

The utility of international human rights law on informed consent in the protection of clinical research participants in Africa: 'The road less travelled'^{*}

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1 Introduction

Recent press reports indicate renewed interest in the plight of Nigerian children who, in 1996, allegedly participated in clinical research without their parents' informed consent.¹ In February 1996 an epidemic outbreak of cerebrospinal meningitis occurred in Kano, Nigeria. The WHO's web site indicated that by 1996-03-17 668 cases had been reported and that more than 2 500 people had died from the disease.² The epidemic left over 18 000 victims suffering from the disease.³

An international pharmaceutical company, Pfizer, acted quickly to counteract the epidemic. It delivered desperately needed medical supplies as well as medical staff to Nigeria,⁴ and started trials of an experimental drug for the treatment of viral meningitis, called Trovan.⁵ At the time Trovan was not

^{*}'The road less travelled' is the title of a poem by Robert Frost.

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¹See eg 'Nigeria sues drug giant over children's deaths' *Legalbrief Today* (2007-06-05) http://www.legalbrief.co.za/index.php?page=Legalbrief_Today (accessed 2007-06-05); 'Nigeria sues drug giant for billions' *Iol* (2007-06-04) http://www.iol.co.za/index.php?set_id=1&click_d=68&art_id=nw20070604215319170C882035 (accessed 2007-06-05).

²WHO (1996-02-19) *Disease outbreak news* <http://www.who.int/disease-outbreak-news/n1996/feb/n19feb1996c.html> (accessed 2006-12-15); Carr 'Pfizer's Trovan trials in Nigeria' (2003) 35 *Case Western Reserve J of International L* 15; Ford and Tomossy 'Clinical trials in developing countries: The claimant's challenge' (2004) 1 *L Social Justice and Global Development* 4.

³The damage done by the virus causes long-term after-effects, such as the loss of sight and hearing and paralysis.

⁴Carr (n 2) 15; Kelleher 'The pharmaceutical industry's responsibility for protecting human subjects of clinical trials in developing nations' (2004) 38 *Columbia J of L and Social Problems* 68 n 1; Ford and Tomossy (n 2) 4.

⁵Trovan had never before been tested on children and during pre-clinical (animal) studies, it was shown to cause joint damage in young mammals (see Kelleher (n 4) 68 n 1). Also see Ford and Tomossy (n 2) 4.

approved for human experimentation by the FDA⁶ in the United States.⁷ Since then Trovan has been withdrawn from the US market;⁸ and is not approved for experimentation that involves children.⁹

Pfizer set up research headquarters in Kano, next to the facility of Doctors Without Borders, and made use of their bed space and a section of their treatment centre.¹⁰ During the two weeks they spent in Kano, Pfizer's researchers treated over 200 children for spinal meningitis: 100 children used an oral or intravenous form of Trovan;¹¹ the remaining children were treated with the antibiotic Ceftriaxone, a drug already approved for use with children in the United States.¹²

At first, the Pfizer researchers selected the most suitable children for treatment, but, as the epidemic raged, they began treating any child presenting.¹³ The ages of the children ranged from a few months to eleven years and varied in levels of infection from the early stages of the disease, to partial paralysis; to near death.¹⁴

Due to the large number of patients treated in such a short time and the high illiteracy rate in Kano, many of the patients did not sign consent forms.¹⁵ Many of the patients consented verbally, relying on an interpretation provided by a nurse, but frequently the nurses did not translate all the details on the consent form to the families.¹⁶ It is alleged that the treatment with Trovan resulted in the deaths of eleven of the 100 children; several more allegedly were left blind or deaf.¹⁷

When the media started to investigate claims regarding unethical and illegal research practices by Pfizer, they uncovered a variety of violations of international research ethical guidelines. Research documents had been forged;¹⁸ there was no oversight and approval of research procedures during

⁶United States Food and Drug Administration.

⁷Trovan is one of relatively few drugs to have been withdrawn in the last five years because of known serious side-effects (see Carr (n 2) 16; Kelleher (n 4) 68 n 1).

⁸Carr(n 2) 16. The drug caused serious liver damage in some patients in the US (see Kelleher (n 4) 68 n 1).

⁹Carr (n 2) 16; Kelleher (n 4) 68-9.

¹⁰Carr18.

¹¹*Ibid.*

¹²*Ibid.* 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 the regular dose of Ceftriaxone to the children (see Kelleher (n 4) 68 n 1).

¹³Carr18.

¹⁴*Ibid.*

¹⁵*Ibid.*

¹⁶*Ibid.* Also see Kelleher (n 4) 68: in particular, it appears that Pfizer failed to explain the experimental nature of Trovan, that the trial participants could refuse it, and that other organisations (Doctors Without Borders) offered conventional treatment free of charge.

¹⁷Carr (n 2) 19.

¹⁸Forged documents included individual consent forms, governmental permission forms and oversight approval forms (Carr (n 2) 16 n 8). Also see Bosely 'New drug 'illegally tested on children': Pfizer accused of irregularities during clinical trial in Nigeria' *The Guardian* (2001-01-17) 19. Parents of the

the trials;¹⁹ and the researchers failed to administer effective treatment to desperate participants.²⁰

In 2001 the families of the children that had participated in Pfizer's Trovan research in Kano brought a case against Pfizer in a US court, claiming that Pfizer had violated international and national laws in carrying out experimental research on humans.²¹ The case against Pfizer in the US represents the first in history in which individuals sued a private corporation in a foreign court for wrongful experimentation in violation of US and international law. Recent press reports, referred to at the start of the article, highlight another court case attempting to obtain redress, this time brought in the Nigerian Federal Court by the parents of the Kano children.²²

The events outlined above certainly do not constitute the first allegation of unethical or illegal conduct by researchers in Africa.²³ However, the Trovan case is the first in which research participants seek redress in a court of law under international law. Traditionally, the violation of the rights of participants in clinical research by trial administrators are regarded as violations of universal (medical or research) ethical principles and not as violations of the human rights of trial participants.²⁴ It is to be expected that this view should predominate, as clinical research is the domain of science and the medical profession: medical professionals, although well-versed in medical or research ethics, are relatively unfamiliar with human rights discourse.

In contrast to the traditional approach, this article places informed consent to participation in clinical research within the context of international human rights discourse. It is argued that international human rights law on informed consent, because it has the force of law, may be used effectively to protect clinical research participants in Africa.

The article is structured as follows: after introductory remarks, the legal force of international codes of ethics used in the protection of research participants is

children participating complained that they did not know that the drug that was being given to their children was experimental.

¹⁹Carr (n 2) 16.

²⁰*Ibid*; Kelleher (n 4) 68; Ford and Tomossy (n 2) 4. Instead of Trovan, all the children could have been given a full dose of Ceftriaxone.

²¹The case is *Abdullahi v Pfizer*, No 01 Civ 8118, 2002 WL 31082956 (SDNY 2002-09-17) see Carr (n 2) 16; Kelleher (n 4) 67-8; Ford and Tomossy (n 2) 4.

²²See (n 1).

²³See, eg, the much publicised controversy surrounding the mother-to-child HIV transmission trials in Uganda (Angell 'The ethics of clinical research in the Third World' (editorial) (1997) 337 *New England J of Medicine* 847; Varmus and Satcher 'Ethical complexities of conducting research in developing countries' (1997) 337 *New England J of Medicine* 1003 and Lurie and Wolfe 'Unethical trials of interventions to reduce perinatal transmission of the Human Immunodeficiency Virus in developing countries' (1997) 337 *New England J of Medicine* 854; Carr (n 2) and the South African male circumcision HIV-transmission trials at Orange Farm (Moodley (2006) 'Responses to Auvert' *et al PoLS Med* <http://0-medicine.plosjournals.org.innopac.up.ac.za/perlserv/request=index-html?request=read-response&doi=10.1371/journal.pmed.0020298#r1053> (2006-11-30).

²⁴See, eg, sources referred to in (n 23).

outlined. Next, the discussion examines human rights instruments at both the universal and at the regional level which are of relevance in the protection of participants in clinical research in Africa. The article concludes with an evaluation of the contribution of human rights law to the protection of clinical research participants in Africa.

In order to restrict the scope of the article, and in the light of the allegations in the Trovan case outlined above, the article is limited to an examination of informed consent to participation in research (as an ethical guideline and as a human right) in Africa. Moreover, because the emphasis is placed on *international* human rights law and codes of ethics, the protection afforded by *national* law (common law, legislation or constitutional law) to participants in clinical research is not elaborated upon.

2 Informed consent in international ethical guidelines

Informed consent, as a way to ensure the autonomy and physical integrity of research participants,²⁵ is dealt with extensively in the various international research ethics documents, such as the Nuremberg Code,²⁶ the World Medical Association's Declaration of Helsinki,²⁷ and the International Ethical Guidelines for Biomedical research involving Human Subjects.²⁸

However, abuses of clinical research participants continue to occur, often violating the cardinal ethical principle that research participants should give informed consent to participation in research. It is submitted that a very important cause for the failure of ethical guidelines to protect the interests of research participants can be attributed to the fact that they are simply guidelines: they do not have the force of law, and, therefore, are difficult to

²⁵Based upon the ethical principle of autonomy, or respect for persons (see Beauchamp and Childress *Principles of biomedical ethics* (2001) 63).

²⁶Informed consent is guaranteed in the first of the Nuremberg Code's ten principles. The Nuremberg trials include the trials of the doctors responsible for some of the inhumane experiments conducted at the order of the Nationalist Socialist German Government during World War II. The judges at the Nuremberg Tribunal provided a list of requirements for doctors conducting experimental research, now known as the Nuremberg Code. This list prescribes the conduct of physicians holding them to a minimum standard of ethical behaviour as required by universal moral, ethical and legal concepts, the violation of which would bring down upon them the condemnation of society (in this regard, see Levine *Ethics and regulation of clinical research* (1986) 425).

²⁷It 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. 'Clarifications' have also been added to the 2000 revision, accepted in October 2002 (Levine (n 26) 427). Guideline 20 protects participants in research against research interventions without their informed consent.

²⁸The CIOMS Guidelines were published by the Council for International Organizations of Medical Sciences (CIOMS) in conjunction with the World Medical Association (WMA) in 1982, and updated these guidelines in 1993 and 2002. Guideline one requires that '[f]or all biomedical research involving human subjects, the investigator must obtain the informed consent of the prospective subject or, in the case of an individual who is incapable of giving informed consent, the proxy consent of a properly informed representative'.

enforce. In the case of transgression, fierce ethical debate may follow, but little else can be done. Though the editor of the *New England Journal of Medicine*, Marcia Angell, regards the peri-natal HIV transmission trials²⁹ undertaken in Uganda as unethical, she published the results of the trials in the journal. To a large extent, observance of ethical guidelines depends on the sanction of various professional bodies and research funding agencies. Other than a refusal to fund or publish unethical research, there is little to guard against unethical research. Meier comments:³⁰

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

and:³¹

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.

Indeed, some international guidelines, themselves, give guidance as to their authority and force. The Declaration of Helsinki, for example, requires that researchers *consider* their own local legal and ethical guidelines, as well as international guidelines on ethics.³² There is, in this case, no absolute duty on the researcher to follow local ethical and legal guidelines – she merely has to *consider* them. Likewise, the Nuremberg Code is a declaration and does not have the force of law. The International Ethical Guidelines for Biomedical Research involving Human Subjects was published by the Council for International Organizations of Medical Sciences, the NGO founded under the auspices of the World Health Organization and the United Nations Educational, Scientific and Cultural Organization (UNESCO). CIOMS's task in the formulation of the CIOMS Guidelines was to 'indicate how the ethical principles that should *guide* the conduct of biomedical research involving human subjects, as set forth in the Declaration of Helsinki, could be effectively applied, particularly in developing countries, given their socio-economic circumstances, laws and regulations, and executive and administrative arrangements'.³³ Again, the CIOMS Guidelines are mere guidelines, as indicated by the use of the word 'guide', and are intended to be 'of use' in

²⁹See (n 23).

³⁰Meier 'International protection of persons undergoing medical experimentation: Protecting the right of informed consent' (2002) 20 *Berkeley J International L* 531.

³¹*Ibid.*

³²Principle A9 (my emphasis).

³³CIOMS 'Background' to the CIOMS Guidelines para 1 (my emphasis).

defining ‘national policies on the ethics of biomedical research involving human subjects’.³⁴

3 Ethical guidelines v human rights

Explicit in the difference between ethical principles and human rights, lies a crucial distinction between the two systems in terms of the enforcement mechanisms devised to monitor a system of non-binding principles as opposed to a system of legally binding rights: in the case of ethical guidelines governing clinical research on human subjects, compliance with, and enforcement of, the system relies on professional sanction and other non-legal means.³⁵ It is assumed that researchers are ‘ethical’ people who, to some extent, are trusted to uphold the guidelines of clinical research. Owing to their non-legal nature, the observance of ethical guidelines depends to a large extent on the sanction of various professional bodies and research funding agencies.³⁶ Other than a refusal to fund or a refusal to publish unethical research, there is little to guard against unethical research being conducted by unscrupulous agencies.³⁷

In respect of international human rights, monitoring and implementation mechanisms are in place.³⁸ These monitoring systems are sophisticated and well-developed. International organisations, such as the United Nations, assume a duty to protect human rights. Similar institutions have been introduced at a regional level as well, and in some regional systems they include a court in which international human rights are litigated and are enforceable against violators.³⁹ 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.⁴⁰

Below, the protection afforded participants in clinical research by international human rights law on informed consent is outlined. The discussion is limited to nine major international human rights declarations and treaties of relevance to clinical research conducted in Africa.

4 Informed consent in international human rights law

4.1 *The Universal Declaration of Human Rights*

The Universal Declaration is not a treaty – it is a resolution of the UN General Assembly and, in theory, has no binding force of law.⁴¹ However, the Universal Declaration has been transformed into a normative instrument that

³⁴*Id* para 12.

³⁵See Nienaber (2007) 168 – 174 (unpublished LLD thesis).

³⁶*Id* 173. Also see Meier (n 30) 530.

³⁷Nienaber (n 35) 173; Meier (n 30) 531.

³⁸Nienaber (n 35) 173-174.

³⁹*Ibid*.

⁴⁰*Ibid*.

⁴¹Buergenthal *International human rights in a nutshell* (1995) 33.

at least creates some legal obligations for member states of the UN, and parts thereof are regarded by many to be binding as customary international law.⁴² Dugard remarks that not all the provisions of the Universal Declaration are part of customary international law but the right to non-discrimination, the right to a fair trial and the prohibition on torture, and cruel, inhuman or degrading treatment, 'undoubtedly belong to the corpus of customary law today despite the fact that they may not always be observed. Their status as custom is assured by both *opinio juris* and *usus*'.⁴³

The Universal Declaration of Human Rights does not mention informed consent explicitly. Nevertheless, in article 3 it guarantees the right of everyone to 'life, liberty and security of person', and in article 5 it guarantees that '[n]o one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment'.

Either article 3 or article 5 may be used to argue that participants in clinical research should provide informed consent to participation. The right to individual autonomy is usually regarded as included under the right to security of the person and, thus, the right not to be subjected to medical experimentation without informed consent, is included as well.⁴⁴ Similarly, as the International Covenant on Civil and Political Rights (ICCPR) includes medical experimentation as part of the right not to be subjected to torture, cruel, inhuman or degrading treatment in article 7, one may argue that the right not to be subjected to medical experimentation without informed consent is part of the same right in the Universal Declaration. However, the opposite argument may also be made: since it is not explicitly mentioned in the Universal Declaration, while it is mentioned in the ICCPR, the equivalent right in the Universal Declaration does not contain a prohibition on medical experimentation without free and informed consent.

Although there is consensus regarding the view that freedom from torture may be regarded as part of customary international law,⁴⁵ there is no evidence in the literature that any international law scholar is of the opinion that a right to free consent to medical or scientific experimentation may be 'read into' the protection against torture offered by the Universal Declaration. That is unfortunate: inclusion would have meant that informed consent becomes a rule of customary international law and is immediately enforceable in all countries.

The position in many African countries, however, is not dependant on this argument, as they have ratified the main UN treaty on this subject, the ICCPR, to which the discussion now turns.

⁴²Dugard *International law: A South African Perspective* (2005) 315.

⁴³*Ibid.*

⁴⁴Eg, as in the South African Constitution 1996; also see Woolman and Bishop in Woolman *et al* (eds) *Constitutional law of South Africa* (2005) 40-57 – 40-58.

⁴⁵Dugard (n 42) 315; Nowak *UN Covenant on Civil and Political Rights CCPR Commentary* (2005) 157.

4.2 ICCPR

The International Covenant on Civil and Political Rights⁴⁶ (ICCPR) is the sole UN human rights treaty to include an express provision on informed consent. Thus, it establishes informed consent as a principle of international law and confers enforceable rights on research participants.⁴⁷ Non-compliance with the prohibition on experimentation without free consent in the ICCPR is thus a matter for international concern.

Article 7 of the ICCPR reads: ‘No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation’.

The wording of the first part of article 7 of the ICCPR mirrors article 5 of the Universal Declaration (widely considered to be binding customary international law), therefore, article 7 (as customary international law) would be binding on states not party to the ICCPR.⁴⁸ This means that the protection offered against torture or inhuman and degrading treatment is available even against countries that have not signed and ratified the ICCPR.

Significantly, article 7 prohibits experimentation without ‘free consent’, not that which lacks *informed* consent. This distinction is attributable to the fact that the article was drafted in the late 1940s,⁴⁹ and at this time the model for informed consent was paternalistic, emphasising the person’s consent and not the information provided, or her understanding of that information.

The phrasing of article 7 suggests that scientific experimentation is seen as a sub-class or even as an *example* of ‘torture’ or ‘cruel, inhuman or degrading treatment or punishment’ – because of the use of the words ‘[i]n particular’. This proposal may be explained by the drafting history of the ICCPR – according to the *travaux préparatoires*, drafting on article 7 started in 1948 soon after the Nuremberg Trials, and article 7 was so phrased in response to the atrocities committed by representatives of the National Socialist German government in the concentration camps under the guise of medical experimentation.⁵⁰ The aim stated in the second sentence of the article is to ‘prohibit criminal experiments on human beings such as those committed in Nazi concentration camps’.⁵¹

⁴⁶GA Res 2200A (XXI) of 1966-12-16.

⁴⁷Art 2(2) of ICCPR states ‘each State party to the present Covenant undertakes to take the necessary steps, in accordance with its constitutional processes and with the provisions of the present Covenant, to adopt such legislative or other measures as may be necessary to give effect to the rights recognized in the present Covenant’. Art 2(2) gives effect to the rights in the Convention, and ensures their enforcement as it requires governments to ‘adopt such laws or other measures as may be necessary to give effect to the rights recognised in the present Covenant’. According to art 3(a), state parties must further ensure that ‘any person whose rights or freedoms as herein recognized are violated shall have an effective remedy’.

⁴⁸Dugard (n 42) 315; Nowak (n 45) 157.

⁴⁹See Nowak (n 45) 188, where he points out that, as early as 1948, art 6 of the draft International Bill of Rights contained a similar provision, prohibiting scientific experimentation against a participant’s will.

⁵⁰Nowak (n 45) 188.

⁵¹*Id* 190. For general information on the *travaux préparatoires* of ICCPR, see Bossuyt *Guide to the ‘travaux préparatoires’ of the International Covenant on Civil and Political Rights*

Nowak comments that it follows from the structure of the article (that is, the fact that it appears that medical experimentation is an *example* or instance of cruel and inhuman treatment) that ‘only experiments that by their very nature are to be deemed torture or cruel, inhuman or degrading treatment are prohibited’.⁵² Thus, according to Nowak, the prohibition in the second sentence of art 7 does not extend to experiments of which the interference with personal integrity does not reach the degree of ‘degrading or inhuman treatment’.⁵³ According to Nowak, for example, the clinical testing of pharmaceuticals without the knowledge and/or consent of the person concerned falls within the scope of article 7 *only if its effect* constitutes degrading or inhuman treatment.⁵⁴ It will seem as if Nowak interprets article 7 to mean that ordinary research experiments, which do not impose the type of harm that may be classified as ‘cruel’, ‘degrading’ or inhuman, are not protected by article 7, *even if* no informed consent to participation was given. Consequently, experimentation is allowed when a person gives his free consent, or ‘when the very nature of the experiment makes it clear that the experiment cannot be deemed torture or cruel inhuman or degrading treatment’.⁵⁵

If this view were held to be correct, it would mean that the article holds ‘free consent’ to experimentation as optional in some cases, rather than prohibiting *all* scientific experimentation without informed consent. Nowak’s interpretation of article 7 is not supported by the Human Rights Committee in General Comment 20.⁵⁶ The Human Rights Committee states, without adding any qualification regarding the nature of the experimentation: ‘Article 7 expressly prohibits medical or scientific experimentation without the free consent of the person concerned’.⁵⁷ Even though such experimentation may not be deemed as ‘cruel’ or ‘degrading’, the very fact that no consent was given contravenes article 7. Further, Nowak admits, if regard be had to the *travaux préparatoires*, the lack of free consent is considered as a ‘sign’ of the inhuman character of the medical experiment.⁵⁸

The drafting history of article 7 was marked by problems regarding phrasing: article 7 had to protect against Nazi-like atrocities but still allow for legitimate experimentation.⁵⁹ France proposed the current phrasing of article 7, replacing the phrase ‘against his will’ in a previous version with ‘without his free consent’.⁶⁰ Nowak stresses, in contrast to the phrase ‘against his will’,

(1987).

⁵²Nowak (n 45) 191.

⁵³*Ibid.*

⁵⁴*Ibid* (my emphasis).

⁵⁵*Ibid.*

⁵⁶Issued by the Human Rights Committee 1992-04-03.

⁵⁷General Comment 20, para 7 <http://www.unhchr.ch/tbs/doc.nsf/0/6924291970754969c12563ed004c8ae5?Opendocument> (accessed 2007-01-31). General Comments are so-called ‘soft’ law, and are not binding, but they do represent an authoritative interpretation of ‘hard’ law.

⁵⁸Nowak (n 45) 191.

⁵⁹*Id* 188.

⁶⁰*Id* 189.

that it is not sufficient that the person ‘merely remains passive’ – ‘consent’ requires an action or an agreement from the person.⁶¹ The phrase ‘free consent’ implies not only that the research participant agrees to the study, but that she does so without any coercion.

Nowak further comments that article 7, when interpreted in the light of the *travaux préparatoires*, reveals that ‘the article refers only to interference that may be termed medical or scientific “experimentation”’.⁶² This view may be supported, as the aim of the prohibition was clearly to protect against illegal ‘experimentation’. Normal medical interventions or treatment do not fall within the ambit of the protection offered by article 7.

Nowak is of the view that proxy consent is not provided for under article 7.⁶³ According to Nowak, the use of ‘without *his* free consent’ makes it clear that the person herself must give informed consent.⁶⁴ Whether Nowak’s view can be supported depends on the interpretive strategy to be followed. A strict, literal interpretation of the article supports Nowak’s view; a more purposive or value-orientated interpretive approach does not. In this regard the Human Rights Committee has commented that ‘... special protection in regard to such experiments is necessary in the case of persons not capable of giving valid consent, and in particular those under any form of detention or imprisonment. Such persons should not be subjected to any medical or scientific experimentation that may be detrimental to their health’.⁶⁵ It seems as if the Human Rights Committee does not support Nowak’s literal reading of the article.⁶⁶ In his study on whether research subjects of clinical trials in developing countries are in a position to sue investigators for human rights violations, Jonathan Todres remarks that ‘it is unlikely that [article 7] intended to ban new therapies for children or others who are unable by law to give informed consent’.⁶⁷

Article 7 prohibits not only experimentation which causes physical suffering, but also that which causes psychological distress. General Comment 20 states, ‘article 7 relates not only to acts that cause physical pain but also to acts that cause mental suffering to the victim ... It is appropriate to emphasise in this regard that article 7 protects, in particular, children, pupils and patients in teaching and medical institutions’.⁶⁸ General Comment 20 additionally states that the aim of the provisions of article 7 ‘is to protect both the dignity and the *physical and mental integrity* of the individual. It is the duty of the

⁶¹See *id* 190 n 187.

⁶²*Id* 188.

⁶³*Id* 191.

⁶⁴*Ibid*.

⁶⁵General Comment 20 para 7.

⁶⁶Also see Woolman and Bishop in Woolman *et al* (n 44) 40-57 – 40-58 for commentary on the interpretation of s 12(2)(c) of the South African Constitution, 1996, where similar phrasing is used.

⁶⁷Todres ‘Can research subjects in developing countries sue physician-investigators for human rights violations’ (1999-2000) 16 *New York Law School J on Human Rights* 737 at 745 n 25.

⁶⁸General Comment 20 para 5.

State party to afford everyone protection through legislative and other measures as may be necessary against the acts prohibited by article 7 ...'.⁶⁹

Article 7 of ICCPR is 'non-derogable', as is stated by the UN Human Rights Committee: 'The text of article 7 allows of no limitation. The Committee reaffirms that, even in situations of public emergency such as those referred to in article 4 of this Covenant, no derogation from the provision of article 7 is allowed and its provisions must remain in force ... No justification or extenuating circumstances may be invoked to excuse a violation of article 7 for any reasons, including those based on an order from a superior officer or public authority.'⁷⁰

General Comment 20 requires that 'States Parties should indicate how their legal system effectively guarantees the immediate termination of all acts prohibited by article 7 as well as appropriate redress. The right to lodge complaints against maltreatment prohibited by article 7 must be recognised in the domestic law'.⁷¹ The General Comment further requires that '[c]omplaints must be investigated promptly and impartially by competent authorities so as to make the remedy effective'.⁷² Although the General Comment appears to be focussed on situations of detention, this paragraph of the Comment is more general in its reach, and seems to require states parties to prevent experimentation without free consent. States parties must enact legislation which 'effectively guarantees the immediate termination of all acts prohibited by article 7 as well as appropriate redress'.⁷³

A number of cases dealing with violations of the first part of article 7, prohibiting cruel, inhuman and degrading treatment or punishment, have reached the Human Rights Committee.⁷⁴ The second part of article 7, relating to experimentation without free consent, has elicited only one communication to the Human Rights Committee. In this case, *Viana Acosta v Uruguay*,⁷⁵ the author of the communication alleges that he was subjected to psychiatric experiments by a doctor⁷⁶ and that for three years, against his will, he was injected with tranquillisers every two weeks. He alleges further, that in May 1976, when he resisted being injected, Captain X⁷⁷ ordered a group of soldiers to subdue him forcibly in order to inject the drug and that he was

⁶⁹*Id* para 2 (my emphasis).

⁷⁰*Id* para 3.

⁷¹*Id* para 14.

⁷²*Ibid*.

⁷³In South Africa the required legislation (in the form of the National Health Act 61 of 2003) has been passed, prohibiting experimentation without free consent, but it does not provide 'appropriate redress' for violations of art 7. This omission should be addressed by the South African legislature.

⁷⁴See, eg, Communication 11/1977 *Grille Motta v Country*; Communication 74/1980 *Angel Estrella v Country*; Communication 464/ 1991 *Ng v Canada* 464/1991 (inhuman and/or cruel treatment); Communications 623-627/1996 *Domukovsky v Georgia* 623-627/1996 (conditions of detention); and so on.

⁷⁵Communication 110/1981 *Viana Acosta v Uruguay* <http://www.unhchr.ch/tbs/doc.nsf/0/658ade4b795d348ac1256ab8004f9b9c?OpenDocument> (accessed 2006-01-31).

⁷⁶The name of the doctor is not included in the communication.

⁷⁷No actual name is given in the communication.

subsequently held incommunicado in a punishment cell for 45 days. On 1977-05-14 and 1977-05-15 he was interrogated and subjected to torture at Libertad prison. He lists the names of several Uruguayan officials who practised torture. However, the Committee in response did not consider in detail free consent as such, but merely found that the treatment of Acosta during his detention was inhuman within the meaning of articles 7 and 10.⁷⁸

In his study of whether the Ugandan AZT-trials⁷⁹ violated any international human rights norms, Fidler states that 'there are no precedents [which] assist international legal analysis'.⁸⁰ The lack of case law dealing with the second sentence of article 7 is unfortunate, as no authoritative determination has been given on exactly what standards of free consent are accepted universally as binding. Although the general prohibition in article 7 may be taken as an international norm, because of the lack of case law it lacks substance and specificity: it is not known for certain what constitutes sufficient free consent nor which actual circumstances would constitute a violation.

A major problem with the ICCPR is, unlike the European and Inter-American systems, that it does not establish an international court of human rights.⁸¹ The decisions of the Human Rights Committee are not legally binding, so that, in practice, it has become a quasi-judicial monitoring body for state reporting and individual complaints procedures.⁸² However, the Human Rights Committee reports to the General Assembly, which to some extent is able to enforce the Human Rights Committee's decisions through political measures.⁸³

The ICCPR is regarded as applying to state actors only. For individuals to access the remedies under the treaty, the states to which they belong need to have signed the Optional Protocol on the Convention on Civil and Political Rights. South Africa has signed and ratified the Optional Protocol in November 2002.⁸⁴

Finally, it is submitted that article 7 of the ICCPR is a self-executing provision. In the case of self-executing provisions, it is not necessary for countries to incorporate the treaty into their domestic law for it to bestow enforceable rights upon individuals. Article 7 of ICCPR, if it were a self-executing provision, would be directly applicable (of course, it depends on the provisions regarding international treaties in the constitutions of countries).

Article 7 meets the 'pointers' set out for it to qualify as a self-executing provision.⁸⁵ First, it is clear from the *travaux préparatoires* that drafting on

⁷⁸*Viana Acosta v Uruguay* (n 75) paras 2.7; 14-15.

⁷⁹See (n 23).

⁸⁰Fidler "'Geographic morality" revisited: International relations, international law, and the controversy over placebo-controlled HIV clinical trials in developing countries' (2001) 42 *Harvard International LJ* 299 at 338.

⁸¹Nowak (n 45) 79.

⁸²*Id* 80.

⁸³South Africa has not yet submitted its initial report under ICCPR, which was due on 2000-03-09.

⁸⁴See <http://www.unhchr.ch/tbs/doc.nsf/22b020de61f10ba0c1256a2a0027ba1e/80256404004ff315802564610078e734?OpenDocument> (accessed 2007-01-31).

⁸⁵See Olivier 'Exploring the doctrine of self-execution as enforcement mechanism of international obligations' (2002) 27 *SA Yearbook of International L* 99.

article 7 started in 1948 soon after the Nuremberg Trials, and that the article was drafted in response to the atrocities committed by representatives of the National Socialist German government in the concentration camps under the guise of medical experimentation.⁸⁶ The aim stated in the second sentence of the article is to ‘prohibit criminal experiments on human beings such as those committed in Nazi concentration camps’.⁸⁷ Second, article 7 is phrased in relatively precise language – medical experimentation without the participant’s free consent is prohibited.⁸⁸ Third, the article (and the ICCPR) establishes negative obligations or prohibitions which are generally regarded as self-executing, as no further measure of implementation is required.⁸⁹ Finally, article 7 benefits individuals, which is one of the ‘requirements’ for it to qualify as a self-executing provision (where a provision creates private rights, it is assumed to be directly applicable).⁹⁰ It employs the words ‘no one’ twice, giving the article an individual character.

4.3 ICESCR

The International Covenant on Economic, Social and Cultural Rights (ICESCR) recognises a wide range of second generation rights which are not immediately enforceable. A state party undertakes, only, to ‘take steps ... to the maximum of its available resources ... with a view to achieving the full realisation of the rights...’.⁹¹ The wording of article 2(1) refers to ‘obligations of conduct’, rather than ‘obligations of result’.⁹²

Although the ICESCR does not contain a provision regarding informed consent, and article 12 establishes ‘the right of everyone to the enjoyment of the highest attainable standard of physical and mental health’.⁹³ The Committee on Economic, Social and Cultural Rights mentions that the right to health ‘contains both freedoms and entitlements’,⁹⁴ such as the right ‘to be free from non-consensual treatment and experimentation’. General Comment 14 reads:⁹⁵

The right to health contains both freedoms and entitlements. The freedoms include the right to control one’s health and body, including sexual and reproductive

⁸⁶Nowak (n 45) 188.

⁸⁷*Id* 190.

⁸⁸*Ibid*.

⁸⁹Olivier (n 85) 107.

⁹⁰See Olivier and above.

⁹¹Art 2(1).

⁹²Nowak (n 45 above) 81. States are merely obliged to achieve progressive realisation of these rights.

⁹³The inclusion of the word ‘attainable’ stresses that the right to health as guaranteed by art 12 is not unqualified – only the best ‘attainable’ health is guaranteed, by obligating state parties to ‘take steps ... to the maximum of its available resources ... with a view to achieving the full realisation of the rights ...’ (art 2(1)).

⁹⁴General Comment 14 para 8.

⁹⁵*Id* para 8 (my emphasis).

freedom, and the right to be free from interference such as the right to be free from torture, non-consensual treatment and experimentation. By contrast, the entitlements include the right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

General Comment 14 observes that the right to health is 'related to and dependent upon the realisation of other human rights as contained in the International Bill of Rights'⁹⁶ as well as dependant upon access to the 'underlying determinants of health'.⁹⁷ The determinants include access to adequate sanitation, an adequate supply of safe food, nutrition, housing, healthy occupational and environmental conditions, and access to health-related education and information, including sexual and reproductive health. The population of state parties to the Convention should participate in all health-related decision-making at the community, national and international levels.⁹⁸

Article 12, in relation to its content of the right to be free from non-consensual medical experimentation, has not yet been litigated under international human rights law.

Although many countries in Africa have not ratified the ICESCR, the Convention is not without relevance to the situation of clinical research participants on the continent. For example, although South Africa has not ratified the ICESCR, section 39(1)(b) of the South African Constitution 1996 orders the judiciary to consider international law in the interpretation of the rights in the Bill of Rights. In the case of *Government of the Republic of South Africa v Grootboom*,⁹⁹ the Constitutional Court made explicit reference to General Comment 3 of the Committee on Economic, Social and Cultural Rights, including its concept of minimum core obligations. General Comments of the Committee thus have persuasive force in South Africa, despite the country's non-ratification of the ICESCR.

4.4 CEDAW

Like the ICESCR, the Convention on the Elimination of all forms of Discrimination Against Women (CEDAW)¹⁰⁰ does not make explicit reference to the protection of the right to free and informed consent. However, article 5(a) obliges states parties to:

take appropriate measures to modify the social and cultural patterns of conduct of men and women, with a view to achieving the elimination of prejudices and customary and all other practices which are based on the idea of the inferiority or superiority of either of the sexes or in stereotyped roles of men and women.

⁹⁶*Id* para 3.

⁹⁷*Id* para 11.

⁹⁸As above. Also see General Comment 3 para 10 (UN Doc E/C12/1990/8), in which the CESCR Committee states:

a State party in which any significant number of individuals is deprived of foodstuffs, of essential primary health care, of basic shelter and housing, or of the most basic forms of education is, *prima facie*, failing to discharge its obligations under the Covenant.

⁹⁹*Government of the Republic of South Africa v Grootboom* 2000 11 BCLR 1169 (CC).

¹⁰⁰UN GA Res 34/180, UN Doc A/34/46; adopted 1979-12-18, entered into force 1981-09-03.

It is not too far-fetched to use the subsection to ensure that consent to participation in clinical trials is an individual informed consent of a woman taking part in the trials, and that customary practice whereby a woman's father or husband or the headman of the community takes a decision on her behalf, is not allowed. The obligation is placed on the states party to CEDAW to fulfil the right under the subsection, and this obligation could also be interpreted to include protecting a woman's right to give individual consent.

The application of the subsection in this way should be viewed in the light of General Recommendation 24 which deals specifically with women and health, issued by the Committee on the Elimination of Discrimination against Women (CEDAW Committee).¹⁰¹ General Recommendation 24 notes that women and girls do not have sufficient power to refuse sex or insist on safe sexual practices, and that they are often subjected to marital rape and polygamy, exposing them to HIV infection, amongst others.

CEDAW may therefore be used to affirm women's right to give free and informed consent to participation in clinical research. Clinical research (whether HIV-related or not) which takes cognisance of the General Recommendation in its research design, or which does not encourage or indirectly support unequal power relations in the research process alone is in line with the Recommendation.

4.5 CAT

In the Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (CAT),¹⁰² 'torture' is defined as 'any act by which severe pain or suffering, whether physical or mental, is intentionally inflicted on a person for *such purposes as obtaining from him or a third person information or a confession, punishing him for an act he or a third person has committed or is suspected of having committed, or intimidating or coercing him or a third person, or for any reason is based on discrimination of any kind, when such pain or suffering is inflicted by or at the instigation of or with the consent or acquiescence of a public official or other person acting in an official capacity*'.¹⁰³ The aim of CAT is therefore to prevent and punish torture that is inflicted by a person who is acting in his personal capacity or a person acting with the consent or acquiescence of another public official. Article 1 states that the term torture 'does not include pain or suffering arising only from, inherent in or incidental to lawful sanctions'.

Article 16 of CAT requires that each state party 'undertake[s] to prevent in any territory under its jurisdiction other acts of cruel, inhuman or degrading treatment or punishment *which do not amount to torture* as defined in article I, when such acts are

¹⁰¹Committee on the Elimination of Discrimination against Women *General Recommendation 24 Women and Health* [http://www.unhchr.ch/tbs/doc.nsf/\(Symbol\)/77bae3190a903f8d80256785005599ff](http://www.unhchr.ch/tbs/doc.nsf/(Symbol)/77bae3190a903f8d80256785005599ff) (2006-05-01).

¹⁰²Adopted by the General Assembly on 1984-12-10 and entered into force on 1987-06-28, after the 20th instrument of ratification required to bring it into force was deposited.

¹⁰³My emphasis.

committed by or at the instigation of or with the consent or acquiescence of a public official or other person acting in an official capacity'.¹⁰⁴ In particular, the article asserts the obligations contained in articles 10, 11, 12 and 13 apply to other forms of cruel, inhuman or degrading treatment or punishment'. Although CAT, therefore, is aimed not only at 'torture', but also 'inhuman or degrading treatment or punishment', it is submitted that experimentation without informed consent does not fall within the scope of the definition although clinical research, in a sense, may be described as 'obtaining ... information', there is no match with the other particulars in the definition: clinical research is not carried out by someone acting in an official capacity (unless the research is carried out by a police, military or prison doctor); or on the orders of someone acting in an official capacity.

4.6 *The African Charter of Human and Peoples' Rights*

There is no mention in the African Charter on Human and Peoples' Rights (African Charter)¹⁰⁵ of free and informed consent to medical experimentation. However, article 4, which states that 'human beings are inviolable', and that 'every human being shall be entitled to respect for his life and integrity of his person', is relevant to the situation of clinical trial participants in Africa. Furthermore, article 6 ensures that every 'person shall have the right to liberty and to the security of his person'. Even though informed consent to research participation is not mentioned, these articles of the African Charter can be used in support of the notion that clinical research participants give free and informed consent to research participation. Research without such consent violates the integrity and security of the person.

4.7 *African Bioethics Resolution*

A Resolution on Bioethics was adopted by the Assembly of Heads of State and Government of the OAU at its 32nd ordinary session (African Bioethics Convention).¹⁰⁶ In paragraph 2, the African Bioethics Resolution endorses the priority placed upon informed consent by the ICCPR and in paragraph 3 stresses the 'obligation to obtain the free and enlightened consent' to research, and makes provision for 'the definition of rules to protect vulnerable populations, the incapacitated, persons deprived of freedom as well as the sick under emergency conditions'.

The African Bioethics Resolution introduces a new term in referring to consent, namely, 'enlightened consent'. It is unlikely that the word 'enlightened' is used here in the context of 'liberal', 'free-thinking' or 'free from prejudice';¹⁰⁷ as in other human rights and ethics documents, it is used as a synonym for 'knowledgeable'; in the sense of being informed about a subject. In all probability the drafters of the Resolution did not intend to establish a higher standard than in other

¹⁰⁴My emphasis.

¹⁰⁵OAU Doc OAU/CAB/LEG/67/3/Rev 5.

¹⁰⁶AHG/Res 254 (XXXII) 1996; also reprinted in *African Ybk International L* 4 (1996) 375.

¹⁰⁷See definition given in *The Concise Oxford Dictionary of Current English* (1987 ed) 320.

documents. It is submitted that the term 'enlightened' in this context is a literal translation of 'éclairé', the term in the French version of the document: *consentement libre et éclairé*.¹⁰⁸ The word 'enlightened' should be understood to mean no more than 'informed consent'.

The African Bioethics Resolution displays an awareness of factors which influence individuals or groups in their ability to give free consent, as well as an understanding of the context in which research is taking place. It requires the definition of rules to protect vulnerable populations, the incapacitated, persons deprived of freedom as well as the sick under emergency conditions - so that they may freely consent. The Resolution does not explain who is in the category of 'vulnerable' populations: it is submitted that 'vulnerable' in this context equates with vulnerable to exploitation in research.

The African Bioethics Resolution does not create any binding obligations upon state parties, and is an example of 'soft law'. It is one of the least known resolutions under the regional system.¹⁰⁹

4.8 *African Charter on the Rights and Welfare of the Child*

Although the African Charter on the Rights and Welfare of the Child¹¹⁰ (African Children's Charter) does not protect a child's right not to be subjected to medical experimentation without their informed consent, it does protect the child's right to survival and development in article 5, which includes the child's right to life; her right to health in article 14 and her right to protection against child abuse and torture in article 16. Under article 16, 'States parties ... shall take ... measures to protect the child from all forms of torture, inhuman and degrading treatment and especially physical or mental injury or abuse'. This article could be interpreted as pertaining to the informed consent of children in research in Africa.

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

The Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa¹¹¹ (Women's Protocol) refers to women's informed consent 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

¹⁰⁸See definition Mansion (ed) *Harrap's French and English Dictionary* (1964) 209.

¹⁰⁹It was very difficult to obtain any meaningful information on the Resolution's drafting history, signatories, etc.

¹¹⁰Adopted by the 26th ordinary session of the Assembly of Heads of State and Government in Addis Ababa 1990-07-11 and entered into force on 1999-11-29 upon ratification by 15 member states (OAU Doc CAB/LEG/153/Rev 2, reprinted in Heyns (ed) *Human rights law in Africa 1997* (1999) 38. It has 29 state parties.

¹¹¹Adopted in Maputu in July 2003, and entered into force on 2005-11-27.

their informed consent'. Apart from article 7 of the ICCPR, the Women's Protocol is thus the only human rights instrument which contains a provision which mentions informed consent explicitly, and which is applicable to the situation of clinical research participants in Africa.

The consent aspect of article 4(2) has not been litigated. The Women's Protocol has not been in effect for long,¹¹² and it is exceptional to use a human rights instrument to litigate what is widely considered an ethical guideline. The fact that so few human rights treaties mention informed consent specifically is symptomatic of a world-view which regards informed consent as falling within the realm of bioethics, rather than in the realm of human rights. A violation of the requirement of informed consent for participation in clinical research is thus seen as a violation of ethical guidelines, instead of as a violation of a human rights treaty.¹¹³

Despite numerous abuses of the rights of research participants in Africa no communication related to research participation, or the right not to be subjected to medical experimentation without informed consent, has reached the African Commission on Human and Peoples' Rights.¹¹⁴

Nevertheless, in three communications, particularly, the jurisprudence of the African Commission establishes general principles potentially relevant to the protection of clinical research participants in Africa (although none of the three cases deals with informed consent). These communications do not concern so-called first generation or civil and political rights, but rather second and even third generation rights.¹¹⁵ They are *SERAC v Nigeria*,¹¹⁶ *Free Legal Assistance Group v Zaire*¹¹⁷ and *Purohit v The Gambia*.¹¹⁸

The communication in *SERAC v Nigeria* concerns the Nigerian state's concerted violation of numerous articles of the African Charter, including sections 2, 4, 14, 16, 18(1), 21 and 24. These rights were violated by the activities of a (government-controlled) oil company, the Nigerian National Petroleum Company (NNPC), the majority shareholder in a consortium with Shell Petroleum Development Corporation, in an oil-producing part of Nigeria known as Ogoniland. The oil company's activities caused wide-scale contamination, degradation and devastation of the area's air, water and soil resources. For example, numerous oil spills occurred in the proximity of Ogoni villages, with serious consequences for the short and long-term health of the inhabitants, such as respiratory ailments, increased risk of cancers, neurological and reproductive problems.¹¹⁹

¹¹²The Women's Protocol came into effect in November 2005.

¹¹³See below.

¹¹⁴Neither has such a communication reached any of the UN bodies.

¹¹⁵As pointed out, this characterisation of rights into three generations is outdated. In this regard, see Viljoen *Human Rights in Africa* (2007) 6-8.

¹¹⁶*Social and Economic Rights Action Centre (SERAC) v Nigeria* (2001) AHRLR 60 (ACHPR 2001).

¹¹⁷*Free Legal Assistance Group v Zaire* (2000) AHRLR 74 (ACHPR 1995).

¹¹⁸*Purohit v The Gambia* (2003) AHRLR 96 (ACHPR 2003).

¹¹⁹*Social and Economic Rights Action Centre (SERAC) v Nigeria* (n 116) para 2.

In finding that violations had occurred, the African Commission argues the indivisibility of the different generations of rights, and emphasises that all three generations of rights entail positive and negative duties.¹²⁰

Internationally accepted ideas of the various obligations engendered by human rights indicate that all rights – both civil and political and social and economic – generate at least four levels of duties for a state that undertakes to adhere to a rights regime, namely the duty to *respect, protect, promote and fulfil* these rights. These obligations *universally* apply to all rights and entail a *combination of negative and positive duties*.

The Commission quoted from various international human rights law precedents¹²¹ and remarked:¹²²

Governments have a duty to protect their citizens, not only through appropriate legislation and effective enforcement, but also by protecting them from damaging acts that may be perpetrated by private parties ... This duty calls for positive action on the part of governments in fulfilling their obligation under human rights instruments.

These comments are relevant in respect of the position of participants in clinical trials in Africa undertaken by international pharmaceutical companies (so-called non-state actors). The Commission reiterates that the relevant articles of the African Charter *impose an obligation* on governments to take (positive) measures (in terms of article 24) to *prevent* pollution and ecological degradation, to promote conservation, and to ensure an ecologically sustainable development and use of natural resources.¹²³ By analogy, the other rights in the African Charter, such as in articles 4, 5 and 6, place obligations of this kind on African governments to *prevent* abuses of research subjects in clinical research, which they can do only if they take proactive measures to ensure these rights.

According to the theory of implied rights, the right to be free from medical experimentation without participants' informed consent may be considered to be *implied* in other rights in the African Charter. Article 4 of the African Charter, which provides that 'human beings are inviolable', and that 'every human being shall be entitled to respect for his life and integrity of his person', and article 5, which ensures that every 'person shall have the right to liberty and to the security of his person', may be used to support the notion that clinical research participants give free and informed consent to research participation. Research without such consent violates the integrity and security of the person.

The *SERAC* communication also concerned article 21 of the African Charter: article 21(1) reads, '[a]ll peoples shall freely dispose of their wealth and natural resources. This right shall be exercised in the exclusive interest of

¹²⁰*Id* para 44 (my emphasis).

¹²¹The Commission eg referred to *Velasquez Rodriguez v Honduras* (before the Inter-American Court of Human Rights) and *X and Y v Netherlands* (European Court of Human Rights).

¹²²*SERAC* (n 116) para 57 (my emphasis.)

¹²³*Id* para 52. My emphasis.

the people ...'. Assuming a correspondence in the communication between the violation of this guarantee and the exploitation by colonial powers of Africa's material resources and its peoples, the African Commission found that Nigeria had violated that right by allowing the oil companies to undertake oil explorations in Ogoniland. The Commission claims: 'colonial exploitation has left Africa's precious resources and people still vulnerable to foreign misappropriation'.¹²⁴ In the same way, clinical research which exploits its human resources, could be regarded as a violation of article 21, as not being in the 'exclusive' interest of Africa's peoples. The Commission adds:¹²⁵

The drafters of the Charter obviously wanted to remind African governments of the continent's painful legacy and restore co-operative economic development to its traditional place at the heart of African society.

In endeavouring to develop new drugs to treat the illnesses afflicting the continent, the collaborative effort between international corporations and African researchers and corporations should be mutually beneficial. A collaborative partnership, for example, would be one which offers training and the development of research capacity in under-resourced African counties. A research endeavour to which participants do not give free and informed consent, by definition, is exploitative.

In *Free Legal Assistance Group v Zaire*¹²⁶ the African Commission dealt with a communication resulting from severe violations during a civil war in Chad. The finding, which identifies a duty on the part of the state to 'protect' civilians against violations by non-state actors, is directly relevant to the position of clinical research participants. In cases where a government's own forces are not responsible for the killings committed by other (non-state) actors, does not absolve it of responsibility if it *fails to prevent or takes no action to investigate* allegations about assassinations and other killings.

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. States have a responsibility to protect the rights of their populations against violations by others. On the finding in the case, Viljoen comments: 'Going beyond the duty to *respect*, the Commission also interpreted rights in the Charter to entail a *positive obligation to protect and fulfil* ... [the *Free Legal Assistance Group* communication] exemplifies the duty (or *positive obligation*) of the state to *protect* civilians against violations by non-state actors'.¹²⁷

In *Purohit v The Gambia*,¹²⁸ the African Commission dealt with a communication submitted on behalf of patients detained at Campama, a psychiatric unit of the Royal

¹²⁴*Id* (n 116) para 56.

¹²⁵*Ibid*.

¹²⁶*Free Legal Assistance Group v Zaire* (n 117).

¹²⁷Viljoen (n 115).

¹²⁸*Purohit v The Gambia* (n 118).

Victoria Hospital, as well as existing and 'future' mental health patients detained under the Mental Health Acts of the Republic of The Gambia.

The complainants allege violations of articles 2, 3, 5, 7(1)(a) and (c), 13(1), 16 and 18(4) of the African Charter on Human and Peoples' Rights, on the basis that legislation governing mental health in The Gambia is outdated; that in the Lunatics Detention Act (the principle instrument governing mental health) there is no definition of who is a lunatic; and that there are no provisions and requirements establishing safeguards during the diagnosis, certification and detention of the patient. Moreover, the complainants allege that there is overcrowding in the psychiatric unit, that there is no requirement of consent to treatment or subsequent review of continued treatment, and this allegation, in particular, is significant.

In the course of delivering a finding, the Commission refers to *Media Rights Agenda v Nigeria*,¹²⁹ in which the African Commission holds that the term 'cruel, inhuman or degrading punishment and treatment' is to be interpreted as extending to the widest possible protection against abuses, whether physical or mental; and to *Modise v Botswana*,¹³⁰ in which the African Commission states that exposing victims to 'personal suffering and indignity' violates the right to human dignity.¹³¹ The Commission emphasises that 'personal suffering and indignity can take many forms, and will depend on the particular circumstances of each communication brought before the African Commission'.¹³²

Finding the state in violation of the articles of the African Charter, the African Commission holds as follows:¹³³

Enjoyment of the human right to health as it is widely known is vital to all aspects of a person's life and well-being, and is crucial to the realisation of all the other fundamental human rights and freedoms. This right includes the right to health facilities, access to goods and services to be guaranteed to all without discrimination of any kind.

Within the obligations imposed on a state which has ratified the African Charter, the Commission orders a positive duty by the state to '[r]epeal the Lunatics Detention Act and replace it with a new legislative regime for mental health in The Gambia compatible with the African Charter on Human and Peoples' Rights and international standards and norms for the protection of mentally ill or disabled persons as soon as possible';¹³⁴ to 'provide adequate medical and material care for persons suffering from mental health problems in the territory of The Gambia';¹³⁵ and '[r]equests the government of The Gambia to report back to the African Commission when it submits its next periodic report in

¹²⁹*Media Rights Agenda v Nigeria* (2000) AHRLR 262 (ACHPR 2000).

¹³⁰*Modise v Botswana* (2000) AHRLR 30 (ACHPR 2000).

¹³¹*Id* para 58.

¹³²*Purohit* (n 118) para 58.

¹³³*Id* para 80.

¹³⁴*Id* para 87.

¹³⁵*Ibid.*

terms of article 62 of the African Charter on measures taken to comply with the recommendations and directions of the African Commission in this decision'.¹³⁶

States ratifying the African Charter have an analogous duty to fulfil the rights guaranteed in the Charter which include the rights to freedom and security of the person, and can be read as prohibiting the indignities committed during clinical trials in Africa.

5 Conclusion

International human rights law protects participants in clinical research by insisting upon their free and informed consent. International human rights conventions, such as the ICCPR (to which many African states are party) and the Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa, explicitly provide for this right. Other international law instruments, as well as customary international law (such as the Universal Declaration of Human Rights), establish a broad range of obligations of governments with respect to the informed consent of participants in clinical research through guarantees to equality, dignity, access to health care and physical integrity.

There are two possible reasons for the lack of explicit provision in other instruments. First, the right not to be subjected to experimentation without free and informed consent is seen as implicitly included in other rights which are guaranteed, such as the right to human dignity, to physical and psychological integrity, to health and so on. Second, the drafters of international human rights instruments regard the issue as in the ambit of ethical guidelines and not human rights and, therefore, is not 'worthy' of inclusion in a human rights instrument. If this is the case, it is extremely regrettable, as a unique opportunity for the protection of research participants has been missed.

Although not current practice, it is submitted that international human rights law affords effective protection to the interests of research participants in Africa. Human rights law need not necessarily replace regulation in the form of ethical guidelines, but its utility lies in reinforcing ethical obligations. Human rights law is a barrier upholding individual freedom and autonomy. Moreover, it requires positive action to be taken by states to ensure that informed consent is obtained from research participants. Human rights law, therefore, compels states to enact legislation that guarantees the right to informed consent for participation in research. A violation of the right, such as that alleged in the Trovan case outlined above, becomes immediately enforceable, under international law, as well as national law.

The utility of a system that designates enforceable obligations, in preference to a frail reliance upon *guidelines*, has become evident from the above discussion.

¹³⁶*Id* para 88.