AFRICAN HUMAN RIGHTS LAW JOURNAL

The protection of participants in clinical research in Africa: Does domestic human rights law have a role to play?

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Summary

This article investigates the protection of clinical research participants in sub-Saharan Africa by domestic human rights instruments. It assesses the weaknesses in the existing regulatory framework in the form of international and national ethical guidelines, and surveys domestic human rights law in selected African countries to ascertain whether domestic human rights law may be used to augment and enhance the existing system of protection. It concludes that domestic human rights law has an important (if hitherto unutilised) role to play in the protection of clinical research participants in sub-Saharan Africa.

1 Introduction

A little over ten years ago Marcia Angell, the editor of *The New England Journal of Medicine*, sparked an acrimonious debate with her editorial in the September issue of that journal when she accused the scientists who conducted HIV peri-natal transmission[1] trials in Uganda of

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The article draws on sections of the writer's unpublished doctoral thesis, entitled 'Ethics and human rights in HIV-related clinical trials in Africa with specific reference to informed consent in preventative HIV vaccine efficacy trials in South Africa', University of Pretoria, 2007.

1 Also known a 'mother-to-child-transmission' or MTCT.

unethical conduct.[2] Angell criticised the scientists conducting the Ugandan trial for using a placebo arm[3] instead of providing the control group with anti-retroviral medication, in violation of the Declaration of Helsinki.[4] She argued that, if the trial had been conducted in the United States or another developed country, this would have been considered unethical, and the trial would not have been allowed.[5]

Angell's fundamental question concerning the ethical issue of conducting a trial in a developing country in a manner that is considered unethical in a developed country[6] continues to haunt research practices in Africa. In light of this, the article investigates the protection of clinical research participants in sub-Saharan Africa, assessing whether the existing regulatory framework, namely, international and national ethical guidelines, provides sufficient protection to research participants. Human rights law, in the form of domestic bills of rights, is proposed as a viable system to augment and enhance the existing system of protection.

The article begins with a brief examination of the burden of disease in sub-Saharan Africa, arguing that it is critical that clinical research be

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2 See M Angell 'The ethics of clinical research in the Third World' (editorial) (1997) 337 *The New England Journal of Medicine* 847; H Varmus & D Satcher 'Ethical complexities of conducting research in developing countries' (1997) 337 *The New England Journal of Medicine* 1003; P Lurie & SM Wolfe 'Unethical trials of interventions to reduce perinatal transmission of the Human Immunodeficiency Virus in developing countries' (1997) 337 *The New England Journal of Medicine* 854. The controversy concerned the use of a placebo in the trial where a known effective treatment exists. Such a trial would not have been allowed in the developed world, as it would have violated various principles of research ethics, such as art II.3 of the Declaration of Helsinki.

3 A 'placebo' is a dummy treatment or no treatment at all. Usually sugar tablets are given to the placebo or control group in a clinical trial, instead of the medication that is being studied.

4 Angell (n 2 above) 847. The Declaration of Helsinki, issued by the World Medical Association (WMA), is an international code of ethics overseeing biomedical research involving human participants. 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.

5 R Bayer 'The debate over maternal-fetal HIV transmission prevention trials in Africa, Asia, and the Caribbean: Racist exploitation or exploitation of racism?' (1998) 88 *American Journal of Public Health* 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). Several authors have subsequently commented upon the views expressed by Angell in her editorial. See eg H Vermus & D Satcher 'Ethical complexities of conducting research in developing countries' (1997) 337 *The New England Journal of Medicine* 1003. Varmus and Satcher argue that placebo-controlled trials alone are able to provide definitive and clear answers about whether the interventions have worked and 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. A more recent response to Angell is presented by EJ Emanuel 'The ethics of placebo-controlled trials — A middle ground' (2001) 345 *The New England Journal of Medicine* 915.

6 Angell (n 2 above) 848. See also the sources referred to in n 26 below.

undertaken to alleviate the problems faced in this regard by the region. Next, the existing system of protection, ethical guidelines, is examined, and an important weakness in the system is pointed out, after which the protection afforded by domestic human rights law to research participants in selected countries is surveyed. The article concludes with a few recommendations regarding the protection of clinical research participants in sub-Saharan Africa.

It is important to note that the article has a very specific focus: the protection of clinical research participants under *domestic* human rights law. The protection afforded to clinical research participants in sub-Saharan Africa by the regional human rights system is investigated in a subsequent article.[7] As well, it is important to stress at the outset that domestic human rights law is not proposed as an *alternative* to the existing system, but that it is suggested as a possible way to augment and strengthen the protection afforded by ethical guidelines.

2 Sub-Saharan Africa's heavy burden of disease

Despite the fact that only 11% of the world's population live in sub-Saharan Africa, the region carries a disproportionate burden of disease. The HIV and AIDS figures of the region are particularly alarming — more than 66,6% of all people living with HIV/AIDS live in sub-Saharan Africa.[8]

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.[9] This is not only due to HIV/AIDS, but also to the incidence of diseases such as tuberculosis (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.[10] 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.[11]

The following tables reflect the core health indicators of selected countries in sub-Saharan Africa (Angola, Benin, Botswana, Burundi, Congo,

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7 See A Nienaber 'The protection of clinical research participants in Africa by the African regional human rights system' (forthcoming).

8 UNAIDS (2006) AIDS epidemic update 6; 58% of them are women.

9 See below.

10 UNAIDS (n 8 above) 20. See Table A below.

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

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.[12]

	Life expectancy at birth (years)	**HIV prevalence rate (adults 15<) per 100 000**[13]	**Infant mortality rate (per 1 000 live births)**	**TB prevalence rate per 100 000**
Angola	39(M) 41(F)	3 3281	154	333
Benin	52(M) 53(F)	1 635	89	144
Botswana	42(M) 41(F)	23 624	86	556
Burundi	46(M) 48(F)	3 132	114	602
Congo	54(M) 55(F)	4 731	79	449
Eritrea	59(M) 63(F)	2 180	52	515
Ethiopia	50(M) 53(F)	...	109	546
Ghana	56(M) 58(F)	2 225	68	380
Kenya	51(M) 51(F)	6 125	78	936
Lesotho	42(M) 41(F)	22 684	102	588
Malawi	47(M) 46(F)	15 528	78	518
Mali	45(M) 47(F)	1 572	120	578
Mozambique	46(M) 45(F)	14 429	100	597
Namibia	52(M) 52(F)	17 676	46	577
Nigeria	47(M) 48(F)	3 547	101	536
Senegal	54(M) 57(F)	837	77	466
South Africa	50(M) 52(F)	16 579	51	511
Swaziland	38(M) 37(F)	34 457	104	1 211
Uganda	48(M) 51(F)	6 304	79	559
Tanzania	48(M) 50(F)	5 909	76	496
Zambia	40(M) 40(F)	15 819	104	618
Zimbabwe	43(M) 42(F)	19 210	60	631
Brazil	68(M) 75(F)	454	28	76
Canada	78(M) 83(F)	222	5	4
India	62(M) 64(F)	747	56	299

Table A: Male (M) and female (F) life expectancy at birth (expressed in years) (2004); HIV prevalence rate in adults 15-49 per 100 000 of population; infant mortality rate (per 1 000 live births); TB prevalence rate per 100 000 of population.

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 20 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 100 000 of the population is 936, 511 and 1 211 respectively, compared to four in Canada.

Due to the impact of diseases such as HIV and TB, the life expectancy

12 Information in both tables from WHO (2007) *World Health Statistics 2007*. These are the same countries that are included in the study of constitutional provisions of countries in sub-Saharan Africa (para 4 below).

13 Of the population.

in the region has dropped very low: Compare the life expectancy of Angola (39 and 41 years) to that of Canada (78 and 83 years).

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

	Physicians per 1 000[14]	Nurses per 1 000	Adult literacy rate (%)	Total expenditure on health as % of GDP[15]
Angola	0.08	1.31	67.4	1.9
Benin	0.04	0.72	34.7	4.9
Botswana	0.40	2.65	81.2	6.4
Burundi	0.03	0.19	59.3	3.2
Congo	0.20	0.96	82.8	2.5
Eritrea	0.05	0.55	...	4.5
Ethiopia	0.03	0.21	45.2	5.3
Ghana	0.15	0.20	57.9	6.7
Kenya	0.14	0.74	73.6	4.1
Lesotho	0.05	0.62	82.2	6.5
Malawi	0.02	0.59	64.1	12.9
Mali	0.08	0.45	19.0	6.6
Mozambique	0.03	0.21	...	4.0
Namibia	0.30	3.06	85.0	6.8
Nigeria	0.28	1.03	...	4.6
Senegal	0.06	0.25	39.3	5.9
South Africa	0.77	4.08	824	8.6
Swaziland	0.16	4.24	79.6	6.3
Uganda	0.08	0.55	66.8	7.6
Tanzania	0.02	0.30	69.4	4.0
Zambia	0.12	1.56	68	6.3
Zimbabwe	0.16	0.72	...	7.5
Brazil	1.15	3.84	88.6	8.8
Canada	2.14	9.95	...	9.8
India	0.60	0.80	61	45.0

Table B: Number of physicians per 1 000 of the population; number of nurses per 1 000 of the population; adult literacy rate as a percentage; and total expenditure on health care as a percentage of the country's GDP.

Again, the position in sub-Saharan Africa is deplorable. 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 one physicians per 1 000 of their populations, Malawi, for example, has 0,02, Mozambique 0,03, and Lesotho only 0,05. As well, 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 1,9%, Burundi 3,2% and Mozambique 4% (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

14 Of the population.

15 Gross Domestic Product. The figure is that of 2004.

disintegrating infrastructure, play a role in increasing the already heavy burden of disease carried by these countries.[16] Benatar places these considerations in a wider context:[17]

> 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 over-population 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.

In light of the 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.[18] The Nuffield Council on Bioethics[19] quotes a 1990 report by the Commission on Health Research for Development[20] to the effect of the vast gap between health needs and research expenditures.[21] The World Health Organisation (WHO)'s *ad hoc* Committee on Health Research refers to the difference as the 10/90 disequilibrium[22] — of the 50 to 60 billion US dollars that each year is spent world-wide on health care-related research, only 10% is spent on the health problems of 90% of the world's population.[23]

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:[24]

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.

Therefore, 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

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16 Nuffield Council on Bioethics (n 11 above) 21.

17 SR Benatar 'The HIV/AIDS pandemic: A sign of instability in a complex global system' in AA van Niekerk & LM Kopelman (eds) *Ethics and AIDS in Africa: The challenge to our thinking* (2005) 75.

18 Benatar (n 17 above) 83.

19 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 (accessed 15 January 2008).

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

21 Nuffield Council on Bioethics (n 11 above) 22.

22 As above.

23 As above.

24 n 21 above.

violations, it is patently obvious that in this climate there exist endless possibilities for the exploitation of research participants.[25]

3 The regulation of clinical research in Africa: Problems with the current system

At the beginning of the article, I referred to an instance of unethical conduct during clinical research in Uganda. This is not an isolated instance — accusations of unethical and illegal conduct by international pharmaceutical companies are many.[26] But why are abuses of this nature occurring?

Africa has become a sought-after destination for multi-national clinical research endeavours and international pharmaceutical corporations increasingly conduct clinical trials here. Africa offers large numbers of treatment-naïve research participants, making it possible to obtain a speedier result which, in turn, leads to the accelerated approval of new drugs.[27] Sponsors of clinical research tend to search out the least expensive, least burdensome regulatory environment with the lowest liability exposure, in order to avoid litigation in the event of injury to participants.[28] In many countries in Africa, there exists little, if any, legislation or even regulation governing clinical trails.[29] Meier writes that

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25 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.

26 See eg R Macklin *Double standards in medical research in developing countries* (2004) chs 1, 3 & 4; DB Resnik 'Exploitation in biomedical research' (2003) 24 *Theoretical Medicine* 233; DM Carr 'Pfizer's epidemic: A need for international regulation of human experimentation in developing countries' (2003) 35 *Case Western Reserve Journal of International Law* 15.

27 J Ford & G Tomossy 'Clinical trials in developing countries: The plaintiff's challenge' (2004) 1 *Law, Social Justice and Global Development* 3.

28 As above; eg Malawi, Tanzania and Zambia lack legally binding informed consent procedures (see BM Meier 'International protection of persons undergoing medical experimentation: Protecting the right of informed consent' (2002) 20 *Berkeley Journal of International Law* 533, fn 124).

29 Kelleher writes: 'Because their impoverished governments would otherwise be unable to provide medical treatment to their citizens, host countries — African nations in particular — have no legislative protection for subjects of clinical trials. Researchers in such countries, faced with dire medical conditions, understaffed hospitals, language and cultural barriers, and research subjects who would otherwise have no access to medical treatment, thus find it expedient to violate the minimum ethical standards for the protection of human subjects' (F Kelleher 'The pharmaceutical industry's responsibility for protecting human subjects in clinical trials in developing nations' (2004-2005) 38 *Columbia Journal on Law and Society* 67).

It should be noted that Kelleher's statement does not present the whole truth. In several African countries, local ethical guidelines exist over and above international guidelines. As well, in many instances a great deal of effort has been put into educating researchers about the content of ethical guidelines and into building the capacity of research ethics committees. Rather, the problem lies with enforcing these guidelines — see below.

'African nations vie to minimise regulation on the conduct of medical research. They fear that legislation, and resulting lawsuits, could have a chilling effect on beneficial research efforts.'[30] As well, in some host countries, 'corruption often prevents [research ethics committees] from protecting the interests of experimental subjects'.[31]

A regulatory framework for the protection of research participants is established by international ethical guidelines, such as the Nuremberg Code, the Council for International Organisations of Medical Sciences' International Ethical Guidelines for Biomedical Research involving Human Subjects and the Declaration of Helsinki.[32] However, this regulatory framework often fails to protect clinical research participants sufficiently, resulting in their injury and death. This failure to protect research participants is due to a number of reasons, the most important of which is the fact that international and national ethical guidelines are not enforceable — they are non-legal, non-binding ethical *principles*. 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 to fund or a refusal to publish unethical research, there is little to guard against unethical research conducted by unscrupulous agencies. Meier comments:[33]

> The medical profession has been shown not to have the ability to police itself. Although physicians have formed international medical organisations to promote medical responsibility, there is little evidence to suggest that these organisations have regulated physician behaviour or protected the rights of subjects to free and informed consent.

And:[34]

> The Nuremberg Code, Helsinki Declaration, and CIOMS Guidelines are not legally binding documents capable of placing legally enforceable obligations on states or individuals. They are not widely accepted or followed by physicians. Because they have no enforcement mechanisms, legal or medical, they have little effect on the regulation of human research.

To augment the current system of protection, this article proposes domestic human rights law as a means of protecting clinical research participants. 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.

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30 Meier (n 28 above) 532.

31 Meier (n 28 above) 533.

32 See RJ Levine *Ethics and regulation of clinical research* (1986) 12-13; 425-427 for more on the history and promulgation of these codes of ethics.

33 Meier (n 28 above) 531.

34 As above.

4 Survey of specific human rights provisions in domestic bills of rights potentially useful in the protection of clinical research participants

This section examines specific human rights provisions in domestic constitutions relevant to the protection against the abuse of participants in clinical research in Africa.

As indicated in the introduction to the article, the investigation is limited to countries in *sub-Saharan* Africa. Moreover, 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 are included. Sudan has been omitted as its Constitution has been suspended in the wake of the civil war.

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;[35] Lesotho; Malawi; Mali; Mozambique; Namibia; Nigeria; Senegal; South Africa; Swaziland; United Republic of Tanzania; Uganda; Zambia; and Zimbabwe. (Also refer to paragraph 3 above for tables presenting the core health indicators of these countries.)

The survey investigates the following questions:

- Is a provision specifically mentioning clinical research contained in the country's Constitution?
- Does the Constitution guarantee freedom from torture and other inhuman and degrading treatment which could be used to defend participants in clinical research against abuses of their person?
- Is the right to physical integrity guaranteed by the Constitution (for similar reasons as above)?
- Is the right to dignity guaranteed (clinical research undertaken without the informed consent of a participant may be regarded as a violation of dignity)?
- Does the Constitution contain 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 men who have sex with men (MSM), women who have sex with women (WSW), sex workers and injection drug users (IDUs)?
- Does the Constitution guarantee the individual's privacy?

[35] Kenya is included in the survey, although its Constitution may be suspended in the light of recent events in that country.

- Does the Constitution guarantee women's and children's rights which may be violated during clinical trial participation?
- Is the right to health care or access to health care 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?

4.1 Angola

Part II of the Constitutional Law of the Republic of Angola[36] 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 'colour, 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.[37]

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.[38] 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 and TB-related clinical research.

Part II, article 23 reads: 'No 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 of Human Rights (Universal Declaration), and article 7 of the International Covenant on Civil and Political Rights (CCPR). Unlike the corresponding article in CCPR, 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.[39] Women's rights are protected only within the context of the family, in which women and men are held to have equal rights.[40]

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36 Constitutional Law of the Republic of Angola, adopted 25 August 1992; http://www.chr.up.ac.za/hr_docs/constitutions/docs/Angola%20Constitution(rev).doc (accessed 31 January 2008).

37 Arts 18 & 20 Constitutional Law of the Republic of Angola.

38 Art 47 Constitutional Law of the Republic of Angola.

39 Art 30 Constitutional Law of the Republic of Angola.

40 Arts 18 & 29(2) Constitutional Law of the Republic of Angola.

4.2 Benin

Title II of the Constitution of the Republic of Benin[41] 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: 'No 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.[42] A duty is placed upon the state to protect the family, especially the mother and child.

4.3 Botswana

Chapter II of the Constitution of Botswana[43] 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'. Article 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.

The individual's right to privacy is protected, and no search of her person may be carried out without her permission.[44] However, the right to privacy is limited by, amongst others, anything that is 'reason-

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41 Constitution of the Republic of Benin, adopted 2 December 1990; http://www.chr.up.ac.za/hr_docs/constitutions/docs/BeninC(englishsummary)(rev).doc (accessed 31 January 2008). 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).

42 Art 26 Constitution of the Republic of Benin.

43 Constitution of Botswana, adopted in 1966, last amended in 1999; http://www.chr.up.ac.za/hr_docs/constitutions/docs/Botswana(summary)(rev).doc (accessed 31 January 2008).

44 Art 9 Constitution of Botswana. However, the right to privacy is limited by, amongst others, anything that is 'reasonably required in the interests of public health'.

ably required in the interests of public health'.[45] No special mention is made of women's or children's rights in the Botswana Constitution.

4.4 Burundi

The Constitution of the Republic of Burundi[46] 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.

4.5 Congo

The Constitution of the Republic of the Congo[47] 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'.[48] Privacy is guaranteed,[49] as is the secrecy of correspondence.[50] The state guarantees the public's health[51] and the rights of the mother and child within the family are guaranteed.[52]

The situation of children and adolescents participating in clinical 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

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

46 Constitution of Burundi, 2004; http://democratie.francophonie.org/article.php3?id_article=368&id_rubrique=94 (accessed 31 January 2008).

47 Constitution of the Republic of the Congo, 1992; http://www.chr.up.ac.za/hr_docs/constitutions/docs/CongoC%20(english%20summary)(rev).doc (accessed 31 January 2008).

48 Art 8 Constitution of the Republic of the Congo.

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

50 Art 20 Constitution of the Republic of the Congo.

51 Art 30 Constitution of the Republic of the Congo.

52 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.'

that the state must protect children and adolescents from 'economic exploitation'.[53] Clinical research of an exploitative nature in which children and adolescents are enrolled is thus prohibited.

4.6 Eritrea

Chapter 3 of the Constitution of Eritrea[54] 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 article 5 of the Universal Declaration and article 7 of CCPR, 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 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'.

4.7 Ethiopia

Chapter 3 of the Constitution of the Federal Republic of Ethiopia[55] 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

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53 Art 34 Constitution of the Republic of the Congo.

54 Constitution of Eritrea, adopted by the Constituent Assembly on 23 May 1997; http://www.chr.up.ac.za/hr_docs/constitutions/docs/EritreaC.pdf (accessed 31 January 2008).

55 Constitution of the Federal Democratic Republic of Ethiopia; http://www.chr.up.ac.za/ hr_docs/constitutions/docs/EthiopiaC(rev).doc (accessed 31 January 2008).

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 CCPR, 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 clinical research from being discriminated against based on their real or perceived HIV 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.

4.8 Ghana

The Constitution of the Republic of Ghana[56] 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 clinical 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

[56] Constitution of the Republic of Ghana, 1991; http://www.chr.up.ac.za/hr_docs/constitutions/ docs/GhanaC.pdf (accessed 31 January 2008).

cruel, inhuman or degrading treatment or punishment', is especially important.

4.9 Kenya

The Constitution of Kenya[57] 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.'[58]

Article 82 prohibits discrimination based upon 'race, tribe, place of origin or residence or other local connexion, political opinions, colour, creed or sex 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'.[59] 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.[60]

An amendment to the Constitution which has been proposed would add health status as a protected ground.[61] Also, women are afforded greater protection in the new amendment,[62] and specific provisions dealing with children have been included.

4.10 Lesotho

The Constitution of Lesotho,[63] 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

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57 Constitution of Kenya, adopted in 1963 and amended in 1999; http://www.chr.up.ac.za/ hr_docs/constitutions/docs/KenyaC(rev).doc (accessed 31 January 2008).

58 Art 76(1) Constitution of Kenya.

59 Art 82 Constitution of Kenya.

60 Art 82(4)(b) Constitution of Kenya.

61 Art 37 Proposed New Constitution of Kenya, 2005.

62 Art 38 Proposed New Constitution of Kenya.

63 Constitution of Lesotho, adopted in 1993, amended 1996, 1997, 1998 and 2001; http://www.chr.up.ac.za/hr_docs/constitutions/docs/LesothoC(summary)(rev).doc (accessed 31 January 2008).

privacy of the person, and article 18 guarantees freedom from discrimination. The prohibited grounds are:[64]

> 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 18 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 customary law of Lesotho with respect to any matter in the case of persons who, under that law, are subject to that law'.[65]

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',[66] 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 research and protect the rights of participants in such research.

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64 Art 18(3) Constitution of Lesotho.

65 Arts 4(b) & (c) Constitution of Lesotho.

66 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.

4.11 Malawi

The Constitution of the Republic of Malawi[67] 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 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 CCPR.

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.[68]

4.12 Mali

The Constitution of the Republic of Mali,[69] 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, colour, 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'.

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67 Constitution of the Republic of Malawi, entered into force on 18 May 1994; http://www.chr.up.ac.za/hr_docs/constitutions/docs/MalawiC.pdf (accessed 31 January 2008).

68 Arts 23 & 24 Constitution of Malawi.

69 Constitution of the Republic of Mali, adopted in 1992; http://www.chr.up.ac.za/hr_docs/ constitutions/docs/MaliC(rev).doc (accessed 31 January 2008).

Health care is to 'constitute some of the social rights'.[70] Women's and children's rights are not singled out for mention.

4.13 Mozambique

The new Mozambican Constitution[71] came into effect in 2005. Article 35 guarantees equality:[72]

> 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.

4.14 Namibia

The Constitution of Namibia[73] 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.

4.15 Nigeria

The Constitution of the Federal Republic of Nigeria[74] does not contain a bill of rights as such, but rather 'fundamental objectives of state

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70 Art 17 Constitution of the Republic of Mali.

71 Constitution of Mozambique 2005; http://www.chr.up.ac.za/hr_docs/constitutions/docs/ Mozambique.doc (accessed 31 January 2008).

72 Art 35 Constitution of Mozambique.

73 Constitution of Namibia, adopted in February 1990, amended on 24 December 1998; http://www.chr.up.ac.za/hr_docs/constitutions/docs/NamibiaC(rev).doc (accessed 31 January 2008).

74 Constitution of the Federal Republic of Nigeria, entered into force on 29 May 1999; http://www.nigeria-law.org/ConstitutionOfTheFederalRepublicOfNigeria.htm#Chapter_1 (accessed 31 January 2008).

policy',[75] the provisions of which could be relevant in the protection of 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 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*'.[76] It is doubtful whether this is a reference specifically to HIV-related clinical research.

4.16 Senegal

The Constitution of the Republic of Senegal[77] 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 13, and the rights of 'wives' to marital property and to 'worldly goods' in article 19.

4.17 South Africa

The South African Constitution[78] contains a Bill of Rights in chapter 2. Apart from a specific provision on informed consent in clinical research in section 12(2)(c), 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: 'Everyone 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'.

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75 See n 66 above.

76 My emphasis.

77 Constitution of the Republic of Senegal, adopted on 7 January 2001; http://www.chr.up.ac.za/hr_docs/constitutions/docs/SenegalC%20(english%20summary)(rev).doc (accessed 31 January 2008).

78 Constitution of the Republic of South Africa 1996.

Children's rights are guaranteed in section 28, as well as their right to 'basic health care services'.

4.18 Swaziland

Chapter III of the 2005 Constitution of the Kingdom of Swaziland guarantees the fundamental human rights and freedoms of the individual.[79] 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 CCPR, article 18(2) could be relied on 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'.[80] 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'.[81] 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.'[82]

There is no provision specifically dealing with the protection of participants in clinical research in the Swaziland Constitution.

4.19 Tanzania

Part III of the Constitution of the United Republic of Tanzania[83] contains several human rights provisions relevant to the protection of participants in clinical research, but does not mention clinical research specifically.

Section 12 guarantees equality and states that all persons are born free and are equal. Everyone is entitled to the recognition and respect

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79 Constitution of the Kingdom of Swaziland, 2005; http://www.chr.up.ac.za/hr_docs/constitutions/ docs/Swaziland.doc (accessed 31 January 2008).

80 Art 20(1)(2) Constitution of the Kingdom of Swaziland 2005.

81 Arts 22(1)(a) & 22(2)(a) Constitution of the Kingdom of Swaziland 2005.

82 Art 27(4) Constitution of the Kingdom of Swaziland 2005.

83 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; http://www.chr.up.ac.za/hr_docs/constitutions/docs/TanzaniaC.pdf (accessed 31 January 2008).

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.

4.20 Uganda

The Constitution of the Republic of Uganda[84] 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 article 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.[85] Article 34 protects children's rights.

4.21 Zambia

The Zambian Constitution[86] guarantees human rights, but clinical research is not referred to specifically. The right to life in articles 12 and 17 protects the privacy of the person. Article 15 prohibits 'torture, or [...] inhuman or degrading punishment or other like treatment'.

Zambia currently has as well a draft Constitution which guarantees human rights. Article 40 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.[87]

Article 41 guarantees equal treatment for men and women. Article 41 further prohibits any law, culture, customs or traditions that undermine the dignity, welfare, interest or status of women or men.[88]

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84 Constitution of the Republic of Uganda, 1995; http://www.chr.up.ac.za/hr_docs/ constitutions/ docs/UgandaC(rev).doc (accessed 31 January 2008).

85 Art 33(6) Constitution of the Republic of Uganda 1995.

86 Constitution of Zambia, as amended by Act 18 of 1996; http://www.chr.up.ac.za/ hr_docs/ constitutions/docs/ZambiaC(rev).doc (accessed 31 January 2008).

87 Draft Constitution of Zambia Cap 1.

88 Art 41(5) Draft Constitution of Zambia.

4.22 Zimbabwe

The Constitution of the Republic of Zimbabwe[89] 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 clinical research 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.

4.23 General

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, 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 clinical research in sub-Saharan Africa.

The following section offers conclusions and recommendations in the light of the survey in this section.

5 Conclusion

In contrast to the traditional approach, this article places the protection of participants in clinical research in Africa within the context of the domestic human rights discourse. It is argued that domestic human rights law, because it has the force of law, may be used effectively to protect clinical research participants in the region. Rather than replacing ethical guidelines altogether, enforceable human rights law may augment and reinforce existing ethical guidelines, where they exist.

Based upon the survey of domestic bills of rights above, the following conclusions may be drawn:

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89 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)); http://www.chr.up.ac.za/hr_docs/constitutions/docs/ZimbabweC (rev).doc (accessed 31 January 2008).

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 constitutions of 16 countries. Many of the constitutions guarantee children's and women' rights as well.

As a vehicle for the protection of clinical research participants, the above-mentioned rights are under-utilised at the present time. For example, the right to equality may be used to guarantee communities participating in research post-trial access to pharmaceutical products developed by that research; or it may be used to ensure that participants in research are selected equitably in cases where participation in research confers some benefit upon participants.[90] The right to privacy and the right to dignity may be employed to ensure that medical facts concerning research participants remain confidential;[91] and children's rights may be used to ensure that the child's best interests are paramount in every research endeavour in which the child participates.

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 12 of the 22 constitutions surveyed and the right to physical integrity or security of the person is guaranteed in the constitutions of six countries. These rights have an important role to play in the protection of research participants against being subjected to clinical research without their informed consent. Although informed consent is guaranteed in countless ethical guidelines, domestic human rights law creates justiciable rights which may be used to litigate against research sponsors who violate consent requirements. Further, these rights may be utilised to ensure that not just the form, but also the spirit of the informed consent requirement is adhered to.[92]

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90 Such benefit may take many forms, such as increased access to anti-retrovirals, antinatal health care or cancer treatment only available at the research site.

91 In this regard, see the South African case of *NM & Others v Smith & Others (Freedom of Expression Institute as* Amicus Curiae) 2007 7 BCLR 751 (CC), which affirms the notion that the unauthorised disclosure of research participants' HIV status during a preventive HIV-related clinical trial or thereafter constitutes a violation of participants' rights to privacy, dignity and psychological integrity.

92 See eg SMC Smith 'Misinforming the uninformed? Issues of informed consent in the multicultural context of HIV vaccine trials' unpublished BHons dissertation, University of the Witwatersrand, 2004. Also see NJ Ives *et al* 'Does an HIV clinical trial information booklet improve patient knowledge and understanding of HIV clinical trials?' (2001) 2 *HIV Medicine* 241, who conclude that, while participants' general knowledge and understanding of clinical trials improved over time, this was not improved by the informed consent process and information booklet and that their recollection of the details of the trial protocols remained poor.

Third, only two of the constitutions surveyed — those of Malawi and South Africa — contain a provision which makes specific reference to clinical research. This may be due to a number of reasons.[93] Importantly, it may be due to the fact that clinical research is not traditionally seen as falling within the ambit of human rights provisions, but rather that of ethical guidelines.

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, and who are therefore likely to participate in HIV-related clinical research.[94] The Constitution of Burundi explicitly protects people living with HIV/AIDS against discrimination.

Fifth, the rights of groups especially vulnerable to 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 African 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',[95] and the South African Constitution provides for the 'progressive realisation' of health care.[96] The tables containing the core health indicators in sub-Saharan African countries in a previous section[97] highlight the lack of access to health care experienced by many Africans. The right to health care, where it is included in domestic constitutions, may be used effectively to convert the duty placed by ethical guidelines upon researchers to provide post-trial access to the products of their research to trial participants and their communities into an enforceable right.

It is therefore possible to conclude that domestic human rights law may be used successfully to protect participants in clinical research in Africa from abuse and exploitation. In the context of clinical research, an

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93 This omission may be ascribed to a variety of reasons which are explored in a different context; see AG Nienaber 'Ethics and human rights in HIV-related clinical trials in Africa with specific reference to informed consent in preventative HIV vaccine efficacy trials in South Africa' unpublished LLD thesis, University of Pretoria, 2007 478-482.

94 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.

95 Art 21 Constitution of Eritrea.

96 Art 27 Constitution of the Republic of South Africa 1996.

97 See para 2 above.

approach based upon domestic human rights provisions goes further than prescribing ways of acting morally or ethically towards research participants. A human 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.

Under domestic human rights law, 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, an ethical guideline that directs 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.[98]

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, as well as the obligations of those engaged in international research towards clinical research participants in sub-Saharan Africa. Thus, it is a framework for reflection that politicises international clinical research sponsorship and participation.

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

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98 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; F Viljoen 'The obligations of governments in a time of HIV and AIDS' (2005) 15 *Interights Bulletin* 47). 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' (Viljoen 47-48).