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The African regional human rights system and HIV-related human experimentation: Implications of *Zimbabwe Human Rights NGO Forum v Zimbabwe*

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Summary

The article investigates the protection by the African regional human rights system of participants in HIV-related human experimentation. It assesses the scope of the protection afforded by the system, and draws upon the jurisprudence of the African Commission on Human and Peoples' Rights in the communication of Zimbabwe Human Rights NGO Forum v Zimbabwe *in order to argue that a failure on the part of African states to act to prevent the abuse of research participants will render those states liable for a finding by the African Commission of a violation of their obligations under regional human rights law.*

1 Introduction

The utility of international and domestic human rights law in the protection of clinical research participants in Africa has been argued elsewhere.[1] Instead of employing clinical research ethics or bioethics

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1 See eg A Nienaber 'The utility of international human rights law on informed consent in the protection of clinical research participants in Africa: "The road less travelled"' (2007) 2 *SA Public Law* 422 (Nienaber (A)); A Nienaber 'The protection of participants in clinical research in Africa: Does domestic human rights law have a role to play?' (2008) 8 *African Human Rights Law Journal* 138 (Nienaber (B)); and 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in Africa with specific reference to informed consent in preventative HIV vaccine efficacy trials in South Africa' unpublished LLD thesis, University of Pretoria, 2007 (Nienaber (C)).

to protect the interests of participants in clinical research in the region, it is argued that participants in such research may benefit from the protection afforded them by human rights law.[2] In order to advance this argument, this article draws upon the decision of the African Commission on Human and Peoples' Rights (African Commission) in the communication of *Zimbabwe Human Rights NGO Forum v Zimbabwe*[3] to argue that states which do not put in place measures which protect participants in HIV-related experimentation conducted in Africa from abuse, are in breach of their obligations under the African regional human rights system.

The article begins with an examination of the protection offered by the regional human rights system to participants in HIV-related experimentation in Africa, providing an overview of the protection afforded by the different treaties. In the next two sections, the African Commission's jurisprudence in the case of *Zimbabwe Human Rights NGO Forum v Zimbabwe* is explored. The article concludes with a few recommendations regarding the protection of HIV-related clinical research participants in Africa.

It is important to note that, as the article investigates the protection of clinical research participants under the regional human rights system, domestic human rights law is not touched upon here.[4] As well, specific mention is made of *HIV-related* clinical research; however, the observations are true for any type of clinical research conducted in Africa.

2 Specific provisions in African regional human rights law relevant to HIV-related human experimentation

In contrast to non-binding ethical guidelines that are usually utilised in the protection of clinical research participants, human rights treaties are able to provide a legal framework for defining state obligations in

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2 Traditionally, international and domestic clinical research ethics or bioethics documents are relied upon to protect the interests of participants in clinical research. One such document is the Declaration of Helsinki, issued by the World Medical Association (WMA), and is an international code of ethics overseeing biomedical research involving human participants. It 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. Clinical research ethics or bioethics is criticised for not adequately protecting the interests of research participants — they are non-binding *guidelines* which cannot be enforced effectively other than by professional sanction and a refusal to publish research which is considered to be in violation of the guidelines — see the sources quoted in n 1 above.

3 *Zimbabwe Human Rights NGO Forum v Zimbabwe* (2006) AHRLR 128 (ACHPR 2006).

4 See Nienaber (B) (n 1 above) for an examination of the role of domestic human rights law in the protection of participants in human experimentation in Africa.

protecting human rights and they may serve as a resource for implementing human rights protection for research participants. International human rights law, in the form of binding treaties and conventions, provides participants in HIV-related human experimentation in Africa with recourse to national and international courts and tribunals.

The section below focuses on specific provisions in African regional human rights instruments that can be of use in this regard. Regional instruments such as the African Charter on Human and Peoples' Rights (African Charter),[5] the African Charter on the Rights and Welfare of the Child (African Children's Charter)[6] and the Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa (African Women's Protocol)[7] are singled out for attention.[8]

Provisions which, primarily, have implications for the position of HIV-related clinical research participants are examined, rather than those that deal with health care or access to health only. The same provisions tend to be included in each of the 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.

2.1 The African Charter on Human and Peoples' Rights

At the outset it is acknowledged that the African Charter was drafted before the first cases of HIV infection were reported, and before the world became aware of an HIV epidemic. It is only in later human rights instruments, such as the African Women's Protocol, that specific reference is made to HIV/AIDS.[9]

The African Charter 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 African Charter recognises the right to respect for life and integrity of the person[10] and the right to human dignity.[11]

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5 OAU Doc OAU/CAB/LEG/67/3/Rev 5.

6 OAU Doc CAB/LEG/153/Rev 2.

7 AHG/Res.240 (XXXI).

8 The Universal or UN system is not discussed here. In this regard, see Nienaber (A) (n 1 above).

9 The [United Nations] Convention on the Rights of the Child (CRC), adopted in November 1989, years after the first HIV cases were reported, makes no mention of HIV/AIDS. See generally in this regard S Gumedze 'HIV/AIDS and human rights: The role of the African Commission on Human and Peoples' Rights' (2004) 4 *African Human Rights Law Journal* 181.

10 Art 4 African Charter.

11 Art 5 African Charter.

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.[12] 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 during World War II under National Socialism is an obvious example.[13] Any research design which treats participants as mere objects instead of as autonomous human beings, by definition, violates their right to dignity. Even though informed consent to research participation is not mentioned explicitly here, articles 4 and 5 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 not only the dignity, but also 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 where Pfizer treated children for spinal meningitis in Kano, Nigeria, with the experimental drug Trovan, violates article 5 of the African Charter.[14] 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.[15]

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12 See eg the sources referred to in n 14 and n 51 below.

13 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.

14 For a discussion of the events in Kano, see eg WHO (19 February 1996) Disease Outbreak News http://www.who.int/disease-outbreak-news/n1996/feb/n19feb1996c.html (accessed 31 January 2008); DM Carr 'Pfizer's Trovan trials in Nigeria' (2003) 35 *Case Western Reserve Journal of International Law* 15; J Ford & J Tomossy 'Clinical trials in developing countries: The claimant's challenge' (2004) 1 *Law, Social Justice and Global Development* 4; and see S 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.

15 See sources referred to in n 14 above.

No matter the urgency, only existing, proven medication should have been used.[16]

Further, the African Charter prohibits discrimination,[17] and guarantees equal protection and equality before the law.[18] Article 2 states:[19]

> Every individual shall be entitled to the enjoyment of the rights and freedoms in the present Charter without distinction of any kind such as race, ethnic group, colour, sex, language, religion, political or any other opinion, national or social origin, fortune, birth or other status.

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 anti-retroviral, but which excludes people who do not belong to the dominant ethnic group in a specific country, is therefore prohibited.

Article 16 provides that 'every individual shall have the right to enjoy the best attainable state of physical and mental health'.[20] 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'.[21] HIV-related human experimentation, 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, it is submitted that research specifically aimed at protecting the health of that particular group of people, and not research 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 monitoring the implementation of the African Charter by state parties.[22] It must promote

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16 The control group was given the antibiotic Ceftriaxone, a drug already approved for use with children in the United States, and which drug was the existing proven treatment for the illness. During a clinical trial of this nature, the experimental drug (Trovan) is compared to the existing treatment (Ceftriaxone) to see whether the experimental drug is as effective or more effective in treating the disease. However, because they were short-staffed, Pfizer researchers injected Ceftriaxone into the children's buttocks, rather than administering it intravenously. More importantly, they administered only one-third of the regular dose of Ceftriaxone to the children; see F Kelleher 'The pharmaceutical industry's responsibility for protecting human subjects of clinical trials in developing nations' (2004) 38 *Columbia Journal of Law and Social Problems* 68 fn 1.

17 Art 2 African Charter.

18 Art 3 African Charter.

19 Art 2 African Charter.

20 Art 16(1) African Charter.

21 Art 16(2) African Charter.

22 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 (n 9 above).

human (and peoples') rights in Africa,[23] it must protect these rights,[24] and it must interpret the provisions of the African Charter.[25] 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'.[26] The African 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'. [27]

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[28]

> [m]illions 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.

The African Commission proceeds to 'read into' article 16 the[29]

> 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.

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 they get access to the products of such research, would advance the right to health in Africa. Conversely, if Africa's people do not get access to the results of such research, the research will be regarded as exploitative.[30]

The African Commission has adopted a number of resolutions and principles of relevance to clinical research in Africa.[31] The 2003 Principles and Guidelines on the Right to a fair Trial and Legal Assistance in

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23 Arts 30 & 45(1) African Charter.

24 Arts 30 & 45(2) African Charter; see paras 3 & 4 below.

25 Art 45(3) African Charter.

26 *Purohit & Another v The Gambia* (2003) AHRLR 96 (ACHPR 2003) para 80. The case was brought in regard to the legal and material conditions of detention in a Gambian mental health institution.

27 As above.

28 Para 84.

29 Para 84 (my emphasis).

30 See R Macklin *Double standards in medical research in developing countries* (2004).

31 This is an example of 'soft' law.

Africa[32] (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.

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 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'.

2.2 African Union resolutions and declarations

Apart from the provisions of the African Charter and the resolutions by the African Commission, the political organs of the Organisation of African Union (OAU), later the African Union (AU), have adopted

[32] 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 C Heyns & M Killander (eds) *Compendium of key human rights documents of the African Union* (2007) 288.

resolutions relevant to clinical research in Africa. For example, the Grand Bay (Mauritius) Declaration[33] reflects upon the vulnerability and human rights of people living with HIV/AIDS:[34]

> 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.[35]

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, tuberculosis, malaria and other diseases. The meeting adopted the Abuja Declaration on HIV/AIDS, Tuberculosis and Other Related Infectious Diseases (Abuja Declaration),[36] 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'.[37] 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 HIV/AIDS and tuberculosis, 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).[38] The African Bioethics Resolution acknowledges that[39]

> 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

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33 Issued by the First OAU Ministerial Conference on Human Rights, which held a meeting from 12–16 April 1999 in Grand Bay, Mauritius.

34 Para 7 Grand Bay (Mauritius) Declaration.

35 See paras 3 & 4 below.

36 http:/www.onusida-acoc.org/Eng/Abuja%20declaration.htm (accessed 31 January 2008).

37 Para 12 Abuja Declaration.

38 AHG/Res 254 (XXXII) 1996.

39 Para 1 African Bioethics Resolution.

> 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 International Covenant on Civil and Political Rights (ICCPR),[40] 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'.[41] The African Bioethics Resolution further reaffirms the right to benefit from scientific progress and the application of such progress without discrimination,[42] and the right of everyone, especially children, to protection 'from all forms of trade and exploitation'.[43]

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.[44]

2.3 The African Charter on the Rights and Welfare of the Child

Article 43(1) of the African Children's Charter compels state parties to submit to the African Committee of Experts on the Rights and Welfare of the Child, through the Chairperson of the Commission of the AU, '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 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.[45]

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'.[46] State parties to the African Children's Charter 'shall undertake to pursue the full implementation of this right'.[47] In particular, they shall take measures which include[48] 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

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40 Para 2 African Bioethics Resolution.

41 Para 3 African Bioethics Resolution.

42 As above.

43 As above.

44 As above.

45 Para 21(g) Guidelines for Initial Reports of State Parties under the African Charter on Rights and Welfare of the Child.

46 Art 14(1) African Children's Charter.

47 As above.

48 Arts 14(2)(a)–(j) African Children's Charter.

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.[49]

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'.[50] 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,[51] the Trovan experiments on children in Nigeria,[52] the testing of medications which will not eventually be available to those children on whom it was 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'.[53]

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

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49 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.

50 Art 14(1) African Children's Charter.

51 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 concern. 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. 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. In this regard, see RJ Levine *Ethics and regulation of clinical research* (1986) 70–72.

52 See para 2.1 above & n 14 above.

53 Art 15(2).

> 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. The duty of state parties to *protect* children, imposed by sub-section 1, is highlighted later in the article.[54]

Harmful social and cultural practices are prohibited in article 21.[55] 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 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 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.[56] Therefore, HIV-related research which aims to benefit children generally, but which is of no direct benefit to the specific child, is contrary to the measure laid down in article 4(1). For example, so-called 'non-thera-

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54 See paras 3 & 4 below.

55 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.'

56 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 CRC. See F Viljoen 'Africa's contribution to the development of international human rights and humanitarian law' (2001) 1 *African Human Rights Law Journal* 18.

peutic'[57] research, such as research to find a vaccine against HIV, does not benefit the individual child directly, and is therefore prohibited by the African Children's Charter.

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'.[58] 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).[59] 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'.[60] Thus far little has been done to give effect to the Tunis Declaration.[61]

2.4 Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa

Article 2 of the African Women's Protocol deals with the elimination of discrimination against women. It prohibits 'all forms of discrimination against women'.[62] 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 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'.[63]

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57 'Non-therapeutic' research aims to benefit people other than the research participant. Such research is aimed at the acquisition of knowledge, and as such may be of no immediate benefit to the participant. 'Therapeutic research' is undertaken to benefit the individual research participant or patient by treating or curing their condition. Therapeutic HIV-related research, eg, is research to develop an effective anti-retroviral agent against HIV infection. Importantly, participants in therapeutic HIV-related research will be living with HIV/AIDS, whereas participants in non-therapeutic HIV-related research will be HIV negative.

58 Art 31(b).

59 AHG/Decl 1 (XXX) 1994.

60 Para 2(1) Tunis Declaration.

61 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 OAU Declarations on HIV/AIDS in Africa was adopted. Governments were urged to implement resolutions and declarations of the OAU, especially the Tunis Declaration.

62 Art 2(1) African Women's Protocol.

63 Art 2(2) African Women's Protocol.

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. 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 differences 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.

Significantly, the African Women's Protocol refers to women's informed consent to participation in clinical research in article 4 which deals with the rights to life, integrity and security of the person. Article 4(2) provides that '[s]tates parties shall take appropriate and effective measures to ... (h) prohibit all medical or scientific experiments on women without their informed consent'. Apart from article 7 of ICCPR, the African Women's Protocol is the only human rights instrument which contains a provision which mentions informed consent explicitly, and which is applicable to the situation of HIV-related research participants in Africa.

The consent aspect of article 4(2) has not been litigated. The African Women's Protocol has not been in effect for long,[64] and it is exceptional to use a human rights instrument to litigate what is widely considered to be an ethical guideline. The fact that so few human rights treaties mention informed consent specifically is symptomatic of a world view

[64] The African Women's Protocol came into effect in November 2005.

which regards informed consent as falling within the realm of bioethics, rather than in the realm of human rights.[65]

Of special importance to the present study are sections in the African 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'.[66]

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 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 about 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'.[67] 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 African 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 African 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 of whether not only women's, but also

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65 A violation of the requirement of informed consent for participation in clinical research is thus seen as a violation of ethical guidelines, instead of a violation of a human rights treaty.

66 Art 14(1)(d) African Women's Protocol.

67 Art 14(1)(e) African Women's Protocol.

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.

Further, state parties must take appropriate measures to 'provide adequate, affordable and accessible health services ...'[68] and 'establish and strengthen existing pre-natal, delivery and post-natal health and nutritional services for women during pregnancy and while they are breastfeeding'.[69] 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.

Having established in this section that the African regional system provides sufficient substantive sections which may be employed in the protection of participants in HIV-related clinical research in Africa, the next two sections use the jurisprudence of the African Commission in *Zimbabwe Human Rights NGO Forum v Zimbabwe* to further investigate the content of the duty of state parties to the different treaties to *protect* participants form abuse.

However, before I turn to the communication, it is necessary to review the African Commission's finding in an earlier but related matter, that of *Commission Nationale des Droits de l'Homme et des Libertés v Chad*.[70] This communication made allegations against the Chad government relating to the direct and indirect harassment, disappearance, torture and killing of journalists by unidentified individuals during the civil war in that country. The African Commission found serious and massive violations of human rights in Chad and that the government of Chad was in violation of the African Charter for, amongst others, failing to secure the safety of its citizens (which included its failure to investigate murders). The Commission remarked that there had been[71]

> several instances in which the government has failed to prevent the assassination and killing of specific individuals. Even where it cannot be proved that violations were committed by government agents, the government had a responsibility to secure the safety and the liberty of its citizens, and to conduct investigations into murders.

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68 Art 14(2)(a) African Women's Protocol.

69 Art 14(2)(b) African Women's Protocol.

70 (2000) AHRLR 66 (ACHPR 1995).

71 n 70 above, para 22.

The African Commission was thus more than willing to find the existence of the duty on the state to protect inhabitants of a country from human rights abuses in that country. This finding set the stage for the finding in *Zimbabwe Human Rights NGO Forum v Zimbabwe*, to which I now turn.

4 *Zimbabwe Human Rights NGO Forum v Zimbabwe*

The communication was submitted by the Zimbabwe Human Rights NGO Forum, a co-ordinating body and a coalition of 12 Zimbabwean human rights non-governmental organisations (NGOs). The complainant alleged a violation of numerous articles of the African Charter. Only those sections of the communication relevant to my argument are discussed here.

The communication has its origins in the events in Zimbabwe following the constitutional referendum of February 2000, in which the majority of Zimbabweans voted against the new government-drafted Constitution. The complainant alleges that the referendum was followed by political violence, which escalated to farm invasions by 'war veterans' and other landless people and that, during the period between February and June 2000, ZANU (PF) supporters engaged in a systematic campaign of intimidation aimed at crushing support for opposition parties.[72]

The complainant further alleges that, in the two months before the parliamentary elections scheduled for 24 and 25 June 2002, the political violence in Zimbabwe was targeted especially at white farmers and black farm workers, teachers, civil servants and rural villagers believed to be supporting opposition parties. The violence included acts such as dragging farm workers and villagers believed to be supporters of the opposition from their homes at night, forcing them to attend 're-education' sessions and to sing ZANU (PF) songs.[73] The complainant alleges that men, women and children were tortured and raped, that homes and businesses in both urban and rural areas were burnt and looted and opposition members were kidnapped, tortured and killed.[74] As well, the complainant alleges that there were reports of 82 deaths as a result of organised violence between March 2000 and 22 November 2001.[75] The complainant claims that even when human rights abuses were brought before the Harare High Court, witnesses were subjected to political violence and victimisation.[76]

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72 *Zimbabwe Human Rights NGO Forum v Zimbabwe* (n 3 above) para 3.

73 n 3 above, paras 4- 5.

74 n 3 above, para 4.

75 n 3 above, para 8.

76 n 3 above, paras 10–11.

Of importance for the present discussion, the complainant states that, prior to the June 2000 parliamentary elections, the Zimbabwean police on numerous occasions had turned a blind eye to violence perpetrated against white farmers and MDC supporters.[77] It is alleged that the police forces have generally failed to intervene or investigate the incidents of murder, rape, torture or the destruction of property committed by the war veterans.[78] Furthermore, a general amnesty for politically-motivated crimes, gazetted on 6 October 2000, absolved most of the perpetrators from prosecution.[79] While the amnesty excluded those accused of murder, robbery, rape, indecent assault, statutory rape, theft, possession of arms or any offence involving fraud or dishonesty, very few persons accused of these crimes have been prosecuted.[80]

The African Commission was asked to determine, amongst other questions, the extent of the Zimbabwean state's responsibility for these human rights violations or acts committed by non-state actors, and whether Clemency Order 1 of 2000 resulted to a violation of Zimbabwe's obligations under article 1 of the African Charter.

In its finding, the African Commission stresses the significance of article 1 of the African Charter in determining whether a violation of the human rights recognised by the Charter may be imputed to a state party. Article 1 states that state parties have a fundamental duty to 'recognise the rights ... and undertake to adopt legislative or other measures to give effect to them'. The Commission underscores the fact that any impairment of those rights which may be attributed under the rules of international law to the action or omission of any public authority constitutes an act imputable to the state, which assumes responsibility in the terms provided by the African Charter.[81]

Furthermore, in its decision the African Commission emphasises that human rights standards do not merely contain limitations on states' authority or that of organs of state, but that they also[82]

> impose positive obligations on states to prevent and [not] sanction private violations of human rights'; and that 'human rights law imposes obligations on states to protect citizens or individuals under their jurisdiction from the harmful acts of others.

Thus, the Commission finds that an act by a private individual, not directly imputable to a state, can generate responsibility on the part of the state, 'not because of the act itself, but because of "the lack of

77 n 3 above, para 14.
78 As above.
79 As above.
80 Clemency Order 1 of 2000; as above.
81 Para 142.
82 Para 143.

due diligence"[83] to prevent the violation or for not taking the necessary steps to provide the victims with reparation'.[84]

The African Commission quotes from the judgment of the Inter-American Court on Human Rights in the case of *Velásquez Rodríguez*, where one of the most significant assertions of state responsibility for acts by private individuals is articulated. A state 'has failed to comply with [its] duty ... when the state allows "private persons or groups to act freely and with impunity to the detriment of the rights recognized by the Convention"'.[85]

Further, the African Commission confirms that the case of *Velásquez Rodriguez* 'represents an authoritative interpretation of an international standard on state duty'[86] and that, therefore, the opinion of the Inter-American Court could also

> be applied, by extension, to article 1 of the African Charter of Human and Peoples' Rights, which requires states parties to 'recognize the rights, duties and freedoms enshrined in the Charter and ... undertake to adopt legislative and other measures to give effect to them.

Thus, according to the African Commission, what would otherwise be wholly private conduct is transformed into a constructive act of state 'because of the lack of due diligence to prevent the violation or respond to it as required by the [African Charter]'.[87] The Commission reiterates that[88]

> an illegal act which violates human rights and which is initially not directly imputable to a state (for example, because it is the act of a private person or because the person responsible has not been identified) can lead to international responsibility of the state, not because of the act itself, but because of the lack of due diligence to prevent the violation or to respond to it as required by the Convention [or the African Charter].

The African Commission holds that the[89]

> standard of due diligence in the *Velásquez Rodriguez* case provides a way to measure whether a state has acted with sufficient effort and political will to fulfil its human rights obligations. Under this obligation, states must prevent, investigate and punish acts which impair any of the rights recognised under international human rights law. Moreover, if possible, it must

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83 The Inter-American Court of Human Rights, in looking at the obligations of the state of Honduras under the Inter-American Convention on Human Rights, first articulated this standard — *Velásquez Rodriguez v Honduras* (Ser C) No 4 (1988) 28 ILM (1989) ser C, No 4; *Human Rights Law Journal* 212.

84 n 3 above, para 143.

85 *Velásquez Rodriguez v Honduras* (n 83 above) para 176, quoted by the African Commission in *Zimbabwe Human Rights NGO Forum v Zimbabwe* (n 3 above) para 144.

86 *Zimbabwe Human Rights NGO Forum v Zimbabwe* (n 3 above) para 144.

87 As above.

88 In n 3 above, para 145, the Commission is quoting from *Velásquez Rodriguez v Honduras* (n 83 above) para 172.

89 *Zimbabwe Human Rights NGO Forum v Zimbabwe* (n 3 above) para 146.

attempt to restore the right violated and provide appropriate compensation for resulting damage.

In *Zimbabwe Human Rights NGO Forum v Zimbabwe*, therefore, the African Commission explicitly recognises the duty of states to regulate the conduct of non-state actors — states must 'take effective measures to prevent private violations of human rights'.[90] A state's 'failure to exercise due diligence to prevent or remedy violation, or failure to apprehend the individuals committing human rights violations gives rise to state responsibility even if committed by private individuals'.[91]

The obligation to *respect* human rights thus also entails that the state should 'protect right-holders against other subjects by legislation and provision of effective remedies', which entails the creation and maintenance of an atmosphere or framework of an effective interplay of laws and regulations so that individuals will be able to freely realise their rights and freedoms.[92]

Although, on the facts, the African Commission finds that the respondent state did not fail to comply with its duty under article 1 of the African Charter to '... adopt other measures to give effect to' its citizens' rights, the Commission's finding has important implications for the protection of clinical research participants in Africa. These implications are discussed in the next section.

5 Implications of the African Commission's finding for HIV-related clinical research conducted in Africa

International pharmaceutical corporations increasingly conduct clinical trials in the developing world. Africa, in particular, 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.[93] International 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

90 Para 147.

91 As above. Also see the jurisprudence of the African Commission in *Social and Economic Rights Action Centre (SERAC) & Another v Nigeria* (2001) AHRLR 60 (ACHPR 2001) and *Free Legal Assistance Group & Others v Zaire* (2000) AHRLR 74 (ACHPR 1995).

92 Para 152. In this regard, also see, eg, P Alston (ed) *Non-state actors and human rights* (2005) 3-36 37-89; A Clapham *Human rights obligations of non-state actors* (2006) 25-83; and PT Muchlinski 'Human rights and multi-nationals: Is there a problem?' (2001) 77 *International Affairs* 31.

93 J Ford & G Tomossy (n 14 above) 3.

of injury to participants.[94] In many countries in Africa, there exists little, if any, legislation or even regulation governing clinical trials.[95] Meier writes that 'African nations vie to minimize regulation on the conduct of medical research. They fear that legislation, and resulting lawsuits, could have a chilling effect on beneficial research efforts'.[96] As well, in some host countries, 'corruption often prevents [research ethics committees] from protecting the interests of experimental subjects'.[97]

In many instances, the regulatory frameworks in African countries are inadequate to cope with HIV-related clinical research. Similarly, as pointed out above and elsewhere, international ethical guidelines governing clinical research lack effective enforcement measures.[98] Furthermore, aspects of African economic, social and political contexts, such as poverty, women's inequality, stigmatisation and poor access to health care, increase not only certain communities' vulnerability to HIV infection, thereby accelerating the spread of the disease, but also their vulnerability to exploitation and abuse during HIV-related clinical trials. Because of these factors, the potential exists for the exploitation of participants in research in Africa.

The African Commission's jurisprudence in *Zimbabwe Human Rights NGO Forum v Zimbabwe* confirms that the African Charter imposes positive obligations on states to act to protect individuals and groups against private actors, including international pharmaceutical corporations. Therefore, the African Charter and other regional human rights instruments create obligations on African governments to act to prevent the abuse of participants in HIV-related research, which they can do only if they take proactive measures.

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94 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).

95 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' (Kelleher (n 16 above) 67).

96 Meier (n 94 above) 532.

97 Meier (n 94 above) 533.

98 In this regard, see Nienaber (C) (n 1 above) 168-177. This is true also in the case of Zimbabwe. Apart from non-binding international ethical guidelines governing clinical research relied upon by local university research ethics committees, there exists no binding regulatory framework governing clinical research in Zimbabwe. The development, importation and registration of drugs are governed by the Medicines and Allied Substances Control Act of 1997 (ch 15:03), which also established the Medicines Control Agency of Zimbabwe. However, the Act does not regulate the way in which clinical research is conducted in Zimbabwe. Clinical research participants have to rely on national tort and criminal law to institute claims for research-related injuries. See S Ratanawijitrasin & E Wondemagegnehu *Effective drug regulation: A multicountry study* (2002) 36.

To protect participants in research, in the words of the Commission, 'entails the *creation* and *maintenance* of an atmosphere or framework of *an effective interplay of laws and regulations* so that individuals will be able to freely realize their rights and freedoms'.[99] A failure to create such a framework to govern research practices in Africa, and a failure to effectively enforce such a framework and to punish perpetrators of abuses will contravene article 1 of the African Charter, even if those abuses were committed by private individuals.

6 Conclusion

The article investigates the protection of HIV-related clinical research participants in Africa by the African regional human rights system. The second section of the article assesses specific provisions in regional human rights instruments that are valuable in protecting participants in HIV-related research in Africa from abuse. Human rights instruments, such as the African Children's Charter and the African Women's Protocol, are singled out for attention and examples of 'soft' law are highlighted.

The analysis demonstrates that regional human rights instruments do indeed 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,[100] or through more general prohibitions against 'degrading treatment' and violations of physical integrity, privacy and equality.

The traditional view holds that, in principle, international human rights law binds states alone, as states are the parties to international agreements and, therefore, the conduct of other parties is not within the ambit of international human rights law.[101] In the context of the present study, human rights violations in clinical research in Africa will most likely be the result of actions by multi-national or transnational pharmaceutical corporations, international research bodies and other individuals.[102] In keeping with the traditional view of international human rights law, then, the third-party perpetrators of abuses of research par-

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99 *Zimbabwe Human Rights NGO Forum v Zimbabwe* (n 3 above) para 152 (my emphasis).

100 The consent requirement in the African Women's Protocol.

101 Clapham (n 92 above) 1 — 3. See also sources referred to in n 92 above.

102 Nowak points out that many of these multinational corporations are more powerful and financially stronger than many states. On that ground, it seems to him 'somewhat anachronistic that states should remain the only subjects of international law capable of signing and ratifying treaties under international law' (see M Nowak *Introducing the international human rights regime* (2003) 343).

ticipants will escape prosecution. However, as 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.[103]

The jurisprudence of the African Commission in the communication of *Zimbabwe Human Rights NGO Forum v Zimbabwe* supports the argument that a failure to act to prevent, investigate or punish human rights abuses committed by non-state actors will result in a finding that the state has failed in its international human rights obligations. In order to comply with the spirit of the different human rights instruments discussed in the article, African states will have to establish an appropriate and effective regulatory environment in which HIV-related clinical research may take place, so ensuring the safety of participants.

[103] See generally Clapham (n 92 above).