their ability to give informed consent, and that efforts should be made to increase the autonomy of research participants in this setting.[244]

The need for placebo-controlled trials is discussed, and the authors of the HIV/AIDS research guidelines comment that it may be justifiable to use placebo-controlled trials in communities where there is no access to the medications that are standard care in resource-rich settings.[245]

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238 See above.
239 Introduction, Guideline 9.
240 Introduction, Guideline 9.
241 Para 9.1 Introduction, Guideline 9.
242 Para 9.2.1.
243 Para 9.2.2.
244 Para 9.3.1. This issue is discussed in ch 5 below.
245 Para 9.3.2. For a detailed discussion on this ethical dilemma, see para 4 below.

Because HIV and AIDS-related clinical research and drug trials could cause short and long term ill effects, the patient information section of the informed consent document should specify what action is to be taken in the event that the study drug or drugs are withdrawn as a consequence of the side effects. The HIV and AIDS research guidelines recommend that in those circumstances appropriate therapy that is required to manage the adverse drug effects should be made available to participants. This therapy should be made available within the study framework and at no cost to the patient, unless exceptions have been agreed upon by all parties. [246]

If a patient withdraws from a study, or upon completion of a study, patients should be advised about the ongoing management of their condition. Ongoing therapy should be according to the local standard of care. Costs of this care should be borne by the local health service, the patient's medical insurance or the patients themselves.[247]

The HIV/AIDS guidelines further stipulate that, because many patients who participate in HIV and AIDS treatment trials have no alternative access to drug therapy, in cases where a patient has a therapeutic response to a study drug, that patient should be offered ongoing treatment. In designing studies, consideration should be given to the costs of long-term provision of study drugs and of clinical monitoring, including the costs of medical staff. The duration of drug therapy in a study should be clearly stated in the patient information section of the informed consent document.[248]

Next, the HIV/AIDS guidelines discuss HIV testing. Situations in which it is necessary to carry out HIV testing are outlined,[249] and the HIV/AIDS research guidelines acknowledge that HIV testing has important implications and consequences for the individual. The guidelines stress that informing individuals that they are HIV positive has an impact on their quality of life and that it should be considered a major intervention.[250] The HIV/AIDS research guidelines outline the ethics of confidential HIV testing[251] and deal with issues such as unlinked anonymous testing[252] and linked anonymous testing.[253]

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246 Para 9.3.3.
247 Para 9.3.4.
248 Para 9.3.5.
249 Para 9.4.
250 Para 9.4.
251 Para 9.4.1
252 Para 9.4.2.

Furthermore, population-based studies to prevent HIV transmission,[254] the difficulty of obtaining informed consent in populations where literacy levels are low,[255] incentives offered to research participants to take part in a trial,[256] and issues relating to the researcher herself, such as incentives that may influence the objectivity of the researcher,[257] and the release and implementation of research results[258] are other topics that are dealt with. Finally, the HIV/AIDS guidelines deal briefly with HIV vaccine research,[259] the involvement of people living with the virus[260] and the need to give special consideration to subgroups in society, such as women, children and prisoners, when conducting HIV and AIDS research.[261]

3.3.5 Research ethics committees

The 1970s witnessed the birth of the research ethics committee (REC), or, as it is called overseas, the institutional review board.[262] RECs are set up to oversee the ethical conduct of clinical research and they are the primary mechanisms intended to protect the interests of research participants. Lisa Eckenwiler writes as follows about the role of RECs:[263]

> Institutional review boards (IRBs) represent a particular approach to answering to people – the public generally, research participants more directly – in terms of responsibilities that have come to be recognised within the research community. Their efforts, indeed, can be understood as a special case of an important move made in moral life: reasoning about the interests of others in coming to conclusions about what is ethically acceptable.

Guideline 9 of the MRC Guidelines requires that all research involving healthy volunteers and patients must be subject to independent ethical review and that this should be conducted by a REC.[264]

Guideline 6.1.9 of the MRC Guidelines sets out the objectives of RECs. They are to:

- maintain ethical standards of practice in research;

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253 Para 9.4.3.
254 Para 9.5.
255 Para 9.6.
256 As above.
257 Para 9.7.1.
258 Para 9.7.2.
259 Para 9.8. See ch 5 below for a detailed discussion of this paragraph of the HIV/AIDS research guidelines.
260 Para 9.9.
261 Para 9.10.
262 Often abbreviated as IRB.
263 Eckenwiler (2001) 11 *Kennedy Institute Ethics J* 37.
264 Guideline 9.1 MRC Guidelines.

- protect research participants and investigators from harm or exploitation;
- preserve the research participant's rights over society's rights; and
- provide reassurance to society that this is being done.

Two principles guide the appointment of members of RECs:[265]

- Committees should command the technical competence and judgment to reconcile the physical and psychological consequences of participation with both the welfare of the research participants and the objectives of an investigation.[266]
- Committees should accommodate lay opinion in a manner that provides effective representation of the non-clinical community as well as clinical interests. Lay opinion includes representation by a lawyer, social worker, religious leader, teacher or similar person of standing able to contend with pressures from individuals within the broad health profession.[267]

Two kinds of RECs function in South Africa.[268] They are the Ethics Committee of the MRC and the ethics committees at various universities and other bodies.[269]

a) The ethics committee of the MRC

Sections 17(1) and 17(2) of the South African Medical Research Council Act[270] empower the Board of the MRC to issue ethical directives which must be followed during research and experimentation on or with humans, animals, human or animal material, and which is performed by its employees and by persons performing research or experimentation for or on behalf of the MRC, or with research funding of the MRC.[271]

b) Other ethics committees

Apart from the MRC's Research Ethics Committee, ethics committees are in place at various academic and other institutions where research is conducted. For instance, the medical faculties of the universities in South Africa each has its own ethics committee. Van Oosten submits that if research is carried out under the auspices of other RECs, such as research conducted at the different universities, and no ethical

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265 Guideline 9.9.1.
266 Guideline 9.9.1.1(i).
267 Guidelne 9.9.1.1(ii).
268 Van Oosten (n 212 above) 6.
269 As above.
270 58 of 1991.
271 Van Oosten 7.

guidelines are in place at that institution, such research should also be governed by the MRC guidelines.[272]

The Department of Health's Good practice guidelines make provision for the establishment of a National Health Research Ethics Council.[273] Once it is established, this body will have overall responsibility to promote, ensure and monitor compliance by approved ethics committees in South Africa with relevant legislation, regulations and guidelines. This body is to be established under the new National Health Act,[274] and will report directly to the Minister of Health.

3.4 Conclusion

The preceding pages surveyed the documents that are a crystallisation of the principles expressed by ethical theory as discussed in paragraph 2. Briefly, the various national and international ethics guidelines and documents have been outlined and the functioning of South African research ethics committees is examined.

The following section moves away from theoretical principles and documents to an examination of how these principles function in practice. The effectiveness of the protection of participants in clinical research over the past decades offered in various ethical guidelines is assessed. Proceeding from the general discussion, the focus shifts to ethics and HIV/AIDS-related clinical research in Africa.

4 FROM PRINCIPLES TO PRACTICE: THE REGUALTION OF CLINICAL RESEARCH ELSEWHERE AND IN AFRICA

4.1 Introduction

In the preceding pages an outline was presented of various ethical theories and their crystallisation into the ethical principles that are included in domestic and international ethics guidelines and documents. What follows is an examination of the manner in which ethical documents have been employed to protect the interests of research participants in HIV and AIDS-related clinical research in the world in general and in Africa, specifically.

Firstly, an overview of the failures of ethical guidelines to safeguard research participants in the rest of the world is given, as well as an outline of the protectionist

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272 Van Oosten 9.

273 Guideline 1.5.3 Good practice guidelines. In this regard, also see the discussion of the National Health Act 61 of 2003 in ch 5 below.

measures which were devised in response to the subsequent outcry. Next, the influence of the HIV/AIDS epidemic on the ethics of clinical research is explored. A much-publicised ethical dilemma - the controversy over the use of a placebo in the AZT trials to prevent MTCT of HIV in Uganda - is analysed and reference is made to difficulties that arose in three other trials. Finally, ethical concerns specifically relevant to clinical research in Africa are discussed and the question is posed whether research participants in developing countries are differently situated from those in developed countries.

4.2 Imperfect practices: Past failures of ethical guidelines

4.2.1 A short history

a) Early failures

Although the history of clinical research may be traced back for many centuries, little attention was paid early on to what was later to become known as bioethics or research ethics. Even the early part of the 20th century saw modest attention in the literature to bioethics. This may be due to several reasons: partly because doctors and scientists did not clearly distinguish between 'research' and 'treatment' and partly because doctors enjoyed a considerable amount of public trust. They were rarely criticised by research 'participants' or their patients.[275]

The middle of the 20th Century saw the adoption of the Nuremberg Code, establishing the primacy of the welfare and interests of the research participant, and the embodiment of its principles into a variety of codes of conduct, including the Helsinki Declaration. The emphasis was on informed consent after disclosure by the investigator of the risks of research. Henceforth, reputable organisations and journals required that researchers include statements affirming that the principles of the Declaration of Helsinki were followed during research, and, specifically, that informed consent had been obtained from participants.

However, abuses of ethical guidelines and research participants continued, showing that a mere reliance on informed consent does not protect research participants against exploitation. In the 1950s, an experiment at Willowbrook State School, in which researchers injected the Hepatitis B virus into mentally-retarded children in order to study the natural progression of the disease, aroused public

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274 Act 61 of 2003.

275 See ch 5 below on the concept of 'paternalism' in research, as well as n 306 below.

concern.[276] Participants were fed extracts from the stools of infected children, and participants who were 'enrolled' in the trial at an earlier point in time, and who were already ill, received injections of 'purified' virus.[277] The parents of children were only able to have their children admitted to hospital upon their agreeing to the children being part of the research.[278]

In the 1960s, details of an experiment at the Jewish Chronic disease Hospital in Brooklyn, New York, came to light.[279] In this instance, researchers injected cancer cells into research participants without informing those participants of the risk or obtaining their informed consent.[280] The researchers defended their actions by saying that they could not tell patients that they were going to receive cancer cells as that would have frightened them unnecessarily.[281] These researchers wanted to gain information on the nature of the human transplant rejection process.[282]

In 1966, an exposé by Henry Beecher, published in the *New England Journal of Medicine,* identifies 55 cases[283] over the preceding ten years in which there were instances of 'unethical and questionably ethical procedures', which put research participants at risk.[284] A staggering 22 cases had their findings incorporated in articles that were published in the *New England Journal of Medicine*.

Beecher argues that two factors determine whether research is ethical - the informed consent of the participant and an 'intelligent, informed, conscientious, compassionate, responsible investigator'.[285] Beecher points out that the 'gain anticipated from the experiment must be commensurate with the risk involved'.[286] Most of the instances Beecher describes involve poor, disadvantaged research participants. Subsequent publications have detailed even more severe abuses, such as those Pappworth[287] and Katz[288] describe.

The 1970s saw the disclosure of one the most serious abuses of research subjects to date: the Tuskegee syphilis study. The study began in 1932, lasted for

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276 Levine (n 1 above) 70.
277 Levine 70; Grady (n 189 above) 40 – 41.
278 Levine 70; Grady 40.
279 Levine (n 1 above).
280 Levine (n 1 above) 71; Grady (n 189 above) 40. It was later asserted by researchers that informed consent was negotiated orally, but not documented.
281 Levine 71; Grady 40.
282 Levine 71.
283 The results of which were published in international journals.
284 Beecher (1966) *New Engl J Med* 1354 – 1360.
285 Beecher 1360.
286 As above.
287 Pappworth (1967) *Human guinea pigs*.

40 years, and is probably the most publicised of the abuses during this period and has caused an outcry around the world.[289] The study recruited 400 black men of a low socio-economic background from Alabama with the promise of free medical care for a study into the natural progression of the disease.[290] 200 of these men were suffering from syphilis, the remaining 200 were healthy and served as controls.[291] The standard treatment for syphilis at the time was an injection of arsenic and bismuth.[292]

None of the men gave informed consent to the treatment; in fact, they were told that some of the experiments, such as spinal taps, were not part of the research at all, but 'special free treatment'.[293] Although penicillin was discovered in the 1940s to be an effective therapy for syphilis, and the fact that syphilis sufferers' life-spans were reduced by 20 per cent when the disease was left untreated by antibiotics, the men taking part in the study were not told, and were left untreated.[294]

Also in the 1970s, the aim of the San Antonio Contraceptive study was to discover which side-effects of oral contraceptive use were due to the drug itself, and which were due to the 'symptoms of everyday life'.[295] Mexican-American women (poor and who had no other access to contraceptives and who had multiple pregnancies), who attended a clinic seeking contraceptive advice, were enrolled in the study.[296] None of the women were advised that they were part of a research study, and that, in some instances, they received placebos instead of contraceptives.[297] Eleven of the 76 research participants became pregnant during the study because of receiving a placebo instead of an active contraceptive.[298]

In the 1990s the Kennedy Kriegler Institute at Johns Hopkins University conducted a research study on lead paint exposure.[299] In order to test their interventions, the presence of small children was required, and researchers from the University encouraged landlords of lead-contaminated housing to rent to families (with otherwise healthy young children) who were told the homes had been abated

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288 Katz (1972) *Experimentation with human beings*.
289 Levine (n 1 above) 69.
290 Levine 69; Grady 40.
291 As above.
292 As above.
293 As above.
294 Levine 70.
295 Levine 71.
296 As above.
297 As above, 72.
298 Levine 72.
299 See Spriggs (2004) 30 *J Med Ethics* 176.

of lead paint.[300] Those families were subsequently recruited to participate in a (fictitious) research study in which blood testing of the children would be done; however, the families were not informed that testing for the presence of lead was to be part of the study.[301] Children living in study houses were also encouraged to continue living in the houses. The levels of lead that accumulated in the children's blood determined the success of the various methods of lead abatement.[302]

Exposure to lead has a detrimental affect on the health and cognitive development of young children.[303] When the true nature of the research study came to light, mothers of two of the children filed court cases, complaining that they were not fully informed of the risks and hazards involved in the study, and were not warned promptly of the high levels of lead in their homes and in their children's blood - information that would have influenced their willingness to continue in the study.[304] The judge in the case likened the lead paint study to the infamous Tuskegee experiments.[305]

From the above examples it is clear that despite the existence of the Nuremberg Code and the Declaration of Helsinki, as well as other international and national codes, they were not sufficient to safeguard the research participants' rights. Researchers either ignored the ethical rules laid down in these documents outright, or thought that their non-ethical actions were justified in the interests of science.

b) Protectionist[306] attitudes in the 1960s and 1970s

The incidents described above and the public outcry which followed the disclosure, led to the United States Senate passing the National Research Act in 1974. This Act requires independent review of all research by an institutional review board before it

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300 As above.
301 As above.
302 Spriggs (n 299 above) 177.
303 As above.
304 As above.
305 See above.
306 According to Carole Levine, during the 1960s and 1970s, the paradigm for ethical analysis in the United States focussed on the risks and burdens of research; she notes that the history of the regulation of clinical research in that country 'was born and reared in protectionism' (Levine 'Changing views of justice after Belmont: AIDS and the Inclusion of "vulnerable" subjects' in Vanderpool (ed) (1996) 106). Research participants had to be protected against abuse by authorities who regarded themselves as better able to judge what is best for participants.

can be funded.[307] The Act also establishes the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research. The National Commission published the Belmont Report[308] in 1979 as an attempt to synthesise the ethical guidelines that are basic to human subject research.

The Belmont Report and the work of bodies such as the National Commission illustrate a pre-occupation with the need to protect the research participant against the evils of irresponsible research. This protectionist attitude lasted until the mid-nineteen eighties when the beginnings of the HIV epidemic brought a change to how research participants are perceived by investigators and how they perceive themselves. This change in attitude is discussed below.

c) The impact of the HIV epidemic

Regarding the extent of the impact of the HIV/AIDS epidemic on medical ethics, Kenneth Boyd writes that the impact of AIDS on medical ethics can possibly be compared to the impact of war on medicine itself:[309]

> In wartime, everydayness is seen in a different light, new solutions are found to old problems, and few wars have ended without some contribution having been made to medical progress. The arrival of AIDS had similar effects on medical ethics. Few clinicians were untouched by it; nor, as in all modern wars, was the civilian population.

The ravages of HIV/AIDS during the mid-nineteen eighties brought dramatic changes to the way in which research participants are viewed by researchers and the way in which research itself is seen.[310] For the first time participation in a clinical research is seen as a benefit, and not a burden.[311] People were desperate for a cure and saw research participation as a way of accessing treatments.

HIV/AIDS activists were instrumental in this shift in perception. Participation in clinical research brought people living with the virus access to investigational new drugs and medical care.[312] The perception of the benefit of research and participation in clinical trials was so strong that participants and their physicians even in some cases falsified participants' medical records in order to comply with the

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307 The Act is a domestic piece of legislation; therefore, it governs research carried out in the United States, or funded by an agency in the United States and carried out elsewhere.

308 See para 3.1.3 above.

309 Boyd quoted in Pinchin *et al* (2000) 26 *J Med Ethics* 6.

310 Beauchamp and Childress (n 5 above) 203.

311 As above.

312 As above.

inclusion criteria of clinical trials for new drugs and treatments.[313]

Developments during the 1980s and 1990s in patient advocacy and activism have their origins in the problems of stigma and alienation felt by PLWHA.[314] Pinchin *et al* comment as follows:[315]

> An emerging solidarity, reinforced by the cumulative personal losses, soon led to action to protect each other through prevention programmes, based on peer-education and influence. These were impressively relevant, focused and unfettered by the constraints limiting official campaigns. Issues of access to care and to information followed, leading to treatment activism, driven by a strong desire for more satisfactory outcomes.

At this time people living with HIV/AIDS in the developed world became an informed, scientifically-educated group. Rather than being inactive recipients of the researchers' protectionist attitudes, they demanded to be part of the process of decision-making. This attitude was often born out of a sense of desperation.[316]

> Physicians in this field have been struck by the way in which people affected have wanted to be involved in decision making. While this has often been ascribed to their social groups, it probably was more a reflection of their younger age and a generation change in expectations of health care. While medicine and medical ethics were already moving towards a more explicit recognition of personal autonomy, AIDS has accelerated and catalysed the process. Faced initially with a disease of overwhelming severity that would so shorten their lives, and the limitations of treatment, it is understandable that patients wanted to explore the options and to make the vital choices.

Thus, AIDS activists demanded early access to research findings, even during the early stages of clinical trials.[317] In turn, this demand resulted in a pool of research participants who were well-informed about the research that was being carried out and about treatment options.[318]

The standard process of ratification the US Federal Drug Administration (FDA) follows was seen by AIDS activists as slow, restrictive and paternalistic.[319] People living with HIV/AIDS criticised the FDA for dragging its feet while people were dying – '[c]oncerns about the conduct of clinical trials and delays in drug availability and licensure became a public expression of the ethics of emergency'.[320] Clinical trial methodologies, such as placebos and randomisation, were seen by AIDS activists as

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313 Beauchamp and Childress 204.
314 Pinchin *et al* (n 309 above) 3.
315 As above.
316 Pinchin *et al* 3.
317 Beauchamp and Childress (n 5 above) 203.
318 As above.
319 As above.
320 Pinchin *et al* 4.

'disempowering, arbitrary and irrational'.[321]

In response to the demands of AIDS activists, the FDA developed expanded access to experimental drugs, allowing the treatment use of experimental drugs that had not yet been approved for seriously ill patients.[322] Furthermore, the FDA allowed for fast-track (expedited approval) of investigational medication for people with life-threatening conditions.[323] For the first time it was considered acceptable for people with life-threatening illnesses to take greater risks in taking medication that had not yet received approval. AZT is one of the drugs that was fast-tracked in this way.[324]

The AIDS pandemic thus brought about a new definition of the research participant's right to be seen as autonomous and capable of making decisions about participation in research, ushering in a new era in research ethics in the 1980s. The perceived paternalism of the previous decades was thoroughly rejected and the shift in attitude was reflected in policy and in revisions to the major international documents.[325] During this period, the debate centres on the inclusion of women and ethnic minorities in clinical trials, which demonstrates clearly the shift towards regarding research participation as a benefit rather than a burden.

However, clinical trials in Africa on the perinatal transmission of HIV, and other medical questions, soon put back in the spotlight the failings of research ethics to adequately protect the interests of the research participant. The following section is an outline.

4.2.2 Four cases in point: Failures of ethical guidelines to protect research participants in Africa

a) Placebo-controlled trials of Zidovudine to prevent MTCT of HIV in Uganda

i) Overview

Mother-to-child transmission of HIV (MTCT) is the manner most common for young children, world-wide, to become infected with HIV.[326] The search for drugs that would limit this form of transmission has been a priority in the battle against HIV/AIDS.

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321 As above.
322 Beauchamp and Childress 203.
323 As above.
324 As above.
325 As above.

In 1994, a large randomised, double-blind, placebo-controlled trial[327] (conducted mainly in the USA) showed the efficacy of the ARV zidovudine or AZT (during the trial known as the PACTG[328] 076 regimen) in reducing MTCT of HIV by almost two thirds, from 25 per cent to 8 per cent.[329] After the results of the trial were published, this regimen became the standard care to prevent MTCT of HIV in the developed world.

In the developing world, however, the situation was less reassuring. Because of the high cost of AZT ($800 per patient at the time of the trials, now far less)[330] and the fact that it has to be administered for several weeks before birth to the mother, intravenously during labour, and as a syrup to the child after birth, meant its administration is an impracticality in countries where mothers often do not attend clinics until immediately before labour or only if complications arise. Further, many rural clinics in these countries do not have the technology to administer intravenous medication.[331] Many mothers never attend a clinic at all. Moreover, the original clinical trial was performed in a setting where mothers were urged not to breastfeed, whereas, in Africa, most mothers breastfeed.

A shorter and cheaper regimen that could be used in a resource-poor setting thus had to be found if the administration of AZT was to be an achievable goal for developing countries. In order to successfully develop a shorter, cheaper regimen, sixteen randomised, double-blind placebo-controlled trials of shorter AZT regimens were undertaken in developing countries, such as Uganda, Tanzania, Ethiopia, Zimbabwe, Thailand and the Dominican Republic. Fifteen of these studies used a placebo in the control arm of the study.

ii) The ethical dilemma

The September 1997 issue of *The New England Journal of Medicine* published the results of a randomised, double blind, placebo-controlled trial determining the efficacy and safety of a shortened, simplified course of AZT[332] in reducing the risk of

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326 See ch 2 above.
327 See para 5.2.2 in ch 2 on the scientific methodology of these trials.
328 Paediatric AIDS Clinical Trial Group.
329 Connor *et al* (1994) 331 *New Engl J Med* 1173. Other interventions such as caesarean section were shown to reduce the risk even further.
330 Bayer (1998) 88 *American J Public Health* 568.
331 See Connor et al (n 329 above) and Bayer (n 330 above) 568 – 569.
332 This trial had taken place long before nevaripine and newer drugs became the preferred treatment in such instances.

MTCT of HIV in Uganda.[333] This article, and the editorial written in response to it by the journal's editor, Marcia Angell, sparked off one the most astringent ethical debates of the nineties.

HIV-infected pregnant women who had not received anti-retroviral therapy and who had a CD4 count of above 2300 per millilitre of blood were enrolled in the Ugandan trial.[334] Trial participants were given AZT before and during birth, and AZT was administered to the child for six weeks after birth. This trial was placebo-controlled, in other words, the control group received no treatment while the experimental group received AZT.

The controversy lay in this fact – even though AZT had been shown to be effective in preventing MTCT (in the previous trials of the 076 regimen), and, therefore, had become the best proven treatment, it had not been given to the control group. They were given a placebo – violating the ethical principle of beneficence.[335]

In her editorial, Marcia Angell asserts that 'only where there is no known effective treatment is it ethical to compare a potential new treatment with a placebo'.[336] If an effective treatment exists (as is the case here), then it is not ethically permitted to use a placebo. Members of the control group should have been given the 'best known treatment'.[337]

In the context of this view, if the trial had been conducted in the United States, or another developed country, the practice would have been considered unethical.[338] Marcia Angell posed a question concerning the ethical nature of conducting a trial in a developing country in a manner that is considered unethical in a developed country.[339] Angell argues from the viewpoint that research participants in a developing country should receive the same standard of care as that provided in the developed world (in other words, the women should not have been given a placebo). Relying on the Declaration of Helsinki, Angell is asserting the requirement

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333 Also see Lurie and Wolfe (1997) 337 *New Engl J Med* 854.

334 As above.

335 Art II.3 Declaration of Helsinki requires the investigator to provide the 'best proven treatment'.

336 Angell (1997) 337 *New Engl J Med* 847.

337 Art II.3 Declaration of Helsinki.

338 Bayer (n 330 above) 568. Such a trial would be considered unethical because it is not trying to find an intervention that is at least as effective as, or better than the prevailing standard of care (the 076 regimen of AZT).

339 Angell (n 336 above) 848.

that control groups receive the 'best' current treatment, not the local one:[340]

> The shift in wording between 'best' and 'local' may be slight, but the implications are profound. Acceptance of this ethical relativism could result in widespread exploitation of vulnerable Third World populations for research programmes that could not be carried out in the sponsoring country.

Based on the conclusion that that she derives from her perception of the practice of 'ethical relativism', Angell maintains that the justifications used by the researchers for the need for the trial is reminiscent of that used in the Tuskegee study; that the research participants will, in any case, not have access to AZT (as it is too expensive):[341]

> Women in the Third World would not receive antiretroviral treatment anyway, so the investigators are simply observing what would happen to the subjects' infants if there were no study. And a placebo-controlled study is the fastest, most efficient way to obtain unambiguous information that will be of greatest value in the Third World.

Her argument is that the limited resources of the developing world cannot justify an attempt to find an affordable intervention if the standard of care is at a level different to that provided in the developed world.[342]

Marcia Angell is not alone in criticising the Ugandan research. In the same issue of the *New England Journal of Medicine*, Peter Lurie and Sidney Wolfe attacked the Ugandan research as unethical on the grounds that it will lead to the preventable infection of hundreds of infants.[343] They regard the research as directly violating the research participants' right not to be exposed to unnecessary risk.[344] In their view, the research violated several existing international research ethics guidelines.

Lurie and Wolf criticise the study because participants in these trials do not have access to antiretroviral treatment, while women in the United States, where similar studies were conducted, do have access to antiretrovirals. They use a similar study in Thailand, in which three shorter AZT regimens were being compared to a regimen similar to the 076 regimen (instead of a placebo),[345] as an example of how the same research could have been conducted in an ethically acceptable manner.[346]

The Thailand study is an equivalency study; a methodology that is used when

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340 Angell 848.
341 As above.
342 As above.
343 Lurie and Wolfe (n 333 above) 853.
344 Lurie and Wolfe 854.
345 The subjects in the experimental arm thus received the shortened experimental regimen, while those in the control arm were not given a placebo, but the active, longer course of AZT.
346 As above.

a particular regimen has already been proven effective and the aim is to determine whether the second regimen is as effective, but is less toxic or expensive.[347] In response to pressure from the USA NIH[348] to change the study to one that is placebo-controlled, the principle investigator in Thailand argued that an equivalency study (using an active control) is feasible in Thailand.

Lurie and Wolfe assert that the wrong research question was being asked in the Ugandan study. Instead of asking, 'Is the shorter regimen better than nothing?' (which would perhaps justify a placebo control), the question asked should have been, 'Can we reduce the duration or prophylactic treatment (AZT) without increasing the risk of perinatal transmission of HIV, that is, without compromising the demonstrated efficacy of the standard ACTG 076 regimen?'[349] They stress that an equivalency study would have yielded more useful results than the placebo study. Therefore, their argument is that the scientific rationale for the research was flawed.[350]

In response to Lurie and Wolfe's argument for the use of an equivalency study, proponents of the use of a placebo maintain that differences in the duration and administration of antiretrovirals agents in the shorter regimens justify the use of a placebo.[351] Lurie and Wolfe assert in response that the data gained from the original 076 trial provides sufficient information, and the equipoise necessary to regard the study as ethical is retained:[352]

> These findings seriously disturb the equipoise (uncertainty over the likely study result) necessary to justify a placebo-controlled trial on ethical grounds.

On similar grounds they dismiss the claim that in Uganda (and the other countries), because the medication was administered orally, in contrast to intravenously in the original trial, this justifies the use of a placebo.[353] They insist that previous pharmacological studies have indicated that the uptake of the drug is the same whether administered orally or intravenously.[354]

Lurie and Wolfe examine the 'standard of care' argument. The version of the argument they contest implies that placebo-controlled studies are acceptable in the

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347 As above.
348 National Institutes of Health.
349 This was indeed the research question that was posed in the Thailand study. See Lurie and Wolfe 853.
350 As above.
351 As above.
352 As above, 854.
353 As above.

developing world as the standard of care here is either to rely on unproven treatment or to have no care at all.[355] In their view, this is a misunderstanding of the concept 'standard of care', as the standard of care that is used as a yardstick should be that of the treatment available in the sponsoring country:[356]

> Acceptance of a standard of care that does not conform to the standard of care in the sponsoring country results in a double standard in research. Such a double standard, which permits research designs that are unacceptable in the sponsoring country, creates an incentive to use as research subjects those with the least access to health care.

Lurie and Wolfe's arguments against using placebos may be summed up as follows.

- A placebo-controlled study is no longer ethically justified as AZt has been proven to be effective in preventing mother-to-child transmission of HIV.
- Research participants in developing countries who take part in research of this nature should have access to the prevailing standard of care in the sponsoring country.
- An AZT control arm should be used, regardless of prevailing local circumstances.

The *New England Journal of Medicine* published a response to Laurie and Wolfe.[357] In their response Vermus and Satcher stress that, because of the poverty of developing countries, placebo-controlled studies were used to obtain a speedy result.[358] They argue that placebo-controlled trials alone are able to provide definitive and clear answers about whether the interventions have worked.[359] They maintain that no clear answer would be gained by testing two or more interventions of unknown benefit against each other as it would not become clear whether either intervention would be more effective than no intervention.[360]

Ronald Bayer, in his article dealing with the controversy relating to the trials, comments that Vermus and Satcher neglect the real ethical difficulty inherent in the trials in their response. In this view, the real ethical difficulty relates to how one[361]

> should balance the claims of research subjects and their offspring against the claims

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354 As above, 855.
355 As above.
356 As above.
357 In their October 1997 edition, written by Harold Vermus and David Satcher: Varmus and Satcher (1997) 337 *New Engl J Med* 1003.
358 As above.
359 As above, 1005.
360 As above.
361 Bayer (n 330 above) 568.

> of those who might be placed at risk if the use of non-placebo designs were to require trials of more extended duration. Time is not an ethically neutral consideration, given that, in the time period before definite answers become available, untreated mothers and their offspring continue to suffer the risk of vertical transmission.

iii) Commentary

The debate in the *New England Journal of Medicine* cannot merely be characterised as an argument between ethical universalists, who believe a single ethical standard should be applied throughout the world, and ethical relativists, who hold the opinion that a different set of ethical principles should apply in local circumstances. Nor is it an argument about the practical application of ethical principles in different circumstances, economic conditions and social situations.[362] Rather, the two groups represent contesting methodologies.

One group suggests that methodological considerations make it necessary to use a placebo control group in clinical research, whereas the other believes that ethical standards and the rights of research participants are sacrificed for methodological considerations.[363] As Emmanuel proposes; is there a compromise or middle ground between the two groups' views?

In philosophical terms, at issue are two approaches to ethical reasoning. Angell, Lurie and Wolfe present the deontological or Kantian approach, by their assertion that actions should not be judged by their consequences. Vermus and Satcher, from a consequentialist or utilitarian point of view of determining whether an action is right or wrong, argue that the best possible outcome is achieved by the use of a placebo.[364]

Supporters of the placebo-controlled clinical trial, in instances where a known treatment exists, point out that a variable response to drugs in certain populations - unpredictable and small effects and high rates of spontaneous improvement in effect in patients – means these trials are necessary and, thus, ethically acceptable.[365] Without a placebo group to ensure validity, there is no assurance as to whether the known therapy is, in fact, better than the placebo, or if there is no difference between the investigational and standard treatment.[366] Most ethicists agree that

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362 See Bayer's argument to this affect, above.

363 Emanuel (2001) 345 *New Engl J Med* 915.

364 See paras 3.2.1 and 3.2.2 above.

365 Emanuel (n 363 above) 915. The argument below is based on Emmanuel's article.

366 Of course, new treatments that are no better than existing treatments may still be valuable, such as is the case when the new treatment has fewer side-effects or is more effective in older people or children.

there are instances where placebo-controlled trials are unethical by definition, such as if a life-saving treatment is withheld.[367]

However, as there is no agreement with regard to when a placebo-controlled trial will be ethical even though a known treatment exists, controversy, such as the one discussed above, is bound to arise. In some instances research participants suffer psychological and physical harm if they are refused a known treatment.[368] In those circumstances, placebo-controlled studies may be said to place the demand of scientific rigour above the need to care for the well-being of the patient.

Advocates of active controls propose that, as prescribed in the Declaration of Helsinki, these should be used whenever possible. Nevertheless, their implementation is not straightforward.

- Active control studies do not always produce a result or may produce misleading results, thus making the trial worthless.[369] In that case the study may be termed unethical, because one of the first requirements for an ethical study is that it should be scientifically rigorous in producing an answer to a specific research question.
- In some cases, the harm done by not treating the participant with the existing treatment is so small that there exists no ethical duty to do so.[370]
- Trials using effective controls (such as equivalency trials) may need to enrol many more participants than is the case with placebo-controlled trials and last longer. Thus, many more people will be exposed to possible harm, such as an undiscovered side-effect of the investigational drug (that may be more toxic or just useless), than is the case with a placebo-controlled trial.[371]

Ethical guidelines require that clinical research that is ethically acceptable be scientifically valid and minimise the risks that research participants are exposed to. Emanuel argues that advocates of placebo-controlled trials are opting for scientific validity, and their opponents for minimising risks.[372] He suggests that there is a middle ground between these positions; asserting that placebo-controlled trials are ethically justifiable only when the methodological reasons for them are compelling,

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367 Emanuel 915; also see Beauchamp and Childress (n 5 above) 142 – 143; 145 – 146; 159 – 160.
368 eg when they suffer from a disease that is treatable.
369 Emanuel (n 363 above) 915.
370 As above. Also see Beauchamp and Childress 133.
371 Emanuel 916.
372 As above.

that patients receiving the placebo will not be exposed to serious harm, and that attempts should be made to minimise the risks associated with receiving the placebo.[373]

Has the ethical dilemma presented by the placebo-controlled trials of AZT to prevent MTCT of HIV in Africa been solved? The methodological reasons for the trials may be compelling – if we wait for the results of a much longer equivalency trial, many more children may die while waiting for a shorter, more effective course of AZT. However, the second requirement that the participants receiving the placebo must not be exposed to serious harm, has not been met by the short course maternal-infant transmission trails. Babies that could have been born HIV negative have been infected; if they were in the active arm of an equivalency trial, they would have received AZT and have been spared. Nevertheless, this benefit is offset by the fact that an equivalency trial lasts longer, so that more babies will be born with the virus in a country where the 076 regimen of AZT is too expensive.

A further problem with the placebo-controlled trials of AZT to prevent MTCT of HIV in Africa is that that they do not meet the distributive justice principle.[374] According to this principle, the sponsoring agency (conducting the trials) should ensure that, after successful testing, a product developed from the results is made 'reasonably available' to inhabitants of the community in which the research was carried out. Exceptions to this requirement are justified, but must be agreed to by all parties before the research begins.[375]

Crouch and Arras, in the *Hastings Center Report*, assert that a violation of this principle amounts to an unjustifiable exploitation of the developing nation for no morally legitimate reason.[376] If it is the case that even the shorter course of AZT is unavailable to the research participants and their community (it is still too expensive), then the information gained from the trial is rendered useless for the community in which the trial was conducted, and, therefore, they were exploited.[377]

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373 As above, 917.

374 See Cooley (2001) 22 *Theoretical Med* 151 for a full discussion of distributive justice and clinical trials in the developing world.

375 Guidelines 8 & 9 CIOMS guidelines. Also see para 3.1.4 above.

376 Crouch and Arras (1998) 28 *Hastings Center Report* 26.

377 As above 27. Also see chs 5 and 6 below. Timing in HIV-related research also is an issue. Because the science develops so fast, and because new antiretrovirals are developed continually, research which is not *per se* exploitative at the beginning of a trial may become so when, during the course of that trial, another, much more efficacious drug is developed.

There are concerns regarding this argument: mostly they are the consequence of the formulation of the distributive justice principle, which is so ambiguous as to make it practically impossible to use.[378]

Cooley asserts that because of the imprecise language in which it is written, the CIOMS principle (of justice) is unlikely 'to help anyone legitimately evaluate medical experiments or to assist people in determining their moral obligations'.[379] Behaviour that is interpreted as impermissible by one researcher may be regarded as permissible by another.[380] According to Cooley, the phrase 'any product developed will be made reasonably available to inhabitants of the underdeveloped country in which the research was carried out' has three aspects to it which are unclear.[381] First, who determines the meaning of 'reasonably available'? Who determines whether something is reasonably available, and on what does that person base her decision? Cooley asks.[382] A reasonable sponsor may regard something as reasonably available if it is made available to the members of the community who took part in the research,[383] in the context that the sponsoring company has to make a profit for its shareholders, and cannot give the drug away.[384] Many products, besides, can only be used appropriately when ancillary services are available - mothers in labour would not only need AZT administered to them, but they would also need the technology to have the medication administered intravenously.[385]

Second, who should be the beneficiaries of the knowledge gained by the research undertaking? To how many inhabitants should the sponsoring company make the drug available: the research participants; the community in which the research took place; the town or village; the province or country?[386]

Third, the meaning of the term 'community'. Is it the people of the immediate area where the drug was tested or is it the citizens of the country where the drug was tested?[387]

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378 Cooley (n 374 above) 152.
379 As above.
380 As above.
381 As above.
382 As above.
383 As above, 153.
384 As above, 153 – 154.
385 As above, 154. In the 'Nestlé baby formula' case, the sponsoring company provided the formula but not the expensive refrigeration or clean water, and many infants were in fact harmed in consequence.
386 As above, 155.
387 As above.

Importantly, Cooley argues that research participants in the developing world decided autonomously to participate in the clinical trial of AZT.[388] The women who participated were given better medical attention, and the opportunity to have their children born HIV negative.[389] The research participants thus acted in their own interests when deciding to participate in the trial.[390] To argue that they were exploited reflect a paternalistic attitude towards the women who made the choice to participate in the research.[391]

Moreover, a utilitarian argument indicates that the trials were a waste of time and resources from their very inception.[392] The populations of many developing countries still are unable to afford even the cheaper version of the drug, so that there was no reason to conduct the study in the first place, which is unethical from its inception.[393] If a cheaper drug is as expensive at $50 as the other version is at $800 a person, in the sense that it is still beyond the per capita expenditure on health care, then only the research participants benefit.[394] For this reason, Cooley regards the placebo-controlled trials of AZT to prevent MTCT of HIV in Africa as unethical.[395]

Cooley's arguments are appealing, because straightforward, and his criticisms of Angell and Lurie and Wolfe are valid, but his dismissal of the principle of distributive justice as being too vague is insufficiently serious. He ignores the great disparity in health care between the developed world and the developing world. In his article 'Distributive justice and clinical trials in the third world', Solomon Benatar makes out a convincing case for retaining the principle of distributive justice, despite its ambiguity and imprecision.[396] Of the annual global expenditure on health care, 87 per cent is spent on 16 per cent of the population who bear 7 per cent of the global disease burden;[397] of the $56 billion that is spent worldwide on medical research and development, 90 per cent is spent on diseases that account for 10 per cent of the

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388 As above 160.
389 As above.
390 As above.
391 As above, 161. This argument, regarding the autonomy of the participants in the trial, will be re-examined later.
392 As above.
393 As above. Only should the drug become affordable, will this argument become invalid.
394 As above.
395 As above, 162.
396 See Benatar (2001) 22 *Theoretical Med* 169 – 176.
397 Benatar 170.

global burden of disease;[398] per capita expenditure ranges from $5 in developing countries to $4000 in the developed countries such as the USA.[399] These statistics demonstrate the reason for the CIOMS guidelines to stress that distributive justice is an essential part of collaborative medical research in the world today.[400] An overly-simplified notion of utility which ignores the concern of distributive justice appears unfair against the background of such inequities.[401]

Benatar is of the opinion that the decisions are best left in the hands of those who are directly affected:[402]

> What makes them think that their insights provide adequate or sufficient means of assessing what is best for those living under dehumanising conditions in which the requirements for achieving improved health are so different from their privileged world?

A narrow utilitarian approach, he concludes, undermines the human dignity of those involved in research in the developing world.[403] Benatar dismisses as unfounded the criticisms levelled by Cooley and others and associates them with imperialistic attitudes.

Because the shorter regimes that were developed by the research outlined above are not being implemented, either because of a lack of resources or a lack of the political will to implement them, that research is not regarded as ethical in the contexts of the remarks of Solomon Benatar and Peter Singer:[404]

> Research ethics must be deeply rooted in the context of global health ... it must ultimately be concerned with reducing the inequalities in global health and achieving justice in health research and care.

An important aspect of the Ugandan trials escaped notice: during the controversy surrounding the trial, it was never questioned whether, considering that their only means of accessing health care was participation in the trial, the women in the trial gave informed consent to participation. This aspect of the trial is discussed in more detail later in the thesis.[405]

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398 World Health Organisation *Report of the ad hoc committee on health research relating to future intervention options World*, quoted in Benatar 170.
399 Benatar 172.
400 Benatar 171.
401 Benatar 172.
402 Benatar 172.
403 Benatar 175.
404 Benatar and Singer (2000) 321 *British Med J* 824.

b) Pfizer's Trovan experiments in Nigeria

i) Overview

In February 1996, an epidemic outbreak of cerebrospinal meningitis occurred in Kano, Nigeria. The WHO's web-site indicated that by March, 17 668 cases had been reported and that more than 2 500 people had died from the disease.[406] The epidemic left over 18 000 victims suffering from the disease.[407]

An international pharmaceutical company, Pfizer, quickly acted to alleviate the epidemic. It delivered desperately-needed medical supplies, as well as medical staff, to Nigeria.[408] It also started trials of an experimental drug for the treatment of viral meningitis, called Trovan.[409] At the time Trovan was not approved for human experimentation by the FDA in the United States.[410] Trovan is one of the few drugs to have been withdrawn from the US market due to known serious side effects in the last five years.[411] Further, it is not approved for experimentation using children.[412]

Pfizer set up research headquarters in Kano, next to the facility of Doctors Without Borders (DWB), using DWB bed space and a section of DWB's treatment centre.[413] The doctors brought in by Pfizer were unaccustomed to offering medical care in a city of more than two million people ravaged by pollution, disease and death.[414] During the two weeks they spent in Kano, Pfizer's researchers treated over 200 children for spinal meningitis: 100 children used an oral or intravenous form of Trovan;[415] the remaining children were treated with the antibiotic Ceftriaxone, a drug already approved for use with children in the United States.[416]

At first, the Pfizer researchers selected the most suitable children for treatment, but, as the epidemic raged, they began treating any child presenting.[417] The ages of the children ranged from a few months to eleven years and varied in

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405 See ch 6 below. Also see Macklin's exposition of the trial in Macklin (2004) 13 – 24.

406 WHO (19 February 1996) *Disease Outbreak News* <http://www.who.int/disease-outbreak-news/n1996/feb/n19feb1996c.html> (15 December 2006); Carr (2003) 35 *Case Western Reserve J of Intl L* 15.

407 The damage done by the virus causes long-term after-effects, such as the loss of sight and hearing and paralysis.

408 Carr (n 406 above) 15.

409 Trovan had never before been tested on children.

410 In fact, Trovan has been one of the few drugs in the last five years that have been withdrawn from the US market due to known serious side-effects (see Carr 16).

411 As above.

412 Carr (n 406 above) 16.

413 Carr 18.

414 As above.

415 As above.

416 As above.

417 As above.

levels of infection from the early stages of the disease, to partial paralysis, to near death.[418]

Due to the large number of patients treated in such a short time and the high illiteracy rate in Kano, many of the patients did not sign consent forms.[419] Many of the patients consented verbally, relying on an interpretation provided by a nurse; but frequently the nurses did not translate all the details on the consent form to the families.[420] It is alleged that the treatment with Trovan resulted in the deaths of eleven of the 100 children; several more allegedly were left blind or deaf.[421]

ii) The ethical dilemma

When the media started to investigate claims regarding unethical and illegal research practices by Pfizer, they uncovered a variety of violations of international research ethics. Research documents had been forged;[422] there was no oversight and approval of research procedures during the trials;[423] and the researchers failed to administer effective treatment to desperate participants.[424]

In 2001 the families of the children that had participated in Pfizer's Trovan research in Kano brought a case against Pfizer in a US court, claiming that Pfizer had violated international and national laws in carrying out experimental research on humans. The case against Pfizer in the US represents the first in history in which individuals are suing in a foreign court a private corporation for wrongful experimentation in violation of US and international law.[425]

iii) Commentary

It is clear from the discussion above that various international ethical guidelines were breached. Importantly, there was no informed consent to participate in Pfizer's

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418 As above.
419 As above.
420 As above.
421 Carr (n 406 above) 19.
422 Forged documents included individual consent forms, governmental permission forms and oversight approval forms (Carr 16, fn 8). Also see Bosely 'New Drug 'Illegally Tested on Children': Pfizer Accused of Irregularities During Clinical Trial in Nigeria', *The Guardian*, 17 January 2001, 19. Parents of the children participating complained that they did not know that the drug that was being given to their children was experimental.
423 As above.
424 As above.
425 As above.

clinical trials, as it appears that the consent process was flawed.[426] Informed consent is a prerequisite for the ethical conduct of clinical research; it is included as the first principle in the Nuremberg Code, in the CIOMS Guidelines and in the Declaration of Helsinki.[427]

On the other hand, it may be argued that in the face of a devastating epidemic Pfizer did the best it could – it expedited medical staff and supplies; its effort was a humanitarian one rather than an example of gross abuse of research participants and a violation of ethical guidelines. This argument lacks validity because Pfizer used their 'humanitarian' effort to test Trovan on children in violation of Nigerian and international ethical guidelines. That Nigerian researchers and politicians collaborated to conceal the fact that ethical approval had not been given by a Nigerian ethics committee,[428] only serves to exacerbate the violation.

The Nigerian Trovan experiment shows that in spite of the existence of international ethical guidelines to protect participants in clinical research, and even after increased media awareness and scrutiny of clinical trials, abuse of research participants continue.

c) The Tenofovir trials in Cameroon and Nigeria

i) Overview

Tenofovir is an experimental antiretroviral pre-exposure prophylaxis aimed at preventing infection with HIV.[429] The first randomised trial to assess the safety and efficacy of Tenofovir was planned for developing countries, such as Thailand, Cambodia, Cameroon and Nigeria.[430] The study was funded by the US NIH and the Bill and Melinda Gates Foundation. It was to recruit 960 sex workers.[431]

The Cambodian trial was shut down before recruitment began due to protests by AIDS activists and sex-worker advocacy groups,[432] thus demonstrating increased vigilance among these groups in the aftermath of the Ugandan MTCT trials. Activists protested that there were no safety data supporting the long term use of Tenofovir in healthy participants; they thus objected to starting phase II trials when phase I

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426 See Carr's description on 15 – 43.
427 See ch 5 below, paras 3.3 and 4.
428 See Carr (n 406 above) 16.
429 Mills *et al* (2005) 331 *British Med J* 1403.
430 As above.
431 As above.
432 As above.

trials had not been conducted on healthy participants.[433] Activists further objected to the lack of long-term insurance against adverse events, inadequate care for participants who seroconvert during the trial, and the lack of community involvement in the design of the trial.[434]

In February 2005, a similar trial was suspended by the Ministry of Public Health in Cameroon.[435] Major concerns that were raised included the quality of care given to participants during the trial and the quality of care that might be available after the trial had been concluded.[436] After a documentary programme on the trial aired on French television, the trial was suspended pending an independent inquiry by the Ministry of Public Health in Cameroon. The inquiry recommended that the trial recommence after certain conditions had been met. However, in July 2005, Family Health International, the organisers of the trial, announced that the trial would not continue as the suspension lasted too long to allow the trial to continue.[437]

In March 2005, Family Health International announced that the Nigerian arm of the Tenofovir trial would be abbreviated. It claimed to be closing the trial voluntarily because of 'logistical difficulties'. In conjunction with external, independent data and a safety monitoring committee, Family Health International states that the study team 'was unable to comply with the required operational and laboratory procedures'.[438]

ii) The ethical dilemma

A number of additional concerns have been raised about the ethics in these trials. Activists contend that, with the primary outcome being HIV infection, the counselling in the prevention of infection might be inadequate.[439] Trial participants have been requested by the trial sponsors to reduce the number of partners they had sex with during the trial. As the participants are impoverished sex workers, who depend for their livelihood on prostitution, this request was regarded as being rather unrealistic, and, arguably, unethical.[440]

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433 As above.
434 As above.
435 As above.
436 As above.
437 As above.
438 n 429 above, 1404.
439 As above.
440 As above.

In Cameroon, participants had been provided with male condoms as a proven prevention strategy. Activists argued that as women are not in a position to decide on safe sex, female condoms should have been provided.[441] Advocacy groups for sex workers claim that enrolling sex workers in trials is wrong as they are a vulnerable group and would not be given the intervention if it should prove beneficial.[442] They quote the trials of nonoxynol-9, which was found to contribute to increase the risk of genital ulceration, and HIV infection, as an example of trials which heighten the risk factor among participants from this community.[443]

iii) Commentary

The controversy outlined above highlights the importance of establishing the standard of care that will be available after a trial. Local research ethics committees should ensure that research is not undertaken in the developing world in order to avoid more rigorous ethical standards relating to care in developed countries.[444] In addition, the media attention and protests by NGOs demonstrate the important role that these play in raising awareness and mobilising public opinion against unethical trials. That these trials were indeed discontinued after ethical questions were raised is a measure of increased awareness about the potential for unethical practices during clinical research as a result of the controvercy surrounding the Ugandan vertical transmission trials.

d) The male circumcision HIV-transmission trials, Orange Farm, South Africa

i) Overview

Although previous studies had indicated that male circumcision may reduce the risk of HIV transmission, this was based on mere chance observation. A study by Auvert *et al* was conducted to confirm the causal relationship between circumcision and HIV prevention,[445] in the area of Orange Farm, near Johannesburg, between 2002 and 2004. The study enrolled 3272 men. At the beginning of the trial 1617 of these men were medically circumcised.

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441 As above.
442 As above.
443 As above.
444 See below.
445 Auvert *et al* (2005) 2 *PLos Med* e298.

The men were tested for HIV at the beginning of the trial, and follow-up visits were scheduled at three, twelve and 21 months. The investigators were not told the HIV status of participants, but the participants were given the option of finding out their status (at a nearby voluntary counselling and testing (VCT) centre).

After the twelve-month follow-up visit, an interim data analysis showed that twenty of the HIV negative men in the intervention group (which were circumcised) had become HIV positive, compared to 49 men in the control group who had become HIV positive. Hence, circumcision was shown to reduce the risk of acquiring HIV by about 60 per cent.

ii) The ethical dilemma

All the men who were circumcised appeared to have given valid informed consent to participation in the trial (which, of course, involved consent to circumcision). In her analysis of the ethical nature of the trial, Keymanthri Moodley comments upon two issues: the inclusion of HIV positive men in the trial, and the non-disclosure of HIV status to trial participants by the investigators.[446]

iii) Commentary

At the termination of the trial it was discovered that 146 HIV positive men were randomised at the beginning of the trial and a further 69 men had sero-converted during the trial.[447] The investigators were thus blinded to the HIV positive status of 215 men over an eighteen-month period.[448] During this period, the men remained undiagnosed and untreated. What is more, they could have infected their partners during this period.[449]

Moodley comments that, because research in South Africa is often conducted at the same site at which health care is provided to the community, it is impossible to conduct research without providing care for illnesses related to the study and even for other conditions.[450] Because the researchers were blinded to the status of the participants, those participants who were HIV positive went without care for

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446 Moodley (2006) Responses to Auvert *et al PoLS Med* <http://0-medicine.plosjournals.org.innopac.up.ac.za/perlserv/request=index-html?request=read-response&doi=10.1371/journal.pmed.0020298#r1053> (30 November 2006).

447 As above.

448 As above. The men were offered VCT, but at a VTC clinic, not as part of the trial.

449 As above.

450 As above.

eighteen months, even though ARV treatment became available at public health care sites while the study was still in progress.

Moodley additionally raises concerns about the publication of the trial in *PLos Medicine* after it had been rejected by *The Lancet*,[451] and the fact that the trial had been approved by two RECs; a French REC and the REC of the University of the Witwatersrand.

As it is expected that research displaying questionable ethics should not be published, and that RECs should take more care in approving trials which may cause harm to participants, Moodley concludes that, 'clearly, this landmark trial has raised many ethical questions and has emphasised the importance of conducting research that is both scientifically and ethically robust'.[452]

The survey of violations and ethical problems raised by clinical research in Africa is concluded by these four cases. The discussion below is more general in nature, and provides an overview of ethical concerns relevant to clinical research in Africa.

4.3 Ethical concerns relevant to clinical research in Africa

Clinical research ethics and practices in the developing world fall loosely into questions surrounding two main issues – issues which relate to the use of research participants (exploitation and informed consent are relevant here) and issues surrounding the distribution of risks and benefit, or distributive justice. These issues are introduced below. Note that the discussion is not meant to be exhaustive, but that it is rather meant as a brief outline of the relevant issues.[453]

The question that is at the centre of the controversy surrounding the placebo-controlled trials of shorter AZT regimens that were undertaken in developing countries - should research participants in the developing world be treated differently from those in the developed world? - is re-examined in this section with Africa as the focus.

At the outset it clear that developing countries cannot be viewed as a homogenous group – they vary in terms of infrastructure, the general levels of literacy and education of the population, levels of health care provision, the burden

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451 Because of the ethical issues raised by the inclusion of HIV positive men in the trial with the associated issues related to lack of treatment

452 Moodley (n 446 above).

453 For more on issues related to exploitation in research, see Macklin (n 405 above) for an excellent account of the controversies.

of disease borne by the population and social and cultural views on health and research. In view of this, it is more accurate to refer to 'least developed', 'less developed' and 'more developed' countries instead of 'developing' countries. Further, countries that are traditionally regarded as 'developed' and that are relatively economically advanced, may contain poorer communities who do not have the same access to resources.[454] The discussion below is general, but endeavours to incorporate an understanding of these differences.

The term 'developing', itself, is contested. La Nauze offers a critique of the terminology that reveals a level of confusion concerning the economic and political applications of the term.[455] He remarks that the terms 'underdeveloped', 'developed', 'First world', 'Third world' continue to be used to define countries and peoples and that these descriptions arose in the immediate post-war period at a time of decolonisation and political realignment:[456]

> Largely based around economic models involving the transfer of Western ideas and practices, it was thought that development would raise the 'Third world' (and I use the words advisedly) towards the West's level of achievement. This would occur through growth in industrialization and thereby increase the size of the economy. A 'trickle down' of these economic benefits would then lead to better conditions for the poor. The idea of development, however, was often confused with modernization as there was a desire by the dominant Western policy-makers to align development with their own strategic and policy interest. Thus the world became defined in terms of us and them, developed and underdeveloped, rich and poor, traditional and modern, and so on.

An ethical concern that is of paramount importance to clinical research in Africa and elsewhere is that of obtaining the informed consent of participants in clinical trials. Local circumstances, such as poverty, cultural differences, the position of women in society and a lack of literacy in scientific matters, are impediments to obtaining a valid informed consent from research participants. This issue is not be discussed here, as it is dealt with extensively in Chapter 5 which focuses specifically on issues related to informed consent in HIV vaccine trials in South Africa.

4.3.1 The burden of disease in sub-Saharan Africa, and particularly southern Africa

Despite the fact that only eleven per cent of the world's population lives in sub-Saharan Africa, the region carries a disproportionate burden of HIV/AIDS – more

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454 See Dickens (1997) 16 *Med and L* 187.
455 La Nauze (2002) 30 *Clinical and Experimental Ophthalmology* 66 – 67.
456 As above.

than 66.6 per cent of all people living with HIV/AIDS live here.[457] UNAIDS estimates that in 2006, 2.1 million people in Africa died of the disease.[458] In this region, the epidemic is showing no signs of slowing down, with southern Africa the hardest hit.[459] The people of the region urgently need clinical research that will produce the results which will alleviate the burden of disease it carries.

Disease has had a dramatic effect on the life-expectancy of the people living in sub-Saharan Africa. While most people born in the developed world have a life expectancy of 70 years or greater, those born in sub-Saharan Africa have a life-expectancy of less than 55, even as low as 40 years.[460] This is not only due to HIV/AIDS, but also to the incidence of diseases such as TB, hepatitis, malaria and diarrhoea.

Not only do people in sub-Saharan Africa carry a heavier burden of disease, but they also have fewer resources available to spend on health care. Because of other priorities, in part, developing countries devote a smaller proportion of their GDP to health care.[461] For example, whereas the United States of America spends $3 724 per year per person on health, Uganda spends $44, Sierra Leone $31 and Somalia $11 per person per year.[462]

The following tables reflect the core health indicators of selected countries in sub-Saharan Africa (Angola, Benin, Botswana, Burundi, Congo, Eritrea, Ethiopia, Ghana, Kenya, Lesotho, Malawi, Mali, Mozambique, Namibia, Nigeria, Senegal, South Africa, Swaziland, Tanzania, Uganda, Zambia, Zimbabwe). Brazil, Canada and India have been included for the purposes of comparison.[463]

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457 UNAIDS (2006) *AIDS epidemic update* 6. 58% of them are women. Also see para 3.3.4 of ch 2.

458 As above. These figures can be compared to those of the developed world. In North America, Western and Central Europe, for example, 1.9 million people are living with HIV/AIDS, and 65 000 people have acquired the disease during 2005.

459 As above, 3. Also see ch 2 above.

460 See below. Also see ch 1 above.

461 As above, 20. See ch 5 below and Table A below.

462 Nuffield Council on Bioethics (2002) *The ethics of research related to healthcare in developing countries* 20.

463 Information in both tables from WHO (2006) *World Health Statistics 2006*. Note that HIV prevalence rates are included for the sake of completeness (see para 3.3.4 of ch 2 for more recent UNAIDS statistics).

	Life expectancy at birth (years)	% HIV prevalence rate adults 15-49	Infant mortality rate (per 1000 live births)	TB prevalence rate per 100 000 of population	Physicians per 1 000 of population
Angola	38(M) 42(F)	3.9	154	310	0.08
Benin	52(M) 53(F)	1.9	90	142.3	0.04
Botswana	40(M) 40(F)	37.3	75	553	0.40
Burundi	42(M) 47(F)	6.0	114	563.7	0.03
Congo	53(M) 55(F)	4.9	79	464.5	0.20
Eritrea	58(M) 62(F)	2.7	52	437.2	0.05
Ethiopia	49(M) 51(F)	4.4	110	533.2	0.03
Ghana	56(M) 58(F)	3.1	68	376.1	0.15
Kenya	51(M) 50(F)	6.7	78	888.4	0.14
Lesotho	39(M) 44(F)	28.9	55	544	0.05
Malawi	41(M) 41(F)	14.2	109	501	0.02
Mali	44(M) 47(F)	1.9	121	577.9	0.08
Mozambique	44(M) 46(F)	12.2	102	635	0.03
Namibia	52(M) 55(F)	21.3	42	586	0.30
Nigeria	45(M) 46(F)	5.4	103	531.3	0.28
Senegal	54(M) 57(F)	0.8	78	451.3	0.06
South Africa	47(M) 49(F)	21.5	54	670	0.77
Swaziland	36(M) 39(F)	38.8	102	1120	0.16
Uganda	48(M) 51(F)	4.1	81	646.4	0.08
Tanzania	47(M) 49(F)	8.8	78	478.6	0.02
Zambia	40(M) 40(F)	16.5	104	707	0.12
Zimbabwe	37(M) 34(F)	24.6	78	673	0.16
Brazil	67(M) 74(F)	0.7	32	76.7	1.15
Canada	78(M) 83(F)	0.3	5	4	2.14
India	61(M) 63(F)	0.9	62	312.2	0.60

Table A: Male (M) and female (F) life expectancy at birth (expressed in years) (2004); HIV prevalence rate in adults 15 – 49 (2003); infant mortality rate (per 1000 live births) (2004); TB prevalence rate per 1000 of population (expressed as a percentage) (2004); and the number of physicians per 1000 of the population (2000 – 2005). The date of the statistic is in brackets.

The information speaks for itself; overall the healthcare situation in sub-Saharan Africa is in a parlous state. The infant morality rate per 1 000 live births is at least twenty times higher in some sub-Saharan African countries than it is in Brazil, Canada and India.

TB is a serious problem in sub-Saharan Africa: in Kenya, South Africa and Swaziland, the TB prevalence percentage per 1 000 of the population is 888, 670 and 1120 respectively, compared to 4 in Canada.

People living in southern Africa experience a lack of access to health care personnel. Whereas in Canada and Brazil there are more than two and more than

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These are the same countries that are included in the study of constitutional provisions of countries in Africa (para 3.3 of ch 4 below).

one physicians per 1000 of their populations, Malawi, for example, has 0.02, Mozambique 0.03, and Lesotho only 0.05.

The following table displays additional health care indicators for these countries:

	Nurses per 1000 of population	**Adult literacy rate (%)**	**% ARV coverage**	**Total expenditure on health as % of GDP**[464]
Angola	1.15	66.8	6	2.8
Benin	0.84	33.6	33	4.4
Botswana	2.65	78.9	85	5.6
Burundi	0.19	58.9	14	3.1
Congo	0.96	82.8	17	2.0
Eritrea	0.58	Not available	5	4.4
Ethiopia	0.21	41.5	7	5
Ghana	0.92	54.1	7	4.5
Kenya	1.14	73.6	24.3	4.3
Lesotho	0.62	81.4	14	5.2
Malawi	0.59	64.1	20	9.3
Mali	0.49	19.0	31	4.8
Mozambique	0.21	46.5	9	4.7
Namibia	3.06	85.0	71	6.4
Nigeria	1.70	66.8	6	5.0
Senegal	0.32	39.3	47	5.1
South Africa	4.08	83.4	21	8.4
Swaziland	6.30	79.2	31	5.8
Uganda	0.61	68.9	51	7.3
Tanzania	0.37	69.4	7	4.3
Zambia	1.74	67.9	26	5.4
Zimbabwe	0.72	79.0	8	7.9
Brazil	3.84	88.4	83	7.6
Canada	9.95	...	>75	9.9
India	0.80	61	7	4.8

Table B: Nurses per 1000 of population (2000–2005); adult literacy rate as a percentage; ARV coverage as a percentage (December 2005); and total expenditure on health care as a percentage of the country's GDP (2003). The date of the statistics is in brackets.

Again, the position in sub-Saharan Africa is deplorable. The region has many fewer nurses than Canada. Significantly, countries in sub-Saharan Africa spend less on health care as a percentage of their GDP – Angola 2.8 per cent, Burundi 3.1 per cent and Mozambique less than 5 per cent (South Africa and Malawi are exceptions).

In sub-Saharan Africa, a heavy burden of disease is combined with a lack of access to health care. Other factors, such as low levels of education, high levels of poverty, poor nutrition and the lack of readily available clean water, inadequate sanitation, civil wars and disintegrating infrastructure, play a role in increasing the already

heavy burden of disease carried by these countries.[465] Benatar places these considerations in a wider context:[466]

> Africans must clearly take some responsibility for the state of their continent since post-colonial independence. Poor governance, corruption, internal exploitation, nepotism, tribalism, authoritarianism, military rule and overpopulation through patriarchal attitudes and disempowerment of women have all contributed to this sad state. However, to be fair, these shortcomings must be seen in the context of powerful external disruptive forces acting over several centuries to impede progress in Africa.

With regards to this heavy burden of disease, health care research is essential in sub-Saharan Africa. However, research is under-funded in the region, as it is in other developing countries.[467] The Nuffield Council on bioethics[468] quotes a 1990 report by the Commission on health research for development[469] to the effect of the vast gap between health needs and research expenditures.[470] The WHO's *ad hoc* Committee on health research refers to the difference as the 10/90 disequilibrium[471] - of the 50 – 60 billion US dollars that each year is spent world-wide on health care-related research, only 10 per cent is spent on the health problems of 90 per cent of the world's population.[472]

Developing countries, generally, lack the resources to carry out health care research by themselves, and spend their limited resources on primary care rather than on research:[473]

> Despite the great need for research to determine the most effective interventions in developing countries, the indigenous capacity to conduct the research is severely limited. The lack of appropriate infrastructures, expertise and resources are major constraints. Externally supported research that does not address this issue of development of capacity in research may greatly limit the long-term value of research.

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464 Gross Domestic Product.

465 As above, 21.

466 Benatar 'The HIV/AIDS pandemic: a sign of instability in a complex global system' in Van Niekerk and Kopelman (eds) (2005) 75.

467 As above, 83.

468 The Nuffield Council on Bioethics was established by the Trustees of the Nuffield Foundation in 1991 to identify, examine and report on the ethical questions raised by recent advances in biological and medical research. Since 1994, if has been funded jointly by the Nuffield Foundation, the Medical Research Council and The Wellcome Trust <http://www.nuffieldbioethics.org/go/print/aboutus/page_2.html> (15 January 2007).

469 CRD (1990) *Health research: Essential link to equity in development.*

470 *The ethics of research related to healthcare in developing countries* (n 462 above) 22.

471 As above.

472 As above.

473 As above, 22.

Developing countries in sub-Saharan Africa and elsewhere, to a large extent, rely on research sponsored by developed countries. Considering high levels of poverty, social inequality and human rights violations, it is patently obvious that in this climate there exist endless possibilities for the exploitation of research participants.[474]

4.3.2 Exploitation

A criticism of clinical research in developing countries is that it is exploitative.[475] Not only the participants enrolled in research in developing countries are exploited, so too are their communities who support and bear the burdens of research. In 1997, in the wake of the controversy surrounding the short-duration perinatal HIV transmission trials in developing countries, Lurie and Wolfe described the potential exploitation of research participants:[476]

> Residents of impoverished, post-colonial countries, the majority of whom are people of colour, must be protected from potential exploitation in research. Otherwise, the abominable state of health care in these countries can be used to justify studies that could never pass ethical muster in the sponsoring country.

The potential for exploitation in clinical research is heightened in developing countries where there is a lack of access to health care and other resources. Consequently, Africa should not be chosen as a setting for research merely because of the 'convenience' of the setting and the vulnerability of its inhabitants.[477]

What should researchers and sponsors do to ensure that participants in clinical research in Africa are not exploited?

Much of the debate is about the acceptable standard of care that should be provided to research participants in developing countries,[478] as was seen in the controversy over the HIV vertical transmission trials in Uganda,[479] and revolves upon the question whether the new intervention or drug that is being tested should be measured against the standard of care of the host or that of the developing country.[480]

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474 It is also self-evident that, despite the prevailing circumstances, research sponsored by developed countries and carried out in developing countries need not, by definition, be exploitative.

475 Macklin (n 405 above) chs 1, 3 and 4; Resnik (2003) 24 *Theoretical Med* 233.

476 Lurie and Wolfe (n 333 above) 853.

477 Barry (1988) 319 *New Engl J Med* 1085.

478 See eg Geller *et al* (2004) *Intl J Gynecology and Obstetrics* 268.

479 See para 4.2.2 above.

480 Macklin (n 405 above) 38 – 65; Geller 268.

Ethicists distinguish between universal and local standards of care.[481] A universal standard of care reflects the best standard of care available in the world; usually, the standard of care available in developed countries. A local standard of care is the level or standard of care available in a specific region. For example, the universal standard of care to prevent perinatal transmission of HIV may be Nevirapine, yet the local standard of care in Somalia does not exist or is a course of vitamin A.

Because of the obligation to provide members of a control group in a randomised placebo-controlled clinical trial with the best proven treatment, in other words, the existing standard of care, the content of the term 'standard of care' becomes very important. It is cheaper on the basis of how the term is defined for a research sponsor company to conduct a clinical trial on a new drug to prevent perinatal transmission of HIV in Somalia than it will be to conduct the same trial in the UK. Equivalency trials[482] not only take longer than placebo-controlled trials and, consequently, cost more money, but, in the UK, researchers will have to provide Nevirapine to thousands of volunteers in the control group as that is the standard of care.

It is not always feasible to deliver the universal standard of care. In the case of developing countries, alternatives often have to be sought to make a treatment easier to administer, or more affordable, but, this reality should not excuse the exploitation of those who are vulnerable in order that cheaper or speedier results may be obtained in a clinical trial.

Geller *et al* remark that the CIOMS Guidelines have recently introduced a new nuance into the debate on 'standard of care'.[483] The CIOMS guidelines call for the 'highest attainable and *sustainable* therapeutic method'; their comment on this development is:[484]

> Sustainable refers to the level of treatment that one can reasonably expect to be continued in the host country after research has been completed. As such, sustainability often serves as a constraint on the highest attainable therapeutic

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481 Article II 3 Declaration of Helsinki originally referred to 'best proven diagnostic and therapeutic method' (1996 revision), but now reads (2000 revision): 'In any biomedical research protocol every patient-subject *including those from the control group*, if any, should be assured that he or she will not be denied access to the best proven diagnostic, prophylactic or therapeutic method *that would otherwise be available to him or her*.' (My emphasis.)

482 Where the control group is given the best proven treatment, in this case Nevirapine; the treatment group is given the new (experimental) treatment.

483 Geller (n 478 above) 268.

484 As above.

> method, particularly if the host country cannot maintain the considered therapy after study completion.

The last word in the standard of care debate goes to Ruth Macklin. She writes:[485]

> The main reason why I reject the typical "standard of care" argument is that it is the lowest-common-denominator basis for determining ethical obligations. If the principle of beneficence has any relevance to the conduct of research, it requires researchers to *maximize benefits* as well as to minimize harms. Since the research subjects themselves are surely among those who should be counted in seeking to maximise benefits, it follows that providing a higher standard of care during the research, when that is feasible, is ethically preferable to providing the minimal standard dictated by background conditions in the country or region.

A related issue is the level of care that is provided to research participants and their community, not only during the clinical trial but also at its conclusion.[486] A trial participant who responds well to the treatment that was tested may deteriorate if that treatment is withdrawn at the end of the clinical trial. What is at stake is a claim that sponsors of research have a responsibility to share the benefits of their research with participants. In this regard, the Declaration of Helsinki requires that:[487]

> [a]t the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified in the study.

As is always possible, the term 'assured of access' is open to interpretation, as is the case with CIOMS Guideline 15:

> As a general rule, the sponsoring agency should agree in advance of the research that any product developed through such research will be made reasonably available to the inhabitants of the host community or country at the completion of successful testing.

Again, the words 'made reasonably available' are open to interpretation – and could mean anything from 'provided for free' to 'marketed in the country in question'.

Paragraph 9.3.5 of the Clinical Trials Working Group of the South African Department of Health's Good practice guidelines[488] directs:

> Where a patient has a therapeutic response to a study drug, that patient should be offered ongoing treatment. In designing studies, consideration should be given to the costs of long term provision of study drugs and of clinical monitoring, including the costs of medical staff.

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485 Macklin (n 405 above) 38 – 39. Original emphasis.

486 For a detailed discussion on this topic, see Dickens 'Research ethics and HIV/AIDS' (1997) *Med and L* 187 – 19 and Macklin (n 405 above) 36 - 65.

487 Guideline 30.

488 See above, para 3.3.3.

Crouch and Arras criticise the requirement of offering ongoing treatment,[489] arguing that it is unreasonable to expect those funding research to commit themselves in advance to making available a treatment with only a hypothetical chance of succeeding, with hypothetical costs and benefits.[490]

The question as to whether the wider community should be provided with the study drug or intervention if that drug or intervention is successful is also controversial. Even the definition of 'community' is contentious – as is pointed out above, a 'community' could be those who took part in the clinical trial, that is, the treatment and control group, or the entire village, province or country.

Researchers have a responsibility towards their participants, expressly, if harm is caused by their research. Guideline 13 of the CIOMS Guidelines requires:

> Research subjects who suffer physical injury as a result of their participation are entitled to such financial and other assistance as would compensate them equitably for any temporary or permanent impairment or disability. In the case of death their dependants are entitled to material compensation. The right to compensation may not be waived.

Ideally, research conducted in Africa should match the health-care priorities of the host[491] developing country.[492] The example of the research into Burkitt's lymphoma in Africa seems egregious. Burkitt's lymphoma is a tumour that accounts for half of all childhood cancers in Africa,[493] but affects only two in every 100 000 African children per year, and is a very rare cause of death when compared to malaria which in some areas account for up to 20 per cent of childhood deaths.[494] Research into the disease would be considered a luxury in most African countries and not a priority. Yet Burkitt's lymphoma has been researched extensively in Africa by sponsoring countries.[495]

In order to obviate this situation, the Nuffield Council on Bioethics recommends:[496]

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489 Crouch and Arras *Hastings Center Report* (1998) 26 – 34.

490 As above, 29.

491 The country in which the research is conducted is referred to as the 'host' country in the literature. The developed country sponsoring the research is the 'sponsoring' country.

492 Barry (n 477 above) 1085. See also CIOMS Guideline 8.

493 *The ethics of research related to healthcare in developing countries* (n 461 above) 31.

494 As above. Unlike HIV/AIDS, malaria and other illnesses that kill countless more children.

495 29.

496 30.

> that when research funded by external sponsors is proposed which fall outside the national priorities for research into healthcare set by a host country, those proposing the research be required to justify the choice of research topic to the appropriate research ethics committee in both the host and sponsoring countries.

Research is considered non-exploitative only if the developed, sponsoring nation, as well as the developing nation, benefits, more or less equally.

Sponsors of clinical trials mostly offer participants a form of inducement to take part in clinical research. The inducement ranges from cash payments, access to free medical care during the trial, free medication, reimbursements for transport to and from trial sites, meals on days that participants have to visit a trial site and so on. In poor communities, even the promise of a free trip into town to visit the trial doctor is a rare opportunity; to shop, visit family members and see friends.

In communities where there is great poverty and deprivation, inducements may, by their nature, be exploitative. Trial participants agree to take part in research solely to access the benefits. In this way they may be exposed to a risk they might otherwise have found unacceptable. In the case of significant risk attached to participation in a clinical trial, researchers in African countries should be careful not to exploit the needs of the host community for medical care or food inducing them to enrol in research. If there is no other access to medical care, seriously ill people and their families may agree to take part in risky experimentation because they have no choice and so be exploited. In this case the research is not ethically justified:[497]

> What appears a horizontal relation of difference among equals may in fact be a vertical distinction of power. Developed countries may have the power of prestige, inducement, wealth or authority to persuade dependant populations in developing countries, at nation, group or individual levels, to accept participation in research studies that pose risks to their physical integrity, emotional health or, for instance, confidentiality. Poverty and related powerlessness leave individuals and groups vulnerable to exploitation and easy inducement to accept disproportionate risks of research participation.

This idea is revisited in chapter 6.

4.3.3 Distributive justice

'Distributive justice', defined as the fair, equitable, and appropriate distribution of goods governed by justifiable norms and values that structure the terms of social

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497 Dickens 196. This idea is reassessed in chs 5 and 6 below.

cooperation,[498] entails a fair and equitable distribution of all rights and responsibilities in society.[499]

The just distribution of benefits and burdens has long engaged the attention of philosophy. Each theory, discussed in paragraph 2 above, has answered the question of how to fairly distribute goods and burdens in society differently. Utilitarianism aims to maximise public utility as a universal principle; communitarian theories, on the other hand, stress traditions of justice that have evolved in different communities.[500] The purpose of the enquiry in this thesis is not to enlarge the philosophical debate, but to understand the practical implications of the principle for clinical research.[501]

In the arena of clinical research, distributive justice determines that there should be fair access to research, which, necessarily, incorporates fair access to participation in, and the benefits of, research.[502] In keeping with the principle of distributive justice, the Declaration of Helsinki requires that participants not be exposed to unnecessary risk and that the risk should be in proportion to the potential benefits of the research.[503] Notions of distributive justice, further, embody the wish that the burdens and benefits of research be fairly distributed among individuals, communities and countries. Ideally, an individual, group, community or country cannot be expected to bear a disproportionate share in the burden of research, nor should they gain a disproportionate share in the benefits of research.

The relevance of the demand for distributive justice in research in Africa is clear: research participants in Africa need access to the benefits created by research but should not be expected to carry a disproportionate share in the burden of research.

Because Africans carry the greater burden in terms of HIV/AIDS, it is viewed as acceptable that they bear a greater share of the risk in research in the field. Clearly, the research into HIV/AIDS and its treatment should relate to African circumstances, for example, research into the efficacy of a vaccine for HIV that does not focus on strains of the virus most prevalent in Africa will not be justified.

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498 Beauchamp and Childress 226; Barry 1085.
499 Beauchamp and Childress 226.
500 230.
501 See Walzer (1983) 3 – 28 for an interesting philosophical (communitarian?) view on the distribution of goods in society.
502 n 497, 227.
503 Art I.4 Declaration of Helsinki.

Similarly, research that results in a drug that is highly successful in treating the disease, but which is only affordable in developed countries, in terms of the demands of the distributive justice principle, is unjustifiable and amounts to exploitation of the research participants. Annas and Grodin's comments are pertinent in this regard:[504]

> Unless the intervention being tested will actually be made available to the impoverished populations that are being used as research subjects, developed countries are simply exploiting them in order to quickly use the knowledge gained from the clinical trials for the developed countries' own benefit. If the research reveals regimens of equal efficacy at less cost, these regimens will surely be implemented in the developed world. If the research reveals the regimens to be less efficacious, these results will be added to the scientific literature, and the developed world will not conduct these studies.

In the case of HIV vaccine trials to find an effective preventive vaccine against HIV, it is submitted that an efficacious vaccine should be made available to the communities who participated in clinical trails to develop it. Macklin uses the example of the AIDSVAX vaccine, where its developer, VaxGen, had promised to make it available to the Thai volunteers who received a placebo during clinical trials.[505] She remarks that such a commitment is in strict compliance of the Declaration of Helsinki. VaxGen also committed themselves to a tiered pricing of the vaccine, which could have increased the likelihood that a successful product eventually could have been available in Thailand.[506] Unfortunately, the AIDSVAX vaccine proved ineffective.[507]

The abuse of research discussed previously[508] illustrates the consequences of ignoring the principle of distributive justice.

4.4 Conclusion

The preceding pages examined the way in which ethical theories and guidelines have been employed to protect the interests of research participants in HIV/AIDS-related clinical research in Africa. This examination sets the scene for a more detailed discussion in Chapter 5 of preventive HIV vaccine efficacy trails in South Africa.

The overview of the failures of ethical guidelines to safeguard research participants in the rest of the world, at the beginning of the chapter, highlights that,

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504 Annas and Grodin (1998) 88 *American J Public Health* 561.
505 Macklin (n 405 above) 257.
506 As above.
507 See para 4 of ch 2 above.
508 Paras 4.2.1 (a) – (c) above.

although ethical guidelines existed, abuses still occurred. The discussion of the influence of the HIV/AIDS epidemic on the ethics of clinical research emphasises the shift from a situation previously in which the medical and scientific community viewed the role of research participants as passive, to one in which they are regarded as agents as well as autonomous beneficiaries of the products of research.

The account of the much-publicised ethical dilemma that arose over the use of a placebo in the AZT trials to prevent MTCT of HIV in Uganda demonstrates that despite the ethical guidelines, interpretation and implementation remain controversial areas and abuses still occur. Sometimes pharmaceutical companies use the urgency of the situation to justify unethical research, as is shown in the discussion of the Trovan trial in Nigeria.

Finally, the examination has shown research participants in developing countries to be especially vulnerable, which introduces the ethical concerns relevant to the discussion of the ethics of preventive HIV vaccine efficacy trials in Chapter 5 below.

5 CONCLUSION

Clinical research on human participants is subject to a superfluity of ethical guidelines. The Chapter explores the origins and nature of the ethical principles that form the foundation of the protection of human research participants in clinical research. The scope of core ethical principles, namely autonomy, beneficence (including nonmaleficence) and justice, as they are embodied in various international and domestic documents, is presented.

The protection afforded by international and national ethics documents is investigated. Although, at fist glance, such protection appears to be extensive, the survey of past non-compliance presented in paragraph 4.2.1 demonstrates that in practice, ethical guidelines do not usually function in preventing abuse.

This failure may be attributed to two causes:[509]

First, ethical guidelines are only that – guidelines – they do not have the force of law, and, therefore, cannot be enforced in the same way that law may be enforced. In the case of transgression, fierce ethical debate may follow, but little else can be done unless publicity drives government to act. Though the editor of the *New England Journal of Medicine*, Marcia Angell, regards the HIV perinatal

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509 For a more extensive discussion on the failures of ethical guidelines to protect the interest of research participants, see pare 4.1 of ch 6 below.

transmission trials[510] as unethical, she published the results in the journal. To a large extent, observance of ethical guidelines depends on the sanction of various professional bodies and research funding agencies. Other than a refusal to fund or publish unethical research, there is little to guard against such research.

Second, ethical principles such as autonomy, beneficence and justice are too general, too vague and ambiguous, to be of much value in specific practical circumstances. The same could be said about legislation. Legislation, however, is given content by interpretation in the courts, whereas ethical principles, on the whole, are rarely litigated.[511] The perinatal HIV transmission trials again serve as a case in point. During the debate on the ethics of these trials, both camps used similar ethical principles in support of their arguments.[512] As well, there was no institution or body that was able to finally determine who the 'winner' in the debate was; no court could give an authoritative interpretation of the relevant principles and the disputed practice.

The chapter analyses the ethical dilemma that was presented in the controversy over the placebo-controlled trials of AZT to prevent MTCT of HIV in Uganda.[513] This analysis not only points to the non-binding nature and inherent

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510 See para 4.2.2 above.

511 There are exceptions where ethical principles were litigated in court. See ch 5 below.

512 See Angell (n 336 above) 847; Lurie and Wolfe (n 333 above) 853; Varmus and Satcher (n 357 above) 1003.

513 The chapter presents only a few examples of unethical research conducted in Africa. Subsequent to the controversy over the ethics of the MTCT trials in developing countries, the *Lancet* in 1999 and the *New England Journal of Medicine* in 2000 published the results of yet other clinical trials (also in Uganda) where the ethics of the investigators are questionable. I refer to the clinical trials of Quinn *et al* that was described in 'Viral load and heterosexual transmission of human immunodeficiency virus type 1' (2000) *New Engl J Med* 921 – 929 and Wawer *et al* 'Control of sexually transmitted diseases for AIDS prevention in Uganda: A randomised community trial' in (1999) *The Lancet* 525 – 535. During the first of the trials, rural Ugandan villagers (who included a number of pregnant women) were studied to determine the risk factors associated with heterosexual transmission of HIV and whether sexually transmitted diseases, such as syphilis and gonorrhoea, increased the risk of transmission of the virus. Villagers in the treatment group were given antibiotics to treat and reduce the incidence of these diseases; in the control group they were given no antibiotics. In the second trial the investigators wanted to study the link between viral load and HIV transmission and the influence of circumcision on transmission of the virus. Couples in which one partner was HIV-positive and the other negative were studied during the trial. Not only were the participants not given any treatments, but, even though both partners were often seen by the investigators, no information was given on safe sex practices. More importantly, the HIV-negative partner was not informed of the status of the positive partner. Participants who were found to suffer from other sexually transmitted diseases were left to seek treatment elsewhere. The abuses described in the Tenofir clinical trials in Cameroon and Nigeria (see para 4.2.2 above and Akoa (2005) 15

ambiguity of principles and ethical guidelines, it highlights some of the priorities of health care provisioning and research in a developing country, such as finding easy and affordable alternatives to complicated or expensive HIV treatment regimens. It further emphasises the disparity that exists in health care provision between developed and developing countries or between resource rich and resource-poor settings. Other contentious issues arising out of clinical trials in Africa are commented upon in further examples.

The question of whether research participants in HIV and AIDS-related clinical research in sub-Saharan Africa should be afforded special protection is the final issue that has been raised. Poverty, social inequality, a lack of resources and a heavy burden of disease make health and HIV-related research in sub-Saharan Africa an imperative, but they are the cause of the situation being fraught with the potential for the abuse of research participants.

The chapter does not offer an extensive critique of principlism in bioethical discourse, such as that presented by feminist and also communitarian theorists. Such a critique forms the substance of some of the conclusions reached in chapters 5 and 6 below and will therefore be dealt with in those chapters.

The next chapter examines human rights as an alternative system in the protection of participants in HIV-related clinical research in Africa, especially seen in the light of the defects in the system of bioethics currently used. The foundation for a more detailed discussion in chapter 5 on preventive HIV vaccine efficacy trials in South Africa is established.

Interights bulletin 66 – 68) are another case in point. Also see Angell 'Investigators' responsibilities for human subjects in developing countries' (2000) *New Engl J Med* 967 – 968.

CHAPTER 4

HUMAN RIGHTS IN CLINICAL RESEARCH IN SUB-SAHARAN AFRICA: AN ALTERNATIVE TO ETHICS?

Outline

1 INTRODUCTION

Chapter 3 examined non-binding ethical guidelines, whereas this chapter explores human rights law as an alternative means for the protection of participants in clinical research in Africa. Human rights law is examined as a system consisting of both international human rights law and national human rights law; each, in turn, composed of binding regulations and so-called 'soft law'.

First, the origin and nature of human rights are explored; a philosophical background to the development of the notion of human rights is given; and arguments relating to the universality or relativity of human rights are outlined. The effects of the forces of globalisation on the international research endeavour are investigated, as well as the interaction between national and international human rights law.

Second, national human rights systems in African countries are scrutinised for specific human rights provisions relating to the protection of participants in clinical research in sub-Saharan Africa. Particular attention is paid to the South African Bill of Rights.

Third, the development and impact of the United Nations' Charter-based and treaty-based systems are explored; three regional systems are outlined; and the African system is discussed in greater detail. Fourth, a critical examination of the protection which international and regional human rights documents and instruments offer participants in clinical research in Africa is presented. Finally, international human rights documents are situated in a South African context. Sections 39(1), 231, 232 and 233 of the Constitution are detailed, and the status of specific international human rights instruments in South Africa is charted.

The focus of this chapter is on HIV-related clinical research in general, and it mentions preventive HIV vaccine efficacy trials only in passing. The foundation for the discussion in chapter 5, which deals specifically with informed consent in HIV vaccine efficacy trials in South Africa, is still being laid.

The focus in the chapter is on clinical research in *sub-Saharan* Africa and not the African continent because sub-Saharan Africa is hit hardest by the HIV epidemic - two thirds or almost 64 per cent of all adults and children living with HIV/AIDS globally are in sub-Saharan Africa, amounting to almost 25 million people.[1] In comparison, Africa north of the Sahara reflects scant evidence of an epidemic.[2] With exception of Sudan,[3] national adult HIV prevalence in the countries of North Africa and on the Red Sea is low, not exceeding 0.1 per cent.[4]

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1 UNAIDS (2006) *AIDS epidemic update* 15.

2 As above.

3 In Sudan, national adult HIV prevalence rate was an estimated 1.6% in 2005. The epidemic is most severe in the country's southern areas (which are flanked by countries with comparatively high HIV prevalence) (UNAIDS 48).

4 UNAIDS (n 1 above) 48.

Moreover, almost nine in ten children (younger than 15 years) living with HIV are in sub-Saharan Africa.[5] An estimated 2.7 million people in the region are newly infected with HIV, and 2.0 million adults and children have died of AIDS.[6] Three-quarters of all women (15 years and older) living with HIV are in sub-Saharan Africa.

These statistics illustrate that it is not a single 'African' epidemic; HIV prevalence rates vary significantly between and within the regions and countries in Africa.[7]

An examination of human rights law as an alternative system for the protection of participants in clinical research in sub-Saharan Africa follows below.

2 HUMAN RIGHTS LAW

2.1 Introduction

Although a great deal of attention is paid in the literature to ethical guidelines governing clinical trials involving human subjects, only limited work has been done on the human rights of trial participants.[8] In the past, violations of the interests of participants in clinical research by trial administrators were viewed as violations of universal (biomedical) ethical principles and not as violations of the human rights of trial participants.[9] This view is to be expected, as clinical research is in the domain of the medical profession and medical professionals who, although well-versed in medical ethics, are relatively unfamiliar with human rights discourse.

In contrast to the traditional approach, this chapter places HIV-related clinical research in Africa within the context of human rights discourse. In the following section, the origins and development of the idea of human rights are explored.

2.2 Conceptual framework

There is an extensive philosophical literature on the definition and nature of rights; for example, the so-called choice or will theories of rights; or alternatively, interest or

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5 As above, 15.

6 As above.

7 As above.

8 In the work of Jonathan Mann alone, who was the head of the WHO's Global plan on AIDS (now the UN joint programme on AIDS or UNAIDS), is there a focus on the link between health and human rights and their value in ensuring human well-being. See eg Mann *et al* (eds) (1999) *Health and human rights: A reader*.

9 See for example, the debate regarding the supposed unethical nature of the short-duration AZT trials in Africa, discussed in ch 3 above.

benefit theories of rights.[10] However, most authors agree on the definition that rights are the *justified claims* of individuals and groups against one another or society.[11] Such justified claims may refer to the right holder being *entitled* to something, thus placing a correlative duty on another person or state; they may refer to *immunity* from having one's legal status altered; they may refer to a *privilege* to do something; and they may also refer to a *power* to create a legal relationship.[12]

The existence of a right presupposes a set of rules under which that right is justified – whether these are legal rules, moral rules, institutional or religious rules.[13] Legal rights, therefore, are claims based upon legal rules.[14]

To have rights enables one to determine what other persons (or the state) should or should not do.[15] In accounting for the moral foundations of liberalism, Joseph Raz determines that rights are 'grounds for holding others to be subject to duties'.[16]

Generally speaking, rights are not absolute.[17] Rights may be limited by other people's rights as individuals or by the interests of society in general. Rights are '*prima facie* claims' which may yield to other claims.[18]

Human rights are a specific type or subspecies of rights. Human rights are born out of the idea that, as human beings, we possess intrinsic rights[19] which are

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10 This thesis is primarily concerned with a specific type of rights – human rights – consequently no account of these theories is given. For more on the different theories of rights, see for example Jones (1994) *Rights*; Freeden (1991) *Rights*; Nelson (2005) 31 *Social Theory and Practice* 359; Kramer *et al* (1998) *A debate over rights: Philosophical enquiries*; Sumner (1987) *The moral foundation of rights* (ch 5); Lyons 'Utility and rights' in Waldron (ed) (1984) *Theories of rights* and Wellman (1985) *A theory of rights: Persons under laws, institutions and morals*.

11 See eg Brown 'Universal human rights: A critique' in Dunne and Wheeler (1999) 105; Beauchamp and Childress (2001) 357. This idea of rights as claims is not universally held - see eg Nelson (n 10 above) 362 – 365.

12 Shestack (1998) 20 *Human Rights Q* 203.

13 Brown in Dunne and Wheeler (n 11 above) 105; Shestack (n 12 above) 203; Beauchamp and Childress (n 11 above) 357.

14 As above.

15 Beauchamp and Childress 357.

16 Raz (1984) 4 *Oxford J Legal Studies* 5.

17 As above.

18 As above.

19 The intrinsic nature of human rights is much disputed. Michael Ignatieff, for example, argues that the Holocaust demonstrates that human rights can have no foundation whatever in natural human moral attributes, since that event negates or explodes the myth of natural human pity or solidarity as being either innate or universally distributed. There can thus be no intrinsic or 'natural' moral attributes among human beings (see Ignatieff (2001) *Human rights as politics and idolatry* 80 - 81).

held to be self-evident.[20] In other words, the idea of human rights emphasises that, simply because we are human beings, there are certain things that should never be done to us, and certain things that should be done to and for us. The idea is not new, and is traceable back at least to the writings of philosophers of the 16th and 17th century.[21]

Human rights have been defined as 'universal moral rights' or 'generally accepted principles of fairness and justice' or 'universal rights that belong to all people simply because they are human beings'.[22] It is claimed, currently, that that human rights are the *only* universally recognised system of values.[23]

Descriptive definitions characterise human rights as the 'sum of civil, political, economic, social cultural and collective rights laid down in international and regional human rights instruments, and in the constitutions of states',[24] or as the 'only universally recognised value system under present international law comprising elements of liberalism, democracy, popular participation, social justice, the rule of law and good governance'.[25]

From these definitions, it can be observed that the concept of human rights is open to varying interpretation. One view holds that human rights are inherent in humankind by virtue of its members being human; the other view is that human rights are concerned primarily with the relationship between the individual - or groups of individuals - and the state. In this view, the individual or group is seen as, potentially, the victim of the state's exercise of authority. In liberal democracies the individual is the ultimate 'owner' of human rights, and the protection of human rights takes the form of a 'bill of rights' which may be invoked against the will of the state or group within a state. Jerome Shestack writes as follows about some of the definitional difficulties inherent in the term 'human rights':[26]

> Some scholars identify human rights as those that are 'important', 'moral', and 'universal'. It is comforting to adorn human rights with those characteristics; but, such attributes themselves contain ambiguities. For example, when one says a right is 'important' enough to be a *human* right, one may be speaking of one or more of the following qualities: (1) intrinsic value; (2) instrumental value; (3) value to the

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20 Self-evident in the sense that they are human beings have rights simply because they are human - in other words independent of 'varying social circumstances and degrees of merit' (Shestack 203).

21 Discussed in para 2.3 below.

22 Jerome Shestack defines human rights as 'a set of moral principles [of which the] justification lies in the province of moral philosophy' (202).

23 Nowak (2003) 1.

24 As above.

25 As above.

26 Shestack (n 12 above) 203.

> scheme of rights; (4) importance in not being outweighed by other considerations; or (5) importance as structural support for the system of the good life. 'Universal' and 'moral' are perhaps even more complicated words. What makes certain rights universal, moral, and important, and who decides?

In the section below the philosophical nature and origin of the idea of human rights are traced in an attempt to provide an answer to a few of Shestack's questions.

2.3 Philosophical background

The contemporary concern with the protection of human rights was born out of a widespread sense of horror at the devastation caused by World War II. The human rights enumerated in the Universal Declaration on Human Rights[27] were intended to address and to redress in some form the atrocities the National Socialist government in Germany committed against the Jewish people during World War II, as well as the crimes of the Japanese Imperial government.[28] The hope was that these rights should serve as a protection for future generations against a repetition of such barbaric behaviour on the part of any state.

However, the post-war era is certainly not the first occasion that reference has been made to human rights, or, to rights that attach to human beings by the mere fact that they are human. Throughout the centuries, the basis of what is now known as human rights has been established among various religions, cultures and peoples. Nowak points out that the value system manifested in human rights is not specifically Western in nature, and that it may be found among all major cultures[29] and religions of the world.[30]

In the Age of the Enlightenment in Europe and in accordance with the theory of natural law, there is a formal realisation that individuals are not objects, but subjects, with rights against society.[31] This shift in focus places individuals at the centre of legal and social systems.[32]

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27 See para 3.1.1 below.

28 Twiss (2004) 32 *J Religious Ethics* 42.

29 In an article on her theory of capabilities and human rights, Martha Nussbaum attempts to identify a range of 'central elements of truly human functioning that can command a broad cross-cultural consensus'. These elements, she argues, permit us to understand why diverse cultures accept human rights norms (See Nussbaum (1997) 66 *Fordham L Rev* 292 – 297).

30 Nowak 9. The moral values underlying human rights may be found in all religions of the world. See Nowak 9 for an interesting outline of the 'golden rule' or moral commandment to be found in all religions. See Shestack (n 12 above) 205 – 206 for his idea that, in a religious context, every human being is considered sacred.

31 Nowak (n 23 above) 9.

32 As above.

In their search for a law that was higher than positive law, the philosophers of the Enlightenment drew on theorists such as Sophocles, Aristotle, the stoics and thinkers of the Greek Hellenistic period. For these philosophers, natural law embodied those 'elementary principles of justice' which were 'right reason', that is, in accordance with nature and never-ending.[33]

The idea of 'natural law' also is not entirely new.[34] George Annas points out that in Sophocles' play, *Antigone*, written over 2400 years ago, there is mention of a higher, universal law to which all humans are held accountable.[35] Antigone justifies her defiance of the king on the basis of this higher, unwritten, moral law: 'Nor did I think your edict had such force that you, a mere mortal, could override the gods, the great unwritten, unshakable traditions'.[36]

Finnis ascribes the basis of the idea of natural law to:[37]

> (i) [a] set of basic practical principles which indicate the basic forms of human flourishing as goods to be pursued and realised, and which are in one way or another used by everyone who considers what to do [and] (ii) a set of basic methodological requirements of practical reasonableness ... which distinguish sound from unsound practical thinking, and which, when brought to bear provide the criteria [which enable us] to formulate (iii) a set of general moral standards.

Enlightenment thought also resulted in a shift in perception with regard to the state and its legitimacy.[38] The state is no longer legitimised by divine order; 'God's anointed King' is 'dethroned' as head of state and the individual as legal subject replaces the individual as legal object. Some interpretations of the social contract caused a shift in understanding, so that the existence of the state is justified solely by the need to protect the natural rights of the individual.[39]

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33 Shestack (n 12 above) 206.

34 Ideas about the source of natural law have varied through the centuries – it has been ascribed to the different gods and to human reason and respect for human dignity. The Nuremberg trials of war criminals rested on the premise that there exists a higher law of humanity and that violators of that law may be tried for their actions.

35 Annas in Gostin (ed) (2002) 99.

36 As above. Shestack points out that, with the decline of feudalism, modern secular theories of natural law emerged, such as those of Grotius and Pufendorf. These theorists detached natural law from religion, laying the foundation for a secular, rationalistic version of natural law (Shestack 206 – 207).

37 Finnis (1980) 23.

38 As above.

39 As above.

The natural rights of the individual are rights inherent in the individual, such as the right to life, property, security and liberty.[40] Natural law thinkers of as varied dispositions as John Locke, Thomas Paine and Jean-Jacques Rousseau, argued that natural rights were the inalienable fundamental freedoms and basic rights of every individual against the unrestricted power of the state.[41]

John Locke imagined the existence of human beings in a state of nature as being a state of freedom and equality, in which they are able to determine their actions and in which no one is subject to the will of another.[42] To escape the hazards of the state of nature Locke's men and women enter into a 'social contract',[43] by which they agree to set up a community and form a political state.[44] In setting up a political authority they retain their natural rights to life, liberty and property.[45] Government's obligation to protect the natural rights of its subjects is the sole source for the validity of its actions.[46] John Locke writes: 'the great and chief end, therefore, of men uniting into commonwealths, and putting themselves under government, is the preservation of their property – that is, their lives, liberties and estates.'[47]

Natural rights theory provided the 'philosophic impetus' for revolution during the late 18th century.[48] Shestack sums up the contribution of natural rights theory to human rights:[49]

> [Natural rights theory] affords an appeal from the realities of naked power to a higher authority that is asserted for the protection of human rights. It identifies with and provides security for human freedom and equality, from which other human rights easily flow. It also provides properties of security and support for a human rights system, both domestically and internationally.

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40 As above. Nowak points out that the schools of thought upon which the concept of human rights of the Enlightenment was founded were those of political liberalism and democracy.

41 Nowak (n 23 above) 9.

42 Shestack (n 12 above) 207.

43 Shestack 207.

44 As above.

45 As above.

46 As above.

47 Locke (1690) *Two treaties of government*. Opposed to this version of natural rights is legal positivism, a doctrine which replaces natural theory during most of the 19th century and 20th century. Legal positivism denies the existence of a *priori* sources of law. For the positivist theorist, all authority stems from the state and its officials. The source of law is to be found only in the enactments of the system of law. Positivism separated the legal system from the ethical and moral foundations of society; no matter how immoral a law may appear to be, it should be obeyed without question, for the law is all there is. See Shestack 209 – 210.

48 Shestack 207.

49 Shestack 208.

> From a philosophical viewpoint, the critical problem that natural rights doctrine faced is how to determine the norms that are able to be considered as part of the law of nature and therefore inalienable, or at least *prima facie* inalienable.

The critical problem Shestack proposes is the central criticism of natural law: the rights considered to be 'natural' by natural law may differ from theorist to theorist, or situation to situation.[50]

The notion of human rights outlined in natural law has close links to the philosophical theory of liberalism or liberal individualism. Liberal individualism indicates a space in which the individual pursues his or her own personal objects.[51] The individual must fulfil himself or herself without interference by the state, church or society.[52]

Central to liberalism is the protection of the basic liberties and interests of the individual. In the essay 'On Liberty' (1859), John Start Mill writes as follows:

> The object of this essay is to assert one very simple principle, as to govern absolutely the dealings of society with the individual in the way of compulsion and control, whether the means used be physical force in the form of legal penalties or the moral coercion of public opinion. That principle is that the sole end for which mankind are warranted, individually or collectively, in interfering with the liberty of action of any of their number is self-protection. That the only purpose for which power can by rightfully exercised over any member of a civilised community, against his will, is to prevent harm to others ... Over himself, over his own body and mind, the individual is sovereign.

The liberal idea of human rights refers to what are sometimes called first generation civil and political rights, freedom of speech, religion, conscience and so on, which require the state to refrain from interfering in the freedoms of the individual. These are the core human rights of the Age of Enlightenment and constitute the substance of the achievements by the French and American Revolutions.[53]

In contrast, in the Russian and in other 'socialist' revolutions, precedence is claimed for economic and social rights.[54] Socialists argue that there is no necessary separation between the state, society and the individual.[55] Men and women in their

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50 Shestack points out that, because of this and other difficulties, natural rights theory became unpopular, only to experience a renaissance during the aftermath of World War II (208).

51 Beauchamp and Childress (n 11 above) 356.

52 Nowak 10.

53 Nowak (n 23 above) 10.

54 Nowak 11.

55 As above.

view are not autonomous individuals with rights derived either from a divine or an inherent nature, but are 'specie beings'.[56] Shestack comments as follows:[57]

> The Marxist system of rights has often been referred to as 'parental', with the authoritarian political body providing the sole guidance in value choice. The creation of such a 'specie being' is a type of paternalism that not only ignores transcendental reason, but negates individuality. In practice, pursuit of the prior claims of society as reflected in the interests of the Communist state has resulted in systematic suppression of individual civil and political rights.

In Marxian terms the philosophical basis for the natural law approach is idealist and 'ahistoric'; human rights are neither inalienable nor natural.[58] The notion of individual rights is an illusory product of bourgeois individualism.[59] The state alone grants rights and their exercise is 'contingent on the fulfilment of obligations to society and to the state'.[60]

In contrast to liberal 'negative' freedom, the socialist state enforces 'positive' access to economic and social rights. The Constitution of the Union of the Socialist Soviet Republics of 1936 included an elaborate catalogue of economic, social and cultural rights.[61]

The division into Western and Socialist ideologies, including human rights, continued throughout most of the 20th century. Nowak writes:[62]

> The conflicting ideologies of the classical human rights concept in the West and the socialist human rights concept in the East, ie of the first two generations, proved a considerable hindrance to human rights and their philosophical and political development right up to the end of the Cold War.

Apart from contributing to the development of a notion of so-called second generation rights, as Shestack remarks, on an international level Marxist concepts were incompatible with the functioning of an international system of human rights:[63]

> The prior claim of a Communist society does not recognise overruling by international norms ... Communist states repeatedly asserted in international *fora* that their alleged abuse of human rights was a matter of exclusive *domestic* jurisdiction, not just as a matter of protecting sovereignty or avoiding the embarrassment of international examination, but the assertions reflected communist theory of the unlimited role of the state to decide what is good for the specie beings.

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56 Shestack (n 12 above) 210.
57 Shestack 211.
58 As above.
59 As above.
60 As above.
61 Nowak 13.
62 Nowak 12.
63 Shestack (n 12 above) 211. Original emphasis.

In the aftermath of World War II there was a renewed concern that principles of morality should be established to protect humanity from a repetition of such events.[64] This concern revived the interest in natural law and natural rights theory, and was reflected in human rights instruments of the time. Phrases, such as 'inherent dignity',[65] 'inalienable rights of all members of the human family' and '[a]ll human beings are born free and equal in dignity', from the Universal Declaration of Human Rights,[66] assert the basic tenets of natural law and natural rights theories – that human beings are born free, autonomous, equal and possess inherent dignity.[67] These rights are seen as 'core' rights, from which all the other elements of a complete system of human rights can evolve.[68]

During the sixty or so years which follow World War II and the Universal Declaration of Human Rights, different theories of human rights have attempted to define the content of, and justification for, a system of human rights. For some, natural rights theories were deficient and outmoded in the late 20th century. John Rawls's theory of rights based on justice, as he expounds it in *A Theory of Justice*, for example, establishes principles of justice that provide 'a way of assigning rights and duties in the basic institutions of society'.[69] Rawls explains:[70]

> [e]ach person possesses an inviolability founded on justice that even the welfare of society as a whole cannot override ... Therefore in a just society the liberties of equal citizenship are taken as settled; the rights secured by justice are not subject to political bargaining or to the calculus of social interests.

A further contribution to the understanding of the origins of human rights are theories that see human rights as a reaction to injustice. Edmund Cahn's theory of 'justice' is such a theory. He writes, '"[j]ustice" ... means the active process of remedying or preventing what would arouse the sense of injustice.'[71] The need to right a wrong, according to Cahn, has the capacity to produce action, and from that need a set of rights arises.[72]

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64 Shestack points out that the horror and revulsion against Nazism coalesced with the rejection of a positivist interpretation 'where the individual counted for nothing' (215). See also Brown (n 4 above) 106 – 108 for a discussion of positivism as opposed to natural law as the philosophical foundation of human rights law.

65 Universal Declaration of Human Rights.

66 See para 3.2.1 below.

67 See Shestack 216 – 217.

68 Shestack 217.

69 Shestack 218.

70 Rawls (1971) 3 – 4.

71 Cahn (1949) 13 – 14.

72 Shestack (n 12 above) 224.

The sociological school[73] of jurisprudence contributes the notion of human rights as a system which is aimed at 'obtaining a just equilibrium of interests among prevailing moral sentiments and the social and economic conditions of time and place'.[74] Consequently, help for the unemployed, the handicapped and the underprivileged exert demands upon contemporary society that cannot be provided for by a system limited to civil and political rights.[75]

Philosophers have constructed theories about the moral basis of a comprehensive system of human rights based on utility,[76] dignity,[77] religion[78] and equality of respect and concern.[79] Although some theorists attempt to justify the existence of a system of human rights on an external set of norms or values, others are more pragmatic, as well as those who are described as 'intuitive',[80] holding that human rights grow out of the lessons we learn from history and from the social knowledge accumulated over time, independent of any specific philosophical theory or system of values. Jacques Maritain writes about:[81]

> the natural operation of spontaneous reason, pre-scientific and pre-philosophic ... at every stage conditioned by the acquisitions, the constraints, the structure and evolution of the social group ... a kind of plant-like formation and growth of moral knowledge and feeling ... independent of philosophical systems and their rational justifications ... where the principal part has been played by the lessons of history and by the kind of practical apprehension.

The thesis does not aim to provide an exhaustive philosophical overview of contemporary and post-modern theories about the origin, content, nature and

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73 Shestack regards the term 'school' to be a misnomer as the 'school' has developed from a number of disparate theories 'all trying to line up the law with the facts of human life in society' (211).

74 Shestack 212.

75 As above.

76 See Shestack 213 – 215.

77 Some human rights theorists have tried to construct a comprehensive system of human rights on a value-policy orientated approach focussed on the protection of human dignity. For philosophers such as Myres McDougal, the ultimate goal is a 'world community in which a democratic distribution of values is encouraged and promoted, all available resources are utilized to the maximum, and the protection of human dignity is regarded as the paramount objective of social policy' (Shestack 226).

78 See eg Perry (1998) *The idea of human rights: Four enquiries* 11 – 41.

79 Such as the theories of Ronald Dworkin. Dworkin postulates a premise that all governments should treat their citizens with equal concern and respect. According to him, no basis for any valid discourse on rights and claims exists in the absence of such a premise (Shestack 226).

80 See Twiss' use of the term to denote theorists who use a kind of 'moral intuitism' to argue that human rights need no explicit justification (Twiss (n 28 above) 60 – 61).

81 Maritain 'Introduction' in UNESCO (1948) *Human rights: Comments and Interpretations* i – ix, iv.

justification for the existence of human rights.[82] The aim is merely to indicate the theoretical foundations that shape the beginnings of an international human rights system in the late 1940s. The discussion concludes with a debate on an issue in contemporary human rights theory that is especially relevant to HIV-related clinical trials in Africa: Is there a place for a notion of cultural relativism in an international system of human rights?

2.4 Cultural relativism or universal human rights?

The concept of human rights, at its centre, has the basic assumption that human rights are universal, that is, that they apply to everyone, everywhere. The Vienna Conference in 1993 proclaimed that the 'universal nature of human rights is beyond question'.[83] If human beings have rights by virtue of their common humanity it can only be because there are general moral standards that are universal in application.[84] 'All human rights for all' refers to the indivisibility and interdependence of human rights,[85] economic, social and cultural rights are equivalent to civil and political rights and should have the same protection. Thus, the right to non-interference for individuals and groups and a right to positive state action are of equal significance.[86] Human rights are, in principle, applicable to all people whatever their class, race, religion or any other attribute.[87]

The debate raised by cultural relativism has its beginnings in the 20th century divisions with regard to different generations of rights, but gained impetus by claims in the developing world that the developed world uses human rights to pursue neo-liberal and neo-colonial policies.[88] Human rights norms impose a world political view upon peoples who have their own cultural and moral principles.[89]

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82 For a lucid exposition of these theories see Shestack (n 12 above) 215 – 226 and Twiss (n 28 above) 56 – 65.
It is also important to remember that there are many critics who express reservations about human rights - in this regard, see generally Kennedy 'The international human rights movement: Part of the problem?' (2002) 15 *Harvard Human Rights L J* 101.

83 Vienna Declaration and Programme of Action, adopted by the World Conference on Human Rights, 24 June 1993, UN Doc A/Conf 157/24 (Part 1), 13 October 1993.

84 See Brown (n 11 above) 106 – 108.

85 Nowak 14.

86 As above.

87 As above.

88 Twiss 57. See generally Renteln (1990) *International human rights: Universalism versus relativism* and Brown in Dunne and Wheeler (n 11 above); Donnelly 'Cultural relativism and universal human rights' (1984) 6 *Human Rights Q* 400.

89 They have argued for the separate, independent value of all cultures. During the 19th century, Western colonisers viewed the colonised peoples of the world and their cultures as barbaric and primitive. In reaction to this, the concept of cultural

Cultural relativism is essentially an anthropological and sociological concept and is loosely based on a theory of moral relativism[90], in which it is claimed that, because different cultures are widely disparate in terms of morality, customs, motivations and preferences, no human rights principles can be said to be self-evident, applicable equally to all peoples, at all times and in all geographic locations.[91] No human right is absolute, instead the society in which one is raised determines the way one views the behaviour of others, and customs are morally equivalent and equally valid, determined by time and place, and in the judgment of one's cultural peers.[92]

Shestack summarises the debate:[93]

> A universal moral philosophy affirms principles that protect universal, individual human rights of liberty, freedom, equality, and justice everywhere, giving them a nontranscient, nonlegal foundation. The relativists defend a cultural conditioning that supposedly reflects a set of wants and goods that members of disparate cultural groups share (and that may include various human rights goods), but are not wants and goods arrived at through individual choices or preserved for individuals in the community as a matter of right.

Cultural relativist arguments have been perverted in the justification of human rights abuses. Political elites reject universal human rights norms as a form of Western cultural imperialism exerted upon local culture. Cultural relativism has served to justify abuses of the right to freedom of speech[94] as well as the suppression of women through cultural practices, such as female genital mutilation in which their physical integrity is violated.

The United Nations, the supposed defender of the universal nature of human rights, adopts the relativist argument with regard to cultural practices. Thus, two UN

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relativism was posited at the end of colonialism to assert that all cultures are equally valid, and that no culture is superior to another. Cultural relativism was given a moral or ethical stance by anthropologists and sociologists – they argue that all cultures are morally equal and that universalist values (such as human rights) are dead (Shestack (n 12 above) 229 - 230).

90 There exists different 'schools' of relativism, such as cultural relativism, ethnic relativism and moral relativism. These schools cannot be seen as a homogenous group, neither can the theorists in each school be seen as holding the same relativist theory. The discussion above is therefore very broad.

91 Shestack 228.

92 As above. Shestack writes: 'To suggest that fundamental human rights may be overridden or adjusted in light of cultural practices is to challenge the underlying moral justification of a universal system of human rights, reflecting the autonomous individual nature of the human being' (Shestack (n 12 above) 228).

93 Shestack 230.

94 The most notable example is President Robert Mugabe of Zimbabwe who considers freedom of speech (or freedom of the press) as an example of Western imperialism.

Special Rapporteurs remarked in the case of a Mali woman who had been given a prison sentence in France for practicing female genital mutilation:[95]

> ... the importance attached to certain traditional practices in some communities must be taken into account ... [The Rapporteurs] firmly and unequivocally condemned all practices that violate individuals' physical integrity ... [but] felt nevertheless that punishments and sentences *based on value judgments* could sometimes be counter-productive and encourage communities to close ranks and cling to practices which ... are the *only means they have of expressing their cultural identity*. Such practices *should not be condemned* in the courts *except as a last resort* when education, information and the proposal of alternative rites ... have not been successful.

These arguments fly in the face of facts. First, most - if not all - cultures display basic universal assumptions about morality.[96] For example, all cultures demonstrate a concern for the value of human life; all oppose crimes, such as murder and rape; all cultures value truth, goodness and justice within groups.[97] For example, Abdullahi An-Na'im points out that the adage 'do unto others as you would want them to do onto you', is present in most societies.[98]

Second, cultural relativism presents culture as static, ignoring changes over time and that cultures accommodate varying individual responses to its norms.[99] Values that may be true for a certain culture at a certain time do change, and within individual cultures, there are clashes over the nature and identity of that culture. An-Na'im recognises that culture itself is not a homogenous or a monolithic institution, and that different versions of local cultures exist apart from the official state-sanctioned one.[100]

Third, change brought about by technology and communication prompt many societies to incorporate values other than those considered 'traditional' into their culture.[101] The role of globalisation in this respect cannot be underestimated.

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95 Observation by UN Special Rapporteur on Violence against Women and the Special Rapporteur on Traditional practices affecting the Health of Women and the Girl Child UN Doc E/CN.4/Sub.2/1999, para 75. (My emphasis.)

96 In this regard, see Yasuaki 'Towards an intercivilizational approach to human rights' in Bauer and Bell (eds) (1999) *East Asian challenges for human rights* 103 – 123; Bielefeldt 'Muslim voices in the human rights debate' (1995) 17 *Human Rights Q* 587 and Engle 'From scepticism to embrace: Human rights and the American Anthropological Association from 1947 – 1999' (2001) 23 *Human Rights Q* 536 – 539.

97 Shestack (n 12 above) 231; Finnis (n 37 above) 83 – 84.

98 An-Na'im 'Islam, Islamic law and the dilemma of cultural legitimacy for international human rights' in Welch and Laery (eds) (1990) 31.

99 Shestack 232.

100 An-Na'im (n 98 above) 36 – 49. Also see An-Na'im (2006) 27 *Third World Q* 785.

101 As above.

Recently, different cultural contexts have been used to identify instead possible shared reasons for a normative agreement on the creation and existence of (universal) human rights:[102]

> It is a fact that globalisation has enhanced cross-cultural contact, awareness, and exchanges about worldviews, moral, political, and religious systems and about diverse patterns of reasoning and justification throughout the world ... In all of these settings, one encounters explicit attempts, for example, to relate cultural moral categories to human rights norms, to identify and negotiate interpretations of these norms, to scrutinise cultural, social, and political traditions for their human rights implications, and even to articulate new social visions combining aspects of different traditions in a manner supportive of the priority interests represented by human rights.

Finally, the relativist argument, in many ways, seems moot. Shestack argues that:[103]

> ... another approach still exists that, in part, renders moot the conflict between universalist and relativist theory. This approach consists of appreciation of what has transpired in international law. Even as theorists have continued to quarrel with each other, fundamental human rights principles have become universal by virtue of their entry into international law as *jus cogens*, customary law, or by convention. In other words, the relativist argument has been overtaken by the fact that human rights have become hegemonic and therefore universal by *fiat* ... the broad acceptance by many nations across the globe of the principal human rights treaties can be taken, at least on the legal level if not yet in practice, as a triumph of universalism over relativism.

What 'has transpired in international law' – in Shestack's words - is a pragmatic international consensus that human rights are a largely self-sufficient and legally binding compact among the different states in the world that needs no further justification in terms of its universality, its acceptance among different cultures, or its ability to transcend different cultural norms.[104]

Fareda Banda remarks as follows about the ability of universal human rights law norms to bring about change in cultural practices which deny women their humanity:[105]

> 'Law' is not to be accepted uncritically. However, an engagement, filtering and implementation of law using feminist tools of analysis can yield positive results for women. Ultimately what matters is not whether we attach the labels 'relativist' or 'universalist', 'northern' or 'southern', but that all change feeds into the goal of according women worldwide their full humanity.

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102 Twiss (n 28 above) 59.

103 Shestack (n 12 above) 233.

104 See generally in this regard Twiss (n 28 above) 59 – 60, who argues that philosophical inquiries into the origins of human rights in natural law are a waste of time as we have a pragmatic agreement among states to acknowledge human rights norms as a self-sufficient system, no matter what their theoretical justification may be.

105 Banda (2003) 17 *Intl J L, Policy and Family* 19.

2.5 The impact of globalisation

Martin Wolf describes globalisation as the 'integration of economic activities, across borders, through markets'.[106] This integration entails the free movement of goods, services, labour and capital, thereby creating a single market.[107] An-Na'im offers an understanding of globalisation as an 'increasing assimilation of economies through international integration of investment, production, and consumption that is driven by market values'.[108] Benatar's more comprehensive definition, declares globalisation to be a 'complex and ambiguous concept with social and ecological manifestations that reflect a long, interwoven economic and political history in which peoples, economies, cultures and political processes have been subject to international influences'.[109]

Globalisation brings both positive and negative consequences: advances in science and technology, enhanced economic growth, freedom and prosperity for many; but also a widening gap between rich and poor within countries as well as globally.[110] Rejectionists claim that globalisation is the spring only of more poverty and greater exploitation.[111] Globalisation functions to reduce barriers to economic activity with little regard to social justice or environmental and public health.[112] For example, in African states as elsewhere, trade liberalisation policies result in the loss of jobs because trade agreements allowing entry to cheaper imports are detrimental to the profits of local manufacturers. Countries, such as in sub-Saharan Africa, 'remain on the periphery of these trends towards progress and economic dynamism'.[113]

Clinical research shares in the multiplication of the forces and effects of globalisation. The research enterprise is international; international collaborative research is the order of the day.[114] Multi-national corporations engage in clinical

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106 Wolf (2004) 14.

107 As above.

108 An-Na'im (2003) 'Politics of Religion and Morality of Globalization', unpublished paper, available at <http://www.sess.smu.edu.sg/events/Paper/Abdhu.pdf> (31 January 2007) 3. For a detailed discussion on the meaning of the concept of globalisation, which is outside the scope of this thesis, see Bartelson 'Three concepts of globalization' (2000) 15 *Intl Sociology* 180.

109 Benatar 'The HIV/AIDS pandemic: A sign of instability in a complex global system' in Van Niekerk and Koplelman (eds) (2005) 72.

110 As above.

111 See eg Went (2000) *Globalization: Neoliberal challenge, radical response.*

112 An-Na'im (n 108 above) 3.

113 Alonso 'Globalization, civil society, and the multilateral system' in Eade and Lightering (eds) (2001) 87.

114 See para 2.2.4 of ch 5 below.

research across the globe, and, increasingly, turn to Africa in search of research participants. Tony Barnett and Alan Whiteside comment on the outcome.

> Investment, cost and productivity and realisation of profit are spread across a world of space through complex networks of finance and organisation, and through decades of time. Cause and effect are often so widely separated through time that it is difficult or impossible to locate responsibility. The same is true of losses and costs associated with the impact of HIV/AIDS.[115]

In a globalised world corporate responsibility is more difficult to monitor, and raises the possibility of exploitation.[116]

A greater emphasis on ideologies such as international human rights law is a by-product of globalisation; the limitations on state sovereignty enhance the chances for supra-national enforcement of international human rights standards. But, is a system of international human rights law better able to protect the interests of clinical research participants in sub-Saharan Africa than bioethics? This enquiry is a major concern in the rest of the chapter.

2.6 Human rights and bioethics

This chapter argues for an approach to the protection of the rights of trial participants in clinical HIV-related research in Africa that is based on human rights rather than on clinical or bioethics.[117] The following paragraphs evaluate the differences and similarities between these systems.

At the outset it is indicated that an approach which argues that there is a place for human rights in the protection of the rights of trial participants in clinical research, rather than the traditional approach which relies on clinical or research ethics, is not widely supported by either the scientific community or by bioethicists.

Critics of a human rights approach to what has traditionally been the field of medical or bioethics claim that human rights discourse cannot cope with the complex moral issues involved in clinical research. They base the claim on the argument that the language of rights is too 'crude and ineffective' to deal effectively with the task of ethical reasoning. David Benatar, a philosopher and bioethicist, writes as follows:[118]

> Morality is a complex matter. This complexity cannot be managed completely with only the concept of rights – and *a fortiori* with only the concept of *human* rights. A health and human rights approach is unable to discover a non-natural right, such as a right arising from a promise or from membership in a medical insurance scheme.

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115 Barnett and Whiteside (2002) 353.
116 See para 2.3.3 of ch 5 below.
117 The approach based on clinical or research ethics is discussed in ch 3.
118 Benatar (2006) 32 *J Med Ethics* 19.

> Even if the notion of human rights were extended to include not only natural rights possessed by humans but also non-natural rights possessed by humans, the human rights approach would still be unable adequately to approach important issues in medicine. For example, it could not take account of the interests of those animals on which medical experimentation is conducted ... Using only the language of rights to grapple with every moral issue is analogous to treating every sickness with the same medication (or class of medication) or it is like trying to speak by using only nouns. It is crude and ineffective.

Benatar's argument is contestable, not least because of its false analogies. A few aspects of the argument are dealt with below.

First, human rights theory does not claim that human rights take the place of ethical or moral reasoning. Ethics, ethical reasoning, morality, moral reasoning and human rights are not equivalents. Human rights are a codification of a small measure of humankind's ideas about morality and morally good actions. Yet, human rights are a 'set of moral principles of which the justification lies in the province of moral philosophy'.[119] Philosophical human rights discourse grapples with the same 'complex moral issues' as does ethics or even bioethics. The strength of human rights lies in the fact that it consists of moral values or principles that are universally held; which have been tried and tested by history; and about which there is a certain amount of international consensus.

Second, Benatar seems to equate human rights and natural rights, as he writes '[e]ven if the notion of human rights were extended to include not only natural rights possessed by humans but non-natural rights ...'. This statement displays an inadequate understanding of the history of human rights. The renaissance of natural rights theory in the 20th century has been responsible for the revival of interest in human rights, but, as was shown above,[120] human rights are not the same as natural rights. Natural rights are the philosophical antecedents of contemporary human rights.

Third, Benatar's objection to natural/human rights that they do not include so-called 'non-natural rights', or rights 'such as a right arising from a promise or from membership in a medical insurance scheme' is unfounded. A promise is not the basis for the existence of a right, natural or unnatural.[121] Promises belong in the sphere of morality and ethics. In any case, membership of a medical scheme does

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119 Shestack (n 12 above) 202.

120 See para 2.3 above.

121 The legal term 'legitimate expectation' is the closest the law comes to enforcing promises.

not rest within the field of clinical - or bioethics – it falls into the ambit of the law of contract or insurance law.

The (human) right of access to social security or health care, may, in certain circumstances, arguably include a (human) right of access to membership of a medical scheme, for example, in the case of a HIV-positive person who is denied membership of a medical scheme because of her status. Such a person may rely on human rights to equality, access to health care and social security to enforce her right.

Lastly, proponents of human rights cannot claim the applicability of human rights to animals; they are *human* rights, after all. Using the situation of animals in experimentation as an example of an 'important issue[] in medicine' that is not covered by natural/human rights, does not strengthen the biomedical argument, but plays on human sensibilities.

The paragraphs that follow illustrate that the 'language of [human] rights' is not 'crude and ineffective', but is, instead, valuable in protecting the rights of participants in clinical research.

Clinical research ethics and human rights are, essentially, products of the spirit and philosophy of the mid-20th century. To a large extent, both arose as a response to humankind's horror at the events of World War II and the atrocities committed by National Socialism and Japanese Imperialism. In the words of George Annas: 'World War II was the crucible in which both human rights and bioethics were forged, and they have been related by blood ever since'.[122]

The Nuremberg Code, written in 1946 as the final part of the judgment delivered in the Nuremberg trials, contains the first comprehensive set of guidelines on how to conduct ethical research on humans.[123] The Nuremberg Code is a consequence of the outrage that was felt at the conduct of doctors under National Socialism in Germany, who, in the guise of science, performed cruel and inhuman medical experiments on German and non-German nationals, including Jewish and 'asocial' people during the Second World War. In the first part of the Nuremberg Code, reference is made to the fact that 'the record clearly shows the commission of war crimes and crimes against humanity ...'.[124] George Annas remarks, '... I believe

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122 Annas (2004) *J L, Med & Ethics* 659.

123 See para 3.1.1 in ch 3 above.

124 Part I Nuremberg Code 'Proof as to War Crimes and Crimes against Humanity'.

it is accurate to conclude that the [Nuremberg] Trial itself marked the birth of American bioethics'.[125]

Similarly, the Universal Declaration of Human Rights is the first comprehensive human rights document to be adopted by an international organisation.[126] It is considered by many to be a milestone in humankind's struggle for the recognition of human rights and the struggle for freedom and human dignity. The Universal Declaration of Human Rights too was adopted after the Second World War in the realisation that international co-operation is needed to protect individuals against abuses of state power. Its preamble reads: 'disregard and contempt for human rights have resulted in barbarous acts which have outraged the conscience of mankind ...'[127]

The Nuremberg Code and the Universal Declaration of Human Rights are thus reactive in nature – both are products of outrage and anger. In Edmund Cahn's words '"[j]ustice" ... means the active process of remedying or preventing what would arouse the sense of injustice'.[128] These two documents are memorative, they epitomise 'lest we forget'.

As well as a shared historical background, clinical research ethics and human rights have a common purpose: broadly, they aim to protect the individual or groups of individuals from harm. In the case of clinical research ethics, such harm may come from abuses by scientists or researchers in a clinical research setting; in the case of human rights, such harm may arise from state action or the actions of other individuals or groups of individuals within a state.

Despite the shared objective to protect individuals or groups from harm, each system has its own focus: ethical principles governing research with human subjects aim at regulating the relationship between researchers and research participants; as apposed to principles regulating the relationship between the individual and the state or the relationship between individuals in a state. Clinical research ethics or bioethics apply to a very specific, narrowly defined situation only, whereas human rights potentially apply to a wide or broadly defined range of situations. Specific human rights conventions which deal with specific human rights topics, for example, the Convention against Torture, are, of course, narrower in their focus.

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125 Annas (n 122 above) 658.
126 See para 3.2.1 (b) below.
127 Preamble Universal Declaration of Human Rights.
128 Cahn (n 71 above) 13 – 14.

The difference outlined above has implications for the way in which the different documents are drafted and worded. Clinical research ethics documents are specific in their content and phrasing, human rights documents tend to be more general. For example, clinical research ethics codes contain phrases giving specific instructions, such as '[t]he subjects should be volunteers – either healthy persons or patients from whom the experimental design is not related to the patient's illness'.[129] Human rights documents tend, on the other hand, to contain general phrases, such as '[e]very individual shall have the right to enjoy the best attainable state of physical and mental health'.[130] Both articles require interpretation to determine their application to a given situation, but the human rights section certainly requires a more extensive interpretation in order to discover the meaning of the value judgment implicit in 'best attainable state of health'.

Despite the necessity to be more precise and exact in phrasing, ethical guidelines are severely criticised for, in general, being too vague and ambiguous. Human rights, it is true, are phrased in yet more general terms, however, human rights are given content by their interpretation in courts or other tribunals, with the consequence that it is not a serious failing as is the case with ethical guidelines which are not litigated.

As a rule, human rights and clinical research ethics both operate in situations of unequal power. Most bioethicists, however, deny theirs is a relationship of unequal power.[131]

> The word *power* is essentially absent from the vocabulary that scholars of medical ethics have constructed for their discipline and that has been accepted by almost everyone who does work in the field or tries to apply medical-ethical insights to the clinical context.

The potential victims of abuse in a human rights situation are vastly less powerful than their abusers – whether government, private individuals or multinational corporations – but, generally, are reasonably well-informed about their human rights through the media and education programmes. Because they have been educated about their human rights, they are generally conscious of any infringement of these rights.

Clinical research subjects are less well-informed about the scientific and clinical issues involved in research. In settings where there are significant levels of

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129 Art III.2 Declaration of Helsinki.
130 Art 16(1) African Charter of Human and Peoples' Rights.
131 Brody (1992) 12.

illiteracy the situation is exacerbated. Furthermore, in settings in which there are high levels of poverty, and where research is a means to access treatment, the potential for exploitation is greatest. Research initiatives seldom are accompanied by large-scale programmes aimed at educating research subjects about the nature and implications of the research for themselves and their communities.

Ethical principles governing clinical research on human subjects often deal with subjects in different countries, in multiple sites, and truly are international in their application, whereas human rights law primarily deals with citizens of a single state. States enter into multilateral agreements with other states, committing themselves to respecting human rights, but, in reality, it is of slight concern to them whether or not the other parties actually adhere to this aspect in relation to their citizens. It is a true case that many states ratify human rights treaties merely to receive aid. In addition, even when a human rights convention is litigated, often this is done first at the domestic level due to the requirement in many treaties that domestic remedies should be exhausted. Many domestic constitutions contain bills of rights, so that human rights are generally litigated first within the domestic courts of a specific state by citizens of a specific state.

A crucial difference between the two systems lies in the nature of each: one system consists of non-legal, non-binding ethical *principles*; the other of legally binding *rights*. It is true that human rights and ethical principles, equally, are systems which embody society's moral values, moral norms or its 'common morality',[132] and it is also true that human rights *contain* principles of ethics, but the values and norms in each system are codified very differently - as principles in the one and rights in the other.

Implicit in this difference between principles and rights, lies another crucial distinction between the two systems in terms of the enforcement mechanisms devised to monitor a system of non-binding principles as apposed to a system of legally binding rights.

In the case of ethical guidelines governing clinical research on human subjects, compliance with and enforcement of the system rely on professional sanction and other non-legal means. It is assumed that researchers are 'ethical' people who will uphold the guidelines of clinical research. Because of the non-legal nature, to a large extent, observance of ethical guidelines depends on the sanction of various professional bodies and research funding agencies. Other than a refusal

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132 See para 2.2 above, as well as para 2.2 of ch 3 above.

to fund or a refusal to publish unethical research, there is little to guard against unethical research conducted by unscrupulous agencies.

In respect of human rights, collective monitoring and implementation mechanisms are in place. These monitoring systems are sophisticated and well-developed. International organisations, such as the United Nations, assume a duty to protect human rights. Similar institutions have been introduced at a regional level as well, and in some regional systems they include a court in which international human rights are litigated and enforceable against violators.[133] At the domestic level, many states have promulgated constitutions which include justiciable bills of rights, making human rights immediately enforceable in a domestic court of law.[134]

2.7 A rights-based approach to clinical research

Much of this chapter is an argument in favour of human rights as an alternative strategy in protecting the interests of participants in clinical HIV-related research. The nature of such a human rights or rights-based approach is examined below.

A 'rights-based' approach is based or founded on *rights*, instead of policy, ethical reasoning or principles of goodness. A rights-based approach usually is seen as the counterpoint for a policy-based approach[135] or a needs-based approach.[136]

Rights are enforceable claims;[137] they are supported by a legal system that considers rights as enforceable or justiciable against other persons or entities in a setting such as a court of law. Specifically, a rights-based approach, in the context

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133 See paras 3.3.2 and 3.3.4 below.

134 See paras 5.1 – 5.2 below.

135 In a policy-based approach, the executive has the discretion whether to act or not; in a rights-based approach there is a legal obligation upon the executive to act in a certain way. Policy-makers usually have the freedom to determine the content and the extent of their policies, they may even determine when it is convenient (for them) to implement their policies. They can decide who the beneficiaries are, how they will allocate resources (eg whether they will support HIV/AIDS-related research financially) and who will be bound by their policies. The provision in the past of anti-retrovirals in South Africa to only a limited number of research sites is an example of the exercise of government discretion.

136 A needs-based approach focuses on securing resources for delivery of services to particular groups, where a greater need exists. Once again this approach depends upon executive discretion, in the sense that making available resources for special needs or priorities is an executive decision and depends on the perception of the executive of the need. Needs may be met by charitable institutions, whereas rights are based on legal obligations.

137 See para 2.2 above.

of this discussion, deals with the legal system established by the international system of human rights, with its binding human rights law instruments.[138]

Frans Viljoen characterises a rights-based approach as follows:[139]

> Rights-based approaches convert needs into justiciable rights. These 'rights' may come in the form of constitutional provisions or national legislation. Violation of, or non-compliance with, these rights gives rise to a claim for redress that may be asserted before a court or other tribunal. Rights thus form the basis for governmental accountability.

Viljoen stresses that, while needs-driven programmes or policies depend on an *ad hoc* exercise of discretion, rights place an obligation on a duty-bearer (mostly governments), creating an expectation of compliance and deliver accountability on the basis of a clear obligation.[140]

In the context of clinical research, a rights-based approach goes further than prescribing ways of acting morally or ethically towards research participants. A rights-based approach provides a justiciable, legal framework by means of which a reliance on ethical conduct or morality is converted into a legal claim. A right-based approach to clinical HIV-related research participation locates the needs of participants in such research within a human rights context, enabling access to a mechanism for claiming and asserting their rights.

In a rights-based approach, the ethical obligation to treat participants in clinical research in a certain way becomes a legal imperative that may be enforced in a court of law if the need arises. For example, a moral or ethical principle, based on an ethical guideline which ensures that research participants give informed consent to participation in research, or that they are given fair access to the products of research, under a rights-based approach becomes a legally enforceable right to informed consent in clinical research and a legally enforceable right of access to the products of clinical research.

There are further, non-legal, consequences in a rights-based approach. Human rights may be used to question the *status quo*, the established way in which things are done.[141] In the previous chapter an illustration was offered of how PLWHA have been able to change the protracted process of drug licensing;[142] by

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138 Such as binding treaties as well as decisions of international human rights organs and judicial or quasi-judicial bodies. They are contrasted with non-binding policy statements, declarations, ethical guidelines and the like.

139 Viljoen (2005) 15 *Interights Bulletin* 47.

140 As above.

141 Viljoen (n 139 above) 47.

142 See para 4.2.1(c) of ch 3 above.

framing their demands in the language of rights, PLWHA in the United States successfully achieved a fast-track in the licensing of anti-HIV medication and speedier access to certain drugs. Viljoen speculates that a rights-based approach, as an alternative way of seeing and thinking about experience, extends outside the courtroom; that human rights discourse is 'a language of moral authority that may be used in many ways, such as lobbying for reform or mobilising and strengthening social movements'.[143] He develops this claim to propose that as justiciable rights raised in court or even as a basis for social conflict, rights which have the effect of destabilising aspects of the *status quo*,[144] result in governments being made accountable by means of an assessment of performance and delivery.[145]

A rights-based approach not only has the power to hold governments and other persons or entities accountable for the violation of clinical research participants' rights, it establishes a standard against which government action may be measured in estimating whether it has fulfilled its obligations.

Talking about rights, of itself, is proposed as a vehicle for 'increasing the accountability of government organisations to their citizens and consequently increasing the likelihood that policy measures will be implemented in practice'.[146] Government action will be tested against human rights standards and inaction monitored. In stipulating an internationally agreed set of norms backed by international law, human rights provides a firmer foundation upon which people have a claim on governments, holding them accountable in the performance of a duty to enhance access in the realisation of human rights.

More broadly, engaging with a rights-based approach is an opportunity to reflect on general issues in research ethics and the practice of international research, including the internal dynamic as well as the obligations of those engaged in international HIV-related research towards clinical research participants. Thus, it is a framework for reflection that politicises international HIV-related clinical research sponsorship and participation.

From the discussion above, six ways can be observed in which a rights-based approach relates to HIV-related clinical research.

- As a set of normative principles to guide the way in which HIV-related research participation is carried out.

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143 Viljoen (n 139 above) 47 – 48
144 As above.
145 As above.
146 Ferguson (1999) 23.

- As a justiciable framework which converts ethical conduct or morality into legal claims, and locates the needs of participants in HIV-related clinical research in a human rights context, offering a mechanism for claiming and asserting rights.
- As a means of questioning the *status quo*.
- As a standard against which government action in the fulfilment of their obligations may be measured, in other words, as a means of judging state performance.
- As a way of making government organisations more accountable to their citizens and, consequently, to increase the likelihood that policy measures will be implemented in practice.
- As an opportunity for a broader reflection on the power dynamic of international research and on questions in research ethics.

Self-evidently, the goal of HIV-related clinical research is the promotion of human health and human well-being. Human rights define and advance human well-being; a rights-based approach to HIV-related research participation delivers a conceptual and a practical framework by which to assess the process.

2.8 Different levels of protection: National and international human rights law

The protection afforded by human rights law functions at different levels. The first line of 'defence' against a human rights violation is at the national level (also called the domestic or municipal level). At this level human rights law takes the form of a domestic bill of rights, a human rights act or human rights provisions included in a constitution, as well a international human rights law that has been 'domesticated'. The next line of 'defence' is at the regional level.[147] Different states in a region or continent adhere to the same system of human rights protection, usually based upon a founding document embodying human rights values.[148] The final line of 'defence' against human rights violations is at the global or UN level. States across the globe adhere to human rights norms contained in different international human rights documents and treaties.

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147 Some authors talk also of a sub-regional level. This is human rights at the level of the sub-region, such as SADC, which is primarily an economic organisation but which includes human rights concerns.

148 See para 4 below.

There is thus a division between 'national' or 'municipal' human rights law, and international (regional or global) human rights law. This division is rather artificial, as the national and international systems apply simultaneously. However, international law does not 'replace' national law: the person whose rights were violated needs first to look for redress at the national level. Only in instances where no remedy is available or possible at the national level, may the person turn to the international (regional or global) level.[149] The international level of protection therefore functions as a 'safety net', to catch victims of human rights violations who fall through the cracks of the national level.

At the national level it is the state which is responsible for the implementation of human rights norms. A state may have its own bill of rights, either standing on its own or embedded in a constitution, which it has to comply with and give effect to, and the state also has to 'domesticate' international human rights treaties and declarations. At the regional or global levels it is a regional or global organisation which is responsible for the implementation of human rights norms.

The existence of international human rights law is a product of the erosion of state sovereignty. When becoming a state party to a human rights treaty, states voluntarily relinquish their own sovereignty: they agree that an independent regional or global body may supervise their compliance with the provisions of that treaty and take steps to interfere if it is deemed necessary.[150] Some treaties allow for individual complaints against states by their nationals for human rights violations.

The 'domestication' of international human rights law in the domestic human rights system is discussed in detail below.[151]

2.9 Conclusion

In this section the origins and development of the idea of human rights were explored in order to introduce the thesis developed in this chapter – that human rights may be used effectively to protect the interests of participants in clinical HIV-related research in Africa.

It was pointed out that human rights discourse is about the use of terms such as 'right', '*prima facie* claims', 'justiciability', 'universal moral rights', 'justice', and so

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149 Known as the principle of subsidiarity – international human rights law is subsidiary to national human rights law.

150 Such interference may take the form of political, military or humanitarian action.

151 See para 6 below.

on, and that human rights are a particular type, or subspecies, of rights. Various definitions of human rights were offered, and some writers have claimed that human rights is the *only* universally recognised system of values.

The philosophical background of human rights was traced, and the merits of a universal system of human rights beyond theories of cultural relativism have been explored. The impact of globalisation upon the international research enterprise was considered. A human rights approach was contrasted with bioethics, and it has been asserted that, because of their enforceable nature, human rights directly benefit participants in clinical research. A distinction is drawn between 'national' and 'international' human rights law, and human rights protection at the regional and global levels is sketched.

George Annas, in pleading for the acceptance of the importance of human rights discourse by bioethicists, comments:[152]

> While bioethics has aspired to be a universal language, the only language that can be said to have attained that status, as tentative as it is, is the language of human rights.

At a point later in chapter 4 the issue raised by George Annas is developed. In the following paragraphs, specific human rights provisions in domestic bills of rights relevant to clinical research in sub-Saharan Africa are inspected.

3 NATIONAL HUMAN RIGHTS NORMS

3.1 Introduction

This section examines specific human rights provisions in domestic constitutions relevant to the protection against the abuse of clinical research participants in HIV-related research Africa. As indicated in the introduction to this chapter, the investigation is limited to countries in *sub-Saharan* Africa because of the comparatively low prevalence of HIV/AIDS in countries north of the Sahara.[153]

Not every country in sub-Saharan Africa is included: the survey is limited to 22 countries selected from each region (north, south, central, east and west). Most countries situated in southern Africa, where the HIV prevalence rate is the highest, are included. Sudan has been omitted as its constitution has been suspended in the wake of the civil war.

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152 Annas (n 122 above) 661.

153 See para 1 above, and para 3.3 of ch 2 above.

The investigation centres in human rights provisions in the constitutions of the following countries (in alphabetical order): Angola; Benin; Botswana; Burundi; Congo; Eritrea; Ethiopia; Ghana; Kenya; Lesotho; Malawi; Mali; Mozambique; Namibia; Nigeria; Senegal; South Africa; Swaziland; United Republic of Tanzania; Uganda; Zambia; and Zimbabwe. (Also refer to paragraph 4.3.1 of chapter 3 for tables presenting the core health indicators of these countries.)

The survey investigates the following:

- Whether a provision specifically mentioning clinical research is contained in the country's constitution.
- Whether the constitution guarantees freedom from torture and other inhuman and degrading treatment which could be used to defend participants in clinical research against abuses of their person.
- Whether the right to physical integrity is guaranteed by the constitution (for similar reasons as above).
- Whether the right to dignity is guaranteed (clinical research undertaken without the informed consent of a participant may be regarded as a violation of dignity).
- Whether the constitution contains a provision guaranteeing equality, which could be used to ensure that the rights of research participants who are, or are perceived to be, HIV positive are protected; as well as a clause ensuring the equality of minority groups taking part in research and who are prone to stigma and discrimination, such as MSM, WSW, sex workers and IDUs.
- Whether the constitution guarantees the individual's privacy.
- Whether the constitution guarantees women and children's rights which may be violated during clinical trial participation.
- Whether the right to health care or access to health care is guaranteed by the constitution, giving an indication of whether clinical research will be seen by research participants as an opportunity to gain access to heath care that is not otherwise available.

3.2 Specific human rights provisions in domestic bills of rights (relevant to clinical research in sub-Saharan Africa)

3.2.1 Angola

Part II of the Constitutional Law of the Republic of Angola[154] sets out 'fundamental rights and duties'. Several provisions are relevant to clinical research, but Part II does not make direct reference to clinical research.

Article 18 of the Angolan Constitution ensures the equality of all Angolan citizens. The list of prohibited grounds of discrimination includes 'color, race, ethnic group, sex, place of birth, religion, ideology, level of education or economic or social status'. Article 20 obliges the state to respect and protect the human person and human dignity.[155]

Article 47(1) of the Angolan Constitution is significant. It guarantees that the state will promote the measures needed to ensure the rights of citizens to medical and health care.[156] Although clinical research is not mentioned explicitly, the article could be interpreted as supporting measures undertaken by the Angolan government that encourage research which promotes medical and health care, such as HIV-related clinical research.

Part II, article 23 reads: '[n]o citizen may be subjected to torture or any other cruel, inhuman or degrading treatment or punishment'. The provision in the Angolan Constitution is identical to article 5 of the Universal Declaration, and article 7 of ICCPR.[157] Unlike the corresponding article in the ICCPR, however, the Angolan Constitution does not contain an additional sentence prohibiting medical experimentation without informed consent. Further, the provision contains an internal qualifier – 'citizens' alone are entitled to the right. These limitations apart, it is submitted that article 23 of the Angolan Constitution can be called upon to protect the rights of research participants in Angola, as well as the rights already mentioned.

Children's rights are protected.[158] Women's rights are protected only within the context of the family, in which women and men are held to have equal rights.[159]

3.2.2 Benin

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154 Constitutional Law of the Republic of Angola, adopted 25 August 1992; available at <http://www.chr.up.ac.za/hr_docs/constitutions/docs/Angola%20Constitution(rev).doc> (31 January 2007).

155 Arts 18 and 20 Constitutional Law of the Republic of Angola.

156 As above, art 47.

157 See para 4.3.1 of ch 5 below.

158 Art 30 Constitutional Law of the Republic of Angola.

159 Arts 18 and 29(2) Constitutional Law of the Republic of Angola.

Title II of the Constitution of the Republic of Benin[160] contains provisions dealing with the 'rights and duties of the individual'. Several provisions are relevant to clinical research, but Title II does not refer directly to clinical research.

Article 8 guarantees the sacred and inviolable nature of the human being. Article 15 reads: 'Each individual has the right to life, liberty, security and the integrity of his person'. This article may be enforceable against clinical research which threatens or violates the life or integrity of the person.

Article 18 reads: '[n]o one shall be submitted to torture, nor to maltreatment, nor to cruel, inhumane or degrading treatment'. Note 'no one': unlike a similar provision in the Angolan Constitution, the Benin provision is applicable to all persons within Benin territory, not only to citizens of Benin. Article 19 prohibits acts of torture and inhuman or degrading treatment carried out by someone in an official capacity.

Article 26 guarantees equality before the law, and the list of prohibited grounds of discrimination are: origin, race, sex, religion, political opinion and social position. Women and men are regarded equal under the law.[161] A duty is placed upon the state to protect the family, especially the mother and child.

3.2.3 Botswana

Chapter II of the Constitution of Botswana[162] contains a bill of rights. Several provisions are relevant to clinical research, but chapter II does not make direct reference to clinical research.

Article 3 protects the fundamental rights and freedoms of the individual, whatever her 'race, place of origin, political opinions, colour, creed or sex'. Art 7(1) reads: '[n]o person shall be subjected to torture or to inhuman or degrading punishment or other treatment'. It is submitted that this provision can be called upon to protect participants of clinical research in Botswana.

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160 Constitution of the Republic of Benin, adopted 2 December 1990; available at <http://www.chr.up.ac.za/hr_docs/constitutions/docs/BeninC(englishsummary)(rev).doc> (31 January 2006).
Interestingly, the Benin Constitution incorporates the human rights guaranteed by the African Charter in its bill of rights (see art 7 Constitution of the Republic of Benin).

161 Art 26 Constitution of the Republic of Benin.

162 Constitution of Botswana, adopted in 1966, last amended in 1999; available at <http://www.chr.up.ac.za/hr_docs/constitutions/docs/Botswana(summary)(rev).doc> (31 January 2007).

The individual's right to privacy is protected, and no search of her person may be carried out without her permission.[163] However, the right to privacy is limited by, amongst others, anything that is 'reasonably required in the interests of public health'.[164] No special mention is made of women's or children's rights in the Botswana Constitution.

3.2.4 Burundi

The Constitution of the Republic of Burundi[165] contains human rights provisions which are relevant to the position of research participants, but the Constitution does not mention clinical research specifically.

Article 15 prohibits arbitrary treatment; article 19 explicitly prohibits discrimination against people living with HIV or AIDS; article 25 ensures confidentiality of personal communications; article 33 concerns participation in public life (which could be interpreted to mean participation in a public good, such as clinical research); and article 35 relates to child health and well-being.

Article 17 is of special significance to clinical research as it guarantees the right to life, security of the person and physical integrity.

3.2.5 Congo

The Constitution of the Republic of the Congo[166] contains a bill of rights in Title II, 'rights and fundamental liberties'. Although no reference is made to clinical research, the Constitution of the Congo does contain provisions which are relevant to participation in clinical research.

Equality is guaranteed, and the prohibited grounds of discrimination are 'origin, social or material situation, racial, ethnic, gender, education, language, religion, philosophy or place of residence'.[167] Privacy is guaranteed[168] as is the

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163 Art 8 Constitution of Botswana. However, the right to privacy is limited by, amongst others, anything that is 'reasonably required in the interests of public health'.

164 This article may be relied upon by proponents of mandatory or 'opt out' HIV testing in public hospitals in Botswana.

165 Constitution of Burundi, 2004; available at <http://democratie.francophonie.org/article.php3?id_article=368&id_rubrique=94> (31 January 2007).

166 Constitution of the Republic of the Congo, 1992; available at <http://www.chr.up.ac.za/hr_docs/constitutions/docs/CongoC%20(english%20summary)(rev).doc> (31 January 2007).

167 Art 8 Constitution of the Republic of the Congo.

168 Art 14 Constitution of the Republic of the Congo. This provision may be limited to privacy of the home.

secrecy of correspondence.[169] The state guarantees the public's health[170] and the rights of the mother and child within the family are guaranteed.[171]

The situation of children and adolescents participating in HIV-related research may be covered by article 34. Although initially not intended for this purpose, article 34 may be used to prevent the exploitation of children and adolescents in such research. Article 34 determines that the state must protect children and adolescents from 'economic exploitation'.[172] Clinical research of an exploitative nature in which children and adolescents are enrolled is thus prohibited.[173]

3.2.6 Eritrea

Chapter 3 of the Constitution of Eritrea[174] contains provisions on human rights, entitled 'Fundamental Rights, Freedoms and Duties'. Several provisions are relevant to clinical research, but Chapter 3 does not refer directly to clinical research.

Article 14 prohibits discrimination on a range of listed grounds. They are: 'race, ethnic origin, language, colour, gender, religion, disability, age, political view, or social or economic status'. Discrimination based on what is referred to as 'other improper factors' is also prohibited. Article 18 protects the individual's privacy.

The right to human dignity is protected in article 16. Article 16(2) reads, '[n]o person shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment'. A verbatim copy of art 5 of the Universal Declaration and article 7 of the ICCPR, this article could be read as prohibiting clinical research in Eritrea which constitutes 'cruel, inhuman or degrading treatment or punishment'. It is submitted that clinical research without proper informed consent, clinical research which is exploitative and clinical research which is not responsive to the needs of the community at the very least, are 'degrading'.

Article 21 provides every citizen with the right to equal access to publicly-funded social services and states that the state shall endeavour to make available to all citizens health, education, cultural and other social services. Women are

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169 Art 20 Constitution of the Republic of the Congo.

170 Art 30 Constitution of the Republic of the Congo.

171 Art 31: 'The state has the obligation to assist the family in its mission as guardian of the morality and the traditional values recognised by the community. The rights of the mother and the child are guaranteed'.

172 Art 34 Constitution of the Republic of the Congo.

173 See para 2.3.3 of ch 5 below.

174 Constitution of Eritrea, adopted by the Constituent Assembly on 23 May 1997; available at <http://www.chr.up.ac.za/hr_docs/constitutions/docs/EritreaC.pdf> (31 January 2007).

protected in the 'Democratic Principles', of which article 7 protects against participation in 'any act that violates the human rights of women or limits or otherwise thwarts their role and participation is prohibited'.

3.2.7 Ethiopia

Chapter 3 of the Constitution of the Federal Republic of Ethiopia[175] sets out fundamental rights and freedoms; several provisions are relevant to the situation of clinical research participants in Ethiopia.

Article 14 protects the individual's 'inviolable and inalienable right to life, the security of [the] person and liberty'. Article 15 protects the right to life and article 16 protects the rights of every person against 'bodily harm'. Under certain conditions, clinical research could constitute 'bodily harm', and the provision may be called upon in an action against perpetrators of research which causes harm.

Article 18 reads: 'Everyone has the right to protection against cruel, inhuman or degrading treatment or punishment'. This article mirrors the protection in the Universal Declaration and in the ICCPR, and could be interpreted to include violations by researchers in clinical research.

A general equality provision is contained in article 25, and the prohibited grounds of discrimination are 'race, nation, nationality, or other social origin, colour, sex, language, religion, political or other opinion, property, birth or other status'. It is not a closed list, and the words 'other grounds' might cover 'real or perceived HIV status'. Article 25 would protect participants in HIV-related clinical research from being discriminated against based on their real or perceived status.

Article 35 prohibits harmful customs and elaborates rights with respect to the transfer of property to women and women's inheritance. Article 36 guarantees children's rights. Article 41 states that every Ethiopian has the right to equal access to publicly-funded social services and that the state must allocate ever-increasing resources to provide to the public health, education and social services.

3.2.8 Ghana

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175 The Constitution of the Federal Democratic Republic of Ethiopia; available at <http://www.chr.up.ac.za/hr_docs/constitutions/docs/EthiopiaC(rev).doc> (31 January 2007).

The Constitution of the Republic of Ghana[176] contains human rights provisions in Chapter 5. Several provisions are relevant to clinical research, but Chapter 5 does not refer directly to clinical research.

Article 12(2) ensures the rights and freedoms in the Constitution to everyone, regardless of 'race, place of origin, political opinion, colour, religion, creed or gender'. Article 15 guarantees the individual's dignity. Article 15(2) reads:

> No person shall, whether or not he is arrested, restricted or retained, be subjected to -
>
> (a) torture or other cruel, inhuman or degrading treatment or punishment;
> (b) any other condition that detracts or is likely to detract from his dignity and worth as a human being.

This utility of this provision in protecting participants in HIV-related research is self-evident.

Article 17 prohibits discrimination on the grounds of 'race, place of origin, political opinions, colour, gender, occupation, religion or creed'. Article 27(1) ensures special care to mothers before, during and after child-birth, and article 27(3) ensures equal training and opportunities for women. Children's rights are protected in article 28. Article 28(3), which reads, '[a] child shall not be subjected to torture or other cruel, inhuman or degrading treatment or punishment', is especially important.

3.2.9 Kenya

The Constitution of Kenya[177] contains human rights provisions that are relevant to the situation of clinical research participants. Chapter 5 is entitled 'protection of fundamental rights and freedoms of the individual'.

Article 74 prohibits 'inhumane treatment' but appears to limit such treatment to 'forced labour'. Article 76 guarantees privacy and reads: 'Except with his own consent, no person shall be subjected to the search of his person or his property or the entry by others on his premises'.[178]

Article 82 prohibits discrimination based upon 'race, tribe, place of origin or residence or other local connexion, political opinions, colour, creed or sex whereby

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176 Constitution of the Republic of Ghana, 1991; available at <http://www.chr.up.ac.za/hr_docs/constitutions/docs/GhanaC.pdf> (31 January 2007).

177 Constitution of Kenya, adopted in 1963 and amended in 1999; available at <http://www.chr.up.ac.za/hr_docs/constitutions/docs/KenyaC(rev).doc> (31 January 2007).

178 Art 76(1) Constitution of Kenya.

persons of one such description are subjected to disabilities or restrictions to which persons of another such description are not made subject or are accorded privileges or advantages which are not accorded to persons of another such description'.[179] The provision includes an internal limitations clause, restricting the general right on the basis of marriage, adoption, burial, devolution of property upon death and so on.[180]

An amendment to the constitution which has been proposed would add health status as a protected ground.[181] Also, women are afforded greater protection in the new amendment,[182] and specific provisions dealing with children have been included.

3.2.10 Lesotho

The Constitution of Lesotho[183] in Chapter 2 contains fundamental rights and freedoms which are relevant to the protection of research participants. No direct reference is made to clinical research.

Article 8 guarantees freedom from inhumane treatment. Article 8(1) reads: 'No person shall be subjected to torture or to inhuman or degrading punishment or other treatment'. Article 11 guarantees privacy of the person, and article 8 guarantees freedom from discrimination. The prohibited grounds are:[184]

> race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status whereby persons of one such description are subjected to disabilities or restrictions to which persons of another such description are not made subject or are accorded privileges or advantages which are not accorded to persons of another such description.

Because this is not a closed list, it is conceivable that perceived or actual HIV status may be 'read into' the provision, giving research participants protection against discrimination during HIV-related clinical research. However, the rights in article 8 are subject to an internal limitations clause in sub-article 4, which includes 'adoption, marriage, divorce, burial, devolution of property on death or other like matters which is the personal law of persons of that description; or for the application of the

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179 Art 89 Constitution of Kenya.
180 Art 89(4)(b) Constitution of Kenya.
181 The Proposed New Constitution of Kenya 2005 art 37.
182 As above, art 38.
183 Constitution of Lesotho, adopted in 1993, amended 1996, 1997, 1998 and 2001; available at <http://www.chr.up.ac.za/hr_docs/constitutions/docs/LesothoC(summary)(rev).doc> (31 January 2007).
184 Art 8(3) Constitution of Lesotho.

customary law of Lesotho with respect to any matter in the case of persons who, under that law, are subject to that law'.[185]

In Chapter III of the Lesotho Constitution, principles of state policy are set out. Article 27 reads:

> Lesotho shall adopt policies aimed at ensuring the highest attainable standard of physical and mental health for its citizens, including policies designed to -
> (a) provide for the reduction of stillbirth rate and of infant mortality and for the healthy development of the child;
> (b) improve environmental and industrial hygiene;
> (c) provide for the prevention, treatment and control of epidemic, endemic, occupational and other diseases;
> (d) create conditions which would assure to all, medical service and medical attention in the event of sickness; and
> (e) improve public health.

From the wording of the article and the fact that it is not contained in the chapter on fundamental rights but as a 'directive of state policy'[186] it is clear that article 27 is not immediately enforceable against the Lesotho state. However, the provision may be used to argue that the state should put in place policies and frameworks which facilitate clinical HIV-related research and protect the rights of participants in such research.

3.2.11 Malawi

The Constitution of the Republic of Malawi[187] contains human rights provisions in Chapter IV relating to the situation of clinical research participants. The Constitution of the Republic of Malawi specifically refers to clinical research.

The right to life is guaranteed in article 16. Article 19 guarantees the human dignity of the person. Article 19(3) dictates that '[n]o person shall be subject to torture of any kind or to cruel, inhuman or degrading treatment or punishment'. This provision is similar to that in other constitutions, however, the Constitution of Malawi goes further. In article 19(5) the following prohibition is added: '[n]o person shall be subjected to medical or scientific experimentation without his or her consent'. The Malawian Constitution is a departure from the norm in taking

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185 Art 4(b) and (c) Constitution of Lesotho.

186 So-called 'directive principles of state policy') and 'fundamental objectives of state policy' (see the Constitution of Nigeria below) are not justiciable human rights. Rather, they serve as a guide to the executive or legislature in the exercise of their functions. They are often used by the judiciary as a guide to the interpretation of the Constitution and other laws.

187 The Constitution of the Republic of Malawi, entered into force on 18 May 1994; available at <http://www.chr.up.ac.za/hr_docs/constitutions/docs/MalawiC.pdf> (31 January 2007).

cognisance of clinical research and guaranteeing the right not to be subjected to medical experimentation without consent. Although not precisely the same, the wording of article 19 mirrors the prohibition on research without consent in article 7 of the ICCPR.

Article 20(1) prohibits discrimination on the grounds of 'race, colour, sex, language, religion, political or other opinion, nationality, ethnic or social origin, disability, property, birth or other status'. 'Other status' may be interpreted to include HIV status. The right to privacy is guaranteed in article 21. Children's and women's rights are protected by the Malawian Constitution.[188]

3.2.12 Mali

The Constitution of the Republic of Mali[189] in Title I contains provisions on human rights that are relevant to the situation of clinical research participants.

Article 1 guarantees human dignity which is regarded as 'sacred and inviolable'. The article further provides that '[e]ach individual has the right to life, liberty, and the security and integrity of his person'. Discrimination based on the grounds of 'social origin, color, language, race, sex, religion, or political opinion' is prohibited. Article 6 guarantees privacy.

Article 3 reads: 'No one will be put to torture, nor to inhumane, cruel, degrading, or humiliating treatment' and is especially significant. The article provides further that anyone found guilty of such an act, 'either on his own initiative, or by another's command', is punishable at law'.

Health care is to 'constitute some of the social rights'.[190] Women's and children's rights are not singled out for mention.

3.2.13 Mozambique

The new Mozambican Constitution[191] came into effect in 2005. Article 35 guarantees equality:[192]

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188 Arts 23 and 24 Constitution of Malawi.

189 Constitution of the Republic of Mali, adopted in 1992; available at <http://www.chr.up.ac.za/hr_docs/constitutions/docs/MaliC(rev).doc> (31 January 2007).

190 Art 17 Constitution of the Republic of Mali.

191 Constitution of Mozambique 2005; available at <http://www.chr.up.ac.za/hr_docs/constitutions/docs/Mozambique.doc> (31 January 2007).

192 Art 35 Constitution of Mozambique.

> All citizens are equal before the law, and they shall enjoy the same rights, and shall be subject to the same duties regardless of colour, race, sex, ethnic origin, place of birth, religion, educational level, social position, the marital status of their parents, their profession or their political preference.

Article 40 guarantees everyone the right to life and physical and moral integrity. Article 41 guarantees the protection of privacy. Article 45(e) states that everyone has a duty to their community to defend and promote health. It is submitted that participation in clinical research with the aim of defending and promoting health could be such a duty.

Article 47 protects children's rights. Article 89 of the Mozambican Constitution guarantees all citizens the right to medical and health care, but within the terms of the law.

3.2.14 Namibia

The Constitution of Namibia[193] contains a bill of rights in chapter 3, setting out the protection of the fundamental rights and freedoms of all persons in Namibia. Several of the provisions in the Constitution are relevant to the protection of clinical research participants though clinical research is not mentioned specifically.

Articles 8, 10 and 13 of the Constitution are of particular interest. Article 8(1) ensures that 'the dignity of all persons shall be inviolable'; article 10 ensures equality. The grounds of prohibited discrimination in article 10 are 'sex, race, colour, ethnic origin, religion, creed or social or economic status'. Article 13 protects the right to privacy and article 15 protects children's rights.

3.2.15 Nigeria

The Constitution of the Federal Republic of Nigeria[194] does not contain a bill of rights as such, but rather 'fundamental objectives of state policy',[195] the provisions of which could be relevant in the protection of HIV-related clinical research participants.

Article 15(2) prohibits discrimination on the grounds of 'place of origin, sex, religion, status, ethnic or linguistic association or ties'. Article 17(3)(d) declares that

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193 Constitution of Namibia, adopted in February 1990, amended on 24 December 1998; available at <http://www.chr.up.ac.za/hr_docs/constitutions/docs/NamibiaC(rev).doc> (31 January 2007).

194 Constitution of the Federal Republic of Nigeria, entered into force on 29 May 1999; available at <http://www.chr.up.ac.za/hr_docs/constitutions/docs/NigeriaC(rev).doc> (31 January 2007).

195 See n 186.

the state 'shall ensure that there are adequate medical and health facilities' for all persons. Article 21 places a duty on the state to 'protect, preserve and promote the Nigerian cultures which enhance human dignity and are consistent with the fundamental objectives as provided in this Chapter; *and encourage development of technological and scientific studies which enhance cultural values*'.[196] It is doubtful whether this is a reference specifically to HIV-related clinical research.

3.2.16 Senegal

The Constitution of the Republic of Senegal[197] in Title II contains provisions relating to 'public liberties and the person'. Clinical research is not mentioned specifically.

> Article 7 reads:
>
> The human person is sacred. The human person is inviolable. The state shall have the obligation to respect it and to protect it. Every individual has the right to life, to freedom, to security, the free development of his or her personality, to corporal integrity, and especially to protection against physical mutilation.

The right of privacy is guaranteed in article 14, and the rights of 'wives' to marital property and to 'worldly goods' in article 19.

3.2.17 South Africa

The South African Constitution[198] contains a bill of rights in chapter 2. Apart from a specific provision on informed consent in clinical research in section 12(2)(c), discussed in detail later,[199] the South African Constitution provides in section 9 for the right to equality; in section 10 for the right to human dignity; in section 11 for the right to life; and in section 14 for the right to privacy.

The Constitution also guarantees the right of access to health care services in section 27: '[e]veryone has the right to have access to health care services, including reproductive health care'. Furthermore, the state must take 'reasonable legislative and other measures, within available resources, to achieve the progressive realisation of each of these rights'.

Children's rights are guaranteed in section 28, as well as their right to 'basic health care services'.

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196 My emphasis.

197 Constitution of the Republic of Senegal, adopted on 7 January 2001 and available at <http://www.chr.up.ac.za/hr_docs/constitutions/docs/SenegalC%20(english%20summary)(rev).doc> (31 January 2007).

198 Constitution of the Republic of South Africa 1996.

199 See para 4.4.2 of ch 5 below.

3.2.18 Swaziland

Chapter III of the 2005 Constitution of the Kingdom of Swaziland guarantees the fundamental human rights and freedoms of the individual.[200] A number of rights in Chapter III are relevant in the protection of participants in HIV-related clinical research.

Personal liberty is guaranteed in section 16(1): 'A person shall not be deprived of personal liberty save as may be authorised by law'. Article 18 guarantees the dignity of the individual. Article 18(2) states that '[a] person shall not be subjected to torture or to inhuman or degrading treatment or punishment'. Reflecting as it does the provisions of the Universal Declaration and the ICCPR, article 18(2) could be relied as a remedy by research participants in Swaziland who have been subjected to inhuman or degrading treatment.

Section 20 guarantees all persons the right to equality before the law: 'All persons are equal before and under the law', specifically, no one is to be 'discriminated against on the grounds of gender ... or disability'.[201] Section 22 guarantees the right against arbitrary searches: '[a] person shall not be subjected ... to the search of the person' except when 'reasonably required in the interests of' fundamental social objectives such as the promotion of 'public order, public morality ... public health'.[202] Children's rights are protected alongside those of mothers in section 27: 'Motherhood and childhood are entitled to special care and assistance by society and the State.'[203]

There is no provision specifically dealing with the protection of participants in clinical research in the Swaziland Constitution.

3.2.20 Tanzania

Part III of the Constitution of the United Republic of Tanzania[204] contains several human rights provisions relevant to the protection of participants in clinical research, but does not mention clinical research specifically.

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200 Constitution of the Kingdom of Swaziland, 2005; available at <http://www.chr.up.ac.za/hr_docs/constitutions/docs/Swaziland.doc> (31 January 2007).

201 Art 20(1)(2) Constitution of the Kingdom of Swaziland, 2005.

202 Art 22(1)(a) and 22(2)(a) Constitution of the Kingdom of Swaziland, 2005.

203 Art 27(4) Constitution of the Kingdom of Swaziland, 2005.

204 Constitution of the United Republic of Tanzania, 1998, incorporates and consolidates all amendments made in the Constitution since its enactment by the Constituent Assembly in 1977 up to 1998; available at

Section 12 guarantees equality and states that all persons are born free and are equal. Everyone is entitled to the recognition and respect of their dignity. Section 13 prohibits discrimination on the grounds of 'nationality, tribe, place of origin, political opinion, colour, religion or station in life'. Section 14 guarantees the right to life and the right to protection of life by the society in accordance with law. Section 16 guarantees the right to respect of the person and privacy.

3.2.21 Uganda

The Constitution of the Republic of Uganda[205] includes a number of rights and entitlements that affect people participating in clinical research, though there is no specific reference to clinical research. Equality and freedom from discrimination are guaranteed in section 21. Article 22 protects the right to life, article 27 the right to privacy and article 33 women's rights. Amongst others, laws, cultures, customs or traditions which are against the dignity, welfare or interest of women or which undermine their status are prohibited.[206] Article 34 protects children's rights.

3.2.22 Zambia

The Zambian Constitution[207] guarantees human rights, but clinical research is not referred to specifically. The right to life in article 12 and article 17 protects the privacy of the person. Article 15 prohibits 'torture, or to inhuman or degrading punishment or other like treatment'.

Zambia currently has as well a draft Constitution which guarantees human rights. Article 39 of the draft Constitution prohibits discrimination based on race, sex, pregnancy, health, marital, ethnic, tribe, social or economic status, origin, colour, age, disability, religion, conscience, believe, future, language or birth.[208] Article 39 prohibits discrimination based on race, sex, pregnancy, health, marital,

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<http://www.chr.up.ac.za/hr_docs/constitutions/docs/TanzaniaC.pdf> 31 January 2007).

205 The Constitution of the Republic of Uganda, 1995; available at < http://www.chr.up.ac.za/hr_docs/constitutions/docs/UgandaC(rev).doc> (31 January 2007).

206 Art 33(6) Constitution of the Republic of Uganda, 1995.

207 Constitution of Zambia, as amended by Act 18 of 1996; available at <http://www.chr.up.ac.za/hr_docs/constitutions/docs/ZambiaC(rev).doc> (31 January 2007).

208 Draft Constitution of Zambia Cap 1.

ethnic, tribe, social or economic status, origin, colour, age, disability, religion, conscience, belief, torture, language or birth.[209]

Article 40 guarantees equal treatment for men and women. Article 40 further prohibits any law, culture, customs or traditions that undermine the dignity, welfare, interest or status of women or men.[210]

3.2.23 Zimbabwe

The Constitution of the Republic of Zimbabwe[211] contains a 'declaration of rights' in Chapter 3. Although clinical research is not mentioned, several of the rights in the Constitution of Zimbabwe apply to the situation of clinical trial participants.

Article 12 protects the right to life, and article 15 protects the individual's freedom from inhuman treatment. Article 15(1) determines that '[n]o person shall be subjected to torture or to inhuman or degrading punishment or other such treatment'; which is relevant to the situation of HIV vaccine trial participants.

Article 17 protects privacy; article 23 prohibits discrimination based on race, tribe, place of origin, political opinions, colour, creed or gender. Real or perceived HIV status is not mentioned, neither are the rights of persons who belong to minority groups subject to stigmatisation and discrimination, such as MSM, WSW, sex workers and IDUs.

3.3 Conclusion

This section delineated specific human rights provisions in domestic constitutions of selected sub-Saharan African countries which may be referred to in seeking to protect clinical research participants. The following conclusions are drawn.

First, all the countries contain provisions guaranteeing human rights in their constitutions and all the constitutions surveyed include at least some provisions relevant to providing protection for research participants. For example, the right to equality is guaranteed in the constitutions of 21 of the 22 countries; the right to human dignity in the constitutions of ten countries; and the right to privacy in the

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209 Draft Constitution of Zambia Cap 1.

210 Art 40(2) Draft Constitution of Zambia.

211 Constitution of the Republic of Zimbabwe, as amended to no 16 of 20 April 2000 (amendments in terms of Act 5 of 2000 (Amendment 16) are at sections 16, 16A (Land Acquisition) and 108A (Anti-Corruption Commission)); available at <http://www.chr.up.ac.za/hr_docs/constitutions/docs/ZimbabweC(rev).doc> (31 January 2007).

constitutions of sixteen countries. Many of the constitutions guarantee children's and women' rights as well.

Second, of special significance in guarding against possible abuses of clinical research participants, the right to freedom from torture and other degrading and inhuman treatment or punishment is declared in twelve of the 22 constitutions surveyed and the right to physical integrity or security of the person is guaranteed in the constitutions of six countries.

Third, only two of the constitutions surveyed – those of Malawi and South Africa - contain a provision which makes specific reference to clinical research. This omission may be ascribed to a number of reasons which are explored in a different context below.[212]

Fourth, of the 22 sub-Saharan African countries, six potentially protect the rights of persons living with HIV/AIDS or perceived to be living with HIV/AIDS.[213] The Constitution of Burundi explicitly protects people living with HIV/AIDS against discrimination. The rights of groups especially vulnerable to HIV infection and abuse in the research process, such as sex workers, MSM, IDUs and prisoners or detainees, are not mentioned in any of the constitutions (although the South Africa's constitution prohibits discrimination based upon 'sexual orientation' and some of the others prohibit discrimination based upon 'social status'). South Africa and Swaziland grant detainees the right of access to health care.

Finally, nine of the 22 constitutions guarantee a form of health care or access to health care either as a right or as a directive principle of state policy. The Eritrean Constitution provides that 'the state shall endeavour to make available to all citizens health, education, cultural and other social services,[214] and the South African Constitution provides for the 'progressive realisation' of health care.[215]

It is not in the purview of the survey to include information on the *implementation* of the constitutional provisions. Factors, such as a dysfunctional state and judiciary, civil war, corruption, poverty, illiteracy and a lack of effective access to the law,

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212 See para 4.5 of ch 5 below.

213 Here open-ended constitutional provisions on equality, such as those including the words 'other status', were taken to indicate a possibility of 'reading in' the protection of people living with HIV/AIDS, or people perceived to be living with HIV/AIDS. This study surveys only constitutional provisions, no account is given of protections provided by other legislation in force in those countries.

214 Art 21 Constitution of Eritrea.

215 Art 27 Constitution of the Republic of South Africa 1996.

compromise the force of human rights provisions guaranteed in a country's constitution. All that is intended is to demonstrate that in national constitutions there are provisions that could be called upon in protecting participants in HIV-related clinical research in Africa.

International human rights systems and instruments are now the focus.

4 INTERNATIONAL HUMAN RIGHTS SYSTEMS

4.1 Introduction

In the following section, international and regional systems for the protection of human rights are described.

First the United Nations (UN) system is described, and Charter and treaty-based instruments are outlined. Then follows an analysis of the three regional systems for the protection of human rights, including the African system which is discussed in relative detail. In the case of each system the implementation mechanisms are presented.

International human rights law divides into so-called 'hard' law and 'soft' law. Treaties and other binding instruments, known as 'hard law', are arrived at by agreement or consensus; whereas declarations, resolutions and other such instruments are known as 'soft' law because of their non-binding nature. This distinction has become of less value as 'soft law', despite its non-binding nature, has grown in importance as a source of international human rights law.

Soft law may not confer binding legal obligations upon states, but it is not without force and effect. For example, the Universal Declaration of Human Rights, technically, is not legally binding, however, many of the provisions have evolved into rules of customary law, and as such, are binding under international law.[216] Again, 'general comments' 'resolutions' and 'recommendations' of different treaty bodies do not generate binding obligations upon states, but they provide an authoritative interpretation of treaties and sometimes are lent a 'binding' nature when they are enforced through political rather than legal measures.

Chinkin asserts that the distinction between hard and soft law represents a false dichotomy;[217] he claims there exists a wide diversity in the instruments which

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216 See paras 4, 5 and 6 of ch 5 below.

217 See Chinkin (1989) 38 *The Intl and Comp L Q* 850.

compose so-called soft law, so that the generic term is a misleading simplification.[218] Soft law instruments vary in form, language, subject matter, participants, addresses, purposes and monitoring procedures. There is an inherent contradiction in the concept; the term 'law', which by its very nature is actionable, is combined with 'soft', designating something which is not enforceable.

Kenneth Abbott and Duncan Snidal argue that international actors deliberately choose soft law as being superior to hard law in institutional arrangements.[219] Soft law often is selected as a precursor to the 'harder' legalisation of obligations, but also is preferred in and of itself because it offers many of the advantages of hard law, while avoiding some of the cost. 'Soft' law has the advantage of being less challenging of state sovereignty and its obligations, therefore, are more acceptable to states.[220] Further, it allows state actors to become accustomed to the impact of commitments over time. Because soft law does not require all the formalities of hard law, it is accomplished in a less complicated and time-consuming manner.[221] Moreover, soft law facilitates compromise and cooperation between actors with different interests and values, different time horizons and different degrees of power.[222]

In the discussion below the focus falls primarily on hard law in the form of binding international human rights law, but occasionally soft law is mentioned.

4.2 The UN system

4.2.1 The Charter-based system

Dating back to the late 1940s, the international system for the protection of human rights is the oldest system. Traditionally, international law has governed the relationships between the different nations of the world.[223] States alone were the subjects of international law, and had rights under international law.[224] After World War I this narrow definition was broadened to include certain international

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218 As above.
219 Abbott and Snidal (2000) 54 *Intl Organization* 423.
220 As above.
221 Chinkin (n 217 above) 860.
222 As above.
223 Nowak (n 23 above) 16; Buergenthal (1995) 2.
224 Nowak 16 – 17; Buergenthal 2.

organisations; as yet individuals were not considered the bearers of international law rights.[225]

Today, individual human beings, as individuals, are considered to have internationally guaranteed human rights, and no longer need to belong to a particular state to claim these rights.[226] Whereas violations of human rights, in the past, were regarded as the 'internal affairs' of sovereign states, the atrocities committed during World War II strengthened the realisation that international co-operation was needed to protect individuals against abuses of state power.[227]

a) The UN Charter

Following a multi-national conference held in San Francisco, in the USA, the UN was formed in 1945 as a successor to the League of Nations.[228] The UN was intended to function as a permanent peace-keeping organisation.[229] The Preamble of the UN Charter sets out its purpose as relieving 'succeeding generations of the scourge of war', through maintaining international peace and security.[230]

The UN Charter did not provide the nations of the world with a comprehensive human rights system, but did lay the 'legal and conceptual foundation for the development of contemporary international human rights law'.[231] Article 1(3) of the UN Charter reaffirms the worth of human beings and describes the aims of the UN as follows (note that no reference is made to *protecting* human rights):[232]

> To achieve international co-operation in solving international problems of an economic, social, cultural, or humanitarian character, and in promoting and encouraging respect for human rights and for fundamental freedoms for all without distinction as to race, sex, language, or religion.

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225 As above.

226 Buergenthal (n 223 above) 19.

227 Nowak 17; Gostin and Lazzarini (1997) 2.

228 Nowak 73.

229 Nowak (n 23 above) 73; Annas in Gostin (n 35 above) 100. At present the UN's membership compromises all the countries of the world, except Nauru, a Pacific island state. Switzerland joined in 2002, after original refusing to join because of its wish to remain neutral.

230 Art 1 UN Charter.

231 Buergenthal (n 223 above) 23.

232 Nowak comments that for years, the UN took the 'promoting' aspects of its duties literally – the Human Rights Commission considered actions that went beyond mere promotion of human rights as 'inadmissible interferences with the domestic jurisdiction of states in accordance with art 2(7) of the UN Charter' (Nowak 73).

Articles 55 and 56 of the Charter outline the basic obligations of UN member states and the organisation.[233] The mandate is broad, but in reality confers very limited power upon the UN and its members.[234] The charge is to 'promote' respect for human rights. Also, articles 2(1) and 2(7) of the Charter reinforce the sovereignty of states, and stress the idea of non-intervention.[235]

Despite the limitations, the UN Charter has had a significant impact on international human rights law.[236] The UN Charter facilitates the acceptance of the notion that human rights are an international matter.[237] Nowak writes:[238]

> While to this day there is no international court of human rights that would compel states to meet their treaty obligations by internationally binding judgments, the significance of this universal codification process as the foundation of a world order rooted in the principles of the rule of law, democracy and human rights must not be underestimated.

The obligation of member states to co-operate in the promotion of human rights has ensured that the UN has the legal authority to define and codify these rights.[239] This promotional mandate, indirectly, has resulted in all the UN instruments for the protection of human rights.[240]

The obligation upon member states to promote human rights has enabled the UN over the years to adopt or create various Charter-based institutions to ensure member states' compliance, such as article 68 of the Charter that requires the Economic and Social Council of the UN to set up commissions for the protection of

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233 Art 55 reads: With a view to the creation of conditions of stability and well-being which are necessary for the peaceful and friendly relations among nations based on respect for the principle of equal rights and self-determination of peoples, the United Nations shall promote:
a) Higher standards of living, full employment, and conditions of economic and social progress and development;
b) Solutions of international economic, social, health, and related problems; and international cultural and educational cooperation; and
c) Universal respect for, and observance of, human rights and fundamental freedoms for all without distinction as to race, sex, language, or religion.
Art 56 reads: 'All members pledge themselves to take joint and separate action in co-operation with the Organisation for the achievement of the purposes set forth in Article 55'.

234 Buergenthal 24.

235 As above.

236 Buergenthal 25.

237 As above.

238 Nowak 73.

239 Buergenthal (n 223 above) 27.

240 As above.

human rights. [241] Resolutions of UN organs have also interpreted and elaborated upon certain provisions of the Charter.[242]

b) The Universal Declaration of Human Rights

Already at the San Francisco Conference proposals were made for the adoption of a human rights instrument.[243] These proposals were acted upon at the first meeting of the UN, which instructed the newly-created Commission on Human Rights to draft an international bill of rights.[244]

The Commission on Human Rights decided that first it should draft a declaration, and then proceed to creating legally binding documents in the form of draft treaties.[245] The Universal Declaration of Human Rights (Universal Declaration) was adopted by the UN General Assembly in December 1948.[246]

The Universal Declaration is the first comprehensive human rights document adopted by an international organisation[247] and it is considered a milestone in humankind's struggle for the recognition of human rights and the struggle for freedom and human dignity.[248]

Nowak comments on the fact that the Human Rights Commission in such a short space of time was able to get the international community to agree to adopt the Universal Declaration of Human Rights. He ascribes this success to the personal commitment of the individual delegates of the Human Rights Commission and to the fact that the international community of the 1940s was small, although ideological differences divided it.[249]

The Universal Declaration contains two classes or categories of rights. These are mostly civil and political rights and fewer economic, social and cultural rights. Civil and political rights in the Universal Declaration include the right to life, to liberty, to freedom of speech and religion, the prohibition on slavery and torture, of special relevance to the present study the right against inhuman and degrading

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241 For example, working groups on specific issues; rapporteurs for the different countries and supervisory committees that monitor compliance with the different treaties.

242 Eg *Reparation Case* ICJ Rep (1939) 174; *Voting Procedure Case* ICJ Rep (1955) 67; *International Status of South West Africa Case* ICJ Rep (1966) 6.

243 Nowak (n 23 above) 75.

244 Nowak 75; Buergenthal 29.

245 As above.

246 Buergenthal 29.

247 Buergenthal 29 – 30.

248 Buergenthal 30.

249 Nowak 75 – 76.

treatment,[250] the right to own property, the right to privacy and the right to a fair trial.

Economic, social and cultural rights included in the Charter are the right to social security, to protection against unemployment, to equal pay for equal work, to rest and leisure, the right to freely participate in the cultural life of the community, to education and to a standard of living adequate for the health and well-being of himself and of his family.

The rights listed above are not absolute; the Universal Declaration permits states to enact laws which limit the exercise of these rights provided their sole purpose is to secure 'due recognition and respect for the rights and freedoms of others ...'[251] Article 30, on the other hand, ensures that a government cannot violate the Universal Declaration by enacting legislation aimed at denying any of the rights in the Universal Declaration.

The Universal Declaration has no force in law as it is not a treaty. Its purpose is to promote a 'common understanding' of the human rights in it.[252] However, despite not having the force of law, the Universal Declaration has become a normative instrument that creates, at least, some obligations on the member states.[253] At the present time, some provisions of the Universal Declaration are recognised to be part of the body of customary international law[254] that may be called upon as the standard for human rights implementation.[255] The Universal Declaration has become the embodiment of what the international community means by the term 'human rights', and is an 'authoritative interpretation' of the term.[256] The Universal Declaration:[257]

> [a]s an authoritative listing of human rights, has become a basic component of international customary law, binding all states, not only members of the United Nations.

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250 See para 4.3.1 of ch 5 below.
251 Art 29(2) Universal Declaration.
252 Preamble Universal Declaration.
253 Buergenthal 33; see para 4.3.1 of ch 5 below.
254 See eg Alfredsson *et al* (eds) (1999) *The Universal Declaration of Human Rights – A common standard of achievement*; Beahr *et al* (eds) *Innovation and inspiration: Fifty Years of the Universal Declaration of Human Rights*; Heyns and Viljoen (2002) *The impact of the United Nations Human Rights Treaties on the Domestic Level*.
Not all scholars agree on whether the Universal Declaration of Human Rights has attained the status of customary international law. See para 5.2.3 below.
255 See para 4.3.1 of ch 5 below; Nowak 76; Buergenthal 34 – 35.
256 Nowak (n 23 above) 76, Buergenthal (n 223 above) 35.
257 Sohn (1982) 32 *American University L Rev* 16 – 17, quoted in Buergenthal 37.

The possibility of some sections of the Universal Declaration constituting customary international law is discussed below.[258]

4.2.2 The treaty-based system

a) The International Covenant on Civil and Political Rights and the Optional Protocol on the Convention on Civil and Political Rights

Background

Upon completion of the Universal Declaration, the Human Rights Committee set out to draft a legally binding treaty on human rights. There was to be a single treaty, containing, as is the case with the Universal Declaration, both civil and political rights and socio-economic rights.[259] Upon the insistence of the Western states, however, the treaty was divided into two – each contains a separate 'generation' of rights.[260]

On 16 December 1966 the International Covenant on Civil and Political Rights (ICCPR) was adopted by the UN General Assembly and opened for signature.[261] Only after ten years had sufficient states ratified both it and the International Covenant on Economic, Social and Cultural rights to bring them into operation.[262]

Because it is a treaty, the ICCPR bestows binding legal obligations on member states.[263] Non-compliance with the human rights enumerated in the ICCPR thus becomes a matter for international concern.[264]

Substantive provisions

The ICCPR is similar in substance to the European and American Conventions on Human Rights, but goes further in scope than these conventions.[265] Apart from many classic civil and political rights, it includes the right to self-determination of peoples and children's rights, as well as minority rights.[266]

The human rights that are guaranteed are not limitless. The ICCPR permits state parties to limit their exercise and protection of human rights. For example,

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258 See para 4.4 below, as well as para 4.3.1 of ch 5 below.
259 Nowak 78.
260 Nowak 78. Nowak explains that this decision was resisted by socialist states, who stressed the interdependence and indivisibility of human rights, while the West argued that 2nd generation rights are only 'programmatic' rights which are not immediately enforceable and which could therefore not be made justiciable.
261 GA Res 2200A (XXI) of 16 December 1966. Nowak 80; Buergenthal 38 - 39.
262 Nowak 79; Buergenthal 38.
263 Beurgethal 38.
264 As above.
265 Nowak 79.
266 As above.

article 18 guarantees freedom of religion, and asserts that 'freedom to manifest one's religion or beliefs may be subject only to such limitations as are prescribed by law and are necessary to protect public safety, order, health, or morals or the fundamental rights and freedoms of others.'[267]

For a limitation of the rights guaranteed to be considered legitimate, a government has to address five criteria spelled out in the Siracusa principles adopted by the UN Economic and Social Council.[268] They are:[269]

- The proposed restriction has to be provided for and implemented *in accordance with the law*.
- The restriction has to be directed towards a *legitimate objective of general interest*, such as preventing transmission of HIV.
- It must be *strictly necessary* to achieve the objective in question.
- *No less intrusive and restrictive means* should be available to reach this objective.
- It cannot be *unreasonable or discriminatory* in its application.

The government that wants to restrict rights has a burden to prove adherence to the principles enumerated above. Any restriction on the rights of participants in clinical research in Africa, therefore, will have to meet these criteria.

Art 2(1) sets out the obligations of state parties to the ICCPR. State parties undertake to respect and ensure that all individuals enjoy the rights enumerated in ICCPR. Art 2(2) requires all states to adopt measures to give effect to the rights in the ICCPR. An immediate obligation is thus imposed on state parties to the ICCPR.[270]

Article 7 of ICCPR reads '[n]o one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment'. This article is of peculiar

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267 Art 18.

268 ECOSOC (1985) *The Siracusa principles on the limitation and derogation provisions in the international covenant on civil and political rights*; available at <http://portal.unesco.org/shs/en/ev.php-URL_ID=5078&URL_DO=DO_TOPIC&URL_SECTION=201.html> (30 November 2006).

269 As above; my emphasis.

270 Unlike the Covenant on Economic, Social and Cultural Rights, which merely obliges states to progressively implement the rights.

importance to this study, since it adds '[i]n particular, no one shall be subjected without his free consent to medical or scientific experimentation'.[271]

Procedures for implementation

The 18 member Human Rights Committee established by the ICCPR was to ensure that state parties comply with their obligations under the ICCPR.[272] The Human Rights Committee was responsible for administering the reporting system of states,[273] as well as the individual and inter-state complaints system.[274] The Human Rights Council was established in April 2006 to replace the Human Rights Committee.[275]

State parties are required to submit reports on the measures they have taken to give effect to the rights in the ICCPR.[276]

The ICCPR also allows an inter-state complaints system where one state party may complain about human rights violations committed by another state party.[277]

'Special procedures' is the general name given to the mechanisms established by the Commission on Human Rights to address either specific country situations or thematic issues in all parts of the world.[278] Currently, there are 28 thematic and 13 country mandates in place.[279] The Office of the High Commissioner for Human Rights provides these mechanisms with personnel and logistical assistance to aid them in the discharge of their mandates.

The UN Commission on Human Rights has appointed a Special Rapporteur to examine questions relevant to torture.[280] The mandate of the Special Rapporteur covers all countries, irrespective of whether a state has ratified the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment.[281]

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271 See para 4.3.2 below.
272 Nowak (n 23 above) 80; Buergenthal (n 223 above) 43.
273 In terms of art 40 – it is mandatory.
274 In terms of art 41 – there have been no cases to date, Nowak 80.
275 UN A/Res/60/251.
276 Art 40(1).
277 Arts 41 & 42. States parties had to have made an optional declaration which recognises the jurisdiction of the Human Rights Committee to receive such complaints.
278 See <http://www.ohchr.org/english/bodies/chr/special/index.htm> (31 January 2006).
279 As above.
280 <http://www.ohchr.org/english/issues/torture/rapporteur/index.htm> (31 January 2007).
281 As above.

The mandate comprises three main activities: transmitting urgent appeals to states with regard to individuals reported to be at risk of torture, as well as communications on past alleged cases of torture; undertaking fact-finding country visits; and submitting annual reports on activities, the mandate and methods of work to the Human Rights Council and the General Assembly.[282] The Special Rapporteur does not require the exhaustion of domestic remedies to act.[283] The Rapporteur has not yet investigated an issue related to inhumane or degrading treatment during medical or scientific research, although this may fall within the Rapporteur's mandate.

The 1st Optional Protocol to the ICCPR, a separate treaty, supplementing the enforcement measures of the ICCPR,[284] entered into force in 1976. It allows individuals to claim violations of their human rights by state parties in the form of individual communications.[285] The Rules of Procedure[286] of the Human Rights Committee determines that the Human Rights Committee examines these complaints or communications in two stages – first, it decides on the admissibility of a complaint, and second it decides on the merits of the complaint.[287] The state that has been complained about in the individual complaint has six months within which to respond,[288] after which the Human Rights Committee reviews the submissions of the individual and the state party and makes a decision. However, many of the large number of individual complaints that have been received have been ruled inadmissible by the Committee due to non-exhaustion of domestic remedies.

A major problem with the ICCPR is that, unlike the European and Inter-American systems, it does not establish an international court of human rights.[289] The decisions of the Human Rights Committee are not legally binding, so that, in practice, it has become a quasi-judicial monitoring body for state reporting and individual complaints procedures.[290] At the UN there is not a body that enforces its decisions through political measures.[291]

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282 As above.
283 As above.
284 104 state parties, similar to procedure before European Court of Human Rights (Nowak 80).
285 Arts 1 and 2.
286 Rules of Procedure, Doc CCPR/C/3 Rev 3 (1994).
287 Rules 93 – 94 Rules of Procedure.
288 Art 4.
289 Nowak 79.
290 Nowak 80.
291 Nowak 81.

The 2nd Optional Protocol to the ICCPR entered into force in 1991. The objective of the Protocol is the abolition of the death penalty.[292]

b) International Covenant on Economic, Social and Cultural Rights

Background

The International Covenant on Economic, Social and Cultural Rights (ICESCR) recognises a wide range of second generation rights.[293] It was adopted by the UN General Assembly on 16 December 1966, and, ten years later, entered into force on 3 January 1976.[294]

Substantive provisions

The rights guaranteed in the ICESCR are not immediately enforceable. A state party undertakes only to 'take steps ... to the maximum of its available resources ... with a view to achieving the full realisation of the rights ...'[295] As Nowak points out, the wording of article 2(1) refers to 'obligations of conduct', rather than 'obligations of result'.[296]

Procedures for implementation

The monitoring body which supervises the implementation of this treaty is the Committee on Economic, Social and Cultural Rights.[297] The ICESCR has not established an individual or inter-state complaints mechanism, but it does require states to submit reports on what they have done to ensure the observance of the rights in the ICESCR.[298] There is a draft Optional Protocol to the ICESCR which proposes to allow for an individual complaints mechanism. The Human Rights

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292 Art 1 Second Optional Protocol to the ICCPR.

293 The right to work, the right to join trade unions, the right to strike, the right to social security, the right to protection of the family, maternity protection, protection of children and young people, the right to an adequate standard of living, the right to health, the right to education and participation in cultural life, etc.
Of importance to the present study is art 2(1) which refers to international assistance and co-operation of a technical nature, implying an obligation on developed countries to help ensure the worldwide realisation of these 2nd generation rights. This provision has implications for international co-operation in clinical testing.

294 GA Res 2200A(XXI) of 16 December 1966; 147 states parties; Nowak 81.

295 Art 2(1)

296 Nowak 81. States are merely obliged to achieve progressive realisation of these rights.

297 Not provided for in the treaty, established by the ECOSOC, Res 1985/17); Nowak 82.

298 Art 16(1).

Commission has deliberated on this draft protocol for several years, but still it has not been adopted.[299]

c) Miscellaneous UN human rights treaties

Over the past decades the UN established a number of treaties which deal with specific types of human rights violations. These treaties include (the list is not exhaustive)[300] the Convention on the Elimination of all forms of Discrimination Against Women (CEDAW);[301] the Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (CAT);[302] and the Convention on the Rights of the Child (CRC);[303] and the Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families (CMW).[304] Each of these treaties establishes a treaty monitoring body (or 'committee') in the form of a supervisory quasi-judicial institution.

CEDAW and CRC will be discussed below as they are relevant to the present enquiry into the human rights of participants in clinical trials. The discussion is general[305] in preparation for a more detailed discussion of selected provisions in paragraph 5 below.

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299 Nowak 83. See also Arambulo (1999) *Strengthening the supervision of the International Covenant on Economic, Social and Cultural Rights: Theoretical and procedural aspects* and Craven (1995) *The International Covenant on Economic, Social and Cultural Rights: A perspective on its development.*

300 See Nowak 95 for a list of other UN treaties and the years they entered into force.

301 UN GA Res 34/180, UN Doc A/34/46; adopted 18 December 1979, entered into force 3 September 1981.

302 UN GA Res 39/46, UN Doc A/39/51; adopted on 10 December 1984 and entered into force on 26 June 1987. It has 133 state parties.

303 UN GA Res 44/25; adopted 20 November 1989, entered into force 2 September 1990. CRC has been ratified by almost every state in the world. The exceptions are Somalia and the USA.

304 UN GA Res 45/158; adopted in 1990, entered into force 1 July 2003.

305 For a more detailed discussion on CRC, see Hammarberg 'The United Nations Convention on the Rights of the Child – And how to make it work' (1990) 12 *Human Rights Q* 97; Viljoen 'Supra-national human rights instruments for the protection of children in Africa: The Convention on the Rights of the Child and the African Charter on the Rights and Welfare of the Child' (1998) 31 *Comp and Intl L J Southern Africa* 199; Detrick *A Commentary on the United Nations Convention on the Rights of the Child* (1999) 415; Van Bueren (1995) *The international law on the rights of the child.* For a more detailed discussion on CEDAW, see Cook (ed) (1994) *Human rights for women: National and international perspectives*; Charlesworth *et al* 'Feminist approaches to international law' (1991) 85 *American J Intl L* 613; Gallagher 'Ending the marginalisation: Strategies for incorporating women onto the United Nations human rights system' (1997) 19 *Human Rights Q* 283.

i) CEDAW

Background

There has been a considerable focus on the rights of women at the UN. A Special Rapporteur has been appointed for women, and various conventions on women's' issues are in existence.[306]

CEDAW entered into force in 1981, after its adoption in 1970.[307] The Preamble outlines reasons for the adoption of CEDAW - the impact of discrimination against women upon their human dignity and the dire situation of women who are poor.

> *Recalling* that discrimination against women violates the principles of equality of rights and respect for human dignity, is an obstacle to the participation of women on equal terms with men, in the political, social, economic and cultural life of their countries ...
>
> and
>
> *Concerned* that in situations of poverty women have the least access to food, health, education, training and opportunities for employment and other needs ...

The drafters of CEDAW demonstrated the realisation that legislation alone is unlikely to change perceptions about women and the position of women in society. Article 5 obliges states:

> to modify the social and cultural patterns of conduct of men and women, with a view to achieving the elimination of prejudices and customary and all other practices which are based on the idea of the inferiority or the superiority of either of the sexes ....
>
> to ensure that family education includes a proper understanding of maternity as a social function and the recognition of the common responsibility of men and women in the upbringing and development of their children ...

Substantive provisions

In article 1, 'discrimination against women' is defined as 'any distinction, exclusion or restriction made on the basis of sex' which results in the impairment of women's enjoyment of their human rights. Apart from this prohibition on discrimination, article 4 of CEDAW explicitly allows affirmative action for the purpose of benefiting women.

Other provisions of CEDAW deal with women's civil and political rights,[308] their social, economic and cultural rights[309] and marriage and family rights.[310]

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306 eg Convention on the Political Rights of Women and the Convention on the Consent to Marriage.

307 Nowak 87.

308 Arts 7 – 9 CEDAW.

Special provision is made with regard to trafficking in women[311] and the problems facing rural women.[312]

Of particular interest for the present investigation is article 12 of CEDAW. State parties are compelled to take 'all appropriate measures' to eliminate discrimination in the field of health care; to ensure 'access to health care services, including those related to family planning'.[313] Women should also be assured of appropriate services in connection with pregnancy, confinement and the post-natal period, 'granting free services where necessary'.[314]

Art 12 of CEDAW corresponds, in some aspects, with article 12 of the ICESCR which also deals with health. Both provisions ensure 'access' to health only, and, in the ICESCR, the right is qualified by 'steps to achieve the full realisation of this right'. However, the obligation on state parties in CEDAW to eliminate discrimination in health services is without qualification.

Implementation procedures

A 23-member Committee on the Elimination of Discrimination against Women monitor state parties in the fulfilment of their obligations under CEDAW to eliminate discrimination against women in all spheres of life.[315] The state reporting procedure is mandatory for all state parties.[316] Upon examining state reports, the Committee makes country-specific observations, as well as general recommendations.[317] There is no inter-state complaints procedure under CEDAW.[318]

Initially, the Committee simply examined state reports, but it has been instrumental in the adoption by the UN General Assembly in 1999 of an Optional Protocol to CEDAW which allows for an individual communications procedure and an enquiry procedure.[319] The Optional Protocol entered into force in December 2000.[320]

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309 Arts 10 – 14 CEDAW.
310 Art 16 CEDAW.
311 Art 6 CEDAW.
312 Art 14.
313 Art 12(1).
314 Art 12(2).
315 Nowak (n 23 above) 86 – 87.
316 Art 18 CEDAW.
317 Nowak 87.
318 As above. For a feminist critique of human rights which draws upon CEDAW, see Charlesworth *et al* 'Feminist approaches to international law' (1991) 85 *American J Intl L* 613.
319 Nowak 87 – 88.
320 GA Res 54/4 of 6 October 1999, entry into force on 22 February 2000. There are 51 states parties to the Optional Protocol.

ii) CRC

Background

CRC reflects a realisation that the specific needs and rights of children require specialised recognition and protection, and that the family is of utmost importance in this regard.[321]

> *Convinced* that the family, as the fundamental group of society and the natural environment for the growth and well-being of all its members and particularly children, should be afforded the necessary protection and assistance so that it can fully assume its responsibilities in the community,
>
> *Recognising* that the child, for the full and harmonious development of his or her personality, should grow up in a family environment, in an atmosphere of happiness, love and understanding ...

The importance of the child's culture and traditions is not neglected:[322]

> *Taking* due account of the importance of the traditions and cultural values of each people for the protection and harmonious development of the child ... .

Substantive provisions

CRC includes a comprehensive selection of civil and political and economic, social and cultural rights, as well as rights that are specific to children.[323] It is the first treaty to place the different generations of rights on an equal footing.[324]

Article 1 of CRC defines a 'child' as every human being below the age of 18 years. Article 2 guarantees every child the enjoyment of the rights in the Convention free from discrimination, and state parties have to ensure that enjoyment to children within their jurisdiction.

Article 3 of CRC provides that in all actions affecting the child the 'best interests of the child must be a primary consideration'. In other words, every decision taken regarding children must have their enhanced growth and development as the purpose, regardless of whether it is made by a private or a public institution, courts of law, administrative authorities or legislative bodies.

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321 Preamble CRC.

322 Preamble CRC.

323 For example, development of children's identity, rights against arbitrary separation from parents and to engage in play and recreational activities.

324 Nowak (n 23 above) 93. Civil and political rights are included in the same document with social, economic and cultural rights.

Article 4 obliges state parties to CRC to undertake all appropriate measures to implement the rights recognised in the CRC. The availability of resources limits social, economic and cultural rights.[325]

Among other rights included in CRC are the child's right to life and development;[326] access to information, which includes the encouragement of state parties to produce and disseminate children's books;[327] the primary responsibility of parents in bringing up their children;[328] the rights of disabled children;[329] the child's right to benefit from social security;[330] an adequate standard of living;[331] the right to education;[332] the right of children belonging to minorities to enjoy his or her culture, religion or language;[333] the right to rest and leisure;[334] and the right to be protected from economic exploitation.[335]

Of interest to the present study is article 24 which guarantees the child's right to the enjoyment of the highest attainable standard of health. Subsection 2 lists a number of steps to be taken by state parties to effect the realisation of this right. These are measures to diminish infant mortality;[336] the provision of medical assistance and health care to all;[337] to combat disease 'through the application of readily available technology';[338] appropriate pre- and post-natal health care for mothers[339]; education on health and accidents;[340] and 'the development of preventive health care'.[341]

Further, traditional practices prejudicial to the health of children are to be abolished.[342] This sub-section is directed at harmful cultural practices, such as

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325 Art 4 CRC.
326 Art 6 CRC.
327 Art 17 CRC.
328 Art 18 CRC.
329 Art 23 CRC.
330 Art 26 CRC.
331 Art 27 CRC.
332 Arts 28 – 19 CRC.
333 Art 30 CRC.
334 Art 31 CRC.
335 Art 32 CRC.
336 Art 24(2)(a).
337 Art 24(2)(b).
338 Art 24(2)(c).
339 Art 24(2)(d).
340 Art 24(2)(e).
341 Art 24(2)(f).
342 Art 24(3) CRC.

female genital mutilation.[343] Finally, state parties shall undertake steps which promote and encourage international co-operation with a view to progressively realising the rights recognised in section 24.[344]

Implementation procedures

The monitoring of state compliance with treaty obligations is carried out by the Committee on the Rights of the Child.[345] The Committee oversees a mandatory state reporting procedure in terms of article 44 of CRC. There is no provision for inter-state complaints or for individual communications.

The UN Committee on the Rights of the Child considers four principles fundamental to the CRC.[346] These four principles underpin the entire Convention. They are the prohibition of discrimination;[347] the right to participation of children;[348] the right to life and development of the child to the maximum extent;[349] and that the best interests of the child shall be a primary consideration in all actions concerning children.[350]

Two Optional Protocols to CRC have been adopted. Each focuses on a specific problem relating to children's human rights. They are the Optional Protocol on the Involvement of Children in Armed Conflicts,[351] and the Optional Protocol on the Sale of children, Child prostitution and Child pornography.[352]

4.3 The regional systems

4.3.1 Introduction

Regional systems for the protection of human rights are an important part of international human rights protection. After domestic remedies are exhausted, usually it is to the regional system that victims of human rights violations turn.

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343 See generally in this regard, Kaime 'The Convention on the Rights of the Child and the cultural legitimacy of children's rights in Africa: Some reflections' (2005) 5 *African Human Rights L J* 221.

344 Art 24(4) CRC.

345 Art 43 CRC.

346 Nowak (n 23 above) 93.

347 Art 3 CRC.

348 Art 12 CRC.

349 Art 6 CRC.

350 Art 3 CRC.

351 GA Res 54/263 of 25 May 2000, entry into force on 12 February 2002, 52 state parties.

352 GA Res 54/263 of 25 May 2000, entry into force on 18 January 2002, 51 state parties.

Consequently, the regional system is a rich source of human rights jurisprudence, to be drawn upon by judges in domestic jurisdictions.[353]

The following paragraphs outline the three regional systems for the protection of human rights; namely, the European system, the Inter-American system and the African system.[354] Because of its relevance to HIV-related clinical research in Africa, the African system is discussed in greater detail than the other two systems.

4.3.2 The European system

Background

The European system for the protection of human rights dates back to 1949.[355] The European system was established by a group of western European nations with the goal of preserving individual freedom and democracy.[356] The system is the oldest regional system, and, is also, arguably, the most effective in its enforcement of human rights.

The European system's human rights law is founded on the European Convention for the Protection of Human Rights and Fundamental Freedoms[357] and the European Social Charter.[358] The European Convention deals with civil and political rights; the Charter deals with economic and social rights. Each treaty establishes its own monitoring mechanism.

The European Convention was signed on 4 November 1950 and entered into force on 3 September 1953.[359] Although ratification of the Convention was not initially required of the members of the Council of Europe;[360] all existing members have ratified the Convention and the Council of Europe has subsequently made the ratification of the Convention a precondition to admission to the Council.[361]

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353 See ch 5 below.

354 For a schematic comparison of the three regional systems, see Heyns *et al* 'A schematic comparison of regional human rights systems: An update' (2005) 5 *African Human Rights L J* 308.

355 Nowak (n 23 above) 158; Buergenthal (n 223 above) 102.

356 As above.

357 It has 45 ratifications. From now on referred to as the 'European Convention'.

358 Buergenthal 102. The European Social Charter is from now on referred to as the 'Charter'.

359 Buergenthal 103.

360 Founded in 1949 by eleven western European states to promote human rights, the rule of law and pluralistic democracy (Nowak 158).

361 Buergenthal 103.

Substantive provisions

The Convention guarantees most of the traditional civil and political human rights. These include the right to life; the right not to be subjected to torture, inhuman or degrading punishment; freedom from slavery; the right to liberty and security of the person; due process of law; freedom of thought, conscience and religion and freedom of expression.

Article 13 of the European Convention stipulates that an 'effective remedy before a national court must be provided to anyone whose rights had been violated'. Also, 'everyone' within the 'jurisdiction' of the state parties is a bearer of the rights in the European Convention, regardless of their nationality.[362]

Several protocols have been appended to the European Convention, each adding to and expanding upon the rights guaranteed in the European Convention. For example, Protocol 1 deals with the right to own property, the right to education, and the right to free and secret elections at regular intervals; Protocol 6 abolishes the death penalty in member states.

Implementation procedures

The adoption in 1998 of the 11th Additional Protocol to the European Convention[363] dramatically changed the implementation mechanism of the European system.[364] Before the 11th Protocol, the European Convention had two mechanisms to ensure the observance of rights: the European Commission of Human Rights (European Commission) and the European Court of Human rights (European Court).[365] The process to bring a complaint before and after the adoption of the 11th Protocol is briefly outlined below.

The European Commission consisted of members equal in number to the 'high contracting parties' to the European Convention.[366] The European Court consisted of judges equal in number to that of the Members of the Council of Europe.[367] The judges served nine-year terms; in their individual capacities; they

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362 Art 1 European Convention.
363 Entering onto force on 1 November 1998 (Nowak 164).
364 Nowak 164.
365 The Committee of Ministers has a supervisory role in relation to overseeing the enforcement of rights (Buergenthal 106).
366 Buergenthal 107.
367 Art 38 European Convention; Buergenthal 107.

had to be of 'high moral character'; and 'possess the qualifications required for appointment to high judicial office or jurisconsults of recognised competence'.[368]

Strasbourg was the seat of the European Commission and Court, but is now the seat of the European Court.[369]

The rights guaranteed by the European Convention are enforced at a national (domestic) and an international level.[370] In a substantial number of member states, the European Convention enjoys the status of national law, and, thus, it may be invoked in the national courts[371] and it creates rights that are directly enforceable by individuals.[372] Only when domestic law does not remedy the violation may the victim turn to the European Court and Commission.[373]

The European Commission allowed for inter-state complaints. In ratifying the European Convention, states were deemed to have accepted the jurisdiction of the European Commission.[374] The requirement of exhausting domestic remedies applied to cases heard in front of the European Commission as well.[375]

Only a small number of inter-state complaints have been lodged with the European Commission.[376] Mostly, the complaints have been against states who have not acknowledged the right of individual's petitioning,[377] however, states have not been eager to lodge complaints against other states in case it is seen as an act of hostility.[378]

The European Commission could hear private petitions for violations of the Convention in terms of art 25 of the European Convention.[379] To be effective, a special declaration in terms of art 25(1) was required and was not automatic upon signing the European Convention. Most state parties accepted the Commission's jurisdiction to deal with private complaints.[380] Further, natural and juristic persons could approach the European Commission.[381]

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368 Art 38(3) European Convention.
369 The new Court also has its seat in Strassbourg.
370 Nowak 160.
371 Nowak 160; Buergenthal 108.
372 As above.
373 Art 26 European Convention; Buergenthal 109.
374 Art 24 European Convention, Buergenthal 110.
375 Arts 26 – 27 European Convention; Buergenthal 110.
376 Nowak 161; Buergenthal 111.
377 As above.
378 Buergenthal 112.
379 Buergenthal 112.
380 Buergenthal (n 223 above) 112.
381 As above.

Private petitions were examined in different stages by individual rapporteurs, committees or by the plenary Commission.[382] Upon their being received, individual complaints were assigned to a commission member designated as a rapporteur. The rapporteur prepared a report on the complaint's admissibility and decided whether to refer the matter to a committee or a chamber.[383]

A chamber dealt with cases 'which can be dealt with on the basis of established case law' or which raised no serious questions related to the application and interpretation of the European Convention.[384] Other complaints were dealt with by the plenary Commission.[385] On the other hand, inter-state complaints went directly from the rapporteur to the plenary Commission.[386]

Only about 10 to 15 per cent of cases have been declared admissible and have proceeded to a hearing by the Commission.[387] The Commission first investigated the facts of the case; it held interviews, received written submissions and examined witnesses.[388] During the process, the Commission sought at the same time to achieve a friendly settlement between the parties.[389] If a settlement was reached, it consisted of an agreement in terms of which the respondent state undertook to pay damages or make amends. This agreement or settlement did not include any admittance by the state that it had violated the convention.[390]

Cases that were not settled in this manner proceeded to the next stage in which the Commission drew up a report stating its opinion on whether the facts disclosed were a breach of the Convention.[391] The report was drafted in the form of a judicial opinion but was not a judgment;[392] and was then given to the Committee of Ministers, along with the Commission's recommendations.[393] The Commission and the parties then had three months within which to refer the case to the Court, failing

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382 Art 20 European Convention, as amended by Protocol 8.
383 Buergenthal 123.
384 Art 20(2) European Convention, Buergenthal 123.
385 Art 20(5) European Convention; Buergenthal 124.
386 As above.
387 Buergenthal 124.
388 Art 28(1)(a) European Convention.
389 Art 28(1)(b) European Convention; Buergenthal 125.
390 Buergenthal 126. This friendly settlement is then recorded in a report of the Commission (art 28(2) European Convention).
391 Buergenthal 126; art 28(2) European Convention.
392 As above. It is not a judgment as the Commission cannot formally decide the case.
393 Buergenthal 126; arts 31(2) and 31(3) European Convention.

which, the Committee of Ministers decided whether there had been a violation of the Convention.[394]

The Plenary Commission took the decision whether or not to refer a case to the Court. Until the entry into force of Protocol 9, individuals were unable to refer a case to court.[395]

If a case had not been referred to the Court within the three months time period, the Committee of Ministers decided whether there had been a violation of the Convention.[396] The Committee of Ministers consisted of the foreign ministers, or their deputies, for each member state of the Council of Europe, and it was, therefore, a political, rather than a judicial, body.[397]

A decision by the Committee of Ministers that there had been a violation of the Convention required a two-thirds majority vote, and the state parties to the dispute were allowed to vote.[398] The decision of the Committee of Ministers, in accordance with article 32, were binding upon the state parties to the Convention, and a time limit could be imposed upon states to comply with the decision of the Committee of Ministers.[399]

Article 54 of the European Convention declared the Committee of Ministers shall ensure the implementation of the Court's decision and 'shall supervise its execution' by means of two rules of its procedure: rule 1 which determines that a judgment of the Court shall be put on the Committee's agenda, and rule 2 by which the state concerned must indicate what it has done to comply with the decision of the Court.[400] If the state failed to comply with the order of the Court, the item was automatically placed on the Committee's agenda to be considered within six months.[401]

In 1998, after the adoption of the 11th Protocol, a single and permanent European Court was established to take over from the earlier Commission and Court.[402] Before this the Commission and Court had been staffed by voluntary part-

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394 Buergenthal 127; art 32 European Convention.
395 Buergenthal 127. This remains a problem for individuals from states who have not ratified this protocol.
396 Art 32(1) European Convention.
397 Buergenthal 128.
398 Buergenthal 128.
399 Buergenthal 130.
400 Buergenthal 131.
401 Buergenthal 131.
402 Nowak (n 23 above) 164.

time commissioners and judges, but now they have been replaced by full-time, permanent staff. [403]

The 11th Protocol deletes the clauses which make access to the Court optional, with the consequence that individual and inter-state complaints procedures before the new Court are compulsory for all states parties.[404] The role of the Committee of Ministers in the decision-making procedure was done away with, instead it oversees the execution of the Court's judgments at the domestic level, streamlining the process.[405]

The Court is the only body to decide on the admissibility and merit of complaints, and is able to deal with a far greater number of cases than before, including the steep rise in individual complaints.[406]

Nowak sums up the consequences following the adoption of a single Court as follows:[407] the length of proceedings is shortened; the judicial character of the system is strengthened; the adjudicative role of the Committee of Ministers has been abolished; the European Commission of Human Rights has been abolished; and the optional clauses concerning individual complaints and the jurisdiction of the Court have been removed.[408]

The European Court's caseload increased dramatically after the change brought about by the 11th Protocol. In 2004, the European Court delivered 21 191 decisions and 718 judgments; by the end of 2004, 78 000 applications were pending before the Court; and an astonishing 44 100 communications have been lodged.[409]

European Social Charter

Background

The European Social Charter was opened for signature in 1961 and entered into force on 26 February 1965.[410] The European Social Charter establishes a system for the protection of social, economic and cultural rights. Nowak remarks that the European community through the years paid lip service to the indivisibility and

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403 As above.
404 Nowak 164.
405 As above.
406 As above.
407 Nowak 165.
408 For a clear schematic exposition of the new procedure before the Court, see Nowak 172.
409 Heyns *et al* (n 354 above) 308 - 311.
410 Nowak 173; Buergenthal 151. It is established under the auspices of the Council of Europe.

interdependence of human rights; they have done little to change the inequality of the two classes or categories of rights.[411] The European Social Charter is still regarded as the 'little sister' of the better known European Convention.[412]

Substantive provisions

The European Social Charter includes 19 categories of rights, including the right to work, to bargain collectively and to fair remuneration. It recognises the right of the family to social, legal and economic protection, as well as the right to protection of health, to social security, and to social and medical assistance.[413]

Implementation procedures

The European Social Charter system establishes a reporting system to monitor state parties' compliance with the Charter and Protocol.[414] Two types of reports are necessary: the first, due every two years, addresses domestic implementation of the rights in the Charter;[415] the second deals with the status of the rights that the particular state did not accept upon ratifying the European Social Charter.[416] These reports are examined by different bodies of the Council of Europe.[417]

Additional protocols, extending the rights protected by the Social Charter, have been added. The first Additional Protocol of 1988, entered into force in 1992, but has been ratified by eleven states only.[418] This Protocol supplements the list of social and economic rights guaranteed, adding four further 'rights and principles'; namely, the right of workers to equal treatment and non-discrimination on the grounds of sex, the right to take part in the improvement of working conditions and the right of elderly persons to social protection.

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411 Nowak 173.
412 As above.
413 In accordance with art 20 of the European Charter, states parties are allowed to 'selectively' ratify the rights they want to be bound to – this is called an 'opting in' system or an '*a la carte*' ratification system.
414 Buergenthal 155.
415 Art 21 European Social Charter; Buergenthal 155.
416 Buergenthal 154.
417 Buergenthal 154.
418 Nowak 173.

A Protocol Amending the European Social Charter was signed in 1991. This Protocol has nineteen state parties.[419] A third protocol provides for a system of collective complaints and was adopted in 1995. It has ten state parties.[420]

The Revised European Social Charter entered into force in 1999. As well as adding rights to the Charter, the revision replaces the Committee of Independent Experts of the earlier Charter with a European Committee of Social Rights to assess state compliance with their obligations under the European Charter.[421] The Committee's conclusions still have to be submitted to a Council of Europe Government Committee and accepted in a Committee of Ministers by a two-thirds majority vote.[422]

The Revised European Social Charter co-exists with the original Charter.[423] It has been ratified by 19 of the 45 European Council members. The others continue to adhere to the original Charter of 1961.[424]

Several additional treaties, each with a specific focus on a specific problem or aspect of human rights protection, have been adopted under the European system. Among these are the European Convention for the Prevention of Torture,[425] the European Framework Convention for the Protection of National Minorities,[426] the European Charter for Regional and Minority Languages[427] and the European Convention on Human Rights and Biomedicine,[428] which is of particular importance to the present study.

European Convention on Human Rights and Biomedicine

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419 Nowak 173. This protocol was superseded by the Revised European Social Charter.

420 A collective complaints system differs from the individual complaints system in that it does not recognise individual complaints, but rather collective complaints through NGOs (Nowak 176).

421 Nowak 175.

422 Nowak 175.

423 Nowak 176.

424 Nowak 176. The unrevised Social Charter has 27 ratifications. For more on the European system for the protection of human rights, see Cameron (2002) *An introduction to the European Convention on Human Rights* (4th ed); Ovey *et al* (2002) *Jacobs and White: The European Convention on Human Rights.*

425 Opened for signature 26 November 1987 and entered into force on 1 February 1989. It has 44 states parties.

426 Opened for signature on 1 February 1995, entered into force on 1 February 1998. It has 35 states parties

427 Opened for signature on 5 November 1992, entered into force on 1 March 1998. It has 17 states parties.

428 Opened for signature on 4 April 1997, entered into force on 1 December 1999. It has 19 states parties.

The European Convention on Human Rights and Biomedicine (European Biomedicine Convention) is an 'open' convention, in the sense that it is open for signature to non-Council of Europe member states.[429] Nevertheless, no state outside of Europe has signed the Convention.

Nowak designates as challenges to human rights protection developments in biomedicine and biotechnology:[430]

> It is to be said though that it is not states which primarily threaten the dignity of human beings, but mostly private persons (in science, economy or private health care). Thus, the question for states and international organisations is not so much to what extent state interventions are to be prohibited, but whether in fact the positive state obligation to protect and ensure life, dignity and privacy of human beings today and in the future is sufficient protection against the interventions on the part of science and economy.

The European Biomedicine Convention applies the language of human rights to issues formerly regarded as purely within the ambit of medical and research ethics. For this reason it is a revolutionary document, which transforms principles of ethics into justiciable human rights norms.[431]

The European Biomedicine Convention guarantees a large number of substantive rights, some of which are viewed as novel formulations of rights that are already in existence, such as the principle of informed consent already contained in the right to human dignity and privacy.[432]

The general provisions of the Convention recognise the primacy of the human being, whose welfare takes precedence to the interests of science or of society.[433] Other rights in the European Biomedicine Convention include: equitable access to health care;[434] the right to the protection of human dignity, identity and integrity;[435] the principle that free and informed consent should be given to every health-related intervention;[436] the right to information;[437] issues related to scientific research;[438]

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429 Nowak 182. The idea was to extend the protection of the Convention as far as possible.

430 Nowak 179 – 180.

431 For more on the European Biomedicine Convention, see Rosenau 'Legal prerequisites for Clinical trials under the revised Declaration of Helsinki and the European Convention on Human Rights and Biomedicine' (2000) 7 *European J Health L* 105.

432 Nowak (n 23 above) 183.

433 Art 2 European Biomedicine Convention.

434 Art 4 European Biomedicine Convention.

435 Art 1 European Biomedicine Convention.

436 Art 5 European Biomedicine Convention.

437 Ch III European Biomedicine Convention.

438 Ch V European Biomedicine Convention.

prohibitions against genetic manipulation;[439] and a prohibition against the use of the human body or its parts for financial gain.[440] Article 27 states that national law granting more far-reaching protection is not affected by the European Biomedicine Convention, thus making the Convention a minimum standard of protection.

The European Biomedicine Convention is supplemented by two additional protocols, the Additional Protocol on the Prohibition of Cloning of Human Beings;[441] and the Additional Protocol on Transplantation of Organs and Tissues of Human Beings.[442]

Because there is no clause in the European Biomedicine Convention that makes provision for a specific treaty monitoring body, the international monitoring system of this treaty is considered particularly weak.[443] Reports by states parties are submitted only upon request by the Secretary-General of the Council of Europe, and not as a matter of course.[444] This state of affairs is regrettable, as the European Biomedicine Convention has the potential to make a significant contribution in the protection of human rights in biomedicine.

4.3.3 The Inter-American system

The Organization of American States[445] includes 35 member states in the Americas and was established in 1948.[446] The functions of the OAS are fulfilled by its General Assembly, the policy-making body of the OAS.[447] Each member state has one vote in the General Assembly.[448] The Permanent Council consists of the permanent representatives of the member states of the OAS, and functions as the OAS's decision-making body between sessions, as well as fulfilling various other functions.[449] Both the General Assembly and the Permanent Council have jurisdiction in matters relating to human rights.[450]

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439 Arts 11 – 13 European Biomedicine Convention.
440 Art 21 European Biomedicine Convention.
441 Opened for signature on 12 January 1998, entered into force on 1 March 2001. It has 13 states parties.
442 Opened for signature on 24 January 2002, not yet in force. One state party only.
443 Nowak 183.
444 Nowak 182.
445 Referred to as the 'OAS' from now on.
446 Heyns *et al* (n 354 above) 309.
447 Nowak (n 23 above) 190; Buergenthal (n 223 above) 175.
448 Buergenthal 175.
449 Buergenthal 175.
450 Buergenthal 175.

Human rights protection in the Inter-American system is based on two documents – the Charter of the OAS and the American Convention on Human Rights.[451] The Charter applies to all member states of the OAS, while the American Convention on Human Rights binds only state parties that have signed and ratified the Convention.[452] The two systems overlap and the same case often draws on both the Charter and the Convention.[453]

The OAS Charter was opened for signature in 1948 and entered into force during 1951.[454] The Charter was amended by the Protocol of Buenos Aires of 1967, which came into force in 1970, and by the Protocol of *Cartagena de Indias*, Columbia of 1985, which came into force in 1988.[455] There are two later amendments to the Charter, the Protocols of Washington and Managua.[456]

The Charter functions as the constitution of the OAS.[457] It makes few references to human rights, most notably in articles 3(j), 3(k) and 16 which refer to civil and political rights as well as to socio-economic rights. The diplomatic conference that adopted the Charter also proclaimed the American Declaration of the Rights and Duties of Man.[458]

The Protocol of Buenos Aires brought about important changes in the protection of human rights in the Inter-American system. It established the American Commission on Human Rights as a Charter organ and described the Commission's main objective to be the protection and advancement of human rights.[459]

The American Declaration of the Rights and Duties of Man proclaimed on 2 May 1948 lists 27 human rights and ten duties.[460] It includes civil and political rights as well as socio-economic rights.[461] The classic civil and political rights, such as privacy, property, equality, health and so on are protected. The duty to society, to children, to parents and to vote, to receive instruction and to obey the law are declared as well. Initially, the Declaration was a non-binding resolution of the

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451 Nowak 191; Buergenthal 175.
452 As above.
453 As above.
454 Buergenthal 177.
455 Buergenthal 178.
456 Buergenthal 178.
457 Buergenthal 177.
458 Buergenthal 178.
459 Arts 52(e) and 111 OAS Charter; Buergenthal 179.
460 Buergenthal 179.
461 Buergenthal 179.

conference and without any legal effect. Today it is considered the main normative instrument of the 'fundamental rights of the individual' in article 3(1) of the current OAS Charter.[462] For Buergenthal, too, it 'embodies the authoritative interpretation' of the Charter.[463]

The Inter-American Commission on Human Rights was mandated in 1959 by a meeting of the Consultation of Ministers of Foreign Affairs.[464] In 1960 the OAS Council adopted the Statute of the Commission and elected the first Commissioners.[465] Article 1 of the Statute proclaims it an autonomous entity of the OAS.[466] Article 2 defines the human rights to be protected by the Commission as those listed in the American Declaration of the Rights and Duties of Man.[467]

The Commission has various powers to promote and protect human rights, including the power to make studies and to prepare reports on human rights in the member states.[468] The Commission undertakes so-called 'country studies' investigating the human rights situation in member states.[469]

In 1965 the Second Special Inter-American Conference authorised the Commission to hear individual petitions on the violation of human rights by member states.[470] This concession applies to only certain rights: the right to life, liberty and security of the person, equality before the law, freedom of religion, freedom of expression, freedom from arbitrary arrest, and the right to due process of the law.[471]

In 1970, with the entry into force of the Protocol of Buenos Aires, the 1948 Charter was amended and the Inter-American Commission was transformed into a formal organ of the OAS.[472] The main function of the Commission is to promote the observance and protection of human rights.[473]

The Inter-American Convention on Human Rights was adopted in 1978 and is binding upon states that ratify it. The Inter-American Convention on Human Rights has been ratified by 24 OAS member states.[474] The Convention guarantees a large

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462 Nowak 191.
463 Buergenthal 180.
464 Nowak 193; Buergenthal 181.
465 As above.
466 As above.
467 Buergenthal 181.
468 Nowak 193; Buergenthal 182.
469 Nowak 193.
470 Nowak 193; Buergenthal 182.
471 Buergenthal 182 – 183.
472 Buergenthal 183.
473 Arts 52 & 111(1) OAS Charter.
474 Nowak 196; Heyns *et al* (n 354 above) 309.

number of civil and political rights, including the right to life; to humane treatment; to freedom from slavery; a right to personal liberty; a right to a fair trial; to freedom of association; to freedom of movement and residence.[475] State parties also undertake, 'progressively', to realise the rights 'implicit in the economic, social, educational, scientific and cultural standards set forth in the Charter of the OAS'.[476]

The Convention has provided for the establishment of the Inter-American Commission on Human Rights and an Inter-American Court on Human Rights.[477] Each consists of seven members, elected in their personal capacities.[478] The Commission has its seat in Washington, DC; the Court in San Jose, Costa Rica.[479] Both bodies hold at least two regular sessions each year.[480] The Inter-American Commission has a dual function: first in relation to all member states of the OAS, second in relation to the parties to the Convention of 1978.[481] Most of the Commission's work relates to country studies and to the examination of individual petitions.[482] Country studies may be initiated by individual complaints or by reports from NGOs that large-scale human rights violations are taking place in a certain member state. The Commission performs on-site investigations into a specific member state to examine a human rights issue.[483]

The Commission also performs a variety of other functions as a Charter organ, including helping to draft OAS human rights instruments; sponsoring conferences; publishing human rights documents and pamphlets; and acting as a consultant to the OAS on human rights issues.[484] It has played an important role in mediating and in protecting human rights during civil wars and armed conflict.[485]

Concerning individual complaints, article 20 of the Statute of the Commission enables the Commission to hear individual complaints on any of the rights enumerated in the Declaration.[486] However, individual complaints may be directed against states that are not parties to the Convention. In that case the decisions of

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475 Nowak 196.
476 Art 26 American Convention on Human Rights.
477 Art 33 American Convention on Human Rights; art 106 OAS Charter (Nowak 193).
478 Buergenthal 198.
479 Buergenthal 198.
480 Buergenthal 198.
481 Arts 41(f), 44 – 51 Inter-American Convention on Human Rights; Buergenthal 184.
482 Buergenthal 187.
483 Buergenthal 189.
484 Buergenthal 186.
485 Buergenthal 186.
486 Art 20 Statute of the Inter-American Commission, no longer limited to the preferred freedoms; Buergenthal 193.

the Commission are sent to the General Assembly, which has shown scant interest in dealing with individual petitions, and, therefore, is not as effective a mechanism for the protection of human rights as is the system based on the Convention. [487]

The Commission's mandate to 'take action on petitions and other communications'[488] allows it to deal with individual and inter-state communications.[489] Article 44 determines that a state by becoming a party to the Convention is deemed to have consented to the individual complaints mechanism. Under the American Convention, not only the individual victim of a violation may petition the Commission, but also other persons or a group on their behalf.[490] The admissibility of a petition is conditional on the exhaustion of domestic remedies and on submission within six months of the victim being notified of the final domestic judgment.[491] The Commission may deal with inter-state complaints if both states accept its jurisdiction to receive such complaints.[492]

The Commission examines the allegation, requests information and investigates the facts.[493] The Commission calls a hearing on the matter in which all parties, including the government, participate.[494] According to article 48(b), the Commission is to 'place itself at the disposal of the parties concerned with the view to reaching a friendly settlement'.[495]

If a settlement is not reached, the Commission draws up a report containing the facts of the case and the conclusions it has reached.[496] The report is transmitted to the government of the state concerned, which has three months to comply with the recommendations or findings of the report.[497] During this period the case may be submitted to the Inter-American Court of Human Rights by the Commission.[498]

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487 Buergenthal 194.
488 Art 41 American Convention on Human Rights.
489 Art 44 – 45 American Convention on Human Rights.
490 Art 44 American Convention; Buergenthal 200.
491 Art 46(1) American Convention on Human Rights; Buergenthal 200. A petition may still be submitted if there were no domestic remedies or if there was no access to domestic remedies or if there was a delay in accessing these remedies (art 46(2).
492 Art 45 American Convention; Buergenthal 204. No such case has reached the Commission to date. The Commission also deals with the petitioning system under the OAS Charter system.
493 Buergenthal 2002.
494 Buergenthal 2002.
495 If such a friendly settlement is obtained, the Commission issues a report containing the facts of the case and the settlement obtained (Buergenthal 2002).
496 Art 50 American Convention on Human Rights; Buergenthal 2003.
497 Buergenthal 2003.
498 Buergenthal 2003.

If a case had not been settled or referred to the Court, article 51(1) determines that the Commission votes on the matter.[499] After a majority vote which agrees that the Convention has been violated, the Commission sets out its recommendations in a report and prescribes a period within which the state is to comply with its recommendations.[500] After the period has expired, the Commission must decide whether the state has complied with its recommendations.[501] The Commission may also decide to publish its report.[502] Although the report and its findings are not formally binding, as would be the decision of a court, it is still an 'authoritative legal determination'.[503] The matter may be placed on the agenda of the General Assembly, in which the report will discussed and may be acted upon.[504]

The Commission may refer cases to the Inter-American Court[505] and the Commission appears in all cases before the Court[506] as a '*Ministerio Publicd*' or protector of the legal order established under the Convention.[507] The Commission may request advisory opinions from the Court.[508]

The Inter-American Court of Human Rights has both contentious and advisory jurisdiction.[509] Article 62 of the American Convention determines that a state party merely by ratifying the Convention does not accept the contentious jurisdiction of the Court.[510]

State parties alone are permitted to bring a case to the Court;[511] individuals have to rely on the Commission or a state to bring a case on their behalf. Before the case reaches the Court, the relevant Commission proceedings applicable to it must have been completed.[512] Thus, the Commission first deals with a case before it is admitted to the Court.

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499 Buergenthal 2003.
500 Art 51(2) American Convention; Buergenthal 204.
501 Art 51(3) American Convention; Buergenthal 2004.
502 As above.
503 Buergenthal 205.
504 Buergenthal 204.
505 Art 61 American Convention; Nowak 192; Buergenthal 205.
506 Art 57 American Convention; Nowak 192; Buergenthal 205.
507 Buergenthal 206.
508 Buergenthal 206.
509 Buergenthal 207.
510 It is required further to make a special declaration to accept the jurisdiction, or enter into a special agreement to the effect (art 62).
511 Art 61(1) American Convention.
512 Art 61(2); Buergenthal 209.

Once a case is admitted, the Court may fully review the Commission's finding as to the facts of the case and the applicable law.[513] The judgment of the Court is final and cannot be appealed.[514] Article 68(1) determines that state parties undertake to comply with the decisions of the Court in any matter to which it is a party.

Article 63(1) determines that the Court may award money as compensation or render a declaratory judgment if it finds a violation of the Convention. A declaratory judgment will often include an order on how the offending state may rectify the situation.[515]

Article 65 of the Convention requires the Court to inform the OAS General Assembly of instances where the state party has not complied with its judgment. The General Assembly will then take the political measures it deems necessary to enforce the decision of the Court.[516]

Article 63(2) of the American Convention authorises the Court to issue temporary restraining orders or provisional measures.[517] The authorisation applies as well to cases before the Commission that have not yet reached the Court.

The Court's advisory jurisdiction is very broad. According to article 64 of the American Convention, it includes the interpretation of the Convention, or any other human rights treaty,[518] and advising a state party on the compatibility of its domestic laws with any of the provisions of the Convention.[519] The Court has rendered a substantial number of advisory opinions during its existence.[520]

Advisory opinions are not legally binding. They do, however, put a state 'on notice' that its actions are not complying with its obligations under the Convention.[521]

By the entry into force on 1 May 2001 of the new Rules of Procedure of the Inter-American Commission, petitioners are now entitled to request the Commission to refer cases on their behalf to the Court if it finds a violation.[522] The Commission is

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513 Buergenthal 211.
514 Art 67 American Convention; Buergenthal 212.
515 Buergenthal 213; Nowak 194.
516 Buergenthal 215.
517 Buergenthal 215; Nowak 194.
518 Art 64(1).
519 Art 64(2).
520 Buergenthal 218; Nowak 194 - 195.
521 Buergenthal 221.
522 Nowak 201. Nowak remarks that the new procedure resembles the 9th Additional Protocol to the European Convention.

obliged to comply with such a request unless a majority of its members vote against it.[523]

4.3.4 The African system

The African Charter on Human and Peoples' Rights (African Charter) was adopted on 27 June 1981 in Banjul,[524] The Gambia, and entered into force on 21 October 1986.[525] It has been ratified by all 53 member states of the Organization of African Unity (OAU), a regional intergovernmental organisation, and functions within the institutional framework of this organisation.[526]

In May 2001 the OAU was replaced by the African Union (AU).[527] The AU aims to achieve greater unity and solidarity between African countries and the peoples of Africa, but its further aim is to 'promote and protect human and peoples' rights in accordance with the African Charter on Human and Peoples' Rights and other relevant human rights instruments'.[528] Article 4 of the Constitutive Act of the African Union lists the principles by which the Union will function, and they include 'respect for democratic principles, human rights, the rule of law and good governance'.[529]

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523 Nowak 201. For more on the Inter-American system, see Buergenthal and Shelton (1995) *Protecting human rights in the Americas: Cases and materials* (4th ed) and Harris and Livingstone (eds) (1998) *The Inter-American system of human rights*.

524 Nowak 205. Its adoption in Banjul is the reason why the African Charter on Human and Peoples' Rights is often referred to as the 'Banjul Charter'.
For more on human rights in Africa, see Eze 'Human rights issues and violations: The African experience' in Shepard and Anikpo (eds) (1990) *Emerging human rights: The African political economy context* and Zeleza 'The struggle for human rights in Africa' in Zeleza and McConnaughay (eds) (2004) *Human rights, the rule of law and development in Africa*.

525 Nowak 203 – 204; Buergenthal 228.

526 The Organization of African Unity was founded on 25 May 1963 in Addis Ababa. All African states are members except for Morocco. The Organization of African Unity was changed to the African Union (see below).

527 The Constitutive Act of the African Union was accepted in Lomé, Togo, in July 2000, and entered into force in May 2001. The Assembly of the African Union had its inaugural meeting in Durban South Africa in July 2002.
For more on the coming into being of the African Union, see Baimu 'The African Union: Hope for better protection of human rights in Africa?' (2001) 1 *African Human Rights L J* 299 and Stefiszyn 'The African Union: Challenges and opportunities for women' (2005) 5 *African Human Rights L J* 358.

528 Art 3(h) Constitutive Act of the African Union.

529 Art 4(m) Constitutive Act of the African Union. The organs of the AU include the Assembly of the African Union, the Executive Council, the Commission, the Pan-African Parliament, the Court of Justice (now amalgamated with the African Court) and an Economic, Social and Cultural Council.

The African Charter differs from the systems discussed previously in this chapter in a number of important aspects. It includes not only rights, but duties, such as the duty to work and the duty to pay taxes.[530] It proclaims not only individual, but also collective or peoples' rights, such as the right to self-determination and the right to development.[531] Apart from guaranteeing a wide array of civil and political rights, the African Charter includes economic, social and political rights as justiciable rights on an equal footing.[532]

The African Charter has been criticised for its so-called 'claw-back' clauses.[533] Whereas other human rights instruments contain general derogation or limitations clauses that prescribe the circumstances under which rights may be limited or derogated, many of the provisions in the African Charter include these claw-back clauses.[534] Claw-back clauses are problematic as many argue that they have the potential to render rights meaningless and that they grant avenues for governments to restrict rights.[535] However, Ankumah argues that, in practice, the African Commission has construed claw-back clauses liberally so as to protect the human rights of victims of violations.[536]

The African Charter is rooted in an interpretation of African culture and tradition; the emphasis on culture and on traditional values is expressed in the Preamble which proclaims 'the virtues of historical tradition and the values of African civilization which should inspire and characterize their reflection on the concept of human and peoples' rights'. The emphasis on second generation rights is also highlighted.[537]

> *Convinced* that it is henceforth essential to pay particular attention to the right to development and that civil and political rights cannot be dissociated from economic, social and cultural rights in their conception as well as universality and that the satisfaction of economic, social and cultural rights is a guarantee for the enjoyment of civil and political rights.

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530 See also Ankumah (1996) 159 – 177; Mutua 'The Banjul Charter and the African cultural fingerprint: An evaluation of the language of duties' 35 *Virginia J Intl L* 339.

531 As above. See also Kiwanuka 'The meaning of "people" in the African Charter on human and peoples' rights' (1988) 82 *American J Intl L* 80.

532 In this regard, also see para 4.3.2 of ch 5 below.

533 Ankumah 176.

534 For example, art 9 guarantees freedom of expression, subject to 'reasons and conditions previously laid down by law'; art 10 guarantees freedom of association, so long as the person 'abides by the law'.

535 Ankumah 176.

536 Ankumah 177. See also Communication 129/94 and para 4.3.2 of ch 5 below.

537 See also Agbakwa 'Reclaiming humanity: Economic, Social and cultural rights as the cornerstone of African human rights' (2002) 5 *Yale Human Rights and Development L J* 177 and Howard 'The full-belly thesis: Should economic rights take priority over civil and political rights? Evidence from sub-Saharan Africa' (1983) 5 *Human Rights Q* 467

The African Charter requires of state parties to 'recognize the rights, duties and freedoms enshrined in this Charter and [...] undertake to adopt legislative and other measures to give effect to them'.[538] According to article 62, state parties are further required to report every two years on the legislative and other measures they have adopted to give effect to the rights listed in the African Charter. State parties should promote and ensure through education and publication respect for the rights in the African Charter,[539] and allow for the establishment and improvement of appropriate national institutions to promote and protect human rights.[540]

The African Charter establishes the African Commission on Human and Peoples' Rights (African Commission) within the institutional framework of the OAU and now the AU.[541] Article 30 of the African Charter outlines its function; it is to 'promote human and peoples' rights and ensure their protection in Africa'. The African Commission consists of eleven members, elected by the OAU Assembly of heads of States and Governments from a list of names presented by the state parties.[542] They serve for six-year terms in their individual capacities.[543] The African Commission meets twice yearly for two week sessions.

The functions of the African Commission as described in article 45 of the African Charter are both promotional and judicial in nature. It is empowered to undertake studies, convene conferences and to disseminate information to promote human and people's rights.[544] It is empowered to protect the rights enumerated in the Charter, to interpret the Charter and perform any other tasks entrusted to it by the Assembly of Heads of State and Government. According to article 45(1)(a) the African Commission may also give its views or make recommendations to governments. In this way, problems highlighted in the biannual reports submitted by the different governments may be addressed.

The African Commission has further powers to interpret human rights documents and to solve problems relating to human rights abuses. According to

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538 Art 1 African Charter.
539 Art 25 African Charter.
540 Art 26 African Charter.
541 Ankumah 1. Under the AU, the African Commission remains the implementing mechanisms for the African Charter and its protocols and all further reference to the OAU includes the AU.
542 Ankumah 13 – 16.
543 See Ankumah 18 – 19 on the independence and impartiality of the African Commission and its Commissioners.
544 Nowak 207; Ankumah 20 – 25; Buergenthal 240.

article 45(3), the African Commission has the power to interpret all the provisions of the African Charter at the request of a state party, the OAU or an African organisation recognised by the OUA.[545]

The African Charter establishes an inter-state complaint mechanism that provides for two different ways of solving disputes. First, during bilateral proceedings, article 47 of the African Charter allows one state party to bring a violation of the Charter by another state party to the attention of that state party in a formal communication which is copied to the Commission. The offending state has three months to submit a reply to the allegation. Either state may also submit the matter to the Commission during these three months or afterwards if the matter is not solved to the satisfaction of the states involved.[546] The African Commission does not necessarily play any active role in the proceedings under article 47.[547]

Second, article 49 of the African Charter allows for another inter-state procedure. It allows for direct communications to the African Commission on an alleged violation of the African Charter without first following the article 47 procedure.

For a complaint to be dealt with by the African Commission, it is required that all domestic remedies must be exhausted or it should be clear to the Commission that the procedure to exhaust these remedies will be unduly prolonged.[548]

Once the African Commission has found the complaint admissible, it embarks on an investigation of the matter, finding out the relevant facts. The African Commission may get its information from any source, not only that provided by the parties to the dispute.[549] It may hold hearings on the matter, during which oral and written submissions by the parties concerned are allowed. Again, the African Commission seeks to find an amicable solution to the process. Article 52 determines that should an amicable solution not be reached, the Commission must prepare a report, stating the facts of the matter and its findings, conclusions and recommendations.[550]

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545 Ankumah 26.

546 Art 47 African Charter.

547 See generally in this regard, Heyns 'The African regional human rights system: In need of reform?' (2001) 1 *African Human Rights L J* 162 – 165; Gutto 'The reform and renewal of the African regional system and peoples' rights system' (2001) 2 *African Human Rights L J* 175.

548 Art 50 African Charter.

549 Art 52 African Charter.

550 Art 52 – 53 African Charter.

The report is submitted to the states concerned and to the Assembly of Heads of State and Government. No further enforcement measures are provided for and it is supposed that the Assembly of Heads of State and Government will bring political pressure to bear on the offending parties.

The individual complaint procedure of the African Charter closely resembles that of the UN's ECOSOC Resolution 1503.[551] The procedure is described in article 55 of the African Charter. The way in which article 55 is phrased implies that not only victims, but also NGOs and other persons or groups may institute a complaint to the African Commission.[552] For the complaint to be considered by the African Commission, however, a majority vote of its members must support its consideration, so that there is no 'automatic' procedural right that a complaint will be considered.[553]

Other admissibility requirements are set out in article 56 of the African Charter, such as the requirement that there is an obligation to exhaust local remedies and the requirement that the victim's case not be based solely on news disseminated through the mass media.

The individual complaints procedure under the African Charter is not an example of a classic complaints procedure, for example, under the European system. Only complaints of a series of systematic and massive violations of human rights are considered admissible, in other words, violations must be large-scale in nature to be considered, individual or isolated violations of human rights are not admissible.[554]

Communications which the African Commission finds to reveal evidence of the existence of such large-scale violations of human rights must be referred to the Assembly of Heads of State and Government. Only if the Assembly of Heads of States and Government decides to request the Commission to undertake an investigation into the situation and to compile a report including its findings and recommendations, may the African Commission proceed.[555]

The Commission's investigation and subsequent report remain confidential and, unless the Assembly of Heads of State and Government gives permission for its findings to be published, the Commission cannot publish its findings. Article 59(3) further determines that the overall report of the African Commission on its activities

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551 Nowak 208; Buergenthal 244 – 245.
552 As above.
553 Nowak 208; Buergenthal 245.
554 Art 58(1) African Charter.
555 Art 58(2) African Charter.

during the year may be published only after it has been considered by the Assembly.[556] The publicity attached to the African Commission's activities, which has the potential to shame or expose violators of human rights, is, potentially, severely restricted.[557]

Both the individual and inter-state complaints procedures are designed to secure a friendly settlement between the parties to the dispute, as considered to be in keeping with an African tradition of consultation and dialogue.[558]

The Protocol to the African Charter on Human and Peoples' Rights on the Establishment of the African Court of Human and Peoples' Rights (Protocol on an African Court) was adopted on 9 June 1998 by the Assembly of Heads of States and Government.[559] The Protocol on an African Court entered into force in January 2004 and by 31 December 2006 has been ratified by 23 states.[560] The African Court of Human and Peoples' Rights (Africa Court) consists of eleven judges and has advisory and contentious jurisdiction.[561] These judges, including two women, were elected in January 2006.[562]

The Preamble to the Protocol establishing an African Court provides the reasons for the Court's creation. The African Court is necessary to 'complement and reinforce the functions of the Commission',[563] and to 'complement the protective mandate of the African Commission'.[564] The exact nature of the relationship between the Commission and the Court remains to be established.[565]

The African Court is to offer advisory opinions on any legal matter pertaining to the Charter or any other relevant human rights instruments. It is to advise on issues of the interpretation and the application of the African Charter and other human rights instruments, as well as its own jurisdiction.[566] According to article 30, judgments of the African Court will be binding. Article 28 determines that the

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556 Art 59(3) African Charter.

557 See further Mugwanya 'Examination of state reports by the African Commission: A critical appraisal' (2001) 2 *African Human Rights L J* 268.

558 Nowak (n 23 above) 211.

559 OAU/LEG/MIN/AFCHPR/PROT (1) Rev 2.

560 Heyns *et al* (n 345 above) 309. In July 2004 the AU Summit took a decision to merge the African Human Rights Court with the African Court of Justice.

561 Nowak 211.

562 See Viljoen (2007) Forthcoming.

563 Preamble Protocol on an African Court.

564 Art 2 Protocol on an African Court.

565 In this regard, see Viljoen (n 562 above) and Murray 'A feminist perspective on reform of the African human rights system' (2001) 1 *African Human Rights L J* 15 – 17.

566 Art 3 Protocol on an African Court.

judgments of the Court are final and not subject to the right of appeal. State parties undertake to comply with the African Court's judgments and to guarantee their execution.[567] The Executive Council is the body responsible for monitoring the execution of the Court's judgments. According to Viljoen what this entails is unclear as yet[568] but, at a minimum, would involve 'keeping a mere record of judgments' implementation in the internal legal order of recalcitrant states'.[569] In line with other regional systems, the Executive Council should inscribe the issue of implementation by a particular state on its agenda until that state complies.[570]

Cases are to be submitted to the African Court by the African Commission; a state party which has lodged a complaint with the African Commission; or a state party against which a case has been lodged at the African Commission.[571]

Article 5(3) deals with the standing of individuals (and NGOs) before the African Court. It provides that 'the court may entitle relevant non-governmental organisations with observer status before the Commission, and individuals to institute case before it, in accordance with article 46(6) of this Protocol'. Additionally, article 34(6) requires states that have ratified the Protocol to make an additional declaration to the effect that they accept the jurisdiction of the Court in these circumstances.

Many commentators are worried that the procedures of the Court will merely replicate the problems now experienced with the African Commission, and assert that, instead of establishing an African Court, attempts should have been made to improve the functioning of the African Commission.[572] These complaints include the fact that the African Commission's findings are not enforceable against the state party concerned, and the Commission's findings are only published after the Assembly of Heads of State and Government has considered them.

On the other hand, the fact that the decisions of an African Court will be binding and enforceable against the state party concerned bodes well. Article 28 of the Protocol establishing the African Court, expressly states that the African Court's decisions will be final and that there will be no right to appeal. This statement

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567 Art 30 Protocol on an African Court.
568 Viljoen (n 562 above).
569 Naldi and Magliveras quoted in Viljoen (n 562 above).
570 Viljoen (n 562 above).
571 Arts 5 – 6, Art 30 Protocol on an African Court.
572 See eg Matua 'The African Human Rights Court: A two-legged stool?' (1999) 21 *Human Rights Q* 342; Odinkalu 'Courting the Court' (1994) *African Topics Magazine* 11; O'Shea 'A critical reflection on the proposed African Court on Human and Peoples' Rights' (2001) 2 *African Human Rights L J* 285.

encourages the hope that the Court will play a positive role in the protection of human rights on the African continent.[573]

The African system for the protection of human rights has a number of additional protocols and instruments that supplement it. These are the OAU Convention Governing the Specific Aspects of Refugee Problems in Africa,[574] the Cultural Charter,[575] the African Charter on the Rights and Welfare of the Child (Children's Charter),[576] the African Convention on the Conservation of Nature[577] and the Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa (Women's Protocol).[578] Of importance to the present study are the Children's Charter and the Women's Protocol, which are dealt with below.

The Children's Charter is similar to the UN Convention on the Rights of the Child. It contains an impressive number of children's rights, and is more comprehensive in the rights that it includes than the UN Convention on the Rights of the Child.[579]

The Preamble to the Children's Charter stresses the need for the Children's Charter:

> Noting with concern that the situation of most African children remains critical due to the unique factors of their socio-economic, cultural, traditional and developmental circumstances, natural disasters, armed conflicts, exploitation and hunger, and on account of the child's physical and mental immaturity he or she needs special safeguards and care...

The Preamble reiterates that the approach to children's rights is in keeping with 'traditional African virtues of their cultural heritage, historical background and the

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573 See also Udombana 'An African Human Rights Court and an African Union Court: A needful duality or a needless duplication?' (2003) 28 *Brooklyn J Intl L* 811.

574 Adopted in Addis Ababa on 10 September 1969, entered into force on 20 June 1974 and has 44 state parties (it has thus been ratified almost universally).

575 Adopted in Mauritius and entered into force in 1990. It deals with issues such as cultural diversity, national identity, education, language, the mass media and cultural co-operation.

576 Adopted in by the 26th ordinary session of the Assembly of Heads of State and Government in Addis Ababa on 11 July 1990 and entered into force on 29 November 1999 upon ratification by 15 member states (OAU Doc CAB/LEG/153/Rev 2, reprinted in Heyns (ed) (1999) 38. It has 29 state parties.

577 Adopted in 1968 and entered into force in June 1969. In 2003 in Maputu the AU adopted an amended version of the Convention, which is not yet in force.

578 Adopted in Maputu in July 2003, and entered into force on 27 November 2005.

579 See Viljoen 'Africa's contribution to the development of international human rights and humanitarian law' (2001) 1 *African Human Rights L J* 18 22 - 23.
For a more detailed discussion on the Children's Charter, see Viljoen (n 305 above) 199 and Lloyd 'A theoretical analysis of the reality of children's rights in Africa: An introduction to the African Charter on the Rights and Welfare of the Child' (2002) 2 *African Human Rights L J* 11.

values of the African civilisation', and these values and virtues should inspire and characterise the content of the rights of the child.[580]

The Children's Charter guarantees, amongst other rights, the right to non-discrimination,[581] that the best interests of the child shall always be paramount,[582] children's rights to survival and development,[583] their right to a name and identity,[584] their freedom of expression, association, thought, conscience and religion,[585] their right to protection of their privacy,[586] and their right to education, leisure, recreational and cultural activities.[587] Special mention is made in the Children's Charter of the rights of handicapped children.[588]

Also protected are children's rights to be free from child labour, child abuse and torture,[589] their right to just administration of juvenile justice,[590] the protection of the family,[591] parental care and protection and to parental responsibilities,[592] their right against sexual exploitation,[593] and the rights of refugee children.[594] As is the case in the Women's Protocol, children are protected against harmful social and cultural practices 'affecting the welfare, dignity, normal growth and development of the child'.[595] Customs and practices prejudicial to the health and the life of the child are specifically outlawed.[596]

Of note to the present study is article 14 of the Children's Charter, guaranteeing children's right to health and health services. Not only does the child have the right to enjoy the best attainable state of health, but state parties to the Children's Charter undertake to take measures to reduce infant and child mortality rates, and to 'combat disease and malnutrition within the framework of primary health care through the application of appropriate technology'.[597] Article 14 will be

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580 Para 6 Children's Charter.
581 Art 3 Children's Charter.
582 Art 4 Children's Charter.
583 Art 5 Children's Charter.
584 Art 6 Children's Charter.
585 Arts 7 – 9 Children's Charter.
586 Art 10 Children's Charter.
587 Arts 11 – 12 Children's Charter.
588 Art 13 Children's Charter.
589 Arts 15 – 16 Children's Charter.
590 Art 17 Children's Charter.
591 Art 18 Children's Charter.
592 Art 19 – 20 Children's Charter.
593 Art 27 Children's Charter.
594 Art 23 Children's Charter.
595 Art 21(1) Children's Charter.
596 Art 21(1)(a) Children's Charter.
597 Art 14(2)(d) Children's Charter.

discussed in more detail below[598] as it may be read as relating to children's participation in clinical research.

Another important feature of the Children's Charter is that it includes not only rights but responsibilities as well. Article 31 outlines children's responsibilities in relation to their family and society, to work for the cohesion of the family, to serve his national community, to strengthen social and national solidarity, and so on.

An implementation mechanism, in the form of a Committee on the Rights and Welfare of the Child, is set up by the Children's Charter to 'promote and protect the rights and welfare of the child'[599] and to fulfil functions relating to that charge.[600] The Committee was established in 2002 as a monitoring body in charge of a state reporting procedure and an individual complaints procedure.[601]

The Women's Protocol addresses human rights of concern to women in Africa.[602] The motivation behind the Protocol is the denial of women's human rights in many spheres of African society and, consequently, to the scant attention paid to their rights in the African Charter. The Preamble states:[603]

> *Concerned* that despite the ratification of the African Charter on Human and Peoples' Rights and other international human rights instruments by the majority of States Parties, and their solemn commitment to eliminate all forms of discrimination and harmful practices against women, women in Africa still continue to be victims of discrimination and harmful practices ...

The Women's Protocol guarantees civil and political rights as well as socio-economic rights. It prohibits all forms of discrimination against women.[604] Sub-section 2 of article 2 of the Women's Protocol requires state parties to:

> modify the social and cultural patterns of conduct of women and men through public education, information, education and communication strategies, with a view to achieving the elimination of harmful cultural and traditional practices and all other practices which are based on the idea of the inferiority or the superiority of either of the sexes, or on stereotyped roles for women and men.

It is clear from the quoted subsection that the drafters of the Women's Protocol realise that the protocol alone will not be able to change peoples' attitudes and that it is only through consistent programmes of education and communication strategies

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598 See para 5.2.7 below.
599 Art 32 Children's Charter.
600 See art 42 Children's Charter where its functions and mandate are outlined.
601 Nowak 211.
602 Generally on the Women's Protocol, see Murray 'A feminist perspective on reform of the African human rights system' (2001) 2 *African Human Rights L J* 205;
603 Preamble Women's Protocol.
604 Art 2 Women's Protocol.

that views may change. Of note also is the realisation in this subsection that it is not only men's attitudes, but also the attitudes of women that need changing.

The Women's Protocol guarantees women's right to dignity,[605] which includes women's right to be free from all forms of violence, especially violence of a verbal or sexual nature,[606] their right to life and integrity and security of their person.[607]

The Women's Protocol orders the elimination of harmful traditional or cultural practices, such as female genital mutilation.[608] Once again it demonstrates the realisation that legislation alone will not alter the situation, as it orders the 'creation of public awareness in all sectors of society regarding harmful practices through information, formal and informal education and outreach programmes'.[609]

The Women's Protocol further addresses topics such as equal rights in marriage, freedom to marry and the freedom of the woman to acquire and manage her own property during marriage.[610] It addresses women's access to justice and their right to equal protection before the law,[611] women's social and welfare rights,[612] as well as the right to a healthy and sustainable environment.[613]

Of importance is the section on women's health and reproductive rights.[614] Women's right to health is guaranteed, which specifically includes their right to have 'self-protection and to be protected against sexually transmitted infections, including HIV/AIDS',[615] as well as the right to be informed as to their 'health status and to the health status of one's partner, particularly if infected with sexually transmitted infections, including HIV/AIDS, in accordance with internationally recognised standards and best practices'.[616] Certain aspects relating to women's right to health of relevance to this study are discussed below.[617]

State parties to the Women's Protocol undertake to 'take all appropriate measures' to provide accessible health services, establish and expand health services

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605 Art 3 Women's Protocol.
606 Art 3(4) Women's Protocol.
607 Art 4 Women's Protocol.
608 Art 5 Women's Protocol.
609 Art 5(a) Women's Protocol.
610 Art 6 Women's Protocol.
611 Art 8 Women's Protocol.
612 Art 13 Women's Protocol.
613 Art 18 Women's Protocol.
614 Art 14 Women's Protocol.
615 Art 14(1)(d) Women's Protocol.
616 Art 14(1)(e) Women's Protocol.
617 See para 4.4.9 below.

related to pregnancy and delivery, and to provide access to abortion in specific circumstances.[618]

The Women's Protocol guarantees, among other rights, the right to food security,[619] the right to adequate housing,[620] the right to a positive cultural context,[621] the right to sustainable development,[622] widow's rights,[623] the right to inheritance,[624] and the protection of elderly women,[625] of women with disabilities,[626] and the protection of women in distress.[627]

Under articles 25 and 26 of the Women's Protocol the measures providing remedies for victims of violations and the implementation of the Women's Protocol are indicated. State parties shall undertake to provide appropriate remedies to any woman whose rights have been violated,[628] 'ensure the implementation of the Protocol at national level',[629] and indicate in their periodic reports legislative and other measures undertaken to achieve the full realisation of the rights contained in the Women's Protocol.[630]

4.3.5 OIC and League of Arab States

The regional protection of human rights is restricted to the three systems mentioned above, there exist no regional organisations in Asia, the Middle East or the Pacific for the protection of human rights. In parts of these regions the universality and thus the legitimacy of international human rights have been challenged and abuses of human rights have occurred.[631] The countries in these regions have not, on the whole, signed or ratified any of the UN instruments.[632] The values of Asian culture and Islamic Sharia law are elevated in preference to international human rights law.[633]

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618 Art 14(2) Women's Protocol.
619 Art 15 Women's Protocol.
620 Art 16 Women's Protocol.
621 Art 17 Women's Protocol.
622 Art 19 Women's Protocol.
623 Art 20 Women's Protocol.
624 Art 21 Women's Protocol.
625 Art 22 Women's Protocol.
626 Art 23 Women's Protocol.
627 Art 24 Women's Protocol.
628 Art 25 Women's Protocol.
629 Art 26(1) Women's Protocol.
630 Nowak 253.
631 Nowak 253.
632 As above. Australia and New Zeeland are the exception.
633 Nowak 253.

A declaration of human rights, the Universal Islamic Declaration of Human Rights, was adopted in 1981 by the Islamic European Council, a private organisation based in London.[634] The Organisation of the Islamic Conference (OIC) in 1990 in Cairo passed the Declaration of Human Rights in Islam,[635] which is based on the Universal Islamic Declaration, and, although non-binding, is the first inter-governmental effort at human rights protection in the region.[636] The Declaration includes all the classic first and second generation rights, as well as several collective rights of peoples, such as the right to self-determination against colonial repression, and principles of humanitarian law.[637] These rights are subject to Islamic Sharia law, which is the sole source of interpretation of these rights.[638]

In 1994 the Council of the League of Arab States (Arab League)[639] adopted the Arab Charter on Human Rights.[640] This document has not yet entered into force as it has not been ratified by any state.[641] The Arab Charter on Human Rights resembles the Universal Declaration of Human Rights and the two UN Covenants. It includes various first and second generation rights as well as rights to self-determination and the protection of minorities.[642] A seven-member Committee of Experts on Human Rights will monitor state compliance with the Arab Charter, and the Arab Charter provides for a state reporting procedure.

These documents should be seen as initial steps towards possible human rights protection in the future rather than determined efforts to provide protection now. Because this study concerns itself with HIV/AIDS and human rights in sub-Saharan Africa - the incidence of HIV is much higher than is the case of North African states - the lack of a regional mechanism for the protection of human rights is of slight relevance.

4.4 The role of customary international law

The term 'customary international law' refers to international law rules or norms that have emerged through custom or practice. Along with treaties, customary international law is the main source of international human rights law. State parties

634 Nowak 254.
635 Nowak 254.
636 As above.
637 Nowak 254.
638 Nowak 255.
639 Established in March 1945 and consists of 22 member states.
640 Nowak 255. From now on referred to as the 'Arab Charter'.
641 Nowak 255.
642 As above.

alone are bound by treaties; human rights obligations can be avoided by not becoming a party to any treaty. However, customary international law binds states which are not party to a specific treaty, if the relevant norm in that treaty has become a rule of customary international law.[643]

Article 38 of the Statute of the International Court of Justice defines custom as 'evidence of a general practice accepted as law'.[644] Courts have identified two elements that need to be proven before a norm is accepted as customary international law: consistent or settled state practice over time (*usus*) and a belief that that practice is law (*opinio iuris*).[645]

4.4.1 Settled state practice (*usus*)

There has to be evidence of consistent and uniform practice by states conforming to a certain norm. In the case of *Columbia v Peru*, the International Court of Justice observed:[646]

> the practice has been so much influenced by considerations of political expediency in the various cases, that it is not possible to discern in all this any constant and uniform usage, accepted as law, with regard to the alleged rule of unilateral and definitive qualification of the offence.

Evidence of consistent and settled state practice may be found in treaties, decisions of international courts, national legislation, diplomatic correspondence, policy statements by government officers, and resolutions of the political organs of the UN.[647]

4.4.2 *Opinio iuris*

A state practice on its own is insufficient to create a customary rule.[648] States should observe these norms because they believe that 'the practice is rendered obligatory by the existence of a rule of law requiring it ... The frequency, or even habitual character of the acts is not in itself enough'.[649] In other words, states must *consider* themselves bound by the rule.

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643 See Dugard (2001) 27 – 28.
644 Art 38(1)(b) Statute of the International Court of Justice (June 26 1995) Stat. 1055 T.S. 993; available at <http://www.icj-cij.org> (31 January 2007).
645 Dugard 28.
646 *Columbia v Peru* (1950) ICJ Reports 266 277.
647 As above; Dugard 28.
648 Dugard 31.
649 *North Sea Continental Shelf* (1969) ICJ Reports 3, para 77; see Dugard 31 - 32.

John Dugard notes that, in certain instances, it is difficult to prove the existence of *opnio iuris*.[650] It is only when actual cases come to court that a norm is confirmed as being a rule of customary international law.

Christian Tomuschat is of the opinion that custom is of little importance in establishing human rights law norms because the lack of empirical proof of the way that states deal with citizens makes it difficult to ascertain custom.[651] Nevertheless, in the field of human rights law, a number of human rights norms have evolved to obtain the status of international customary law. International customary law rules have developed primarily from those norms that are considered to be universal in character and that are proclaimed in various international instruments, for example, several of the principles contained in the Universal Declaration.[652] The following human rights norms are generally considered rules of customary international law: rules prohibiting arbitrary killing, slavery, torture, detention and systematic racial discrimination.[653] These rules of customary international law apply to all states, regardless of whether or not they subscribe to treaties prohibiting these actions. Customary international law may be more relevant than treaty law in terms of ensuring liability and accountability at the national level for non-state actors, according to Andrew Clapham.[654]

Customary international law can be influential in the implementation of human rights law in domestic legal systems. First, provisions in human rights treaties often permit the implementing body to consider customary international law.[655] For example, article 61 of the African Charter requires the African Commission to take into consideration, amongst other sources, 'African practices consistent with international norms on human and people's rights', and 'customs generally accepted as law'.[656] Second, domestic constitutions with similar provisions instruct a court to look at customary international law in the interpretation of domestic law.[657] Third, a domestic constitution may incorporate customary

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650 Dugard 32.
651 Tomuschat (2003) 34.
652 Clapham (2006) 86.
653 As above.
654 Clapham 86. In this regard, see Clapham chs 7 and 10.
655 Clapham 85.
656 Art 61 African Charter.
657 See para 6 below.

international law directly into municipal law, without the need for specific implementing legislation.[658]

Issues that relate to the significance as well as the implementation of customary international law are revisited in paragraph 6.

4.5 The role of *jus cogens* or peremptory norms and *erga omnes* obligations of international law

Jus cogens rules or 'peremptory norms' on human rights, unlike customary international law, merely need to be accepted by the international community of states to be considered binding international law, and are norms from which no derogation is permitted either by treaty of any other source of international law.[659] A *jus cogens* or peremptory norm is a norm 'accepted and recognized by the international community of States as a whole' to be of that nature.[660] In 'Serious breaches of obligations under peremptory norms of general international law', a chapter of its Articles on state responsibility, the International Law Commission states that peremptory norms that are accepted and recognised include the prohibitions of aggression, genocide, slavery, racial discrimination, crimes against humanity and torture, and the right to self-determination.[661] Other examples of prohibited acts are the 'slave trade ... apartheid ... the prohibition against torture as defined in article 1 of the Convention against Torture and Other Cruel, Inhuman and Degrading Treatment or Punishment and the basic rules of international humanitarian law applicable to armed conflict'.[662]

Erga omnes obligations are obligations owed by states to all other states – in other words, obligations owed to the international community as a whole.[663] In the *Barcelona Traction, Light and Power* case, the International Court of Justice asserted that certain basic human rights give rise to such 'obligations *erga omnes*', for example, outlawing acts of aggression, and genocide and assuring the right to

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658 Clapham 86. See para 6 below.
659 Clapham (n 652 above) 87; Dugard (n 643 above) 40 - 41.
660 Art 53 Vienna Convention on the Law of Treaties (1969).
661 Commentary to art 26, para 5. Report of the International Law Commission, GAOR, Supp. No 10 (A/56/10) 208.
662 Commentary to art 40, paras 3 – 5 Report of the International Law Commission, GAOR, Supp. No 10 (A/56/10) 283 - 284.
663 Clapham 96.

protection from slavery and racial discrimination.[664] These norms occupy an elevated status in international law.[665]

4.6 Conclusion

This section surveys the international system that contributes to the protection of human rights. First, the UN system is discussed, including the treaties which constitute human rights protection under the UN system. Next, regional human rights protection is sketched, and the European, Inter-American and African systems are described.

The interaction between the national and international systems of human rights law is debated; and questions are asked about the validity of drawing a distinction between 'soft' and 'hard' human rights law. It is suggested, in some circumstances, so-called 'soft' law creates binding obligations upon states and it sometimes has strong persuasive force.

The role customary international law plays in the protection of human rights was raised and its value was found to lie in that provisions in human rights treaties permit the implementing body to consider international law or that domestic constitutions have similar provisions, as well as other valuable contributions.

Finally, the concepts of *jus cogens* or peremptory norms and *erga omnes* obligations are introduced to highlight their function in the international implementation of human rights norms.

Within the framework of the international human rights law system that has been outlined, the next section of the thesis analyses specific provisions in international human rights instruments which are relevant in protecting the interests of clinical HIV-related research participants in Africa.

5 INTERNATIONAL HUMAN RIGHTS NORMS RELEVANT TO CLINICAL RESEARCH IN SUB-SAHARAN AFRICA

5.1 Introduction

Over the past decades, various international bodies have used a rights-based approach as a basis for programmes fighting HIV/AIDS. For example, the World Health Organization (WHO) has committed itself to strengthening its 'capacity to

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664 *Barcelona Traction, Light and Power Co (Belgium v Spain)* (1970) ICJ Reports 4 para 33.

665 Dugard 41.

integrate a human rights-based approach in its work'; to supporting 'governments in integrating a human rights-based approach in health development'; and to advancing 'the right to health in international law and international development processes'.[666]

In September 1996 UNAIDS[667] and the Office of the High Commissioner for Human Rights (OHCHR) convened an international consultation on HIV/AIDS in response to a request by the United Nations Commission on Human Rights to elaborate guidelines on promoting and protecting respect for human rights in the context of HIV/AIDS.[668] At this consultation the International Guidelines on HIV/AIDS and Human Rights (UNAIDS Human Rights Guidelines) were adopted. The intention is for states to use the UNAIDS Human Rights Guidelines in 'promoting and protecting a respect for human rights in the context of HIV/AIDS'.[669] There are twelve guidelines, aimed at implementing 'an effective rights-based approach'. The guidelines translate international human rights principles into practical steps for action in the context of HIV/AIDS.

Following another international consultation on HIV/AIDS in 2002, Guideline 6, dealing with 'access to prevention, treatment, care and support' was revised to reflect recent developments in the medical treatment of HIV/AIDS and international law on HIV/AIDS. A central tenet of the revised Guideline 6 is that '[u]niversal access to HIV/AIDS prevention, treatment, care and support is necessary to respect, protect and fulfil human rights related to health; including the right to enjoy the highest attainable standard of health.[670] HIV/AIDS prevention, treatment and care are therefore considered a prerequisite for the full realisation of an individual's human rights.

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666 See WHO *Health and human rights* <http://www.who.int/hhr/en/> (1 April 2006).

667 UNAIDS was established by six international organisations as a joint programme on HIV/AIDS. They are the UN Children's Fund (UNICEF), the UN Development Programme (UNDP), the UN Population Fund (UNFPA), the UN Educational Scientific and Cultural Organisation (UNESCO), the World Health Organisation (WHO) and the World Bank. As the organ assigned with the role of co-ordinating the global strategy for combating HIV/AIDS and its consequences, its mission is to lead, strengthen and support an expanded response. This response is aimed at preventing the transmission of HIV, providing care and support for people living with HIV/AIDS, reducing the vulnerability of individuals and communities to HIV/AIDS, and also of alleviating the effects of the epidemic.

668 E/CN.4/1995/45, para 135.

669 E/CN.4/1997/37, available at <http://daccessdds.un.org/doc/UNDOC/GEN/G97/102/19/PDF/G9710219.pdf?OpenElement> (1 April 2006).

670 UN *HIV/AIDS and Human Rights: International Guidelines – Revised Guideline 6,* HR/PUB/2002/1.

In June 2001, the member states of the United Nations General Assembly adopted the Declaration of Commitment on HIV/AIDS (Declaration of Commitment).[671] The Declaration of Commitment endorses an international commitment to human rights as a central element of the global response to HIV/AIDS. It recognises that the full realisation of human rights and fundamental freedoms for all is an essential element in a global response to the HIV/AIDS pandemic. It also recognises that it reduces vulnerability to HIV/AIDS and prevents stigma and related discrimination against people living with or at risk of HIV/AIDS.[672]

In relation to Africa, the Declaration of Commitment notes as follows:[673]

> Noting with grave concern that Africa, in particular sub-Saharan Africa, is currently the worst-affected region, where HIV/AIDS is considered a state of emergency which threatens development, social cohesion, political stability, food security and life expectancy and imposes a devastating economic burden, and that the dramatic situation on the continent needs urgent and exceptional national, regional and international action.

UNAIDS delivered its first report on the progress that has been made toward the targets set in the Declaration of Commitment in 2003. In Gillian MacNaughton's view, progress has been slow and disappointing.[674] She declares that, although there is international consensus on the necessity of respecting and protecting human rights in efforts to combat HIV/AIDS, translated into resolutions, declarations and guidelines at the international level, this consensus has not been put into law or action at the national level.[675] This failure may be ascribed to the fact that the documents and declarations outlined above are not legally binding on the member states of international organisations.[676]

The section above outlines the declarations and indications of commitment of international political bodies such as the United Nations. Because these are mere declarations, they have not the power to legally bind state members of international organisations, although as instances of soft law, they have considerable persuasive and political power.[677]

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671 UN General Assembly *Declaration of Commitment on HIV/AIDS*, A/RES/S-26/2, <http://www.unhchr.ch/huridocda/huridoca.nsf/e06a5300f90fa0238025668700518ca4/7e8440165be48ce0c1256aaa0052d754/$FILE/N0143484.pdf> (1 April 2006).

672 Para 16 Declaration of Commitment.

673 Para 8 Declaration of Commitment.

674 See MacNaughton (2004) 14.

675 As above.

676 See para 3.5 above.

677 See para 4.1 above.

In contrast to soft law and non-binding ethical guidelines, international human rights treaties are able to provide a legal framework for defining state obligations in protecting human rights and they may serve as a resource for implementing human rights protection for research participants.[678]
International human rights law in the form of binding treaties and conventions provides participants in HIV-related clinical research in Africa with recourse to national and international courts and tribunals.

The section below focuses on specific provisions in international and regional human rights instruments that can be of use in this regard. International human rights instruments such as ICCPR, ICESR, CRC and CEDAW, as well as regional instruments such as the African Charter on Human and Peoples' Rights, the African Charter on Rights and Welfare of the Child and the Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa are singled out for attention.[679]

Provisions which, primarily, have implications for the position of clinical research participants are examined, rather than only those that deal with health care, or access to health. The same provisions tend to be included in each of the seven international and regional documents discussed below, for example, the right to dignity which is included in various forms in each of the documents, so, to avoid repetition, the discussion will focus on different rights in each document.

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678 It is important to note that, although these instruments generally place the duty to fulfil their obligations upon state parties, the duty to protect and promote human implies that state parties must also ensure that others (such as members of the clinical research team or research sponsors) do not violate these rights. States do this by enacting legislation. In that way, not only state actors, but also private entities and groups are bound by the obligation to respect human rights. See Clapham (n 652 above).

679 The Universal Declaration of Human Rights is not included in this discussion as, by definition, it is not a legally binding instrument, although it has become the 'common standard' against which to evaluate attempts by the world to promote a respect for human rights.
Although not a binding treaty, certain provisions in the Universal Declaration of Human Rights have established themselves as a part of the body of customary international law, and, as such, may be regarded as binding upon many states. See the discussion in para 6 which deals with sec 232 of the South African Constitution, which stipulates that customary international law is the law of the Republic. If the Universal Declaration could successfully be argued to be part of international customary law it will be binding upon South Africa. See also Humphrey 'The Universal Declaration of Human Rights: Its history, impact and judicial character' in Ramcharam (ed) (1979) *Human rights: Thirty years after the Universal Declaration* 21 - 28.

5.2 Specific human rights provisions in universal and regional instruments relevant to HIV-related clinical research in Africa

5.2.1 ICCPR

At the outset it is acknowledged that both the ICCPR and the ICESCR were drafted before the first cases of HIV infection were reported, and before the world became aware of a HIV epidemic. It is only in later human rights instruments, such as the Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa, that specific reference is made to HIV/AIDS.[680]

The ICCPR recognises a number of rights that are relevant in the context of responding to the needs of participants in HIV-related clinical research in Africa. For example, the ICCPR recognises the right to life,[681] the right to physical integrity, the right to dignity and the right to be free from 'arbitrary or unlawful interference' with one's 'privacy, family, home or correspondence'.[682]

All clinical research touches upon the participants' right to life and their right to physical integrity. Clinical research tests unproven methods and experimental medicines, so, at worst, participants' lives are threatened, and, at best, their physical integrity is put at risk. There are numerous examples in the literature of clinical research participants who have lost their lives, and also of participants who were seriously injured.[683] All the effects of new medications and treatments are not known at the time they are tested upon humans and they thus pose a potential threat.

Participants' right to dignity may be infringed during the clinical research process. Again, there are many examples in the literature of how participants in research were degraded and dehumanised; the experimentation undertaken by doctors under National Socialism is an obvious example.[684] Any research design which treats participants as mere objects instead of as autonomous human beings, by definition, violates their right to dignity.

With respect to the autonomy of research subjects, article 7 of the ICCPR provides for free consent to research participation:

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680 CRC, adopted in 1989, years after the first HIV-cases were reported, makes no mention of HIV/AIDS.

681 Art 6(1) ICCPR.

682 Art 17 ICCPR.

683 See para 4.2 of ch 3 above.

684 See ch 3 above. Also, no person is treated with dignity if that person is not respected as an individual capable of making his or her own decisions. The right to dignity therefore implies autonomy, and the right not to be subjected to clinical research without having given informed consent.

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

Article 7 of the ICCPR is discussed in detail in chapter 5.[685] Nevertheless, it is important to recognise that, although the term *informed*[686] is not used, the use of 'free' prescribes that the research participant should be viewed as an autonomous agent and not as a means to achieving an end (a certain outcome in the research). Research which permits undue influence on research participants so that their consent is no longer 'free', is not in line with the ICCPR, for example, in a situation in which consent is compromised by offers of excessive monetary compensation, free medical care in a setting of dire poverty and other rewards for participation.[687] General Comment 20, which deals with article 7, is presented in detail elsewhere in the thesis.[688]

Research participants' right to privacy may be violated by their participation in research. It is conceivable that their status is made known to others without their consent; or that other people perceive them, as participants in HIV-related clinical research, to be HIV positive. The violation of privacy may result in discrimination and stigma.[689] Article 17 of the ICCPR prohibits the unlawful and arbitrary interference in a person's 'privacy, family, home or correspondence'. Knowledge about the health status of a clinical trial participant, especially the participant's *HIV* status, according to article 17, should be kept strictly private by researchers. In settings in which HIV positive status leads to stigmatisation and discrimination, a guarantee of privacy should be issued by research sponsors to HIV-related clinical trial participants.

Further, the ICCPR prohibits discrimination,[690] and guarantees equal protection and equality before the law.[691] Article 26 states that 'the law shall prohibit any discrimination and guarantee to all persons equal and effective protection against discrimination on any ground such as race, colour, sex, language, religion,

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685 See para 4.3.1 of ch 5 below.

686 Probably because it is a relatively new term. It was only during the eighties with the shift in thought away from the traditional paternalistic attitude of doctors towards their patients, that emphasis was placed on the nature of the information given, and that the term 'informed' consent was first used. See ch 5 below.

687 See ch 5 below.

688 See para 4.3.1 of ch 5 below.

689 See paras 2.3.2 and 2.3.3 of ch 5 below.

690 Art 2(1) ICCPR.

691 Art 26 ICCPR.

political or other opinion, national or social origin, property, birth or other status'.[692] Research initiatives contrary to these guarantees are prohibited. An example would be instances where research brings a significant benefit, but which excludes a certain class or group of people. Research testing a promising new antiretroviral, but which excludes people who do not belong to the dominant ethnic group in a specific country is therefore prohibited.

The UN Human Rights Committee (HRC) is charged with monitoring compliance with the ICCPR. Aside from its other functions, it receives and reviews state reports and individual complaints[693] submitted under the ICCPR. In General Comment 6, the UN Human Rights Committee commented that the right to life too often has been interpreted to narrowly:[694]

> The expression 'inherent right to life' cannot properly be understood in a restrictive manner, and the protection of this right requires that states adopt positive measures. In this connection, the Committee considers that it would be desirable for states parties to take all possible measures to reduce infant mortality and to increase life expectancy, especially in adopting measures to eliminate malnutrition and epidemics.

The Human Rights Committee expressly includes health issues, specifically epidemics, in its understanding of the realisation of the right to life. This General Comment has implications for HIV-related research as aimed at lessening or eliminating the HIV epidemic. From General Comment 6 one may deduce that there is a positive duty on states to undertake HIV-related research, not only in terms of the right to health in the ICESCR, but also in terms of the right to life in the ICCPR.[695] Domestic constitutions containing a guarantee of the right to life may be interpreted in a similar vein.

5.2.2 ICESCR

Article 2(1) of the ICESCR provides that each state party must take steps, individually and through international assistance and co-operation, especially economic and technical, 'to the maximum of its available resources, with a view to achieving progressively the full realisation of the rights recognised in the present

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692 Art 26 ICCPR.

693 Individual complaints may only be filed in cases where states have signed and ratified the Optional Protocol to the ICCPR.

694 Para 5 General Comment 6 Right to Life.

695 Ratifying only the ICCPR and not the ICESCR in order to escape the obligations imposed by the right to health in this regard will thus not enable states to escape the wider obligations they incur under the right to life in ICCPR. (South Africa, for example, has signed but not ratified ICESR.)

Covenant by all appropriate means, including the adoption of legislative measures'. Article 2(1) therefore places a positive obligation on member states to realise the rights enumerated in the ICESCR. The 'full realisation' of the rights should be aimed for, and the only limitation expressed is the resources that a country has at its disposal. States must further guarantee the rights enunciated in the ICESCR 'without discrimination of any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status'.[696]

The ICESCR contains several provisions relevant to the protection of participants in HIV-related clinical trials. Among these is the right 'to enjoy the benefits of scientific progress and its applications'.[697] These 'benefits' include advances in medical treatment and methods against HIV/AIDS. This subsection should be useful in compelling states to ensure that research is undertaken to fight disease, and that the results of such research are available to the benefit of their people, with the result that, as science develops new technologies to combat HIV/AIDS, these technologies should become accessible.

This subsection has further important implications for the design aspect of clinical trials. In a previous chapter the Ugandan vertical HIV-transmission trials, in which a placebo was used in the control arm of a study, while AZT is the standard of care in the developed world, has been mentioned.[698] The 'right to enjoy the benefits of scientific progress' could be interpreted to render illegal a research design such as that, as it denies the women in the placebo arm of the trial the benefit of an existing treatment, or 'scientific progress'.

Moreover, this subsection could also be read to prohibit other exploitative research, such as if research is undertaken to develop new drugs and treatments, but which does not give individuals and the community who participated in the research post-trial access to the drugs and technologies developed. In these circumstances it cannot be said that research participants or the wider community realises 'the benefits of scientific progress and its applications'.

In the context of the right to enjoy the benefits of scientific progress, the UN's General Assembly has requested member states to 'promote access of all peoples to appropriate preventive, diagnostic, and therapeutic technologies and

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696 Art 2(2) ICESR.
697 Art 15(1)(b) ICESCR.
698 See para 4.2.2 of ch 3 above.

pharmaceuticals and to help make these technologies and pharmaceuticals available at an affordable cost'.[699]

The ICESCR guarantees the right of everyone to the 'enjoyment of the highest attainable standard of physical and mental health'.[700] States should take steps to achieve, among other things, 'the prevention, treatment and control of epidemic, endemic, ... and other diseases',[701] and to create 'conditions which would assure to all medical service and medical attention in the event of sickness'.[702] The right to health in the ICESCR is, probably, the most comprehensive of all the documents.

The right to health isolates aspects of health which need special attention. They are the still-birth rate and infant morality,[703] as well as environmental and industrial hygiene.[704] The *travaux préparatoires* clearly indicate that the right to health in ICESCR was formulated along the lines of the World Health Organization's Constitution.[705] Article 12 of ICESCR 'delineates concrete steps and establishes a measure of accountability through the use of specific indicators, such as the reduction in stillbirths and infant mortality'.[706]

Article 12 has successfully been used in the past to implement the right to the highest attainable standard of health at the domestic level, forcing a state to respond adequately to an epidemic. In the case of *Mariela Viceconte v Ministry of Health and Social Welfare,*[707] a number of community groups brought an application to ensure that the state of Argentina would manufacture a vaccine against Argentine hemorrhagic fever. This disease is endemic to Argentina, threatening the lives of 3.5 million people, most of whom do not have access to adequate health care.

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699 UN General Assembly Resolution 44/236, 22 December 1989 Prevention and control of Acquired Immunodeficiency Syndrome (AIDS).

700 Art 12 ICESCR.

701 Art !2 (2)(c) ICESR.

702 Art 12(2)(d) ICESR.

703 Art 12(2)(a) ICESR.

704 Art 12(2)(b) ICESR.

705 Gostin and Lazzarini (n 227 above) 5. The Preamble of the World Health Organization's Constitution reads:
'The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social conditions'.

706 As above, 6. However, the right to health does not give a standard that these indicators have to comply with. We do not know when there are few enough still births, or exactly when the 'highest attainable standard of physical and mental health' will be reached.

707 Case no 31.777/96 (1998). Also see Byrne 'Making the right to health a reality: Legal strategies for effective implementation' paper delivered at the Commonwealth Law Conference, London, UK, September 2005.

The Argentine government succeeded in vaccinating 140 000 people between 1991 and 1995, far short of the number of people threatened by the disease. The application was aimed at compelling the Argentine Ministry of Health to manufacture and distribute further doses of the vaccine to people who live in the areas most affected by the disease.

The Argentine Court of Appeals decided that there exists a duty upon the Argentine state to manufacture and provide the vaccine. In reaching its judgment, the court drew on regional and international human rights instruments guaranteeing the right to health, including the right to health as guaranteed in article 12 of ICESR.[708] In this case, ICESR was used both as an interpretive tool and as a substantive right.[709]

By analogy, because of the magnitude of the threat posed by HIV/AIDS, in terms of article 12 of ICESR, there is a duty on all governments to undertake HIV-related clinical research. This is especially true in the case of sub-Saharan Africa, where the threat of HIV/AIDS is the greatest.

The Committee on Economic, Social and Cultural Rights, which monitors compliance with the ICESCR, has issued General Comment 14 on the right to health in article 12, in order to provide guidance to state parties on the content and implementation of the right.[710] General Comment 14 details various state obligations related to HIV/AIDS:[711]

> The right to health contains both freedoms and entitlements. The freedoms include the right to control one's health and body, including sexual and reproductive freedom, and the right to be free from interference, such as the right to be free from torture, non-consensual medical treatment and experimentation. By contrast, the entitlements include the right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

General Comment 14 observes that article 12 prohibits 'any discrimination in access to health care and underlying determinants of health, as well as to the means and entitlements for their procurement, on the grounds of . . . health status (including HIV/AIDS)',[712] and outlines the content of the right to health:[713]

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708 All these instruments have been incorporated into domestic law by the Argentinean legislature.

709 See n 707.

710 Committee on Economic, Social and Cultural Rights General Comment 14 (2000), The right to the highest attainable standard of health, UN Doc E/C/12/2000/4.

711 Para 8 General Comment 14.

712 Paras 8 and 18 General Comment 14.

713 Para 9 General Comment 14.

> The right to health must be understood as the right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realisation of the highest attainable standard of health.

The fact that General Comment 14 indicates that the right to health includes the right not to be subjected to 'non-consensual medical treatment'[714] is of especial relevance to the issue of informed consent to HIV-related clinical research.

The right to 'essential drugs, as defined by the WHO',[715] is guaranteed, as well as the right to 'seek, receive and impart information and ideas concerning health issues'.[716] Research participants' privacy is guaranteed in the right to health facilities, goods and services 'designed to respect confidentiality'.[717]

General Comment 14 stipulates that article 12 requires state parties to respect, protect and fulfil the right. With regard to their mandate 'to respect' they are required to refrain from interfering directly or indirectly in the enjoyment of the right, for example, through discrimination against individuals or groups within a health system; their protective mandate requires them to take measures (legislative and other measures) to prevent third parties from interfering with the right to health, for example, putting legislation in place governing the conduct of clinical trials by multinationals in a specific country; and, 'to fulfil the right', state parties are required to adopt budgetary, administrative, legislative, promotional and judicial measures, amongst others, towards the full realisation of the right to health. These measures would include establishing prevention and education programmes for behaviour-related health concerns such as HIV/AIDS,[718] ensuring the provision of a 'health insurance system which is affordable for all', establishing a comprehensive national health policy aimed at realising the right to health,[719] and promoting medical research, education and information campaigns with respect to HIV/AIDS.[720]

General Comment 14 stresses that any limitations on rights imposed by state parties with respect to health or on the grounds of protecting public health, such as restricting the movement of or incarcerating people with transmissible diseases such as HIV/AIDS, should be in accordance with the limitations clause in article 4 of the

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714 Para 8 General Comment 4.
715 Para 12(a).
716 Para 13(b).
717 Para 13(c).
718 Para 16.
719 Para 36.
720 Para 36.

ICESCR.[721] Therefore, such limitations must be 'in accordance with the law, including international human rights standards, compatible with the nature of the rights protected by the Covenant, in the interest of legitimate aims pursued, and strictly necessary for the promotion of the general welfare in a democratic society'.[722]

Further, the General Comment asserts the requirement that any limitations must be 'proportional'; that the 'least restrictive alternative' must be adopted, and that such a limitation must be of 'limited duration and subject to review'.[723]

Finally, it is important to remember that the right to health is interlinked with various other rights. The General Comment remarks that the right to health is closely related to, and dependant upon, the realisation of other human rights, as contained in 'the international Bill of Rights'.[724] The rights that are mentioned include the rights to food, housing, work, education, human dignity, life, non-discrimination, equality, the prohibition against torture, privacy, access to information, and the freedoms of association, assembly and movement. The General Comment stresses that these and other rights and freedoms 'address integral components of the right to health'.[725]

5.2.3 CEDAW

The CEDAW also enumerates rights which are relevant in protecting the interests of participants in HIV-related clinical research. The Committee on the Elimination of Discrimination against Women (CEDAW Committee) receives and reviews state reports and individual or group complaints,[726] and has the task of implementing the rights listed in CEDAW.

Article 11(1) guarantees women's right to 'protection of health and to safety in working conditions, including the safeguarding of the function of reproduction'.[727] On that basis, women may not be exposed to risks in HIV-related clinical research which can not be justified in relation to the potential benefits of the research.

Article 12 compels state parties to the Convention to 'take all appropriate measures to eliminate discrimination against women in the field of health care

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721 Para 28.
722 Para 28.
723 Para 29.
724 Para 3.
725 Para 3.
726 Individual complaints may only be filed in cases where states have signed and ratified the Optional Protocol to CEDAW.
727 Art 11(1)(f) CEDAW.

services, including those related to family planning'[728] and to 'ensure to women appropriate services in connection with pregnancy, confinement and the post-natal period, granting free services where necessary'.[729]

Unless research into issues relating to the HIV-related health-care needs of women is promoted, there will be no scientific advance and women will suffer harm as a result. For example, research into antiretrovirals or microbicides that limit specifically vaginal transmission of HIV should be undertaken; otherwise women are discriminated against, contrary to article 12. Excluding women as a group from the clinical research design and process could also cause women to lose access to medical care during the research process and access to the knowledge and advances that resulted from such research.

The CEDAW Committee has issued several general comments that address women's health issues and HIV/AIDS, including General Recommendation 24 which deals specifically with women and health.[730] General Recommendation 24 declares that the issues of 'HIV/AIDS and other sexually transmitted diseases are central to the rights of women and adolescent girls to sexual health'.[731] The General Recommendation notes that women and girls suffer from a lack of adequate information and of services, that they do not have sufficient power to refuse sex or insist on safe sexual practices, and that they are often subjected to marital rape and polygamy, exposing them to HIV infection.[732] HIV-related clinical research which takes cognisance of the General Recommendation in its research design, or which does not encourage or indirectly support unequal power relations in the research process alone is in line with the Recommendation.

General Recommendation 24 compels states to ensure the right to sexual health information for all women and girls, especially sex workers and trafficked women and girls, in programmes designed to respect their rights to privacy and confidentiality.[733] It is mandatory under the Recommendation to provide such information in a HIV-related clinical research setting. The privacy and confidentiality of participants during the research is guaranteed.

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728 Art 12(1) CEDAW.
729 Art 12(2) CEDAW.
730 Committee on the Elimination of Discrimination against Women *General Recommendation 24 Women and Health* <http://www.unhchr.ch/tbs/doc.nsf/(Symbol)/77bae3190a903f8d80256785005599f> (1 April 2006).
731 Para 18.
732 As above.
733 As above.

5.2.4 CRC

The CRC contains a number of rights relevant to the protection of participants in HIV-related clinical research. The Committee on the Rights of the Child (CRC Committee), amongst other tasks, is responsible for the implementation of the Convention.[734]

While article 2 prohibits 'discrimination of any kind, irrespective of the child's or his or her parent's or legal guardian's race, colour, sex, language, religion, political or other opinion, national, ethnic or social origin, property, disability, birth or other status',[735] article 3 determines that 'in all actions concerning children ... the best interests of the child shall be of primary consideration'.[736]

This sub-section establishes a strict requirement with which HIV-related clinical research must comply: children's participation in HIV-related research should be in the 'best interests of the *child*' - in the singular. It would seem as if HIV-related clinical research which is not in the best interests of the *specific child* who is taking part in the research is not in accordance with this sub-section. Most HIV-related clinical research which aims to develop effective drugs for illnesses, other than that from which the specific children taking part in the research suffer, is thus prohibited. Even if the research aims to find a drug to treat that specific child's condition, the research and participation of children must still be shown to be in the best interests of the child. Research which exposes the child to too high a risk in relation to the potential benefits of the research, therefore, will not be acceptable in terms of CRC.[737]

Article 16 establishes the child's right to privacy. This right has obvious implications for children's participation in HIV-related clinical research. The privacy of a child participating in such research should always be guaranteed, especially in matters such as HIV-status.

Article 24 is of especial importance with reference to HIV-related clinical research in Africa. It guarantees 'the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and

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734 Such as monitoring state compliance with CRC.
735 Art 2(1) CRC.
736 Art 3(1) CRC.
737 See also the discussion of art 4(1) of the African Children's Charter in para 4.3.8 below.

rehabilitation of health'.[738] State parties to the Convention further undertake to pursue the 'full implementation of this right'[739] and shall take appropriate measures to diminish child mortality,[740] to combat disease and malnutrition,[741] to ensure the provisioning of medical assistance and health care to all children,[742] to develop preventive health care[743] and so on.[744] Research which supports state parties' duties only as outlined above will be in line with the CRC.

Article 36 of the CRC demands state parties protect 'the child against all other forms of exploitation prejudicial to any aspect of the child's welfare'. As a kind of catch-all prohibition on exploitation, this sub-section is of particular relevance to children's participation in HIV-related clinical research in Africa. No research that is exploitative in nature is allowed, for example, in terms of the use of placebo groups in settings where there is no standard of care available, or where research is done in Africa because it is cheaper or because it would never have been allowed to take place in the 'developed world'.

In 2003 the CRC Committee issued General Comment 3 on HIV/AIDS and the rights of the child.[745] In General Comment 3 the Committee notes that 'the majority of new HIV infections are among young people' and that 'women and girls are increasingly becoming infected'.[746] The General Comment emphasises that 'effective HIV/AIDS prevention requires states to refrain from censoring, withholding or intentionally misrepresenting health-related information' and that states must ensure that children 'acquire the knowledge and skills to protect themselves'.[747] Furthermore, it stipulates that state parties should ensure children 'access to voluntary, confidential HIV counselling and testing'.[748]

General Comment 3 addresses issues concerning children who are especially vulnerable to HIV infection and to discrimination on the basis of their HIV status.

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738 Art 24(1) CRC.
739 Art 24(2) CRC.
740 Art 24(2)(a) CRC.
741 Art 24(2)(c) CRC.
742 Art 24(2)(b) CRC.
743 Art 24(2)(f) CRC. This sub0section is of particular relevance to HIV-related and other vaccine efficacy research.
744 See art 24(2)(a) – (f) CRC.
745 Committee on the Rights of the Child General Comment 3 (2003) CRC/GC/2003/3 (17 March 2003) <http://www.unhchr.ch/tbs/doc.nsf/(Symbol)/309e8c3807aa8cb7c1256d2d0038caaa ?opendocument> (1 April 2006).
746 Para 2.
747 Para 16.
748 Para 22.

This group includes children who are orphaned by HIV/AIDS, child victims of sexual and economic exploitation and child victims of violence and sexual abuse.[749] It is difficult to think of any example of HIV-related clinical research undertaken in such a setting, which would not violate the CRC. Before clinical research in these settings complies with the CRC, extra safeguards against violating the welfare of the children would have to be implemented.

5.2.5 African Charter on Human and Peoples' Rights

The African Charter on Human and Peoples' Rights (African Charter) states in article 4 that 'human beings are inviolable', and that 'every human being shall be entitled to respect for his life and integrity of his person'. Article 5 ensures that every 'person shall have the right to liberty and to the security of his person'. Even though informed consent to research participation is not mentioned, these two provisions of the African Charter can be used in support of the notion that HIV-related clinical research participants give free and informed consent to research participation. Research without such consent violates the integrity and security of the person.

However, it is not only informed consent that is at issue. Research which harms the person or which is exploitative can also be regarded as violating the integrity and security of the person. It is submitted that research such as that described in chapter 3, where Pfizer treated children for spinal meningitis in Kano, Nigeria with the experimental drug Trovan, violates article 5 of the African Charter. At the time the drug was being tested in Nigeria, Trovan had never been tested on children, and earlier that year it had been withdrawn from US markets due to its serious side-effects.[750] No matter the urgency, only existing, proven medication should have been used.

Article 16 provides that 'every individual shall have the right to enjoy the best attainable state of physical and mental health'.[751] Also, state parties are to 'take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick'.[752] HIV-related clinical research, whether state-sponsored or not, is a measure to protect the health of Africa's people, and, thus, fulfils the duty assigned by this article. However, research specifically aimed at protecting the health of that particular group of people, and not research

749 Arts 30 –39.
750 See para 4.2.2 of ch 3 above.
751 Art 16(1) African Charter.
752 Art 16(2) African Charter.

which is aimed at meeting the health needs of another country or continent, alone meets the requirement of this article.

The African Commission is responsible for the implementation of the African Charter.[753] It must promote human (and peoples') rights in Africa,[754] it must protect these rights,[755] and it must interpret the provisions of the African Charter.[756] As far as its interpretive and protective mandates are concerned, the African Commission has given substance to the right to health in the African Charter by stipulating that the enjoyment of the human right to health 'is vital to all aspects of a person's life and well-being, and is crucial to the realisation of all other fundamental human rights and freedoms'.[757] The Commission considers the right to health to 'include the right to health facilities, access to goods and services to be guaranteed to all without discrimination of any kind'. [758]

On the impact of the prevailing conditions in Africa on the realisation of the right to health, the Commission states that it is aware that 'millions of people in Africa are not enjoying the right to health maximally because African countries are generally faced with the problem of poverty which renders them incapable to provide the necessary amenities, infrastructure and resources that facilitate the full enjoyment of this right'.[759] The African Commission proceeds to 'read into' article 16 the 'obligation on part of states party to the African Charter to *take concrete and targeted steps, while taking full advantage of its available resources*, to ensure that the right to health is fully realised in all its aspects without discrimination of any kind'. [760]

HIV-related clinical trials can be viewed as an example of 'concrete and targeted steps' that take 'full advantage of [...] available resources'. The results of such trials, if used to improve the condition of the health of Africa's people and if

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753 According to art 45(4) of the African Charter it must also perform any other tasks 'which may be entrusted to it by the Assembly of Heads of State and Government. See also Gumedze 'HIV/AIDS and human rights: The role of the African Commission on Human and Peoples' Rights' (2004) 4 *African Human Rights L J* 181.

754 Arts 30 and 45(1) African Charter.

755 Arts 30 and Art 45(2) African Charter.

756 Art 45(3) African Charter.

757 Communication 241/2001 *Purohit and Moore v The Gambia* Sixteenth Annual Activity Report of the African Commission on Human and Peoples' Rights, para 80. The case was brought in regard to the legal and material conditions of detention in a Gambian mental health institution.

758 As above.

759 Para 84.

760 Para 84. My emphasis.

they get access to the products of such research, would advance the right to health in Africa.

The African Commission has adopted a number of resolutions and principles of relevance to clinical research in Africa.[761] The 2003 Principles and Guidelines in the Right to a fair Trial and Legal Assistance in Africa[762] (Principles and Guidelines) in paragraph M.7(f) stipulate that 'no detained person shall, even with his or her consent, be subjected to any medical or scientific experimentation which could be detrimental to his or her health'.

Detainees and prisoners constitute easy prey for unscrupulous researchers. Usually an easily accessible population, in an environment where outside factors influencing research results can be controlled, detainees and prisoners have been approached to take part in 'harmless' research, without cognisance of the fact that, in such a setting their consent is probably not 'free' and 'informed'.

The qualifying words in the paragraph are significant: 'even with his or her consent'. The consent of a detained person is not valid: the guidelines protect against instances where consent is obtained by means of coercion and other measures; insisting, in these circumstances, that research is illegal.

The phrase 'which could be detrimental to his or her health' implies that not *all* research is prohibited, only that which could be detrimental to the health of the detainee or prisoner. The drafters of the Principles and Guidelines might have had in mind a measure akin to the 'minimal harm' or 'negligible harm' principle that is often seen in ethical guidelines.[763]

It is submitted that there are a number of problems associated with the phrase 'which could be detrimental to his or her health'. Who is to judge what is detrimental to the prisoner or detainee's health - the prison authorities; the detainee herself; the researcher or research sponsor? The damage a person's health sustains may manifest only after several years. All side-effects of a specific drug are not known at the beginning of the research. Research which appears harmless may have unexpected consequences later. All research endeavours, carry this risk, however, where there is doubt about the research participant's informed consent as

761 This is an example of 'soft' law. See para 2.1 above.

762 Adopted by the African Commission following the appointment of the Working Group on the Right to a Fair Trial per its 1999 Resolution on the Right to a Fair Trial and Legal Assistance. Reprinted in *Compendium of key human rights documents of the African Union* (2005) 210.

763 See para 3.4.1 of ch 5 below.

a result of his or her incarceration or detention, no research that has the potential to harm the participant should be allowed.

It is submitted that the drafters of the Principles and Guidelines should not have inserted the qualification, and the guideline should read, 'no detained person shall, even with his or her consent, be subjected to any medical or scientific experimentation'.

Apart from the provisions of the African Charter and the resolutions by the African Commission, the political organs of the OAU, later the AU, have adopted resolutions relevant to clinical research in Africa. For example, the Grand Bay (Mauritius) Declaration[764] reflects upon the vulnerability and human rights of people living with HIV/AIDS:[765]

> The Conference notes that the rights of people with disability and people living with HIV/AIDS, in particular women and children, are not always observed and urges all African states to work towards ensuring the full respect of these rights.

These reflections require that HIV-related clinical research sponsors have mechanisms in place which ensure the protection of vulnerable research participants, such as those living with HIV/AIDS.

In April 2001, the Heads of State and Government held a special summit to deal with issues specifically related to the challenges of HIV/AIDS, TB, malaria and other diseases. The meeting adopted the Abuja Declaration on HIV/AIDS, Tuberculosis and other related infectious diseases (Abuja Declaration),[766] and the Abuja Framework for Action for the fight against HIV/AIDS, tuberculosis and other related infectious diseases (Abuja Framework). The latter has as its aim the implementation of the Abuja Declaration.

The Abuja Declaration acknowledges that 'stigma, silence, denial and discrimination against people living with HIV/AIDS increase the impact of the epidemic' and that they constitute 'a major barrier to an effective response to it'.[767] Consequently, the Abuja Framework expresses strategies and activities by means of which states may implement the contents of the Abuja Declaration. Amongst these are relevant legislation to protect the rights of people infected and affected by

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764 Issued by the First OAU Ministerial Conference on Human Rights, which held a meeting from 12 – 16 April 1999 in Grand Bay, Mauritius.

765 Para 7 Grand Bay (Mauritius) Declaration.

766 <http:/www.onusida-acoc.org/Eng/Abuja%20declaration.htm> (30 April 2006).

767 Para 12 Abuja Declaration.

HIV/AIDS and TB, strategies to strengthen existing legislation aimed at addressing human rights violations and gender inequalities and to promote a respect for the rights of infected and affected people and assistance to women in taking appropriate decisions to protect themselves against HIV infection.

The Assembly of Heads of State and Government of the OAU at its 32nd ordinary session in Yaounde, Cameroon, from 8 to 10 July 1996, adopted the Resolution on Bioethics (African Bioethics Resolution).[768] The African Bioethics Resolution acknowledges that:

> scientific progress benefits the individual human being and is achieved under condition of respect for fundamental human rights, and *stressing* the need for international co-operation in order to enable humanity as a whole to benefit from the achievements of the science of life and obviate any use thereof for purposes other than the promotion of humanity's well-being ...

The African Bioethics Resolution endorses the priority placed upon informed consent by the ICCPR,[769] and stresses the 'obligation to obtain the free and enlightened consent' to research, and 'the definition of rules to protect vulnerable populations, the incapacitated, persons deprived of freedom as well as the sick under emergency conditions'.[770] The African Bioethics Resolution further reaffirms the right to benefit from scientific progress and the application of such progress without discrimination,[771] and the right of everyone, especially children, to protection 'from all forms of trade and exploitation'.[772]

The African Bioethics Resolution pledges to take legislative and other measures to give effect to the Resolution, as well as setting up consultative bodies at all levels to promote the exchange of experience.

5.2.6 African Charter on Rights and Welfare of the Child

Article 43(1) of the Children's Charter compels state parties to submit to the African Committee of Experts of the Right and Welfare of the Child, through the Chairperson of the Commission of the African Union, 'reports on the measures they have adopted to give effect to the provisions of the Children's Charter, as well as the progress made in the enjoyment of the rights guaranteed in the African Children's Charter'. According to the Guidelines for Initial Reports of State Parties under the African

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768 AHG/Res 254 (XXXII) 1996.
769 Para 2 African Bioethics Resolution.
770 Para 3 African Bioethics Resolution. See also para 4.3.2 of ch 5 below.
771 As above.
772 As above.

Children's Charter, states should indicate the measures that are in place to ensure the safety of children in need of special protection, such as in the case of AIDS orphans.[773]

Article 14 of the African Children's Charter guarantees to every child the 'right to enjoy the best attainable state of physical, mental and spiritual health'.[774] State parties to the African Children's Charter 'shall undertake to pursue the full implementation of this right'.[775] In particular, they shall take measures which include[776] the reduction of the infant and child mortality rate; the provisioning of necessary medical assistance and health care to all children with emphasis on the development of primary health care; and measures ensuring the provision of adequate nutrition and safe drinking water, to combat disease and malnutrition within the framework of primary health care through the application of appropriate technology and to ensure appropriate health care for expectant and nursing mothers.[777]

Article 15 of the African Children's Charter deals with child labour. Although participation in HIV-related clinical research cannot be seen as 'labour', the phrasing of article 15 compels state parties to protect children from 'all forms of economic exploitation'.[778] The participation of children in clinical research which is exploitative is thus strictly prohibited by the African Children's Charter. Examples of exploitative treatment of children in clinical research are easily found in the literature. These examples include experiments such as those performed at the Willowbrook State School,[779] the Trovan experiments on children in Nigeria,[780] the testing of medications which will not eventually be available to those children on whom it was

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773 Para 21(g) Guidelines for Initial Reports of State Parties under the African Charter on Rights and Welfare of the Child.

774 Art 14(1) African Children's Charter.

775 As above.

776 Art 14(2)(a) – (j) African Children's Charter.

777 They have the further task of ensuring the development of preventive health care and family life education and provision of service, the integration of basic health service programmes in national development plans; that all sectors of the society, in particular parents, children, community leaders and community workers are informed and supported in the use of basic knowledge of child health and nutrition, the advantages of breastfeeding, hygiene and environmental sanitation and the prevention of domestic and other accidents; the meaningful participation of non-governmental organisations, local communities and the beneficiary population in the planning and management of basic service programmes for children; and to support, through technical and financial means, the mobilisation of local community resources in the development of primary health care for children.

778 Art 14(1) African Children's Charter.

779 See para 4.2.1 Ch 3.

780 See para 4.2.2 of ch 3 above and para 5.2.6 above.

tested, the testing of HIV-medication which, due to its toxicity, is not suitable for use in children, and the exploitation of children through payment for participation in clinical research in poverty-stricken communities where participation in such research is the only means of income for those children and their families. According to article 15 of the African Children's Charter, state parties are to 'take all appropriate legislative and administrative measures to ensure the full implementation of this article'.[781]

Article 16 deals with the protection of children against child abuse and torture. Sub-section 1 reads as follows:

> State parties to the present Charter shall take specific legislative, administrative, social and educational measures to protect the child from all forms of torture, inhuman or degrading treatment and especially physical or mental injury or abuse, neglect or maltreatment including sexual abuse, while in the care of a parent, legal guardian or school authority or any other person who has the care of the child.

HIV-related clinical research which exploits children in the ways described above may be considered within the ambit of the prohibition in this sub-section.

Harmful social and cultural practices are prohibited in article 21.[782] The relevance of this sub-section to HIV-related research becomes clear when one considers that much research in Africa necessarily takes place within a context in which these practices are present. For example, practices such as female genital mutilation have implications for the transmission of HIV, as do traditional practices which support girl-children's and women's subordinate role in African society. Research which supports or turns a blind eye to the existence of these practices is necessarily in violation of the African Children's Charter. HIV-related clinical research cannot be complicit in the perpetration of practices that are harmful.

The African Children's Charter prescribes a measure or standard against which children's participation in HIV-related clinical research can be measured. Article 4(1) reads as follows, '[i]n all actions concerning the child undertaken by any person or

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781 Art 15(2).

782 The article reads:

1. State parties to the present Charter shall take all appropriate measures to eliminate harmful social and cultural practices affecting the welfare, dignity, normal growth and development of the child and in particular:

(a) those customs and practices prejudicial to the health or life of the child; and
(b) those customs and practices discriminatory to the child on the grounds of sex or other status.

2. Child marriage and the betrothal of girls and boys shall be prohibited and effective action, including legislation, shall be taken to specify the minimum age of marriage to be eighteen years and make registration of all marriages in an official registry compulsory.

authority, the best interests of the child shall be the primary consideration'. HIV-related clinical research which does not have the best interests of the child as its aim is thus prohibited. As in the case of CRC, the singular noun, 'child', indicates that the best interests of the specific child taking part in the research is to be considered, and not the interests of children generally. [783]

The African Children's Charter also ascribes responsibilities that children have in relation to their family and society. The child is to 'serve his national community by placing his physical and intellectual abilities at its service'.[784] Children's participation in HIV-related research, if it is not exploitative and is in the best interests of the child, can be viewed as sanctioned by this sub-section of the African Children's Charter. In this view, children are part of a community which may benefit from their participation.

The Tunis Declaration on AIDS and the Child was adopted by the OAU at the Assembly of Heads of State and Government in Tunisia in 1994 (Tunis Declaration).[785] The Declaration embodies Africa's commitment to elaborate 'a national policy framework to guide and support appropriate responses to the needs of [HIV/AIDS] affected children covering social, legal, ethical, medical and human rights issues'.[786] Thus far little has been done to give effect to the Tunis Declaration.[787]

5.2.7 Protocol to the African Charter on Human and Peoples' Rights on Rights of Women in Africa

Article 2 of the Women's Protocol deals with the elimination of discrimination against women. It prohibits 'all forms of discrimination against women'.[788] State parties must take measures which modify 'social and cultural patterns of conduct of women and men', 'achieving the elimination of harmful cultural and traditional practices and

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783 Viljoen points out that the use of '*the* primary consideration' (instead of '*a* primary consideration' as used in CRC) sets a higher level of protection for children under the African Children's Charter than under the CRC. See Viljoen 'Africa's contribution to the development of international human rights and humanitarian law' (2001) 1 *African Human Rights L J* 18.

784 Art 31(b).

785 AHG/Decl 1 (XXX) 1994.

786 Para 2(1) Tunis Declaration.

787 As evidenced by the fact that at the 32nd ordinary session of the Assembly of Heads of State and Government in 1996, the Resolution on Regular Reporting of the Implementation Status of OU Declarations on HIV/AIDS in Africa was adopted. Governments were urged to implement resolutions and declarations of the OAU, especially the Tunis Declaration.

788 Art 2(1) Women's Protocol.

all other practices which are based on the idea of the inferiority or the superiority of either of the sexes, or on stereotyped roles for women and men'.[789]

HIV-related clinical research that collaborates with harmful cultural practices or stereotyped roles for women is consequently prohibited. For example, in many African cultures, because of the inferior position society assigns to women, it is expected that the researcher first asks 'permission' for a woman's participation in research from the woman's father or husband, sometimes even before the woman herself is approached. Researchers react in two ways to this practice. Firstly, they may follow the cultural norm and approach the woman's father or husband, but make sure that the woman herself also consents. In doing this, they reinforce harmful practices and stereotypical roles of women: they 'buy into' the idea that women's consent of itself is not sufficient, and that someone in a role of authority over her should consent on her behalf as well. Secondly, they may exclude women altogether from their research design because they do not want to enforce such negative cultural practices. Consequently women are excluded from the benefits attaching to research participation, and are discriminated against indirectly as any knowledge gained from the research will not be applicable to women. Even worse still, the results and knowledge gained from the research will be applied to women despite the fact that they did not take part in the research, without taking into account the specific peculiarities of the female body.

The dilemma sketched above presents a very difficult choice for researchers, and there is no easy answer. The first alternative presented is marginally better than the second, in the sense that, at least, women are not excluded from the possible benefits of the research. However, research which reinforces society's stereotypical views of women should never be condoned.

Of special importance to the present study are sections in the Women's Protocol which deal with women's health and reproductive rights.

Under section 14 of the Women's Protocol, state parties undertake to ensure that the right to sexual and reproductive health of women is respected and promoted, specifically their right to have 'self-protection and to be protected against sexually transmitted infections, including HIV/AIDS'.[790]

The implications of this provision of the Women's Protocol for HIV-related clinical research in Africa are clear. The assurances that women are protected

789 Art 2(2) Women's Protocol.
790 Art 14(1)(d) Women's Protocol.

against sexually transmitted diseases, such as HIV, during the duration of the research, and, by the nature of the research design, are not exposed to these diseases, are requirements in terms of the Women's Protocol. Women need to be educated, not only by government but also by researchers, about the possibility of contracting sexually transmitted diseases, including HIV/AIDS, and also the ways in which they may protect themselves against such diseases. It may also be necessary for research sponsors to provide medication and other treatment for such diseases during the research endeavour.

Women have the right to be informed on their 'health status and the health status of [their] partner, particularly if infected with sexually transmitted infections, including HIV/AIDS, in accordance with internationally recognised standards and best practices'.[791] If a researcher, or a member of the research team, becomes aware of the health status, especially the HIV status, of a woman's sexual partner, the Women's Protocol places an obligation upon the researcher, 'in accordance with internationally recognised standards and best practices' to inform her of the health status of the partner, failing which they are in violation of the Women's Protocol. With this provision the drafters of the Women's Protocol make a laudable effort to protect women's health.

However, the matter is not as straightforward as it appears. The situation may arise that the researcher becomes aware of the woman's HIV-positive status. The Women's Protocol does not place a similar obligation upon the research team to inform her sexual partner (nor can it really be said that such a duty is implied by the Women's Protocol). One could argue that, in some societies, women may be stigmatised, ostracised or even killed if their status becomes known, and therefore, there should be no such obligation to inform her partner. But that begs the question: not only women's, but also men's health surely should be protected, especially in the case of an epidemic as devastating as HIV/AIDS. It is submitted that the impact of this provision of the Women's Protocol, if adhered to by researchers, could have a disproportionately negative impact on men. It is further submitted that, unless there are clear prohibitive indications, such as that it endangers the woman's life or exposes her to harm, researchers should inform a woman's sexual partner of her status. Women should also be informed at the beginning of the research endeavour that the possibility exists that their partners will be told if it becomes clear that they are HIV-positive.

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791 Art 14(1)(e) Women's Protocol.

Further, state parties must take appropriate measures to 'provide adequate, affordable and accessible health services ...'[792] and 'establish and strengthen existing pre-natal, delivery and post-natal health and nutritional services for women during pregnancy and while they are breastfeeding'.[793] This obligation relates to the duty of state parties to human rights treaties to *fulfil* the human rights of the inhabitants of the country, HIV-related research which assists in this task is in support of the fulfilment of that duty.[794]

5.3 Conclusion

The section focuses on specific provisions in international and regional human rights instruments that are valuable in protecting participants in HIV-related research in Africa from abuse. International human rights instruments, such as ICCPR, ICESR, CRC and CEDAW, as well as regional instruments such as the African Charter on Human and Peoples' Rights, the African Charter on Rights and Welfare of the Child and the Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa are singled out for attention. Examples of 'soft' law are highlighted.

The analysis demonstrates that international human rights instruments do provide an effective legal framework for the protection of participants in HIV-related clinical research in Africa. Many of the provisions contained in these instruments enunciate rights that are relevant in the context of HIV/AIDS-related clinical research participation in Africa, either through specific reference to clinical research or experimentation, or through more general prohibitions against 'degrading treatment' and violations of physical integrity, privacy and equality.

Significant progress has been made in the implementation of international human rights, despite the challenges which remain, such as holding non-state actors responsible for the violation of human rights under international law. In the context of the present study, human rights violations in clinical research in Africa most likely will be the result of actions by multi-national or transnational pharmaceutical corporations, international research bodies and other individuals.[795] However, as

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792 Art 14(2)(a).

793 Art 14(2)(b).

794 For more about the obligations of governments to respect, protect and fulfil human rights, see para 6.4 below.

795 Nowak points out (on 343) that many of these multinational corporations are more powerful and financially stronger than many states. On that ground it seems to him

human rights treaties confer a duty upon state parties to *protect* the human rights enunciated in the treaties, a violation by third parties (both state and non-state actors) in terms of those treaties holds the states accountable for failing to protect the rights of research participants.[796] Political pressure could be brought to bear on the government of countries in which the multinational corporations, international research bodies or individuals have their headquarters or on the government of the countries in which they operate and carry out their research[797] in the hope that they will force these organisations to comply with human rights standards, and will act as the 'watch-dogs' of the international community.

Consumer boycotts and the 'mobilisation of shame', usually by NGOs and the press are alternative strategies.[798] The public outcry created by these strategies changes the behaviour of corporations and individuals so that they adopt voluntary codes of conduct and of corporate responsibility.[799]

A more far-reaching proposal to make non-state perpetrators of human rights violations bear responsibility for their actions is to transfer responsibility to the individual.[800] Under international criminal law, not only governments but also the individual perpetrators of gross and systematic human rights violations are held responsible for their actions, for example, members of the Bosnian Serb armed forces, as well as 'individual' perpetrators of genocide in Rwanda have been found guilty and sentenced for war crimes.[801] It is to be doubted, however, whether violations during clinical research are ever going to be of the magnitude that they can be considered 'gross and systematic' human rights violations. International criminal law, therefore, has little to offer the victims of violations of human rights during clinical research.

Ultimately it is up to governments to adopt measures which make international human rights binding and justiciable within their own territories under domestic

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'somewhat anachronistic that states should remain the only subjects of international law capable of signing and ratifying treaties under international law'.

796 See also Clapham (n 652 above).

797 Nowak 343.

798 As above.

799 Nowak 343. Examples are the UN Global Compact and the OECD Guidelines for Multinational Enterprises.

800 Nowak 343.

801 Nowak (n 23 above) 244.

law.[802] Cognisant of this fact, the next section of the chapter scrutinises the domestication of international human rights in sub-Saharan Africa, with special reference to South Africa.

6 DOMESTICATION OF INTERNATIONAL HUMAN RIGHTS IN SUB-SAHARAN AFRICA, WITH SPECIAL REFERENCE TO SOUTH AFRICA

6.1 Introduction

As indicated in the preceding sections, international human rights law depend on a functioning national system of human rights law: not only is the national system the first line of defence against human rights abuses, but international human rights treaties have value only if states give effect to the provisions by implementing them at a national level.

In instances in which effective national human rights systems coexist with international systems for the protection of human rights the primary responsibility for the protection rests with the national authority and the protection offered under the international system is subsidiary.[803] An effective remedy is available at national level and, therefore, the requirement is that domestic remedies be exhausted before a complainant turns to a regional or UN forum.

By becoming a state party to an international human rights treaty, states undertake to fulfil a variety of obligations.[804] Governments of states must 'respect',[805] 'protect',[806] 'fulfil'[807] and 'promote'[808] the human rights contained in the

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802 See para 6 below. See also generally Adjami 'African courts, international law and comparative case law: Chimera or emerging human rights jurisprudence?' (2002) 24 *Michigan J Intl L* 103.

803 Nowak 37.

804 Dugard defines a 'treaty' or 'convention' as a 'written agreement between states or between states and international organisations, operating within the field of international law'. There are three different types of treaties, namely, contractual, which deals with matters such as trade and air and landing rights; legislative, which codify existing rules of customary international law or which create new rules of law; and constitutional treaties which create international organisations such as the UN. The Charter of the UN is thus a constitutional treaty (see Dugard (n 643 above) 26 - 27).

805 Individual states must *respect* rights by refraining from interfering with the enjoyment of these rights, such as not enacting legislation which limits freedom of the press.

806 Individual states must *protect* rights by protecting the people within a state from violations of those rights by third parties. This is usually done by means of legislating, for example, in the case of South Africa which adopted legislation (Act 4 of 2000) which protects against discrimination.

treaty. However, these obligations do not require states to transform the treaty or convention word for word into national constitutional law, but rather that the obligations deriving from international law are implemented under national or domestic law.[809]

The following section investigates the ways in which international human rights obligations are implemented under domestic or national law in sub-Saharan Africa. Later specific reference is made to the South African system, in preparation for the next chapter which deals with informed consent in preventive HIV vaccine efficacy trials in South Africa.

6.2 General overview of different views on the place of international law with regard to national law

Differing views exist on the relationship or place of international law with regard to national law. These views have consequences not only for the mechanisms used for incorporating international human rights law into national law, they affect the interpretation of the place of international human rights law in national law as well.

The first view of international law falls into the monist or monistic system. The monist view, as the name indicates, considers international law and national law as one system of law.[810] In other words, international law and national law are a single integrated system. International human rights treaties in 'monist' states are thus considered equal to, or superior to, the national constitution by virtue of an express constitutional order.[811] In cases such as these,[812] international law is incorporated into national or municipal[813] law without any act of adoption or transformation, and courts have to apply the rules of international law directly.[814]

In the second view, a strict distinction is made between international and national law, as they are seen as two different systems of law.[815] It is referred to as

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807 State parties to a treaty must *fulfil* human rights by taking positive measures aimed at ensuring the fulfilment of those rights, for example by building schools and training teachers to give effect to the right of access to education.

808 Individual states *promote* human rights by making sure that people are aware of the nature and extent of their human rights. This is usually done through awareness-raising campaigns.

809 Nowak (n 23 above) 37.

810 Dugard 43.

811 Nowak 36.

812 The Netherlands is an example; additional examples are given below.

813 The term 'municipal' is used in international law to refer to the national law of a state.

814 Dugard 43.

815 As above.

the dualist or dualistic view or theory. 'Dualist' states may not incorporate or transform international human rights treaties into national law except through an express order from the national legislator.[816] Tijanyana Maluwa remarks that, as a general rule, dualists accord international law primacy over municipal law in the international sphere, and municipal law enjoys primacy over international law in the national sphere.[817]

States do not necessarily adhere to the same system consistently; some states follow a dualist view in respect of some aspects of international law, and a monist view in respect of others.[818] The degree of implementation can also differ. For example, in some states which follow a monist view, international human rights law may be considered even superior to domestic law. In others, which adhere to the dualist view, international law has no force and effect unless and until it has been given substance by domestic courts.[819]

Moreover, a rigid distinction between 'monist' and 'dualist' systems is less credible in practice and the 'antithesis between monist and dualist approaches to the relationship between international and municipal law must be viewed with some caution'.[820] First, the application of international human rights law depends upon *municipal law* in the specific country; usually the constitution assigns the status of international law in the legal system.[821] Second, a wide range of approaches spans the two systems, incorporating to some extent elements of both.[822] Finally, countries in the monist tradition, in some circumstances, refuse in practice to give effect to treaties which under international law are binding.[823] Viljoen characterises it as an 'unhelpful and deceptive' categorisation and is in favour of discarding the distinction for an approach which identifies whether treaty provisions serve as grounds *for independent legal action* in the absence of domestic enactments 'grounding' these treaties.[824]

With regard to the situation of international human rights law in Africa, Maluwa indicates that the practice in African states in incorporating the substantive norms of international human rights law into national law, or in using them as an aid

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816 The United Kingdom is an example; Nowak 36.
817 Maluwa (1998) 23 *SA Ybk Intl L* 49.
818 Dugard 43.
819 Nowak 36.
820 Maluwa (n 817 above) 49 – 50.
821 As above, 50.
822 As above.
823 As above.
824 Viljoen (n 562 above). See the section on self-executing treaties below.

to interpretation, depends in part upon the colonial experiences and their inherited colonial legal cultures and systems.[825] It is possible to distinguish African countries with an English common law tradition (former British colonies) from countries with a civil law tradition (former colonies of France, Germany, Italy, Portugal and Spain).[826]

African countries in an English common law tradition follow a dualist approach. Their constitutions stipulate that international human rights law does not become part of national or domestic law without explicit incorporation by an act of parliament.[827] For example, the Malawi Constitution in article 211(1) stipulates that an agreement ratified by Parliament 'shall form part of the law of the Republic *if so provided for in the Act of Parliament ratifying the agreement*'.[828]

African countries in a civil law tradition follow a monist approach. The rules of international law are part of domestic or municipal law in terms of the constitution of the state and, in certain instances, enjoy preference over domestic legislation.[829] For example, article 9 of the Constitution of the Federal Republic of Ethiopia provides that '[a]ll international agreements ratified by Ethiopia are an integral part of the law of the land'. Article 147 of the Constitution of Benin provides that '[t]reaties or agreements lawfully ratified shall have, upon their publication, an authority superior to that of laws, without prejudice for each agreement or treaty in its application by the other party'. The Preamble to the Constitution of Benin declares that principles of international law as contained in UN Charter, the Universal Declaration and the African Charter 'make up an integral part of this present Constitution and of Benin law and have a value superior to the internal law'.

An alternative approach to role of international human rights law in the domestic legal system is presented below.

6.3 Self-executing provisions

'Self-executing' provisions are rules of international law which are considered to apply *directly* in domestic legal systems or, stated differently, they are treaty provisions or a treaty which of their own force constitute rules of municipal law which municipal courts must apply in deciding cases involving the rights of

825 Maluwa 50.
826 As above, 50 – 51.
827 Maluwa (n 817 above) 51.
828 My emphasis.
829 Maluwa 52.

individuals.[830] Self-executing treaties do not require legislation to make them private rights of action, while non-self-executing treaty provisions do require such legislation.

The South African Constitution makes provision for the self-execution of treaty provisions in section 231(4), which reads (my emphasis):

> Any international agreement becomes law in the Republic when it has been enacted into law by national legislation; but a *self-executing provision* of an agreement that *has been approved by Parliament* is law in the Republic *unless it is inconsistent with the Constitution or an Act of Parliament.*

There are three important aspects to self-executing provisions in this provision: First, Parliament has to have approved the agreement containing the self-executing provision. Michéle Olivier argues correctly that this proviso does not imply that parliament must recognise the self-executing status of a treaty provision, but rather that the agreement, itself, had been approved.[831] In other words, in the case of self-executing provisions there is no necessity for legislative incorporation of the treaty.[832] Second, the self-executing provision must not be inconsistent with an act of Parliament or the Constitution. Third, it is for the national courts to decide whether a particular treaty provision is self-executing or not.

Self-executing treaties are recognisable in the following ways: the intention of the drafters of the treaty;[833] the intention of the contracting parties to the treaty;[834] the precision of detail in the language employed in the treaty (the broad and general nature of a provision may prevent it from being regarded as self-executing);[835] the subject matter of a treaty (for example, treaty provisions establishing negative obligations or prohibitions are regarded generally as self-executing as no measure to implement them is required);[836] and if the provision benefits individuals (a provision which creates private rights is assumed *prima facie* to be directly applicable).[837]

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830 Olivier (2002) 27 *SA Ybk Intl L* 99.
831 In terms of sec 231(2); Olivier 115.
832 As above.
833 See Craven (1993) 40 *Netherlands Intl L Rev* 372 384; Olivier 104.
834 See Olivier 105.
835 Olivier (n 830 above) 106.
836 Olivier 107.
837 Treaties such as the ICESR, generally, are usually worded in such a way that they lay down obligations on states and their legislators rather than addressing the position of individuals. The ICCPR, instead, refers directly to the rights of individuals (see Olivier 107). This approach is criticised by Craven (n 830 above) 394.

Olivier is of the opinion states adopt policies favouring direct application for a number of theoretical and practical reasons.[838] Since all law belongs to one system in a monist system, direct application enhances the effectiveness of international law as it decreases the possibility that states will refuse or neglect to transform treaties into domestic law. It increases the effectiveness of a treaty in that individuals may rely on such a treaty in domestic legal institutions and it gives an assurance that all parties will honour their obligations in terms of the treaty.[839]

Dualists, however, have arguments against self-execution. In their view national and international law are separate systems, so there is no *a priori* reason why an international instrument should automatically form part of a national system. Parliamentary transformation of a treaty into domestic law serves as a democratic check and compensates for the lack of direct participation by parliament in the treaty-making process.[840] Further, it may be necessary to change or 'tailor' the treaty to match domestic circumstances. For example, legislators may wish to limit direct application to specific provisions in the treaty. Olivier holds the view that in domestic law the interpretation of a treaty by an international body is definitive and, therefore, is binding on domestic courts.[841]

Self-execution appears to offer an effective method of incorporating treaty obligations into national law. However, it is not guaranteed that the interpretation adopted by the domestic court coincides with either that of the treaty supervisory body or with those of courts in other states. Usually, national courts are in the best position to apply provisions of a treaty in a domestic context, and provide realistic and suitable interpretations of the norms in the treaties.[842]

Self-executing treaties are discussed in the South African context in paragraph 6.5 below.[843]

6.4 Implementation measures

In a period of 50 years, international human rights law has progressed through three stages, namely, promotion, protection and prevention.[844]

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838 Olivier 108.
839 As above.
840 As above, 109.
841 Olivier 109.
842 Olivier 112. Not all scholars agree with Olivier. Dugard, for example, holds that the term 'self-executing' is 'essentially meaningless'. See Dugard (n 643 above) 56 – 58.
843 Also see para 4.3.1 of ch 5 below.

From the discussion on the UN system above, it is clear that the UN Charter requires state parties only to 'promote' human rights.[845] The subjects of international law were independent states rather than individuals, groups or peoples, and interference in state sovereignty was not even hinted at, and the international protection of human rights was a rarity.[846]

In the decades which followed the international community took steps to go beyond promotion, drafting human rights treaties which would constitute legally binding obligations under international law.[847] The universal system and the regional systems for the protection of human rights are the products of this endeavour.

The prevention of human rights violations relies on strategies such as objective fact-finding missions, early warning systems that are effectively implemented, preventive visits, educational activities, publicity and campaigns like Amnesty International's 'mobilisation of shame'.[848] Nowak adds effective enforcement and implementation measures to the list.[849]

Nowak rightly observes, the terms 'human rights protection or implementation' apply only in instances where international bodies (such as political bodies of international organisations or international courts) are granted the right to monitor compliance with international human rights agreements.[850] Without the monitoring or 'policing' function of these bodies, state compliance depends on the goodwill of individual governments.

Latterly, a system of mechanisms for the implementation of international human rights has developed. Some are more successful than others.

Measures exist for the implementation or protection of international human rights; namely, the state reporting procedure, the inter-state reporting procedure, the individual complaints procedure, the inquiry procedure and on-site visits. Each is discussed below.

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844 Nowak (n 23 above) 27. Nowak refers to the three stages as the 'three P's'.
845 Art 1(3) of the UN Charter, for example, merely speaks of the 'promotion' of human rights.
846 Nowak 27.
847 As above.
848 Nowak 29 – 30.
849 Nowak 29.
850 Nowak 28.

State reporting is relied upon by organisations such as the UN, the AU and the Council of Europe and is usually mandatory for states parties.[851] State reporting is considered less effective than other measures of treaty monitoring.[852] It aims to attain a 'comprehensive overview' of the state party's measures, at a domestic level, to implement its obligations under international human rights law.[853] State reports are usually prepared on a biannual basis by the individual state, and reflect the human rights situation in that state, reporting on difficulties that have been observed, as well as legislative or other measures taken to improve the situation.

Nowak argues that the effectiveness of state reporting requires governments to take their obligations under international law seriously, and draft honest, objective and serious state reports, engaging in constructive dialogue during the examination stage.[854]

The inter-state complaints procedure requires states parties to make a complaint against other states parties about human rights violations. This procedure is used at both the universal and the regional level. The procedure is optional or mandatory.[855]

Generally, very few inter-state complaints have been lodged. States are hesitant to criticise their neighbours, fearing that it will be seen as an act of hostility or that the state accused will retaliate. In any case, states are reluctant to criticise other states if they have no interest in the outcome of the complaint.[856]

The individual complaints procedure is designed to provide relief to victims of specific human rights violations.[857] The procedure is either mandatory or optional.[858] Sometimes it is relegated to an optional protocol, which allows states parties to opt out.[859]

The individual complaints procedure investigates a 'concrete individual human rights violation' or a situation in which there are 'gross and systematic human rights violations'.[860] Further hurdles are admissibility criteria, such as the exhaustion of

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851 Nowak 265.
852 As above.
853 Nowak 266.
854 Nowak 266.
855 Eg mandatory for, amongst others, the European Charter, the African Charter and CERD, but optional for ICCPR and CAT.
856 As above.
857 Nowak 266 – 267.
858 Eg mandatory for, amongst others, the European Charter and the UN 1503 procedure but optional for CERD and CAT.
859 Eg Optional Protocol to ICCPR.
860 Nowak 267.

domestic remedies, requirements relating to standing, and others.[861] The outcome of the procedure may be legally binding or have non-legally binding effects. Examples of outcomes are: a report from a Special Rapporteur or a commission of experts, a decision of a quasi-judicial treaty monitoring body, a resolution of a political body or a binding judgment of a human rights court. Mediation is frequently called upon during the process of investigation in order to reach a friendly resolution.[862] Procedures for collective complaints, the *actio polularis*, as well as inquiry procedures and fact-finding missions, are all part of the individual complaints procedure.[863]

Presently, the individual complaints procedure under Protocol 11 of the European Charter is the most effective and accessible in dealing with individual complaints.[864] The individual complaints procedure may, amongst other remedies, result in relief to the victim, interpretation of the normative content of the provision, changes in national law and practice and may have a preventive effect on the national level.[865]

The inquiry procedure, like the individual complaints procedure, is the result of evidence of concrete instances of human rights violations, but is not dependent on actual complaints of human rights violations.[866] It functions as *ex officio proceedings*, usually held *in camera*.[867] The fact that the proceedings for this mechanism usually are confidential is its greatest weakness.[868] The proceedings, also, are often long and complicated.[869] The procedure is optional or mandatory. Visits to the sites where the violations are reported to have occurred depend on permission being granted by the state party.[870]

Other forms of human rights implementation exist, such as Commissions of experts, *ad hoc* human rights tribunals that hear cases of violations, other methods of fact-finding by missions of experts and Rapporteurs, and human rights monitoring by NGOs who report cases of violations to the various international bodies.[871]

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861 See Nowak 267.
862 Nowak 267.
863 As above.
864 See para 3.2.2 above.
865 As above.
866 Nowak 268.
867 As above.
868 As above.
869 As above.
870 Nowak 268.
871 Nowak 269.

Unlike the individual complaints procedure that deals with violations of human rights that have already taken place, the system of preventive visits attempts to forestall human rights violations.[872] International bodies carry out unexpected visits to sites, especially to sites where prisoners are held, where there is evidence of possible gross human rights violations such as torture and the like.[873] It is hoped that the anticipation of these visits will have a restraining effect on the perpetrators of human rights violations.[874]

The implementation measures outlined above can be considered effective only if the international body's or court's recommendation or decision on the human rights violation is enforced against the state concerned.[875] Non-compliance with a recommendation or decision is censored in a variety of ways; by exerting political or other pressure, by expelling countries from international organisations, suspending development or financial co-operation, and imposing economic or other sanctions against that country.[876] If these measures fail, not much remains to be done at the international level. David Thomasma comments: '[s]tigmatizing violators of human rights with international sanctions and public outcries, although necessary, does not seem to be enough to ensure the protection of human rights'.[877]

International implementation of human rights cannot be as effective as the domestic implementation of human rights. If a bill of rights is incorporated in a domestic constitution within a system of constitutional supremacy, it is immediately justiciable.[878]

The implementation of human rights law, which for long had been seen as a matter that fell within the domestic jurisdiction of sovereign states, is now part of international law. Human rights apply universally across state borders, and can be protected and implemented through the various mechanisms that were established under the international and regional systems.

Increasingly, human rights have become the shared responsibility of individual states and the international community. Not only do non-justiciable human rights declarations exist but binding human rights treaties as well. States

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872 Nowak 268.
873 Nowak 268 – 269.
874 Nowak 267 – 268.
875 Nowak 28.
876 Nowak 29.
877 Thomasma (1997) 25 *J L, Med & Ethics* 296.
878 See para 5.2 ch 5 below.

are monitored and forced to account for the measures undertaken to enforce human rights within their borders. Under certain treaties individuals may compel state parties to answer to the violations of human rights. This development constitutes a break with previous concepts of state sovereignty and non-interference of the international community in the domestic affairs of a state.

6.5 International human rights in the South African system

6.5.1 A constitutional approach

The development of a notion of justiciable human rights or human rights as legal rights is closely linked to the development of the concept of constitutionalism.[879] Constitutionalism 'is a movement born out of the spirit of enlightenment to ensure that the state's main tasks and structures were written down in a constitution, which as the highest legal standard within the state, was considered binding and lasting'.[880] Constitutionalism, in other words, is the notion that government should 'derive its powers from a written constitution and that its powers should be limited to those set out in the constitution'.[881]

Constitutions usually consist of two distinct parts. The first is formal; describing aspects such as the functioning of the organs of the state, the separation of powers, procedures for the appointment of office bearers, and so on.[882] The second is the material part which lays down the values, aims and objectives professed by the state, as well as fundamental human rights if these are included in the constitution.[883] Bills of rights, therefore, are a representation of the values and aims a particular state wants to pursue.[884]

As government derives its power from a constitution; a constitution serves to limit the power of government. This is done in two ways. First, a constitution imposes limitations on power that are structural or procedural.[885] Government

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879 Up until after World War II, human rights were rights contained in national constitutions rather than international human rights instruments.

880 Nowak 15.

881 de Waal *et al* (2000) 7. See generally, Udombana 'Interpreting rights globally: Courts and constitutional rights in emerging democracies' (2005) 5 *African Human Rights LJ* 47.

882 Nowak (n 23 above) 15.

883 Nowak 15. Initially it was thought that the state merely had to respect human rights through non-interference. Presently, with the acceptance of theories related to the interdependence and indivisibility of human rights, it is accepted that these are positive obligations upon the state.

884 Nowak 17.

885 de Waal *et al* (n 881 above) 7.

institutions may exercise constitutionally prescribed powers, in a prescribed way.[886] Second, through the operation of a bill of rights, substantive limitations are imposed as government cannot exercise its power in such a way that it will violate the human rights of the inhabitants of the country.[887]

Under international human rights law, states have the obligation to respect, fulfil and protect human rights.[888] States respect human rights through refraining from intervention, provided their intervention is not permissible under any reservation clauses. Unjustified interventions are considered violations of human rights.[889] South Africa is a party to the Charter of the United Nations and, therefore, is bound to respect human rights.[890]

Nowak explains the effect of the out-sourcing of state assets upon the protection of human rights. As current trends encourage the state to privatise or outsource assets, such as health care, the state's duty with respect to health care consequently is diminished,[891] but its obligation to protect the right to health care has increased proportionately as the extensive transfer of state responsibility may have the violation of rights as a consequence.[892]

The obligation to fulfil human rights is the state's obligation to take legislative, administrative, judicial and other measures (such as resource allocation) that are necessary to ensure that the rights are implemented to the greatest extent possible.[893] Here attention should also be given to prevention of human rights violations – legislation and other measures should be in place to prohibit actions which could interfere with the fulfilment of human rights. In South Africa, equality legislation is an example of such an action by the state to fulfil and protect human rights.[894]

The obligation to protect human rights requires state action in that it requires the state to avoid human rights violations by private persons.[895] The extent to which the state has to protect private persons, however, is still unclear.[896]

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886 As above.
887 As above. Other principles which support constitutionalism are constitutional supremacy, justiciability and entrenchment
888 Nowak 49. Dugard argues that the observation of human rights is an international legal norm (see Dugard in Chaskalson *et al* (1996) 13 – 17.
889 Nowak 49.
890 See Dugard in Chaskalson *et al* 13 – 18.
891 Nowak 49.
892 Nowak 49.
893 Nowak 49.
894 Act 4 of 2000.
895 As above.

Because, under international law, individuals are the bearers of rights and states are the bearers of duties, private persons are generally not obliged by international agreements to act or refrain from acting.[897] The exception is in terms of international criminal law – persons who commit gross and systematic human rights violations, as state or as private persons, are responsible for these actions.[898] Nevertheless, the classical procedures used by international human rights law to protect human rights are directed at states (such as, state reporting, individual complaints procedure).[899] Private individuals do not have the same accountability as states that have to show what has been done to offer protection against human rights violations.[900]

Furthermore, human rights that are codified in international treaties are to be protected first and foremost by the relevant national legal protection institutions. International courts and monitoring bodies are appealed to only as a last resort in the event that the national legal process is unsuccessful or the treaties are interpreted in conflicting ways.[901] Many treaties require that domestic remedies be exhausted before an appeal may be made to an international body.

As mentioned above,[902] human rights were first incorporated into national constitutions, and national legal systems were responsible for their implementation and enforcement. The constitutions of countries such as the United States of America contained justiciable bills of rights long before human rights became part of international law,[903] and before their implementation became a matter for international law.

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896 As above. Nowak argues that states usually take measures to protect the rights of its citizens. In the case of domestic violence legislation, the state is taking legislative measures to protect the rights of its citizens, and to ensure that a violation does not happen. Also, historically, the aim of human rights protection was protection against private abuses – such as freedom of religion is against the monopoly of a universal church. Therefore, at national level, such human rights violations are always enforceable against private persons and state bodies.
An example in international law where the same situation exists is in international criminal law. Art 3 of four Geneva Conventions of 1949 and the 2nd additional protocol of 1977 are binding also on non-state combatants (Nowak 53).

897 Nowak 50.

898 As above.

899 As above.

900 Nowak 53. Such as a state must have sufficient penal provisions etc to ensure the citizen's right to personal security – else states fail to fulfil the treaty obligation to respect or protect.

901 Nowak 38.

902 Para 2.3.

903 Nowak 38.

The international human rights system not only coexists with the national system, but the national system is usually the first level of defence against human rights abuses. In states in which a national system for the protection of human rights is in place, it is often contained in a national constitution; the victim of abuse first turns to the national system, and then to the international system for human rights protection.

In South Africa, a national system of human rights protection exists within the Constitution.[904] In the following paragraphs, the relationship between international and national human rights law is explored with specific reference to sections 39(1)(b), 231, 232 and 233 of the South African Constitution.

It is important to remember that until 1994 international human rights instruments played a minor role in South African jurisprudence. Dugard indicates that South Africa was party to the Charter of the United Nations alone, and that was not incorporated into national or municipal law.[905] South Africa was not a party to other human rights conventions, which, therefore, could not be used as a guide to statutory interpretation.[906]

The promulgation of the 1993 Constitution introduced a dramatic change. Dugard comments on this development.[907]

> As a result of the new Constitution it has now become common place for the Constitutional Court and other courts to invoke human rights norms and decisions by international human rights tribunals and supervisory bodies to interpret the Bill of Rights and to set aside laws and administrative practices that violate human rights.

The following paragraphs explore the interaction between the international human rights system and the South African national system for the protection of human rights, including the implementation of international human rights obligations within the South African system.

a) Section 39(1)(b)

Section 39(1) requires an interpretation of the Bill of Rights which promotes the values which underlie an open and democratic society based on human dignity, equality and freedom. Of particular relevance to the present thesis is subsection 39(1)(b) which demands that, when interpreting the Bill of Rights, a court, and

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904 Constitution of the Republic of South Africa 1996.

905 Dugard 263. For a list of international human rights instruments to which South Africa is a party, see para 5.3 below.

906 As above.

907 Dugard 265.

tribunal or forum 'must consider international law'. This section of the Constitution compels the use of international law as an interpretive tool when interpreting the Bill of Rights. Guidance should thus be sought from international human rights declarations, treaties, conventions and covenants.

Whether these treaties have been signed or ratified by South Africa is not significant as no qualification to that effect is included in section 39(1). In this regard, the Constitutional Court stated the following in *S v Makwanyane*[908] about section 35(1) of the Interim Constitution,[909] the section equivalent to section 39(1):[910]

> In the context of section 35(1), public international law would include non-binding as well as binding law. They may both be used under the section as tools of interpretation. International agreements and customary international law accordingly provide a framework within which chapter 3 can be evaluated and understood, and for that purpose, decisions of tribunals dealing with comparable instruments, such as the United Nations Committee on Human Rights, the Inter-American Commission on Human Rights, the Inter-American Court on Human Rights, the European Commission on Human Rights, the European Court of Human Rights and, in appropriate cases, reports of specialised agencies such as the International Labour Organisation, may provide guidance as to the correct interpretation of particular provisions of chapter 3.

Apparently a wide interpretation is to be given to the term *public international law* as it was used in the Interim Constitution,[911] and includes international human rights treaties, declarations, agreements and decisions of international bodies such as commissions and courts under the universal and the different regional systems, as well as the decisions of so-called 'specialised agencies' such as the International Labour Organisation.[912] In *Makwanyane* the Constitutional Court referred to a wide

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908 *S v Makwanyane and Another* 1995 (3) SA 391 (CC).

909 Act 200 of 1993.

910 Paras 36 - 37.

911 The Final Constitution uses the term 'international law', which is a wider term than public international law as it would encompass private international law as well. There is uncertainty about what exactly qualifies as international law. Does international law encompass all forms of international law such as *ius cogens* and customary international law, or only public international law?

912 In this regard, the Court refers to Dugard in fn 36 of its judgment. According to Dugard, a court must in terms of s 39(1) consider not only those treaties and conventions to which South Africa is a party to, but also:
(a) international conventions, whether general or particular, establishing rules expressly recognised by the contesting states;
(b) international custom, as evidence of a general practice accepted as law;
(c) the general principles of law recognised by civilised nations;
(d) judicial decisions and the teaching of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law.
This definition is taken from the definition of international law given in art 38(1) of the Statute of the International Court of Justice.

range of sources of international law, such as the International Covenant on Civil and Political Rights, the European Convention on Human Rights, the American Convention on Human Rights and the African Charter on Human and Peoples' Rights, as well as the writings of well-known and qualified authors in the field.[913]

It is important to note that section 39(1) should be used as an interpretive tool and in determining the scope of the rights in the Bill of Rights, and not for proving that they exist.[914]

In *Government of the Republic of South Africa and Others v Grootboom and Others*[915] the Court held that the relevant international law may act as a 'guide to interpretation but the weight to be attached to any particular principle or rule of international law will vary'.[916] The Court stated that, where the relevant principle of law binds South Africa, it may be directly applicable.[917]

The statement by the Court appears to distinguish between two different aspects or roles of international law in relation to the South African Constitution and the Bill of Rights: first, as an interpretive tool in accordance with section 39(1), and second, as a binding international agreement in terms of section 231 and 232 of the Constitution, in which case 'it will be directly applicable'.

Another aspect of section 39(1)(b) needs to be mentioned. The section requires a court, tribunal or forum to *consider* international law; it does not provide that a court, tribunal or forum will be *bound by* international law, but merely that it should consider such law when interpreting the rights in the Bill of Rights. In this regard, the Court remarks as follows in *Dawood and Another v Minister of Home Affairs and Others; Shalabi and Another v Minister of Home Affairs and Others; Thomas and Another v Minister of Home Affairs and Others*:[918]

> [section 39(1) of the Constitution] provides that a court, when interpreting the Bill of Rights, '(b) must consider international law; and (c) may consider foreign law'. As pointed out by Chaskalson P in *S v Makwanyane and Another* at para [39] 'in dealing

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See generally Dugard in Chaskalson *et al* 1 (n 888 above) 13 – 17 and Dugard (1994) 101 *SA J Human Rights* 208.

913 Dugard (n 643 above) 206 observes that recourse to international law under s 39(1)(b) may be detrimental to the rights of the individual. He points out that in *Prince v President of the Law Society, Cape of Good Hope* 1998 (8) BCLR 976 984 – 5 and 988 – 989, the court found that international norms on religious freedom were outweighed by South Africa's international obligations to suppress drug abuse.

914 de Waal *et al* (n 881 above) 130.

915 2001 (1) SA 46 (CC).

916 Para 57.

917 Para 57.

918 2000 (1) SA 997 (C) 1035D.

> with comparative law we must bear in mind that we are required to construe the South African Constitution, and not an international instrument or the constitution of some foreign country, and that this has to be done with due regard to our legal system, our history and our circumstances, and the structure and language of our own Constitution'.

Significantly, the Court acknowledges it can derive *assistance* from public international law and foreign case law, but is not bound to follow them: [919]

> It must, however, also be borne in mind that the lawmakers of the Constitution should not lightly be presumed to authorise any law which might constitute a breach of the obligations of the state in terms of international law.

A court has to take into account 'the history and our circumstances, and the structure and language of our own Constitution' when applying international law to the interpretation of the Bill of Rights. In the words of Kriegler J in *Sanderson v Attorney-General, Eastern Cape*:[920]

> In this context I wish to repeat a word of warning I have expressed in the past. Comparative research is generally valuable ... Nevertheless the use of foreign precedent requires circumspection and acknowledgement that transplants require careful management. Thus for example, one should not resort to the *Barker* test or *Morin* approach without recognising that our society and our criminal justice system differ from those of North America.

b) Section 231

Unlike section 39(1), which gives guidance on the interpretation of the rights in the Bill of Rights, section 231 deals with the negotiation and signing of international agreements,[921] the steps to be taken before such an agreement is binding upon the Republic,[922] and the binding nature of international agreements that were entered into before the Constitution came into effect.[923]

According to section 231(1), all international agreements should be negotiated and signed by the national executive. The conclusion of international agreements is thus an executive prerogative.[924] The legislature has no part in the process of concluding international agreements; their powers are limited to transforming international agreements into national or municipal law.[925]

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919 Para 1035E – 1036F.
920 1996 3 SACLR I (SE) para 26.
921 Art 231(1).
922 Arts 231(2) – 231(4).
923 Art 231(5).
924 Dugard (n 643 above) 49.
925 See below.

The term used in section 231(1) is 'international agreement' instead of 'treaty'. Dugard observes that the term 'international agreement' is not a wider term than treaty, but, more or less, is synonymous with the term 'treaty'.[926]

Section 231(2) states that international agreements bind the Republic only after they have been approved by resolution[927] in both the National Assembly and the National Council of Provinces, unless they are of the type of agreement referred to in subsection (3). International agreements that require ratification, thus require an act in the form of a resolution by the legislature to transform them into national or municipal law.[928]

According to section 231(3), an international agreement of a technical, administrative or executive nature, or an agreement which does not require either ratification or accession, entered into by the national executive, binds the Republic without approval by the National Assembly and the National Council of Provinces, but must be tabled in the Assembly and the Council within a reasonable time.

It is unclear exactly what is an agreement of a 'technical, administrative or executive nature'.[929] It could be argued that many agreements fall within this category, especially subsidiary agreements that give effect to, and provide for the implementation of principal agreements (such as the technical details and implementation, for example, of environmental agreements). Until this provision is given substance through interpretation by the South African courts, it will remain unclear exactly what is meant by its wording.[930] Olivier suggests that the approach

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926 Dugard 59.

927 'Resolution' refers to a number of actions used to make an international agreement part of national law. They are: an Act of Parliament; subordinate legislation made in terms of an Act of Parliament; and legislation that was in force when the Constitution took effect and that is administered by the national government (sec 239 Constitution of the Republic of South Africa 1996.

928 Dugard 56 - 57. This was the position even before the 1993 and 1996 Constitutions. The need for legislation to transform an international agreement into municipal law was explained by Steyn CJ in *Pan American World Airways Inc v South African Fire and Accident Insurance Co Ltd* 1965 (3) SA 150 (A):
'... that in this country the conclusion of a treaty, convention or agreement by the South African government with any other government is an executive and not a legislative act. As a general rule, the provisions of an international agreement so concluded, are not embodied in our law except by legislative process ... In the absence of any enactment giving ... relevant provisions the force of law, [it] cannot effect the rights of the subject' (para 161C-D).

929 See eg Botha (1997) 22 *SA Ybk Intl L* 95, where he comments on the confusing nature of these terms.

930 Dugard is of the opinion that the intention of the parties concluding the agreement will determine the nature of the agreement. He remarks that art 14 of the Vienna Convention on the Law of Treaties emphasises the intention of parties in deciding

to section 231(3) adopted by the state international law advisors, who interpret the terms used in the section to 'refer to agreements of a routine nature, flowing from the daily activities of government departments', may help the courts in determining the meaning of these terms.[931]

Another aspect of section 231(3) requires comment. An agreement entered into by the national executive which does not require either ratification or accession binds the Republic without approval by the National Assembly and the National Council of Provinces. Such a treaty would thus become binding upon signature.

Section 231(4) provides that any international agreement becomes law in the Republic when it is enacted into law by national legislation; on the other hand, a self-executing[932] provision of an agreement that has been approved by Parliament is law in the Republic unless it is inconsistent with the Constitution or an Act of Parliament.[933]

Section 231(5) makes it clear that international agreements that were in effect when the Constitution came into effect, will continue to bind the country. This subsection is significant for our discussion below;[934] a number of international human rights agreements were concluded before the Final Constitution came into effect, which will continue to be binding.

Section 231 of the Constitution was the subject of litigation in the case of *S v Harksen; Harksen v President of the Republic of South Africa and Others; Harksen v Wagner NO and Another.*[935] In this case, Harksen, in terms of the Extradition Act[936]

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whether a treaty requires ratification or not. This principle was also supported in *S v Eliasov* 1967 (4) SA 583 (A). See Dugard 56.

931 See Olivier (1997) 22 *SA Ybk Intl L* 63 64.

932 Dugard 58 remarks that the concept of a self-executing treaty is problematic, as it is never exactly clear when the provisions of a treaty are self-executing or not. (In the case of a self-executing treaty, existing legislation is considered enough for the Republic to comply with its obligations under that treaty without any further act by the legislature incorporating that treaty into South African law.) He is of the opinion that to decide which treaties are self-executing, the courts will have to decide each case on its own merits, and that courts will have to have due regard to the nature of the treaty, the precision of its language and the existing South African law on the subject.

933 Dugard distinguishes three main methods by which the legislature may transform treaties into municipal or national law. They are the embodiment of the provisions of a treaty in the text of an Act of Parliament; the treaty may be included as a schedule to a statute; and an enabling Act of Parliament may give the executive the power to bring a treaty into effect in municipal law by publishing a notice or proclamation in the *Government Gazette* (see Dugard 57 – 58).

934 See para 6.5.2 below.

935 2000 (1) SA 1185 (C).

936 Act 67 of 1962.

appealed against his extradition to Germany where he was wanted for fraud. The Court had to consider whether the President's consent to Harksen's extradition was constitutional, in the light of the fact that no extradition agreement existed between South Africa and Germany. It was argued that the President's consent to Harksen's extradition brought into existence an international agreement in contravention of section 321 of the Constitution. The court had to determine the meaning of the term 'international agreement' in terms of section 231, and whether the President's correspondence with the German government constituted an international agreement in terms of the Constitution.

The Court held that, in order to establish whether an international agreement had been established, it had to consider the relevant documentation and correspondence to find out whether the parties had intended to conclude an internationally binding agreement with reciprocal rights and duties.[937]

The Court examined the definition of a treaty in the Vienna Convention,[938] and held that there could be no agreement without the requisite intention or consensus between the parties.[939] The Court further held that it is this intention and consensus which separates formal international agreements from mere informal arrangements between parties. The Court thus held that no international agreement had been concluded between the parties.

In the light of this case, the phrase 'international agreements' as used in section 231 must be given a very narrow interpretation, to mean formal and legally binding international agreements only. Section 231 would not include informal international arrangements and agreements and international law as contemplated in section 233.[940]

The distinction between informal international arrangements and formal agreements is potentially of great importance when considering that most

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937 1200 paras D – E.

938 The Vienna Convention on the Law of Treaties 1969 defines a treaty as:
'An international agreement concluded between states in written form and governed by international law, whether embodied in a single instrument or in two or more related instruments and whatever its particular designation'.

939 1201 paras A – B.

940 See Olivier (n 931 above) 63 who argues: 'the term 'international agreement' as it appears in section 231 is used in the narrow sense of the word to refer only to legally binding documents. Informal or legally non-binding international agreements fall outside the ambit of section 231, although they can, strictly speaking, also be regarded as agreements of an international nature' (on 75).

arrangements for international collaborative clinical research could be classed as merely informal arrangements.

To sum up: international law, other than customary international law,[941] is not law in the Republic unless it meets the requirements of section 231, that is, that it has been approved by resolution in the National Assembly and the National Council of Provinces; or, if it is an international agreement of a technical, administrative or executive nature, it meets the requirements in section 231(3).

c) Section 232

Section 232 of the Constitution deals with customary international law.[942] It provides that customary international law 'is law in the Republic unless it is inconsistent with the Constitution or an Act of Parliament'. Even if South Africa has not ratified an international human rights treaty (in which case that treaty would be binding as international law in terms of section 231), its provisions could be considered part of customary international law and binding in terms of section 232.

As stated, customary international law is national law of South Africa, unless it is inconsistent with the Constitution or an Act of Parliament. Unlike other international law, customary international law is national law, is not subject to subordinate legislation,[943] and is not simply a tool for interpreting the Bill of Rights in terms of section 39(1)(b). It implies that, when interpreting a right in the Bill of Rights, according to section 39(1)(b), a court, tribunal or forum must apply customary international law as it is the law of the country.

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941 See para 4.4 above.

942 'Customary international law' is a narrower term than 'international law' and can be considered a component of international law. Customary international law, however, is not easily defined. It is formed by a general state practice that is accepted as law (as per the definition given in section 38 of the Statute of the International Court of Justice). For a custom or rule of law to qualify as international customary law, there must be a wide and uniform practice of states in the belief that the practice is binding upon them and legally required. The International Court of Justice, for example, requires sufficient state practice and *opinio juris* before it accepts that a certain rule is a rule of customary international law (in this regard, see O'Shea *International law and organization: A practical analysis* 20 – 23). Many of the rights contained in the Universal Declaration of Human Rights, for example, may be considered part of international customary law, as well as humanitarian conventions, such as the Geneva Conventions. A rule of international law may become customary international law if enough time has elapsed in which the legal rule is considered as binding by states, and if states generally consider the rule as binding upon them. The distinction between international law generally, and customary international law, specifically, does not seem very clear-cut. See Dugard 24 – 32.

943 Dugard 52.

It is important to note the proviso contained in section 232. Customary international law is national law only if it does not conflict with the Constitution or an Act of Parliament.

Section 232, however, does not provide any guidance as to exactly which rules of customary international law apply in South Africa. Keightley argues that, because the 1996 Constitution no longer includes the words 'customary international law *binding on the Republic*', as contained in the Interim Constitution, all rules of customary international law are now part of South African national law, whether they are binding upon the Republic or not, and regardless of whether South Africa supports them.[944] Keightley uses the *dictim* in the *Makwanyane* case[945] to support his argument, forgetting, it seems, that *Makwanyane* referred only to the use of customary international law in the interpretation of the Constitution.

In contrast to Keightley, Botha argues that the words 'binding on the Republic' were not included in the 1996 Constitution merely because they were unnecessary and tautologous.[946] Botha's interpretation is more acceptable, as the proviso in section 232 that customary law should not conflict with an Act of Parliament or the Constitution suggests that rules of customary international law which are not supported by South Africa are not applicable to the country.

In order to decide exactly which rules of international customary law are binding on South Africa, and how they should be proved, is a matter for judicial precedent as no guidance is given in this regard in section 232.[947] Dugard argues that the omission of the word 'binding' in the 1996 Constitution lends support to the idea that customary law rules that are generally accepted - instead of those which are universally accepted - is sufficient for proof of the existence of customary international law.[948] He observes that this is the standard set by the International

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944 Keightley (1996) 12 *SA J Human Rights* 408. See also Kinney (2001) 34 *Indiana L Rev* 1457, where she argues that widespread ratification of UN and regional treaties recognising international human rights norms establishes an international customary law of human rights. Treaties, declarations and the like become evidence of a general state practice in which states take part because of their sense of legal obligation. She further argues that the International Convention on Economic, Social and Cultural Rights is customary international law due to its widespread acceptance in many countries around the world.

945 See n 782 above, '[i]n the context of section 35(1), public international law would include *non-binding* as well as *binding* law' (my emphasis).

946 Botha (1994) 9 *SA Public L* 255.

947 As above.

948 Dugard 54.

Court of Justice, and that there is no reason why South Africa should require proof of rules which are *universally* accepted.[949]

It is also important to note that, according to section 232, customary international law is law in South Africa, and that the courts have no discretion whether to apply it or not – they must apply customary international law as it is the law of the Republic.

d) Section 233

Section 233 deals with the application of international law when interpreting legislation. It provides that, 'when interpreting any legislation, every court must prefer any reasonable interpretation of the legislation that is consistent with international law over any alternative interpretation that is inconsistent with international law'. The common law presumption requiring a court to interpret legislation in compliance with international law is now made a constitutional provision.[950]

As the Constitution and the Bill of Rights were promulgated as legislation, their interpretation should be included in section 233.[951] If section 233 is read together with section 39(1)(b), when interpreting the Bill of Rights, a court must not only consider international law but it should also prefer an interpretation of the rights in the Bill of Rights that is consistent with international law over one which is not.

Again, the term 'international law' presents problems. Unlike section 39(1) where the courts have interpreted the term to include both binding and non-binding international law,[952] section 233 has not yet been given substance by the courts. However, in terms of the rules of statutory interpretation, the term 'international law' in section 233 should be interpreted in the same way as it was interpreted in section 39, unless clear indications to the contrary exist; in this case they do not. Given that the Constitutional Court in *Makwanyane* gave a wide interpretation to the term as used in the 1993 Constitution,[953] it follows that the same interpretation will be given

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949 As above.

950 Dugard 60. See also Devenish (1992) 212.

951 This is not the only view on the issue. Some writers hold that the Constitution and the Bill of Rights are not just 'any legislation' as used in s 233, and that, therefore, there is express provision for their interpretation in terms of s 39. According to this view, sec 233 refers only to legislation other than the Bill of Rights and the Constitution (see in this regard eg Dugard in Chaskalson *et al* 13 – 17).

952 See para 4.1 above.

953 n 908 above.

to the term as used in section 233, which means that 'international law' as used in section 233 includes both binding and non-binding international law.

Further, it should be noted that section 233, in its requirement to prefer any reasonable interpretation of the legislation that is consistent with international law, does not contain the same condition as the one contained in section 232 – that it should not be inconsistent with the Constitution or an Act of Parliament.

What will happen when a court interprets legislation in compliance with international law, but that interpretation is in conflict with an Act of Parliament or the Constitution? The second possibility, if the interpretation is in conflict with the Constitution, does not present a substantial problem: the Constitution, as the 'supreme law of the Republic',[954] will always be the preferred interpretation, making an interpretation in conflict with its provisions invalid.

In the case of the first possibility, an interpretation which is in keeping with international law but in conflict with an Act of Parliament, it should be noted that section 233 uses the phrase 'reasonable interpretation'. Although the courts have not yet interpreted section 233, it is expected that in the future an interpretation that is in conflict with an Act of Parliament will not be considered 'reasonable'. [955]

6.5.2 The status of international human rights instruments in South Africa

The mechanisms used by states to transform or translate international (human rights) law obligations into national law consist of a variety of possible actions. International treaties may be 'adopted', 'signed', 'accepted', 'approved', 'acceded to' and/or 'ratified' by states. Each of these terms has a different meaning.

The adoption of a treaty or agreement under international law refers to the formal or legal act by which the content or text of a treaty is accepted or established. For example, treaties or agreements are often established by a meeting or international conference of a (political) body which is held for the express purpose of setting up or agreeing on the content of such a treaty. Voting on the treaty or agreement usually completes this process.

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954 Art 2 Constitution of the Republic of South Africa 1996.

955 Also see *Azapo v President of the Republic of South Africa* 1996 (4) SA 671 (CC) para 26, which reads '[i]nternational law and the contents of international treaties to which South Africa might or might not be a party at any particular time are, in my view, relevant only to the interpretation of the Constitution itself, on the grounds that the lawmakers of the Constitution should not lightly be presumed to authorise any law which might constitute a breach of its obligations of the state in terms of international law'. See also Botha (n 946 above) 102.

The signing of a treaty or international agreement reflects a state's willingness to be bound by the provisions of the treaty. It does not mean that the state is automatically bound to the provisions of the treaty upon signature. Signature is often subject to ratification and merely indicates the state's agreement to proceed to the next step. Usually, the signing of the treaty, indicates a state's acknowledgment that it will refrain from actions which may defeat the objects of the treaty.

The acceptance or approval of a treaty or international agreement refers to the action by which a state expressly consents to be bound by the treaty and its obligations. It has the same legal effect as ratification, and is used in instances where the national constitution of a state does not require international agreements to be ratified before they have the force of law.

To accede to a treaty or international agreement refers to the act by which the state accepts an offer or opportunity to become a party to a treaty. The treaty by this act is binding upon the state in question. This act has the same effect as ratification.

Ratification refers to the act by which a state indicates that it wishes to be bound by the treaty or international agreement, and is carried out by enacting national law or by another act. In some systems,[956] a treaty is ratified when domestic law is enacted to give effect to the treaty.

Dependent on the character of the domestic or national constitutional system, and the specific provisions of the constitution or enacting legislation, the status international human rights law may have in relation to the constitution and other domestic law differs in the various domestic legal systems. In some systems international law is elevated above domestic law and even the domestic constitution; in others international law is superior in status to ordinary domestic law, but not to the constitution. In this case international law may have an equal status with the domestic or national constitution. Yet others view international law as inferior to all domestic law – whether ordinary law or constitutional law. The latter situation seldom occurs because a state party to a treaty undertakes to hold itself bound to the provisions of that treaty; if international law is deemed inferior to national law, such an undertaking would be defeated.

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956 See below.

The present status of international human rights instruments in South Africa is set out below in schematic format.[957] Only human rights instruments of relevance to the present study are included.[958] Abbreviations are used, and in cases where human rights instruments have not been ratified by South Africa, the date of signature is indicated in the right-hand-side column.

Declaration / Treaty /Convention	**Ratification / accession by South Africa**	**Signature by South Africa[959]**
UN		
Universal Declaration of Human Rights		SA abstained.[960]
ICCPR	10 March 1999	
Optional Protocol I to ICCPR	28 November 2002	
Optional Protocol II to ICCPR	28 August 2002	
ICESCR		3 October 1994
CEDAW	14 January 1996	
CEDAW Optional Protocol	X	X
CRC	16 July 1995	
OTHER		
European Convention on Human Rights and Biomedicine	N/A[961]	N/A
AU		
African Charter on Human and Peoples' rights	9 July 1996	
African Charter on Rights and Welfare of the Child	7 January 2000	
African Women's Charter	17 December 2004	
African Court Protocol	3 July 2002	

6.6 Conclusion

South Africa's new democratic constitutional order, which requires courts to interpret all legislation,[962] and particularly the Bill of Rights,[963] to accord with international law, shows the importance international human rights holds in the South African legal order. From the analysis of the different roles of international law in the Constitution

957 Information on South Africa's ratification of these instruments obtained from the websites of the different treaty organisations.

958 These are the instruments referred to in para 4 above.

959 In cases where South Africa signed the treaty, but has not yet ratified it. In general, once having signed a treaty, that country should in good faith not do anything that would violate the provisions of that treaty.

960 South Africa abstained together with seven other countries. 48 votes were in favour of the Universal Declaration. However, should the Universal Declaration be accepted as part of customary international law, as is argued by many, its content is law in South Africa.

961 This Convention is not limited to members of the EU, but makes specific provision for states outside of the EU to sign and ratify it. South Africa has done neither and it appears that this instrument is relatively unknown in South Africa.

962 Sec 233 Constitution of the Republic of South Africa 1996; see above.

963 Sec 39(1)(b) Constitution of the Republic of South Africa 1996.

in the first part of this section, it is clear that international law can be used as an interpretive tool (in terms of section 39(1)(b) and section 233) and as a source of law (when it satisfies the requirements of sections 231 and 232 of the Constitution). In cases where a rule of customary international law is not in conflict with the Constitution or an Act of Parliament, the rule may be used as an interpretive tool in terms of section 39. In terms of section 232, international customary law is also to be applied as law in South Africa. In cases where the rule of international law is in conflict with the Constitution and an Act of Parliament, it may still be used as an interpretive tool.

From the table outlining the status of different international and regional human rights instruments in South Africa it is clear that South Africa has ratified the major international human rights treaties, and that, as international law, these treaties are the law of South Africa.

7 CONCLUSION

A major problem in relation to clinical research ethics is that it tends not to take account of the wide range of inequalities in a research setting.[964] Not only is there a gap in knowledge between the researcher and the research participant, but in Africa, where there is poverty, little attention is paid to the unequal distribution of power created by poverty and other social circumstances.[965] In their criticism of bioethics, Paul Farmer and Nicole Gastineu Campos comment:[966]

> The majority of such international biomedical research has inequality as its foundation, and ethical codes developed in affluent countries are quickly ditched as soon as affluent universities undertake research in poor countries. Then come a series of efforts to develop alternatives (read, less stringent) codes 'appropriate' to settings of destitution.

Their sentiments are echoed by dos Anjos:[967]

> First, to what level of quality can medical ethics aspire, if it ignores callous discrimination in medical practice against large populations of the innocent poor? Second, how effective can such theories be in addressing the critical issues of medical and clinical ethics if they are unable to contribute to the closing of the gap of socio-medical disparity?

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964 Farmer and Gastineau Campos (2004) 4 *Developing World Bioethics* 23.

965 Farmer and Gastineau Campos comment: 'It [the research enterprise] is also a fundamentally inegalitarian exercise in the sense that medicine and science are expanding rapidly, but in a social context of growing global inequality, which ensures that the fruits of medicine and science are not available to many who need them most' (on 25).

966 As above, 22.

967 Dos Anjos (1996) 21 *J Med and Philosophy* 629.

These statements are generalisations; there are countless instances of research initiatives in the developing world which take account of inequalities, as there are of researchers who rigorously follow clinical research ethical guidelines. There are, on the other hand, instances in which research undertaken in the developing world would never be performed in the developed world.[968] Marcia Angell comments:[969]

> The fact remains that many studies are done in the Third World that simply could not be done in the countries sponsoring the work. Clinical trials have become big business, with many of that same imperatives. To survive, it is necessary to get the work done as quickly as possible, with a minimum of obstacles.

Farmer and Gastineau Campos quote a Haitian woman who is dying of AIDS: 'We are good enough to study but not good enough to care for'.[970] If true, this statement would be a terrible indictment of the clinical research undertaken in the developing world. It represents the view of the research participant who feels that she has been let down by the research initiative, and has been exploited and discarded.

With regard to exploitation or the perception of exploitation, the chapter has explored justiciable human rights as an alternative means to protect participants in clinical research in Africa. The international system for human rights protection has been contrasted with the ethical guidelines that were examined in chapter 3.

The origin and nature of human rights were explored and a brief philosophical background to the development of the notion of human rights has been given. It was mentioned that the application of human rights to a field traditionally considered the ambit of clinical research ethics or bioethics is criticised by bioethicists. Some bioethicists consider human rights discourse incapable of accommodating the philosophical moral reasoning that is a necessary part of bioethics or clinical research ethics.[971]

Critics of bioethics, on the other hand, consider bioethics and clinical research ethics 'too philosophical'. Churchill asserts:[972]

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968 See para 4.2.2 of cha 3 above.

969 Angel (1997) 337 *New Eng J Med* 847.

970 Farmer and Gastineau Campos (n 964 above) 22. They comment that such critiques of research ethics are often dismissed as 'confused and ill-informed commentary' or as 'conspiracy theories' (Farmer and Gastineau Campos 20).

971 See para 2.6 above.

972 Churchill (1999) 128 *Daedalus* 255.

> Bioethical disputes – as measured by the debates in journals and conferences in the United States – often seem to be remote from the values of ordinary people and largely irrelevant to the decisions they encounter in health care.

Arguments which relate to the universality or relativity of human rights have been presented, and the position is argued that human rights, by definition, are universally applicable. If human beings have rights by virtue of their common humanity, it can only be because there are general moral standards that are universal in application.

In this chapter the protection international and regional human rights documents and instruments offer participants in clinical research has been critically examined and the development and impact of the United Nations' Charter-based and treaty-based systems and the three regional systems have been surveyed.

The investigation of human rights provisions which are relevant to the protection of clinical research participants in domestic constitutions of selected sub-Saharan African countries, shows that an adequate human rights framework exists for the protection of participants in HIV-related clinical research in Africa.

Specific human rights provisions, as contained in international human rights documents, are applied to a clinical research setting in order to determine the measure of protection they offer participants in clinical research in Africa. In this regard, the discussion demonstrates that these provisions are able adequately to accommodate many of the issues relevant to clinical research in Africa that were traditionally considered the exclusive jurisdiction of clinical research ethics, such as distributive justice, access to treatment and autonomy.

Finally, in this chapter international human rights are situated in a South African context. Sections 39(1), 231, 232 and 233 of the Constitution were sketched, and the status of specific international human rights instruments in South Africa charted. The chapter shows that the most important human rights treaties have been ratified by South Africa, and that human rights norms thus offer a justiciable framework for the protection of clinical trial participants in South Africa.

Chapter 4 aims to establish the foundation of the discussion in chapter 5 below, which deals specifically with informed consent in HIV vaccine efficacy trials in South Africa. Chapter 5 investigates the effectiveness of ethical guidelines and human rights standards for the protection of participants in these trials.