The researcher's liability for HIV-related clinical research without the participant's informed consent: South Africa's common law, case law and legislation*

Annelize G Nienaber
BA(Hons) LLB LLM LLD
Senior Lecturer, Faculty of Law, University of Pretoria

OPSOMMING

Die navorser se aanspreeklikheid vir MIV-verwante kliniese proewe sonder die deelnemer se ingeligte toestemming: Die Suid-Afrikaanse gemenereg, regspraak en wetgewing

Verskillende kliniese proewe word tans in Suid-Afrika onderneem om middels en strategieë vir die voorkoming van MIV-besmetting te ontwikkel. Hierdie artikel ondersoek die aanspreeklikheid van die navorser wat MIV-verwante kliniese proewe onderneem sonder die deelnemer se ingeligte toestemming aan die hand van die gemenereg, regspraak en wetgewing. In die besonder word navorser-aanspreeklikheid tydens voorkomende of nie-terapeutiese MIV-verwante kliniese proewe ondersoek. Alhoewel ingeligte toestemming tot deelname aan kliniese proewe in artikel 12(2)(c) van die Suid-Afrikaanse Grondwet vervat word, is die omvang van hierdie bespreking beperk tot die Suid-Afrikaanse gemenereg, regspraak en wetgewing, aangesien 'n latere artikel grondwetlike aspekte aanspreek. 'n Oorsig van die juridiese basis van ingeligte toestemming in die Suid-Afrikaanse reg word weergegee asook die regsgevolge van 'n navorsingsingreep sonder die ingeligte toestemming van die deelnemer.

1 INTRODUCTION

Various clinical trials aimed at developing agents and strategies for the prevention of HIV infection are underway in South Africa, such as trials to test the efficacy of various anti-HIV microbicides, pre-exposure prophylaxes, preventive HIV vaccines and male circumcision.[1] In order for these trials to be considered

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* This article draws upon sections of the author's LLD thesis *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* (UP 2007; hereinafter Nienaber *Thesis*).

1 See generally Ramjee "Microbicides and other prevention technologies": Paper delivered at the XVI International HIV/AIDS Conference, Toronto, Canada, 13–18 August 2006; Ramjee *et al* "Challenges in the conduct of vaginal microbicide effectiveness trials in the developing world" 2000 *AIDS* 2553–2557; the South African male circumcision HIV-transmission trials at Orange Farm (Moodley "Responses to Auvert *et al*" 2006 *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> (visited 30 November 2006)).

lawful and ethical,[2] trial participants must give their informed consent to participation.

The difficulties in ensuring the informed consent of clinical research participants in South Africa, as well as in the rest of the world, have been outlined by many.[3]

A research participant's ability to comprehend or understand information is a function of her intelligence, maturity and linguistic abilities. Information of a scientific or technical nature is difficult to understand for lay people all over the world, no matter their level of education. In the context of the developing world, where poverty, low levels of education and illiteracy are the order of the day, the comprehension of scientific and technical information poses significant challenges to the research participant. Ramjee *et al* evaluated the comprehension of participants in a HIV vaginal microbicide study conducted in KwaZulu-Natal.[4] According to the results of her study, almost 70% of participants failed to understand vital scientific information regarding the study, as well as factual aspects related to the drug, such as the fact that the microbicide was experimental, that it could not protect against HIV and other sexually transmitted diseases, and that a placebo microbicide was used on some of the participants.[5]

In 2004, Smith conducted a pilot qualitative study aimed at exploring the process of obtaining informed consent within a Phase I HIV vaccine trial that was being initiated at the Perinatal HIV Research Unit at the Chris Hani Baragwanath Hospital in Soweto.[6] She documented obstacles and facilitators to the informed consent process such as *ad hoc* interpreting and cultural, social and linguistic differences amongst participants, researchers and the individuals who originally devise informed consent protocols. Smith concludes: "Results from this research study have thus identified significant compromises within the current informed consent protocols in HIV vaccine trials within this particular reviewed context."[7] Although Smith's study, by her own admission, is limited

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2 Various ethical guidelines on informed consent to participation in clinical research exist in South Africa, but will not be discussed here. In this regard, see van Wyk "Guidelines on medical research ethics, medical 'experimentation' and the Constitution" 2001 *THRHR* 3.

3 See Moodley *et al* "Informed consent and participant perceptions of influenza vaccine trials in South Africa" 2005 *J Med Ethics* 727. Moodley *et al* conclude that participants' recall of informed consent in randomised controlled trials in South Africa and other developing countries may "often be inadequate" (731). See also Abdool Karim *et al* "Informed consent for HIV testing in a South African hospital: Is it truly informed and truly voluntary?" 1998 *American J Public Health* 637–640; Coletti *et al* "Randomized, controlled evaluation of a prototype informed consent process for HIV efficacy trials" 2003 *J Acquired Immune Deficiency Syndromes* 161; Lynöe *et al* "Informed consent: Study of the quality of information given to participants in a clinical trial" 1991 *British Med J* 610; Schultz *et al* "Are research subjects really informed?" 1975 *West J Med* 76.

4 Ramjee *et al* (fn 1) 2553–2557.

5 *Ibid*.

6 Smith *Misinforming the uninformed? Issues of informed consent in the multicultural context of HIV vaccine trials* (BHons dissertation Wits 2004).

7 Smith (fn 6) 83. Also see Ives *et al* "Does an HIV clinical trial information booklet improve patient knowledge and understanding of HIV clinical trials?" 2001 *HIV Medicine* 241, who conclude that while participants' general knowledge and understanding of clinical trials improved over time, this was not improved by the information booklet and their recollection of the details of the trial protocols remained poor.

due to its poor generalisability,[8] it does have important implications for the informed consent process in South Africa. From the transcribed interviews with the two participants in Smith's study, it is clear that informed consent was not obtained from them.[9] This result is especially alarming when one considers that both participants in Smith's study had a Grade 12 education.

In light of these difficulties, and in the light of accusations levelled in the past against researchers for their failure to obtain valid informed consent from participants,[10] this article investigates the liability of the researcher in preventive HIV-related clinical trials who fails to obtain the informed consent of trial participants.

The research participant's right not to be subjected to clinical research without his or her informed consent is guaranteed in section 12(2)(c) of the South African Constitution. However, the constitutional guarantee is but one of a number of sources – albeit an important one – of informed consent law in South Africa and it cannot be seen in isolation from the wider relevance of informed consent in South African common law, case law and statutes.[11] Therefore, this article investigates the liability of a researcher who undertakes preventive HIV-related clinical research without the research participant's informed consent, based not upon the Constitution, but upon the South African common law, case law and legislation. Another work investigates researcher liability in the light of section 12(2)(c) of the Constitution.[12]

The article is structured as follows: an overview of the juridical basis of informed consent in South African law is provided after which the legal consequences of a research intervention without informed consent are described. Difficulties which relate to the requirement of causation in the context of research-related liability are deliberated upon and the provisions of the new National Health Act[13] on informed consent to participation in research are analysed.

The article has a very specific focus – informed consent to participation in preventive or non-therapeutic HIV-related clinical research. As a consequence the discussion on informed consent in South African law is limited to:

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8 Because of the limited number of participants studied.

9 See Smith (fn 6) 20–83.

10 See sources in fn 3 above, as well as 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 *New England J of Medicine* 847; Varmus and Satcher "Ethical complexities of conducting research in developing countries" 1997 *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 *New England J of Medicine* 854).

11 In *Pharmaceutical Manufacturers Association of South Africa In re: Ex Parte Application of the President of the Republic of South Africa* 2000 3 BCLR 241 (CC) para 44 the Constitutional Court observed that "there are not two systems of law, each dealing with the same subject matter, each having similar requirements, each operating in its own field with its own highest court. There is only one system of law. It is a shaped by the Constitution which is the supreme law, and all law, including the common law, derives from the Constitution and is subject to constitutional control".

12 See Nienaber *Thesis*.

13 61 of 2003.

- a discussion of the law as it pertains to *competent*[14] *adult*[15] persons;
- a discussion of the law as it pertains to *clinical research* and not to standard medical interventions or treatment;[16] and
- a discussion of the law as it pertains to *non-therapeutic*[17] HIV-related research or experimentation (and therefore not research to find a cure or treatment for HIV, or so-called pure "therapeutic"[18] research).

As common law and case law do not deal with informed consent in a research setting, general principles of informed consent to standard medical interventions need to be extrapolated to a research setting.

2 JURIDICAL FOUNDATIONS OF INFORMED CONSENT

Any medical intervention – therapeutic or experimental – is considered lawful only in the presence of certain grounds of justification, namely, consent, necessity and *negotiorum gestio*;[19] the list of justifications, however, is not closed.[20]

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14 In light of current ethical, legal and constitutional provisions, non-therapeutic HIV-related clinical trials are unlikely to be undertaken on incompetent or mentally incapacitated persons. Regarding informed consent to research participation by mentally incompetent persons, see eg Van Staden "Can involuntary admitted patients give informed consent to participation in research?" 2007 *SA J Psychiatry* 10.

15 A discussion of the participation of children in HIV-related clinical research (specifically HIV vaccine efficacy trials) falls outside the scope of this article. For more on the participation of children in HIV-related clinical research, specifically HIV vaccine research, see eg Van Wyk 2005 *THRHR* 35; Strode *et al* 2005 *SA J Science* 225; Slack and Kruger 2005 *SA Med J* 269; Jaspan *et al* 2005 *SA Med J* 685; Slack *et al* 2005 *SA Med J* 682. On the scientific justification for adolescent participation, see Jaspan *et al* 2005 *SA Med J* 785.

16 Although the distinction between "standard medical interventions" and "clinical research" is less clear than is often supposed (as many standard medical interventions include a measure of "experimentation", and, sometimes, an individual patient's illness may lead a clinician to look for treatments outside of what is considered the standard clinical practice), the author uses "standard medical interventions" to indicate routine patient care or activities aimed exclusively at benefiting an individual patient and which have a reasonable chance of success, and "clinical research" to indicate research involving human subjects that is " a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalisable knowledge" (see MRC *Guidelines on ethics for medical research* (2002) para 2.1.2). Most preventive HIV-related clinical research is done through clinical trials which are "organized studies to provide large bodies of clinical data for statistically valid evaluation of treatment" (Anderson (ed) *Mosby's medical, nursing & allied health dictionary* (1998) 1E13).

17 "Non-therapeutic" research aims to "benefit people other than the research participant. The participant or healthy volunteer may unexpectedly become a direct or indirect beneficiary of non-therapeutic research. The acquisition of knowledge may be of no immediate benefit to the participant or healthy volunteer" (MRC (fn 16) para 2.1.2.2).

18 The aim of "therapeutic" research is "to benefit the individual research participant or patient by treating or curing their condition" (MRC (fn 16) para 2.1.2.1). Therapeutic HIV-related research, for example, is research to develop an effective antiretroviral 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.

19 Strauss *Doctor, patient and the law: A selection of practical issues* (1991) 31; other commentators mention additional grounds, such as therapeutic privilege, unauthorised administration and relative impossibility (see Carstens and Pearmain *Foundational principles of South African medical law* (2007) 873) and unauthorised agency and therapeutic

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The general criterion determining lawfulness is the *boni mores* or legal convictions of society.[21] The grounds of justification are merely a crystallisation of the *boni mores* test for circumstances that frequently occur in practice. Thirion J, in *Clarke v Hurst*, remarks that the "stereotyped grounds of justification are specific grounds of justification of otherwise wrongful conduct which with the passage of time have become crystallised, with their own rules limiting the scope of their application".[22]

Consent is a prerequisite for lawful medical interventions based on the principle or defence of *volenti non fit iniuria*.[23] The defence of *volenti non fit iniuria*, in certain circumstances, may exclude the wrongfulness or unlawfulness of a crime or delict:[24] the literal meaning is "no harm is done to someone who consents thereto".[25]

Consent therefore excludes unlawfulness: "where a person legally capable of expressing his will gives consent to injury or harm, the causing of such harm will be lawful".[26] *Volenti non fit iniuria* can be interpreted narrowly (the research subject consents to *specific* harm) or more widely (the research subject consents to the assumption of the *risk* of harm).[27] Consent to harm is consent to a *specific* harm, but not harm which is not yet determined or which is not defined,[28] and constitutes a one-sided action. An example is a patient who consents to an operation for a certain medical condition.[29] At the time the consent is given it is certain that the operation (or harm) will take place. In consenting to the *risk* of harm there is a possibility or even the likelihood that the actions of the other party will cause harm, but no certainty.[30] The person who consents to the operation,

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privilege (see Claassen and Verschoor *Medical negligence in South Africa* (1992) 75–78). For some, therapeutic privilege is a sub-species of *negotorium gestio* – see eg the discussion by Coetzee *Medical therapeutic privilege* (LLM dissertation Unisa 2001) 77.

20 Snyman *Strafreg* (2006) 95; Neethling *et al The law of delict* (2006) 71; Carstens and Pearmain (fn 19) 937.

21 See eg *Clarke v Hurst* 1992 4 SA 630 (D) 653B. See also Neethling *et al* (fn 20) 70.

22 *Clarke v Hurst* 650.

23 The ground of justification of consent is based on the rule that when a legally competent person consents to an action which would otherwise be unlawful, that infringement of her rights is regarded as lawful (Carstens and Pearmain (fn 19) 875; Neethling *et al* (fn 20) 71). See also Van Oosten *The doctrine of informed consent in medical law* (LLD thesis Unisa 1989) 10. Similar grounds of justification exist in other countries; however, they are not always based on the doctrine of *volenti non fit iniuria*, but on the doctor's duty of care towards her patient (see *Rodgers v Whitaker* (1993) 67 ALJR 47).

24 *Ibid*; *Stoffberg v Elliott* 1923 CPD 148.

25 "No man can complain of an act which he has expressly or impliedly assented to. This principle, which was well known to the Roman and Roman-Dutch law, is commonly expressed by the maxim *volenti non fit injuria*. Literally interpreted, the maxim is applicable only to cases where a person has consented to suffer something which would otherwise be an intentional wrong, eg consent to undergo a surgical operation or consent to the publication of a defamatory statement. But the maxim is used in a wider sense, and is applied to cases where a person has consented to run the risk of unintentional harm, which would otherwise be actionable as attributable to the negligence of the person who caused it" (McKerron *Law of delict* (1952) 95–96, cited in *Lampert v Hefer* 1955 2 SA 507 (A) 512).

26 Neethling *et al* (fn 20) 89.

27 Van Oosten (fn 23) 14; Neethling *et al* (fn 20) 92.

28 Neethling *et al* 93.

29 *Ibid*.

30 *Ibid*.

consents to the *risk* of a certain side-effect materialising during the operation and, therefore, to the risk of harm.[31]

In a research setting, the second of the two forms, the assumption of the *risk of harm*, is more likely to be present. Though some of the risks of a researched drug or intervention are known at the beginning of a trial, not all risks can be known, neither can the researcher predict the likelihood of known risks materialising. In the case of preventive HIV-related clinical trials, there are a number of unknown risks[32] that may materialise and, therefore, subjects can be said to assume the risk of possible harm.

The next section outlines aspects of a researcher's liability for subjecting participants to preventive HIV-related clinical research without their informed consent.

3 LEGAL CONSEQUENCES OF RESEARCH INTERVENTIONS WITHOUT INFORMED CONSENT

Van Oosten outlines the potential liability of a health care worker for a medical intervention undertaken without effective consent:[33] she may be liable for breach of contract;[34] civil or criminal[35] assault (a violation of physical integrity);[36] civil or criminal *iniuria* (a violation of the *dignitas* – dignity or privacy);[37] or negligence.[38] Importantly, the health care worker (or, in this case, researcher) is liable regardless of whether the medical intervention or research eventuates as having been in the best interest of the patient or participant, or whether it was performed with the necessary care and skill.[39] Although the duty to inform rests primarily upon the health care worker or researcher, it may be delegated to qualified health care personnel.[40]

Below, a researcher's civil liability, based upon the commission of a delict, is outlined, followed by criminal liability, based upon the commission of a crime. A researcher who proceeds with research without obtaining the participant's prior informed consent may be liable on both these grounds simultaneously. Throughout, specific reference is made to preventive HIV-related research. The discussion, in certain instances, is general, and does not focus only on the lack of consent but upon negligently performed actions during research as well.

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31 *Ibid*.

32 See eg UNAIDS *Ethical considerations in HIV preventive vaccine research* (2000) 28; Graham and Wright 2003 *New England J of Medicine* 1335; Slack *et al* 2000 *SA J Science* 293.

33 Van Oosten (fn 23) 12. See also Strauss (fn 19) 178–179; Carstens and Pearmain (fn 19) 890.

34 Eg *Behrmann v Klugman* 1988 (W) (unreported) but discussed by Strauss (fn 19) 41 176–177.

35 Van Oosten (fn 23) 51; *S v Kikunyana* 1961 3 SA 549 (E).

36 Eg *Stoffberg v Elliott* (fn 24); *Esterhuizen v Administrator, Transvaal* 1957 SR 48 55; *S v D* 1998 1 SACR 33 (T).

37 Eg *Stoffberg v Elliott* (fn 24) (where the patient's right to self-determination was recognised); *C v Minister of Correctional Services* 1996 4 SA 292 (T).

38 Eg *Stoffberg v Elliott* (fn 24); *Lymbery v Jefferies* 1925 AD 236; *Richter v Estate Hammann* 1976 3 SA 226 (C). See also Carstens and Pearmain (fn 19) 676.

39 Van Oosten 1995 *De Jure* 167. See below.

40 Slabbert 2006 *THRHR* 37.

3 1 Civil or delictual liability

3 1 1 The right to the corpus *or body (civil assault)*

Civil assault is the physical infringement of a research participant's body without her consent: the "*corpus* (bodily and psychological integrity) is protected against every factual infringement of a person's physique or psyche".[41] Even infringements of the senses, whereby a physical feeling of disgust, discomfort or repugnance is caused, are included in the protection afforded to the *corpus*.[42] Physical infringements may occur with or without violence and with or without pain.[43] In order to establish liability under the *actio iniuriarium*, the bodily infringement need not be accompanied by *contumelia* in the form of an insult.[44] Certain requirements must be met before the *actio iniuriarium* may be relied upon: the infringement must not be trivial; it must be wrongful; and it must be committed *animo iniuriandi*.[45] For the *actio iniuriarum*, the plaintiff must prove intent on the part of the wrongdoer.[46] A justified violation of the body is "naturally also lawful".[47] Consent constitutes such a justified violation. In *Castell v De Greef*[48] the court commented upon this issue as follows:[49]

> "The issue is not treated as one of negligence, arising from the breach of the duty of care, but one of consent to the injury involved and the assumption of an unintended risk. In the South African context the doctor's duty to disclose a material risk must be seen in the contractual setting of an unimpeachable consent to the operation and its *sequelae*."

The application of the concept of assault is a result of the placement by South African courts of a medical practitioner's duty to disclose information to obtain informed consent within the framework of the wrongfulness element (with *volenti non fit iniuria*) rather than with the fault element of the delict (intention or negligence).[50]

Boberg supports the view that liability for non-disclosure or defective disclosure of information to the patient should be based on assault rather than negligence: [51]

> "The answer is that this liability is based, not upon negligence, but upon his intentional invasion of the patient's body without the patient's consent. Though the patient purported to consent, his consent was legally ineffective because he did not appreciate the attendant risks. In other words, the doctor is liable for assault, not negligence (for there was none), and it is the defence of consent, not assumption of risk, that fails."

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41 Neethling *et al* (fn 20) 301.
42 *Ibid*.
43 *Ibid*.
44 *Idem* 302.
45 *Ibid*.
46 See para (a)(ii) below.
47 Neethling *et al* (fn 20) 302.
48 1994 4 SA 408 (C). The plaintiff's action, based upon a lack of informed consent, did not succeed, but her claim based upon negligence succeeded.
49 425F–G.
50 Van Oosten (fn 39) 178; *Castell v De Greef* (fn 48) 425.
51 Boberg *The law of delict* Vol 1 (1989) 751.

What about instances where the intervention was *not* to the benefit of the patient because an undisclosed risk materialised?[52] Van Oosten maintains that it would be wrong to argue that an action based upon negligence is impossible in cases where the medical intervention

> "was performed with due care and skill, but the undisclosed risk or danger materialised and it has been established that the patient, had he been properly informed of the undisclosed risk or danger, would not have suffered an impairment of his health".[53]

This is what happened in *Richter v Estate Hammann*:[54] the plaintiff alleged that it was negligent of the neurosurgeon not to have warned her that there were certain serious risks attached to the administration of a phenol block, and that she may have elected not to have the procedure had she been aware of these risks. The court found that, as there was only a remote possibility of the risk materialising, the neuro-surgeon had not been negligent in not warning her of the risks. The court observed:[55]

> "It may well be that, in certain circumstances, a doctor is negligent if he fails to warn a patient, and, if that is so, in principle his conduct should be tested by the standard of the reasonable doctor faced with the particular problem."

Strauss disagrees. In commenting upon *Richter v Estate Hammann*, he remarks:[56]

> "It is to be noted that the court did not conclusively decide that failure of the doctor to adequately inform the patient would in fact constitute negligence. If this was decided, a new principle would be introduced into our law . . . It is submitted that to consider failure to inform as negligence would not be in accordance with the Roman-Dutch concept of *culpa* which until now has been defined as the failure to foresee the damaging consequences and to take reasonable measures to avoid it. The essence of negligence in the medical context is unskilful treatment."

In *Broude v McIntosh*[57] the court again questioned the notion that a lack of consent should be characterised as assault and expressed the hope that this basis will be re-evaluated in due course. The court remarked: [58]

> "Pleading a cause of action such as this as an assault to which the patient did not give informed consent is of course a familiar and time-honoured method of doing so. However, I venture to suggest with respect that its conceptual soundness is open to serious question and merits reconsideration by this Court when an appropriate case arises . . . It seems to me to be inherent in the notion that, even if the risk does not eventuate and the surgical intervention is successful, the practitioner's conduct would nonetheless have constituted an assault. That strikes me as a bizarre result which suggests that there is something about the approach which is unsound."

It is submitted that a medical or research intervention without informed consent does not constitute negligence, but rather that it constitutes an assault. The relevant element of the delict and/or crime is that of wrongfulness or unlawfulness and not that of fault. A medical or research intervention without proper informed consent amounts to assault as it is a violation of the individual's physical integrity. This is not a "bizarre result" as the court in *Broude v McIintosh*

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52 See eg *Lymbery v Jefferies* (fn 38); *Prowse v Kaplan* 1933 EDL 257; *Dube v Adminstrator, Transvaal* 1963 4 SA 260 (W), where the court found that the defendants were liable based upon negligence.
53 Van Oosten (fn 39) 178.
54 Fn 38.
55 232H per Watermeyer J.
56 Strauss (fn 19) 268.
57 1998 3 SA 60 (SCA).
58 *Idem* 67–68; these remarks were made *obiter*.

remarked, but in fact the conceptually most sound approach. The court in *Broude* criticised the fact that the "conduct would still have resulted in an assault".[59] This is of course true, but it seems that the court is here disregarding the fact that it is not the consequences, but the initial act of violating the patient's physical integrity that is blameworthy. Assault can therefore be the only logical basis of liability.[60]

It is therefore submitted that preventive HIV-related clinical trails in which participants have not given fully informed consent to participation result in liability based upon the delictual ground of assault. An action based upon assault exists regardless of whether harm is suffered by the participant, as the action is based upon the physical infringement without the justification of the consent of the participant.

3 1 2 Rights related to the dignitas*: dignity and privacy (civil* iniuria*)*

Under South African law, the rights to dignity and privacy are recognised as independent personality rights.[61] Dignity includes a person's subjective feelings of dignity or self-respect.[62] An infringement of a person's dignity arises from an insult to the person by word or belittling or contemptuous behaviour.[63] Publication of the insult to third persons is unnecessary; publication to the person herself is sufficient.[64] The plaintiff must allege *animus iniuriandi*.[65]

Privacy is "an individual condition of life characterised by seclusion from the public and publicity, the extent of which is determined by the individual himself".[66] Privacy is infringed by unauthorised acquaintance by outsiders with the individual and her personal affairs in two ways: first, when an outsider herself becomes acquainted with the individual or her personal affairs (instances of acquaintance or intrusion); or, second, where the outsider acquaints third parties with the individual or her personal affairs which, although known to the outsider, remains private (instances of disclosure or revelation).[67]

The wrongfulness of a factual infringement of dignity and privacy is determined by means of the *boni mores* or reasonableness criterion and the presence of a ground of justification excludes the wrongfulness of the action.[68]

In the context of preventive HIV-related clinical trials, it is unlikely that participants' dignity is infringed by their participation in such trials, unless a situation arises in which a participant's sense of herself is demeaned by the researcher's conduct.[69] It is, however, conceivable that a participant's privacy may be infringed by events during a trial. Blood tests taken without the informed consent of the participant may be regarded as a wrongful invasion of privacy by

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59 *Ibid*.
60 See also Carstens and Pearmain (fn 19) 687.
61 Neethling *et al* (fn 20) 321–322.
62 *Idem* 321.
63 *Ibid*.
64 *Ibid*.
65 Carstens and Pearmain (fn 19) 962; *Jansen Van Vuuren NO v Kruger* 1993 4 SA 842 (A).
66 Neethling *et al* (fn 20) 322.
67 *Ibid*.
68 *Idem* 322–323.
69 For example, where the participant is "talked down to" or patently regarded as someone of no or little intelligence.

intrusion, and the disclosure of private facts, such as a participant's HIV status,[70] is an example of a violation of a participant's privacy by disclosure.[71]

An illustration of a violation of privacy rights constituting the delict of *iniuria* is found in *C v Minister of Correctional Services*[72] which deals with a HIV test on a prisoner without his informed consent. While C was incarcerated at Johannesburg Prison, a blood sample was taken from him for a HIV test. C was a member of a group of prisoners standing in a passage in a hospital when he had been informed, together with the other prisoners, by a sergeant in the Department of Correctional Services, that the blood test was for HIV and other transmissible sexual illnesses and that he had the right to refuse to undergo the test. This information was repeated to C in the closed consulting room in which the blood was taken, and in the presence of W, a prisoner assisting the sergeant with the drawing of blood. C was accordingly fully aware that the test was, *inter alia*, for the HI virus and that he had the right to refuse to be tested when he consented to undergo the test. However, he was given no pre- and post-test counselling[73] in conformity with the Department of Correctional Services' policy and national guidelines.

Kirk-Cohen J held that there could be informed consent only if C appreciated and understood what the object and purpose of the HIV test were, what an HIV-positive result entailed and what the probability of AIDS occurring thereafter was.[74] Further, he held that the principles with regard to the definition of *animus iniuriandi* applied in C's case, that is, that it is sufficient that the injury suffered by C had been inflicted by the sergeant with deliberate intention and that it was not necessary to prove ill-will or spite on his part or his motive.[75] Therefore, even though C knew what the test was for, he did not give true informed consent, and the taking of blood not only constituted an assault on C's *corpus*, it constituted an *iniuria* as it was an invasion of his privacy.

As a consequence of the light it sheds upon the issue of the unauthorised publication of the HIV status of a participant in HIV-related clinical research, *NM v Smith (Freedom of Expression Institute as Amicus Curiae)*[76] needs mention. The case was an appeal to the Constitutional Court against an order handed down in the Johannesburg High Court in an action for damages based upon the *actio iniuriarum* against the respondents for their violation of the applicants' rights to privacy, dignity and psychological integrity arising from the unauthorised disclosure by the respondents of the applicants' HIV status.

In March 2002, New Africa Books published the names and HIV status of the three applicants, in a biography entitled *Patricia de Lille*, written by Charlene

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70 See *Jansen Van Vuuren v Kruger supra*.
71 See above.
72 Fn 37.
73 Pre-test counselling entails informing the prisoner of the meaning of HIV infection; the manner of transmission of the disease; the nature of the test and that consent is required; the social, psychological and legal implications of the test; what was expected if the result of the test proves positive; and the prisoner has to be granted time to consider the information before consenting to the test being administered. In the event of a positive blood test, post-test counselling requires that psychologists, social workers and nursing staff be at hand to support the prisoner and to provide advice so that the result can be accepted.
74 *C v Minister of Correctional Services* 301B.
75 *Ibid*.
76 2007 7 BCLR 751 (CC).

Smith. NM and two other women (SM and LH) had taken part in a clinical trial that was to determine the efficacy and safety of a combination of HIV antiretrovirals, which trial De Lille had investigated after complaints surrounding the high number of serious adverse events (including deaths) experienced during the trial, as well as whether trial participants, in fact, had given informed consent to participation in the trial.

De Lille's enquiries prompted two investigations by the University of Pretoria into the trial, which had been conducted by its Faculty of Health Sciences. A report of the second enquiry, by Professor Strauss, was sent to De Lille, but without its annexures attached.[77] These annexures contained the terms of the consent forms that the three women had signed, and did not permit public disclosure of their identity or their HIV/AIDS status – only limited disclosure for the purposes of the University's investigation was permitted.

Before the Constitutional Court the applicants contended that as a result of the disclosure of their names and HIV status to the public the respondents had wrongfully and intentionally or negligently violated their rights of personality, more particularly their right to privacy, dignity and psychological integrity and that they had suffered damages as a result.[78] The respondents, denying any liability to the applicants, relied on the fact that the applicants' names had previously been disclosed in the Strauss Report and that the report was not marked "confidential".

In finding that the publication by the respondents of the HIV status of the applicants constituted a wrongful publication of a private fact and that the applicants' right to privacy was therefore breached by the respondents, the court found that, although there is "nothing shameful about suffering from HIV/AIDS",[79] the "social construction and stigma associated with the disease make fear, ignorance and discrimination the key pillars that continue to hinder progress in its prevention and treatment",[80] and it is an "affront to the infected person's dignity for another person to disclose details about that other person's HIV status or any other private medical information without his or her consent".[81]

Although the Constitutional Court's decision in the case is open to criticism,[82] it affirms the notion that the unauthorised disclosure of participants' HIV status

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77 The annexures contained the informed consent forms signed by the three applicants and which revealed their identity.

78 Para 29.

79 Para 48.

80 *Ibid*.

81 *Ibid*.

82 In order for a court to award damages based upon the *actio iniuriarum*, it must be shown that the injury to the dignity and privacy of the applicants was done *intentionally*. The applicants, however, alleged that the invasion of their privacy by the respondents was not intentional but negligent. As a result they enquired whether or not the common law of privacy should be developed so as to impose liability on those who negligently (instead of intentionally) publish confidential medical information (in particular a person's HIV status) through not first obtaining the express informed consent of that person, unless the public interest clearly demands otherwise (para 54). The court responded to this enquiry by stating that the present case was not appropriate for departing from the age-old approach to the *actio iniuriarum*. The majority of the court found that, on examination of the conduct of the respondents and despite their denial of having acted *animo iniuriandi* and their further contention that they acted reasonably, it was satisfied that the "respondents were certainly

continued on next page

in a clinical trial or thereafter, constitutes a violation of their rights to privacy, dignity and psychological integrity. It is therefore submitted that a researcher who intentionally publishes trial participants' HIV status is similarly liable.

3 1 3 Negligence[83]

Even had the consent of the research participant been obtained, the researcher remains civilly (and, criminally) liable for negligently performed actions during the research endeavour. As a from of fault, negligence is an attitude or conduct of "carelessness, thoughtlessness or imprudence because, by giving insufficient attention to his actions he failed to adhere to the standard of care legally required of him".[84] The standard referred to is that of the reasonable person or *bonus paterfamilias*[85] laid down by Holmes JA in *Kruger v Coetzee*.[86]

The criterion of the fictitious reasonable person is central to the determination of negligence.[87] In the case of an expert the criterion of the reasonable *expert* is used – a reasonable doctor or researcher with the same level of knowledge and skill as the defendant.[88] The highest level of care is not expected – only that of the *reasonably* careful, knowledgeable, able, experienced, skilful researcher.[89] No exceptional ability is called upon – a reasonable amount of expertise and care is sufficient.[90]

A research participant claiming delictual damages based upon injuries sustained during negligently-conducted HIV-related research relies on the duty of reasonable care owed to her by the researcher. The facts that could or should have been foreseen by the researcher and which led to the delict must be declared. The onus is on the research participant to establish that a *bonus paterfamilias* in the position of the researcher:[91]

(a) would have foreseen the possibility of her conduct injuring her and causing her patrimonial loss; and

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aware that the applicants had not given their consent or at least foresaw the possibility that the consent had not been given to the disclosure" (para 64). The court was here arguing that intention in the form of *dolus eventualis* was present.

83 See generally, Carstens *Die strafregtelike en deliktuele aanspreeklikheid van die geneesheer op grond van nalatigheid* (LLD thesis UP 1996).

84 Neethling *et al* (fn 20) 116.

85 *Idem* 117.

86 1966 2 SA 428 (A) 430. The court stated:
"For the purposes of liability culpa arises if –
(a) a *diligens paterfamilias* in the position of the defendant –
(i) would foresee the reasonable possibility of his conduct injuring another in his person or property and causing him patrimonial loss; and
(ii) would take reasonable steps to guard against such occurrence; and
(b) the defendant failed to take such steps.
This has been constantly stated by this Court for some 50 years. Requirement (a)(ii) is sometimes overlooked. Whether a *diligens paterfamilias* in the position of the person concerned would take any guarding steps at all and, if so, what steps would be reasonable, must always depend on the particular circumstances of each case. No hard and fast basis can be laid down."

87 Neethling *et al* 117 120–122.

88 *Idem* 120–122 124–126; see eg *Esterhuizen v Administrator Transvaal* (fn 36) 723; *Richter v Estate Hammann* (fn 38) 231–235.

89 Neethling *et al* 124–126.

90 *Idem* 125.

91 *Kruger v Coetzee* (see above, esp fn 86).

(b) would have taken reasonable steps to guard against such injury; and that

(c) the researcher had been negligent in failing to take those steps.

The criterion of the fictitious reasonable person, if applied to a researcher in preventive HIV-related clinical trails, demands that the researcher will carefully and diligently conduct the procedures involved in the trial and will, furthermore, carefully consider the potential adverse effects of participation upon those involved in the trial. For example, she will carry out the physical examination of research participants with skill and competence; adhere carefully to the inclusion and exclusion criteria of the trial; conduct the informed consent process with competence and diligence; and generally perform all trial-related procedures with due care and skill.

However, if the reasonable researcher in the position of the defendant would only have undertaken the research after extensive and sufficient examination of the attendant risks or complications, and the researcher had not done so before embarking upon the trial, the researcher will have acted negligently.[92]

As noted earlier, a diligent researcher obtains informed consent based upon the known or foreseen risks of participation in HIV-related clinical research. Politis argues that, if a research intervention has been performed with due care and skill, but the undisclosed risk or danger materialises and it is established that the participant, had she been properly informed of the undisclosed risk or danger, would not have undergone the intervention or procedure, a researcher faces liability in negligence.[93] It is submitted that this view cannot be correct. The liability of a researcher in HIV-related clinical research who fails to disclose known or foreseen risks to participants is based upon assault, as she has infringed their physical integrity without their consent.[94] The conduct amounts to assault regardless of whether or not those risks later materialise.

The situation in which *unforeseen* risks materialise during the research needs to be examined as well. Is the researcher negligent in the case of unforeseen (and consequently undisclosed) risks? In respect of preventive HIV-related clinical research it is conceivable that a hitherto unknown risk may materialise during the research process because of the precarious state of preventive HIV science. It is submitted that in this instance the researcher cannot be held liable based upon negligence. The risks are unknown at the start of the trial, and the researcher cannot take steps to avoid the risks materialising. In other words, the risks are unknown even to the researcher, thus, the first part of the test for negligence fails – the researcher could not have foreseen the possibility of her conduct injuring the research participant as the risk which materialised is unknown to her. Consequently, in preventive HIV-related clinical trails the researcher is obliged diligently to disclose known and foreseen risks – she cannot be considered negligent it she fails to disclose unforeseen or unknown risks.

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92 Politis *Aspects of legal liability for medical research and experimentation in South Africa and England: A comparative study* (LLM dissertation UP 2003) 143–144. It is sometimes argued that if standard or accepted treatment is ineffective, a researcher will be justified in taking greater risks in an attempt to provide effective treatment, provided that the *utmost level of care* and caution is observed and steps are taken to prevent any harm to the patient (see Politis 144).

93 *Idem* 145.

94 See para 3 1 2 above.

The following section examines possible criminal liability for actions performed during preventive HIV-related clinical trails.

3 2 Criminal liability

3 2 1 Assault

In criminal law assault is the unlawful and intentional (i) application of force, directly or indirectly, to the person of another, or (ii) inspiring a belief in another person that force is immediately to be applied to him.[95] The sanctity of a person's physical being flows out of society's belief in the sanctity of human life.[96] Criminal law punishes the unlawful application of force to a person's physical being.

Criminal assault is excluded by the consent of the individual: a surgeon operating upon the person of someone who has given legally valid consent is not committing a crime.[97] The situation of a researcher conducting preventive HIV-related clinical trials is the same – the prospective participant's informed consent excludes the possibility of the researcher being held liable for criminal assault. Conversely, should such consent be absent, the researcher may be found guilty of criminal assault.

There is no possibility of negligent assault in South African criminal law; therefore, in order for assault to be proved the defendant needs to have acted with intent.[98]

3 2 2 Crimen iniuria

Crimen iniuria is the unlawful and intentional impairment of the dignity or privacy (*dignitas*) of another person.[99] A person's *dignitas* is described as a person's right to dignity, self-respect, privacy, and mental tranquillity.[100]

To determine in which circumstances an invasion of someone's privacy amounts to the crime of *crimen iniuria*, one has to look at the *boni mores* of society at that time and place.[101] Unlike an infringement of someone's dignity, of which the victim needs to be aware, it is not necessary that a person whose privacy has been infringed should be aware of the infringement.[102] Not all infringements of the dignity or privacy of others amount to *crimen iniuria* – the infringement needs to be reasonably serious:[103] the court remarked in *S v Walton*[104] that "[i]n the ordinary hurly-burly of everyday life a man must be expected to endure minor and trivial insults to his dignity".[105]

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95 Burchell *Principles of criminal law* (2005) 161; Snyman (fn 20) 432 (definition translated from the Afrikaans).
96 *Ibid*.
97 Burchell 161; Snyman 437–438.
98 Burchell 162; Snyman 438; *R v Steenkamp* 1960 3 SA 680 (N).
99 Burchell 165; Snyman 457 (definition translated from the Afrikaans).
100 Snyman 458. Previously, *dignitas* was understood to refer only to dignity, but it is now understood to include privacy rights as well (458).
101 Snyman 462.
102 Snyman 462; *R v Holliday* 1927 CPD 395 401–402.
103 Burchell (fn 95) 165.
104 1958 3 SA 693 (R).
105 *Idem* 696.

Conduct during a research endeavour which involves not only an infringement of the research participant's physical security, but also her *dignitas*, amounts to the crime of *crimen iniuria.* The *boni mores* of society is likely to support the view that information about one's HIV status should remain private.[106] This was discussed in detail above.[107]

3 2 3 Culpable homicide

Culpable homicide is the unlawful negligent killing, or causing the death of another human being.[108] For culpable homicide to be proved it must be shown that the accused acted negligently and that the action was the factual and legal cause of the deceased's death.[109] The test for negligence is virtually the same for culpable homicide as under delictual liability outlined above:[110] it must be shown that a reasonable medical practitioner (or researcher) in similar circumstances, would have foreseen death as a result of the proposed course of conduct and that she would have taken steps to prevent it.[111] The burden of proof, however, differs.

In respect of preventive HIV vaccine research, if the researcher did not foresee the risk of death as a consequence of a research-related activity, in an instance in which the reasonable researcher would have foreseen such a risk and the research participant subsequently dies, the researcher will have acted negligently and may be charged with culpable homicide. However, as argued above,[112] if a risk is *not* foreseeable, negligence is not present and the researcher cannot be charged with culpable homicide. Similarly, if the reasonable researcher would have foreseen the risk, and have taken steps to prevent the risk materialising, yet the accused did not take such steps, she is guilty of acting negligently and may be charged with culpable homicide in the event of the research participant subsequently dying.

Due to the many unknown factors related to HIV science, it may be impossible to foresee the risk of death occurring as a result of the HIV-related research intervention. In this instance a researcher is not liable, if the reasonable researcher in her position could not have foreseen the risk of death materialising. However, participants in preventive HIV-related research are healthy volunteers,[113] therefore, there is a compelling duty placed on the researcher to take extra care to avoid any risk of death (or HIV-infection, which may lead to death). It is submitted that HIV-related clinical trials, such as preventive HIV vaccine trials, which are carried out on healthy volunteers, should not be undertaken if a risk, however remote, of death exists.

Slabbert[114] raises a further important aspect to the negligence requirement: non-compliance and non-observance of statutory regulation may amount to

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106 See *NM v Smith* (fn 76) and *C v Minister of Correctional Services* (fn 37).
107 Para 3 1 2 above.
108 Burchell (fn 95) 159; Snyman (fn 20) 427 (definition translated from the Afrikaans). Culpable homicide need not be "gross" in nature to constitute sufficient negligence for a conviction of culpable homicide (Burchell 160).
109 Burchell 160; Snyman 427; *S v Ntuli* 1975 1 SA 429 (A); *S v Kramer* 1987 1 SA 887 (W).
110 See para 3 1 3 above.
111 Burchell 160; Snyman 428.
112 See para 3 1 3 above.
113 The research intervention being tested is, after all, aimed at *preventing* HIV infection.
114 Slabbert (fn 40) 42.

evidence of negligent conduct.[115] It is submitted that preventive HIV-related clinical trials carried out in contravention of the various statutes may constitute negligence.[116]

3 2 4 Murder

Murder is the intentional unlawful killing or causing the death of another human being.[117] Consent is not a ground of justification for murder.[118] Intention needs to be proved for an accused to be guilty of murder; either direct intention or indirect intention or *dolus eventualis*.[119]

It is unlikely that direct intention will be present in the case of a researcher conducting clinical research. The researcher is conducting the trials with the hope of eventually saving lives and not to intentionally murder participants in the trial. However, *dolus eventualis*, as a form of intention, requires that the researcher must merely foresee the possibility of the death of a research participant and must have reconciled herself to that possibility.[120] Although not directly willing a participant's death she would have *reconciled* herself to the *possibility* that her research may bring about the participant's death.

It is on occasion difficult to distinguish between a negligent action which causes another person's death and the intentional killing (in the form of *dolus eventualis*) of another person. In respect of negligence, the researcher does not foresee the eventuality of death, where she should reasonably have foreseen it, and, therefore, does not take the steps reasonably required of her to prevent the death of a participant. In the case of *dolus eventualis*, the researcher foresees the risk of death but reconciles herself to that risk. Research conducted in such a manner shows a wanton disregard for human life and may be likened to the criminal actions that have occurred in the dark history of medical research.[121]

These remarks conclude the discussion of a researcher's liability for research undertaken without the participant's informed consent. Before turning the discussion to the examination of statutory provisions on informed consent, consideration is given to causation as a requirement for delictual and criminal

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115 See Slabbert (fn 40) 42 who quotes *Sand & Co v SAR&H* 1948 1 SA 230 (W) 243 where Ettlinger AJ remarked: "It is clear that a breach of a statutory regulation may sometimes in itself be taken for negligence. Where a statute prescribes that certain precautions are to be taken for the safety of others, then a failure to take such precautions resulting in injury will, *per se*, found an action for damages provided that if the statute was enacted for the benefit or protection of a particular class of person, the injured person was of that class."

116 Research carried out in contravention of the various ethical guidelines, such as the MRC's *Guidelines on ethics for medical research* (fn 16) (promulgated in terms of the Medical Research Council Act 58 of 1991), does not of itself constitute negligence. Ethical guidelines do, however, provide an indication of the *boni mores* of society, and as such may be used in the determination of negligence.

117 Burchell (fn 89) 159; Snyman (fn 20) 423 (definition translated from the Afrikaans).

118 Burchell 326; Snyman 425; *S v Robinson* 1986 1 SA 666 (A). Of course, other grounds of justification exist – self-defence and necessity.

119 Burchell 157; Snyman 425.

120 *Ibid*.

121 See eg Katz *Experimentation with human beings* (1972); Pappworth *Human guinea pigs* (1967) and Rothman *Strangers at the bedside: A history of how law and bioethics transformed medical decision making* (1991).

liability for preventive HIV-related research conducted without the participant's informed consent.[122]

4 THE ELEMENT OF CAUSATION: AN IMPOSSIBLE HURDLE IN ESTABLISHING RESEARCH-RELATED LIABILITY?

The section deliberates upon difficulties arising from the requirement of causation in the context of preventive HIV-research-related liability. The discussion is not exhaustive but aims to hint at the anticipated difficulties.[123]

To be found guilty of the commission of a crime or to establish liability for the commission of a delict, a causal connection or link is required between the act and the damage that ensues.[124] Applied to the research context, the act (the research intervention without or with deficient consent) should be causally connected to damage suffered by the research participant.

Causation has two components: factual and legal.[125] The former component relates to the factual causal link between the researcher's action (the research intervention without informed consent) and the damage suffered by the research participant. This factual causal link has to be established on a balance of probabilities;[126] the test to be applied in this regard is the *conditio sine qua non* or "but for" test.[127]

In accordance with the *conditio sine qua non* test, in order to determine if the conduct of the researcher caused the damage, that conduct has to be mentally eliminated in considering whether the damage still exists.[128] If the damage is still present it has not been caused by the actions or conduct of the researcher.[129] An examination of this sort requires a retrospective analysis of what probably would have occurred, based upon the evidence and on what can be expected in the ordinary course of events during a research-related intervention of this kind.[130] It should be borne in mind that for factual causation to be established it is sufficient that the researcher's conduct contributed in any way to the eventual damage.[131] It is not necessary, therefore, to establish that the conduct in question was the only, primary or sole cause of the damage that ensued.[132]

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122 Actual damage will have to be established – in the present context damage resulting from an assault will usually consist of patrimonial damage (such as medical costs and loss of income) and non-patrimonial damage (eg pain and suffering, loss of amenities in life, etc) (Neethling "Delictual protection of the right to bodily integrity and security of the person against omissions by the state" 2005 *SALJ* 572 589).

123 For a more comprehensive discussion on the topic, see Politis (fn 95) 155–165 and Carstens and Pearmain (fn 19) 509–515.

124 Burchell (fn 95) 209; Neethling *et al* (fn 20) 159; Snyman (fn 20) 76–92; Carstens and Pearmain (fn 19) 509.

125 Burchell 209; Neethling *et al* (fn 20) 150–160; Neethling (fn 122) 588; Carstens and Pearmain (fn 19) 509.

126 Neethling *et al* (fn 20) 150–160; Neethling (fn 122) 588; Carstens and Pearmain (fn 19) 509.

127 Burchell 212; Neethling *et al* (fn 20) 161–171.

128 Neethling *et al* (fn 20) 162–163.

129 As above.

130 As above; Neethling (fn 122) 588; *Minister of Safety and Security v Carmichele* 2004 3 SA 305 (SCA) 328.

131 Neethling *et al* (fn 20) 171; Snyman (fn 20) 87; Neethling (fn 122) 588.

132 *Ibid*.

The latter component, legal causation, relates to the question for which harmful consequences of her wrongful and culpable actions (research intervention without the informed consent of the participant) the researcher should be held liable; in other words, which consequences should *legally* be imputed to the researcher.[133] In the ordinary course of events, a single act on the part of the researcher may set in motion a chain of events – it needs to be established which of these events legally may be imputed to be the consequences of the researcher's act. Generally, the researcher cannot be held liable for consequences or damage that is too remote.[134]

In this regard South African courts adopt a flexible approach since none of the existing criteria for legal causation (such as adequate causation and foreseeability) is suitable in all instances.[135] In *S v Mokgethi*, Van Heerden JA remarks:[136]

> "Wat die onderskeie kriteria betref, kom dit vir my ook nie voor dat hulle veel meer eksak is as 'n maatstaf (die soepele maatstaf) waarvolgens aan die hand van beleidsoorwegings beoordeel word of 'n genoegsame noue verband tussen handeling en gevolg bestaan nie. Daarmee gee ek nie te kenne nie dat een van die kriteria nie by die toepassing van die soepele maatstaf op 'n bepaalde soort feitekompleks subsidiêr nuttig aangewend kan word nie; maar slegs dat geen van die kriteria by alle soorte feitekomplekse, en vir die doeleindes van die koppeling van enige vorm van regsaanspreeklikheid, as 'n meer konkrete afgrensingsmaatstaf gebruik kan word nie."

In accordance with a flexible approach, the question that needs to be answered is whether there is a sufficiently close link between the researcher's act and the harmful consequences that may be imputed to her in view of policy considerations based upon aspects such as reasonableness, fairness and justice.[137]

In the area of clinical research it is peculiarly difficult to establish a sufficiently close link between an act and the damage suffered. This is especially the case in a field such as preventive HIV-related science and experimentation, as the science is in its infancy and many side-effects of the candidate drugs, interventions and vaccines are unknown,[138] or side-effects may become apparent only many years after the actual research intervention.[139] It may be difficult, if not impossible, to attribute a certain consequence to participation in a preventive HIV-related clinical trial. Unlike other medical interventions, in which a lack of informed consent prior to an operation or test may have immediate and direct consequences (such as unexpected risks materialising), in the case of, for example, preventive HIV vaccine clinical research the harm or injury suffered may take years to become manifest. Even then it may appear unrelated to participation in the clinical trial.

It is submitted that, in the case of damage suffered because of participation in preventive HIV-related research, the flexible approach to causation needs to be adapted in order to take into account the unique situation of trial participants and

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133 Neethling (fn 122) 588.
134 Neethling *et al* (fn 20) 178–179; Burchell (fn 95) 209–213; Snyman (fn 20) 82–83.
135 Neethling (fn 122) 588; *S v Mokgethi* 1990 1 SA 32 (A).
136 *S v Mokgethi* 40I–41B.
137 Neethling (fn 122) 588–589. Also see *S v Counter* 2003 1 SACR 143 (SCA).
138 See works referred to in fn 32.
139 Such as, eg, the possibility of immune tolerance after participation in a preventive vaccine trial, which will become apparent only when the research participant is given a subsequent vaccine.

in line with policy considerations based upon aspects such as reasonableness, fairness and justice.[140]

Below, statutory requirements on informed consent to participation in research are discussed.

5 THE NATIONAL HEALTH ACT AND DRAFT HEALTH RESEARCH REGULATIONS

With the enactment of the National Health Act,[141] informed consent in research or experimentation became a statutory imperative. Section 71(1)[142] provides that[143]

> "research or experimentation on a living person may only be conducted in the prescribed manner; and with the *written* consent of the person after he or she has been informed of the object of the research or experimentation and *any possible* positive or negative consequences to his or her health".

This section represents a radical departure from the precedent created by *Castell v De Greef*[144] in so far as it alters the *extent* of the information that is required before consent may be considered informed in a research setting. The prospective research participant needs to be informed of "any possible" positive or negative consequences, not just those that are "material" or those that a reasonable research participant would want to know about. This expectation therefore places a heavier burden on the researcher than was insisted upon in *Castell v De Greef* – the participant should be informed of *all* positive and negative consequences of participation, no matter how remote.

Section 71(1) of the National Health Act has important implications for informed consent to preventive HIV-related clinical trial participation in South Africa. Because the research interventions are experimental, some of their potential side-effects remain unknown. Is a research sponsor expected to inform the prospective participant of side-effects that are yet not known? It is submitted that this is not what is intended by the legislature. Only side-effects of the microbicide, vaccine or other intervention which are known at the time that consent is given need to be included in the information provided to research participants. However, a prospective research participant will have to be informed of *all* known side-effects, and not only the *material* ones.

Section 71(1) brings about yet another change in the existing legal position: whereas there were previously no formalities for informed consent, according to

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140 Of course these terms are rather vague and empty – and will have to be given content through interpretation by the courts – the true essence of the flexible approach.

141 61 of 2003.

142 S 71(1) should be read together with ss 6(1) and 7(1) of the same Act which deal with the knowledge or information aspects of informed consent. According to s 6(1), informed consent encompasses knowledge about: (a) the user's health status except in circumstances where there is substantial evidence that the disclosure of the user's health status would be contrary to her best interests; (b) the range of diagnostic procedures and treatment options generally available; (c) the benefits, risks, costs and consequences generally associated with each option; and (d) the user's right to refuse health services and the implications, risks and obligations of such refusal.

143 My emphasis. The National Health Act has entered into force in 2006, but ch 9, which deals with issues related to health research, has not yet come into effect as of 30 September 2007.

144 *Supra*.

section 71(1) such consent must now be in writing. Although written consent to participation in research is already common practice in South Africa, the section ensures that such consent is obtained.

Various draft regulations have been published for comment in the *Government Gazette* in terms of section 90 of the National Health Act.[145] One, entitled "Regulations relating to research on human subjects" (Draft health research regulations),[146] published on 23 February 2007, is of particular relevance to the present discussion.

Chapter 1 of the Draft health research regulations delineates "principles on health research", in terms of which any health research "conducted in South Africa involving the participation of human subjects"[147] must ensure that research participants are "well informed to make informed choices".[148]

Apart from the circularity of "well informed to make informed choices", the description does not add to the current debate on informed consent as provided for in the National Health Act. The draft health research regulations give no indication of what is meant by "well informed" or the extent of the information which determines that a prospective participant is "well informed". In linking "well informed" with the requirement to make an "informed choice", clause 2 limits the scope of the information that is provided to research participants: only information that is relevant to the *choice* as to whether or not to participate is required. It could be argued that it is always the aim in the consent process to produce a well-informed participant; however, information of a different type, such as details with regard to the procedure of withdrawing from the research intervention, which do not have bearing on the decision to participate, nevertheless is essential. Clause 2 appears to be in contradiction with a later clause in the Draft health research regulations, that specifically gives an account of the nature of the information that the participant has a "right to be informed of".[149]

Clause 6 of the Draft health research regulations exclusively focuses on informed consent in health research participation. Participants "have the right to be informed of", amongst others, the purpose of the research;[150] treatments and the possibility of random assignment of each treatment, if the research involves treatment;[151] methods and procedures to be followed or used during the research;[152] alternatives apart from participating in the research;[153] potential or real harm and risks involved in participation;[154] expected benefits for the participant and other persons in the research;[155] extent to which confidentiality and privacy

145 Eg Regulations on the "Use of DNA, RNA, cultured cells, stem cells, blastomeres, polar bodies, embryos, embryonic tissue and small tissue biopsies for diagnostic testing, health research and therapeutics: Draft" (*GG* 29526) published 5 January 2007; "Artificial fertilisation and related matters: Draft" (*GG* 29527) published 30 January 2007.

146 R 135 (*GG* 29637) published 23 February 2007.

147 Cl 2 Draft health research regulations.

148 Cl 2(d).

149 See below.

150 Cl 6(a) Draft health research regulations.

151 Cl 6(b).

152 Cl 6(c).

153 Cl 6(d).

154 Cl 6(e).

155 Cl 6(f).

will be maintained;[156] incentives given for participation as well as differences in incentives, if any;[157] and, in cases of clinical trials, the availability of treatment beyond the duration of the trial.[158]

Clause 6 attempts to regulate the extent of the information provided to participants in health-related research so as to ensure informed consent. The clause is modelled on the requirements pertaining to information governing many ethics committees in the country and is not a departure from common practice.[159] However, it sets a minimum standard of information that needs to be provided to the research participant, even if "have a right to be informed of" at the beginning of the clause is phrased tentatively and would have more impact as an imperative.

6 CONCLUSION

This article explores the South African common, case and statute law on informed consent applicable to preventive HIV-related clinical research. As South African common law and case law on informed consent do not deal specifically with informed consent in a research setting, the article extrapolates general principles to the preventive HIV-related research setting.

A researcher or health care worker who fails to obtain trial participants' informed consent may be liable for civil or criminal assault; civil or criminal *iniuria*; or negligence. It is argued that where a researcher in preventive HIV-related clinical trails fails to obtain participants' informed consent, liability is based upon assault, and that the action exists regardless of whether harm is suffered by the participant. The notion that in such circumstances negligence may be a cause of action is rejected, as the action is based upon the physical infringement without the justification of the consent of the participant, and, therefore, the relevant element of the delict and/or crime is that of wrongfulness or unlawfulness and not that of fault. The decision in *Broude v McIntosh*,[160] questioning the notion that a lack of consent should constitute an assault, is criticised, and it is concluded that assault can be the only logical basis of liability.

The discussion of *NM v Smith (Freedom of Expression Institute as Amicus Curiae)*[161] affirms the notion that the unauthorised disclosure of participants' HIV status during a preventive HIV-related clinical trial or thereafter, constitutes a violation of participants' rights to privacy, dignity and psychological integrity.

A researcher conducting preventive HIV-related clinical research, who does not perform trial-related procedures with the necessary degree of care and skill, is liable for negligence. Furthermore, hitherto unknown risks may materialise during preventive HIV-related clinical research because of the precarious state of preventive HIV science. In such an instance, it is argued, the researcher cannot be held liable based upon negligence as the risks are unknown at the start of the

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156 Cl 6(g).
157 Cl 6(j).
158 Cl 6(k).
159 Eg the University of Pretoria Health Research Ethics Committee, and that of the University of the Witwatersrand, already require informed consent documents to include the information in cl 6.
160 Fn 57.
161 Fn 76.

trial, and the researcher could not have foreseen the possibility of her conduct injuring the research participant. Consequently, in preventive HIV-related clinical trials the researcher is obliged diligently to disclose known and foreseen risks – she cannot be considered negligent it she fails to disclose unforeseen or unknown risks.

Conduct during a research endeavour which involves not only an infringement of the research participant's physical security, but also her *dignitas*, amounts to the crime of *crimen iniuria.* The *boni mores* of society is likely to support the view that information about one's HIV status should remain private, and unauthorised disclosure of such facts could make a researcher guilty of *crimen iniuria*.

In isolated cases, participation in preventive HIV-related research may result in a participant's death. In such instances, if a researcher did not foresee the risk of death as a consequence of a research-related activity, in an instance in which the reasonable researcher would have foreseen such a risk, the researcher will have acted negligently and may be charged with culpable homicide. Conversely, if a risk is *not* foreseeable, negligence is not present and the researcher cannot be charged with culpable homicide. Similarly, if the reasonable researcher would have foreseen the risk, and have taken steps to prevent the risk materialising, yet the accused did not take such steps, she is guilty of acting negligently and may be charged with culpable homicide in the event of the research participant subsequently dying.

Due to the many unknown factors related to HIV science, it may be impossible to foresee the risk of death occurring as a result of the HIV-related research intervention. In this instance a researcher is not liable, if the reasonable researcher in her position could not have foreseen the risk of death materialising. However, participants in preventive HIV-related research are healthy volunteers, therefore, there is a compelling duty placed on the researcher to take extra care to avoid any risk of death (or HIV-infection, which may lead to death). HIV-related clinical trials, such as preventive HIV vaccine trials, which are carried out on healthy volunteers, should not be undertaken if a risk, however remote, of death exists. A researcher who foresees the possibility of the death of a research participant and who reconciles herself to that possibility may be charged with murder (as the form of fault here would be *dolus eventualis*).

The requirement of causation to found researcher liability may present problems as it may be peculiarly difficult to establish a sufficiently close link between an act and the damage suffered in preventive HIV-related clinical trials. HIV science is in its infancy and many side-effects of the candidate drugs, interventions and vaccines are unknown, or side-effects may become apparent only many years after the actual research intervention. It may therefore be difficult, if not impossible, to attribute a certain consequence to participation in a preventive HIV-related clinical trial. It is therefore recommended that, in the case of damage suffered because of participation in a preventive HIV-related clinical trial, the flexible approach to causation needs to be adapted in order to take into account the unique situation of trial participants. Such an approach is in line with policy considerations based upon aspects such as reasonableness, fairness and justice.

The provisions of the National Health Act on informed consent in research or experimentation are examined. Section 71 of the Act represents a radical departure from the precedent created by *Castell v De Greef* in so far as it dictates that

the research participant needs to be informed of all positive or negative consequences, not just those that may be considered as "material", thus placing a heavier burden on the researcher than is insisted upon in *Castell v De Greef*.

Finally, chapter 1 of the Draft health research regulations is criticised for not adding to the current debate on informed consent.

In this case the evidence points inescapably to the conclusion that Mr Geyser custom-built the building to operate as a brothel – albeit a brothel with a bar – and, but for minor intervals which are immaterial, operated it with Ms Basson until the NDPP's intervention. The drawing of that conclusion is in no way hampered by evidence that some visitors to "Ambassadors" came merely to socialise or that the business earned more from liquor sales than from prostitution or that the prostitutes were not employees but free agents. The fact remains that commercial sex was the drawcard and the focal activity.

In any event brothel-keeping in contravention of the Sexual Offences Act does not have to involve, in counsel's terms, personally selling commercial sex. If what Mr Geyser did was to let the upper rooms for the purposes of prostitution then, on the facts stated, clearly the building was a "house . . . used for purposes of prostitution or for persons to visit for the purpose of having [commercial sex]". In addition he is deemed to have kept a brothel because he knowingly received a share of the moneys of the business.

As to the question whether the property or part of it was an instrumentality of Mr Geyser's offence of brothel-keeping, the evidence shows that the ground floor housed the bar and provided convenient space and facilities for people to socialise. It was also the venue for performances of erotic dances and strip shows. It was the place where the prostitutes could be seen and chosen by their intending customers and where those visitors as yet uncertain might, induced by liquor or the staged entertainment, or both, incline to customer status. More specifically it was where the customer, having decided on the prostitute of his choice, booked and paid for her services and for the use of an upstairs room. Those arrangements were made at the reception area on the ground floor where the management of "Ambassadors" was conducted. The ground floor was therefore an essential component of the brothel.

Howie P in National Director of Public Prosecutions v Geyser *[2008] 2 All SA 616 (SCA) paras 14–16.*