**UNIVERSITY RESEARCH ETHICS CLEARANCES: SAFETY NETS, OR A FALSE SENSE OF LEGAL IMMUNITY?**

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**ABSTRACT**

Ethics reviews loom large in the world of a researcher at a university. Ethics committees review research project applications meticulously and critically. They attempt to ensure that in all projects that are approved, the human respondents and participants suffer no harm that could have been prevented. However, there seems to be little acknowledgement of the possible legal repercussions of unethical research conduct.

This article investigates the protection that ethics review protocols (particularly in the human sciences) offer researchers and their institutions against legal ramifications emanating from research projects where participants do suffer harm.

The main finding is that research ethics protocols may offer less protection against legal implications of ethical misconduct than would generally be thought to be the case.

I will make some observations on liability, vicarious liability, and the basic rights of subjects in research, after which I will offer a conclusion on the implications of this analysis for ethics reviews.

**KEYWORDS**

Ethics clearance, (vicarious) liability, harm, breach of contract, delict, informed consent

**INTRODUCTION**

The central questions asked in this article may be formulated as follows:

1. What are the legal implications in cases where employees or students at a university (or other higher education institution or research agency) have submitted institutional ethics applications, which have been approved by the relevant bodies and authorities, and harm still comes to the subject(s), or the respondent(s), or the participant(s), during the course of the research?
2. If harm because of a wrongful deed can be established, who can be blamed for the damage and be required to compensate the subject(s) for the harm, or the damage? In other words, who can be held liable for such damage, or such harm? What protection, if any, do institutional ethics clearance forms and processes afford the researcher(s) or institution(s) concerned against claims for damage or harm by the subject(s), or the participant(s), or the respondent(s)?

**2** **AN ACADEMIC INSTITUTION OR RESEARCH AGENCY, AND ITS**

**EMPLOYEES AND STUDENTS**

Although education on the effects of research may form part of a university’s brief, the limited scope of this article does not allow a thorough discussion of the functions and duties of an academic institution regarding, among other things, academic teaching and research and the legal implications thereof. Where necessary, I will highlight relevant aspects of such duties. I can also not examine the full scope of the employment relationship between an academic institution or research agency and its employees, and the various reciprocal rights and duties of the contracting parties in a research project. Should the issue of liability for harm suffered during research be raised, the employer-employee relationship, including acceptance of vicarious liability (as discussed in section 7 below) for the wrongs committed by an employee, may be introduced when considering possible compensation for harm.

Similarly, I cannot explore in depth the specific legal relationship that exists between enrolled master’s and doctoral students and the institution or agency concerned regarding the teaching of specific aspects of the undertaking of research, and the supervision of student research. Where necessary, relevant aspects will be highlighted for the purposes of this article.

**3 MORALITY, ACCOUNTABILITY, AND LEGAL LIABILITY IN RESEARCH**

**3.1 Morally acceptable conduct**

Research ethics concerns what is wrong and what is right in the conduct of research. Because scientific research is a form of human conduct, it follows that such conduct has to conform to generally accepted norms and values. As in any sphere of human life, certain kinds of conduct are morally acceptable, while others are not. Scientific (scholarly) communities have developed codes of conduct in order to regulate the behaviour of members who engage in research with human participants, and such codes of conduct are usually enforced through professional societies and associations, universities, and universities of technology, and, in some cases, funding agencies (Mouton 2001, 238-239).

**3.2 Accountability and legal liability**

The most important principle that guides the relationship between researchers and the rest of society is that of *accountability*. This principle implies that scientists/researchers are to some degree accountable to society for what they do. This accountability does not involve the specifics of research projects, but refers to a general obligation that researchers have to conduct their craft in a socially responsive and responsible manner (Mouton 2001, 241-242). Academic freedom demands that a profession (in this case the academic community) regulate its own practices and its own members internally (Bruhn et al. 2002, 462).

Morally unacceptable conduct, or transgression of a professional code of conduct, may constitute unethical research, but it does not necessarily cause loss or damage, or constitute a breach of contract which may lead to a claim for reparation based on breach of contract or delict. It is the role of the law of delict to indicate which interests are recognised by law, under which circumstances these interests are protected against infringement, and how such disturbance of the harmonious balance of interests may be restored.

The fundamental premise in law is that damage (harm) rests (lies) where it falls, that is, each person must themselves bear the damage that they suffer (*res perit domino*, or the thing is lost to the owner (http://legal-dictionary.thefreedictionary.com).

However, damage does not always rest (lie) where it falls. There are indeed certain legally recognised instances where the burden of damage is shifted from one individual to another, with the result that the latter incurs the obligation to bear the former’s damage, or to provide compensation for it. For example, where damage arises from delict, the wrongdoer is legally obliged to compensate the aggrieved party. In general terms, the law of delict thus determines the circumstances in which a person is obliged to bear the damage they have caused another, or, in other words, when they may incur civil liability for such damage. Because the wrongdoer has an obligation to compensate a person for damage or harm suffered, the person prejudiced has a corresponding right to claim compensation (Neethling, Potgieter and Visser 2001, 3).

It is important to note that a delict is not the only form of unwarranted or inadmissible conduct that the law takes cognisance of. For the purposes of this article, and with regard to potentially ethically unacceptable research behaviour, a distinction can be made between a delict and a breach of contract (Neethling, Potgieter and Visser 2001, 6).

Breach of contract constitutes another form of wrongful conduct in private law in South Africa. As with a delict, breach of contract is normally an act by one person (a contracting party), which, in a wrongful and culpable way, causes damage to another person (another contracting party). The primary remedy for breach of contract is directed at enforcement, fulfilment, or execution of the contract, while claiming for damages as a remedy plays only a secondary role in regard to breach of contract. However, it is also true that one and the same act may render the wrongdoer liable *ex contractu* (from breach of contract) as well as *ex delicto* (from commission of a delict) (Neethling, Pogieter and Visser re2001, 6-7).

**4 RESEARCH ETHICS**

Nancy Walton (n.d.) provides a succinct overview of research ethics reviews. She enumerates the following objectives of research ethics reviews, which have a bearing on this article (Walton n.d.):

1. The first and broadest objective [of ethics reviews] is to protect human participants.
2. The second objective is to ensure that research is conducted in a way that serves the interests of individuals, groups and/or society as a whole.
3. The third and final objective is to examine specific research activities and projects for their ethical soundness, looking at issues such as the management of risk, protection of confidentiality and the process of informed consent.

It is noticeable that she does not regard making researchers aware of the possible legal consequences of unethical conduct as being an objective of ethics reviews.

Walton (n.d.) points out that peculiar kinds of ethical issues arise in the humanities and social sciences (and, more specifically, educational) research, which is the lens through which this article is approached. She states that “[n]ew and emerging methods of conducting research, such as auto-ethnography and participatory action research raise important but markedly different ethical issues and obligations for researchers”. The issues are different from research within the discipline of medicine, for example, or research within the discipline of physics.

Although the statement that research methods such as auto-ethnography and participatory action research are new and emerging is debatable, the statement that “[r]esearch involving vulnerable persons, which may include children, persons with developmental or cognitive disabilities, persons who are institutionalized, the homeless or those without legal status, also raises unique issues in any research context” (Walton n.d.) is fairly indisputable. One can add that the law would require special care on the part of researchers not to harm the psychophysical integrity of the subjects (the participants, or the respondents). However, like all other persons, researchers are susceptible to the notion that such vulnerable participants are beings with less dignity than other “normal” human beings, and that vulnerable participants are therefore not deserving of a particularly high level of protection, because the consequences of untoward research behaviour towards them are deemed to be less serious than the consequences of untoward research behaviour towards other subjects, or participants, or respondents.

**5 CHALLENGES ASSOCIATED WITH ETHICS REVIEWS**

Researchers have argued that reviews of research protocols at academic institutions can complicate research participation considerably (Human-Vogel and Coetzee 2011, 166). Dingle and Stuber (2008, 188), cited in Human-Vogel and Coetzee (2011, 166), comment that “taking the most ethical and professional path can be inconvenient, financially disadvantageous, time-consuming, frustrating, or complicated”. Fitzgerald and Phillips (2006, 47), in Human-Vogel and Coetzee (2011, 166), refer to the complications caused by “the cumbersome and costly process of ethics review”.

Despite such criticism, Human-Vogel and Coetzee (2011, 167) argue that ethics reviews are “a necessary social practice that serves to encourage researchers and institutions to be accountable to the society they serve”. Human-Vogel and Coetzee (2011, 167) also argue that:

[i]n many respects, higher education institutions act as factories of civilised society, ensuring scientific knowledge production and societal progress, the development of society’s human resources as well as stimulation and growth of the economy. Universities rely on academic scholars to pursue these goals by offering them the opportunity and the resources to conduct research to a large extent unhampered, to socialise and develop the next generation of scholars and researchers, and to push the boundaries of science.

Human-Vogel and Coetzee (2011, 167) agree with Bruhn et al. (2002, 462) that “[a]cademic freedom demands that the academic community regulate its own practices and its own members internally”. Furthermore, Human-Vogel and Coetzee (2011, 167) point out that both Bruhn et al. (2002, 461) and Wolpe (2006, 1023) highlight the responsibility of academic researchers and their universities towards society, in general, and towards the communities and the students that they serve, in particular. Nowhere do the above authors suggest that unethical conduct is sanctioned.

However, this article proposes that even if research ethics reviews neglect or do not consider the possible legal implications and consequences of unethical research practices, the psychophysical integrity of all people (including research participants) is protected by law, which may even compel a wrongdoer to make good the harm they may have caused in the course of a research project.

**6 THE INTERACTION BETWEEN THE RESEARCHER AND THE SUBJECT (THE PARTICIPANT, OR THE RESPONDENT)**

**6.1 Informed consent as a contract or requirement**

Citing Jefford and Moore (2008, 485), Wolpe (2006, 1024), and Haggerty (2004, 405), Human-Vogel and Coetzee (2011, 176) conclude that “[t]he necessity for informed consent in research is widely acknowledged […] although researchers may disagree as to the best way of obtaining informed consent”.

Human-Vogel and Coetzee (2011, 176) state that from a modernist perspective, “informed consent is viewed as a contract or a requirement that is dispensed with at the start of the study”. Although the word “contract” suggests a definite and considered commitment to an activity, the phrase “is dispensed with” seems to suggest that not much time and effort is spent on obtaining informed consent. They also mention that in general, postmodernist researchers “experience problems with informed consent because it can be viewed as a quality of the emerging relationship between the researcher and the participant”. While I argue that the possible legal liability that a researcher may face should be one of the considerations when ethics reviews are undertaken, Human-Vogel and Coetzee (2011, 176-177) make the valid point that the information that researchers put before ethics committees is the:

[o]nly information reviewers have at their disposal to judge the extent to which researchers are ethically aware, and whether they have applied sound reasoning in terms of the decisions they will make in respect of their potential participants, as well as assessing potential risk to participants”. Submission of an application to a committee is no guarantee of how the researcher will ultimately conduct the actual research, and it makes it difficult for reviewers to be able to detect and comment on possible legal consequences.

A further problem pointed out by Human-Vogel and Coetzee (2011, 177), citing Jefford and Moore (2008, 486), is that “[t]he signing of informed consent is recognised as a symbolic act that does not necessarily indicate understanding on the part of the participant”. They argue that “[e]thics committees need to know how the applicant proposes to obtain informed consent” (Human-Vogel and Coetzee 2011, 177). Jefford and Moore (2008, 486), cited in Human-Vogel and Coetzee (2011, 177), mention that participants place a great deal of trust in the researcher, and that they are prepared to consent to more risky research even if less risky options are also presented to them. This could be an indication of the trust of participants that the researcher would not unnecessarily put them in harm’s way.

Providing information about risk and benefit is a key aspect of informed consent (Jefford and Moore 2008, 486, cited in Human-Vogel and Coetzee 2011, 178). In the majority of the protocols that they analysed, reviewers regarded it as a problem that researchers did not make formal statements to the participant about the possible benefits of participation in the research, or, otherwise, the nature of the risk, even if negligible, associated with participation (Jefford and Moore 2008, 487).

The limited protection that ethics reviews afford participants is spelt out by Human-Vogel and Coetzee (2011, 178-179) as follows:

It can be argued that researchers can still behave unethically despite an acceptable letter of informed consent and ethics review. Ethics committees cannot be expected to regulate the personal integrity of applicants. However, the letter of informed consent remains an important document indicating the extent to which applicants considered the ethical dimensions of their proposed study.

The question about what institutions under whose auspices researchers operate could do to better protect participants and researchers alike inevitably arises from the above matter-of-fact comment that ethics committees cannot be expected to regulate the personal integrity of applicants. The fact that committees cannot actually regulate all research behaviour does not obviate the possibility of harm for the participants, and the possibility of liability being incurred by the researcher. It also does not absolve the ethical clearance-awarding agency of all blame in the case of unethical conduct.

**6.2 Informed consent and information regarding risk and benefit**

Jefford and Moore (2008, 489) note that disclosure of facts about a planned research project to a potential participant requires not only a statement of the facts, but also that the researcher promotes the participant’s understanding of the research project, as well as the voluntary nature of their participation, among other things, by using easily understandable short words and short sentences. Limits or threats to privacy and confidentiality as a result of the particular type of sampling strategy employed represent risks, to which potential participants should be alerted. Where applicable, persons invited to participate in a research project should also be made aware if there is an absence of direct benefit to them from participation in the project (Human-Vogel and Coetzee 2011, 178). It is conceivable that failure to disclose details about possible risks associated with participation in a research project, as well as an absence of benefits, could lead to legal repercussions for the researcher(s) and the authority issuing the ethics clearance.

**7 LIABILITY**

**7.1 The general principles of vicarious liability**

In the recent Constitutional Court case of *F v Minister of Safety and Security and Another*, the Court dealt with the general principles of vicarious liability and how they had evolved until the so-called case of K was decided.

With regard to vicarious liability in general, the Court stated that vicarious liability means that a person may be held liable for the wrongful act or omission of another even if the former did not, strictly speaking, engage in any wrongful conduct (see paragraph 40). Such liability would arise where there is a particular relationship between those persons, such as an employment relationship.

**7.2 The test(s) for vicarious liability**

As a general rule, an employer is vicariously liable for the wrongful acts or omissions of an employee committed within the course and scope of their employment, or while the employee was engaged in any activity reasonably incidental to the course and scope of their employment. Furthermore, the Court stated that two tests apply when determining vicarious liability (see paragraph 41). One test applies when an employee commits the delict while going about the employer’s business. This is generally regarded as the *standard test*. The other test finds application where wrongdoing takes place outside the course and scope of the employee’s employment. These are known as *deviation cases*. Sometimes the latter is referred to as “being on a frolic of your own”.

**7.3 Actionable wrongs or delicts**

It is commonly recognised that an actionable wrong or delict (a wrong or delict in regard to which legal action could be taken) has five elements, or requirements, namely

1. the commission or omission of an act (*actus reus*)
2. which is unlawful or wrongful (wrongfulness)
3. and is committed negligently or with a particular intent (*culpa*, or fault),
4. and which results in or causes harm (causation) and
5. the suffering of injury, loss, or damage (harm).

These are separate and distinct components of the same delict, where each component has its own requirements and test.

**7.4 Liability for loss or damage**

More recently, in *Minister of Safety and Security v Van Duivenboden*, Nugent JA formulated the principle as follows at 441E-442B (see paragraph 12):

Negligence, as it is understood in our law, is not inherently unlawful – it is unlawful, and thus actionable, only if it occurs in circumstances that the law recognises as making it unlawful. Where the negligence manifests itself in a positive act that causes physical harm it is presumed to be unlawful, but that is not so in the case of a negligent omission. A negligent omission is unlawful only if it occurs in circumstances that the law regards as sufficient to give rise to a legal duty to avoid negligently causing harm. It is important to keep that concept quite separate from the concept of fault. Where the law recognises the existence of a legal duty it does not follow that an omission will necessarily attract liability – it will attract liability only if the omission was also culpable as determined by the application of the separate test that has consistently been applied by this court in *Kruger v Coetzee*, namely whether a reasonable person in the position of the defendant would not only have foreseen the harm but would also have acted to avert it.

The *locus classicus* in respect of negligence is the case of *Kruger v Coetzee* at 430E-F, where Holmes JA said the following:

For the purposes of liability, *culpa* (fault) arises if

1. a *diligens paterfamilias* (good, caring father of a family) in the position of the

defendant

1. would foresee the reasonable possibility of his conduct injuring another in his

person or property and causing him patrimonial loss,

(ii) and would take reasonable steps to guard against such occurrence,

(b) and the defendant failed to take such steps.

From the authorities cited above, it would appear that a negligent omission is unlawful only if it occurs in circumstances that the law regards as sufficient to give rise to a legal duty to avoid negligently causing harm. Where the law recognises the existence of a legal duty, it does not follow that an omission will necessarily attract liability. It will attract liability only if the omission was also culpable.

It appears highly unlikely that a social sciences researcher would wilfully and culpably commit a wrongful act that would result in (or cause) harm to their participants. It is more likely that a social sciences researcher could cause harm negligently, through commission of a wrongful act. A culpable act could foreseeably negligently cause harm to a participant if one or more of the basic rights mentioned in section 8 below is violated, where the researcher would then be held liable for such damage. The likelihood that a researcher could cause their subjects harm is greater if one considers that harm could be physical, psychological, or emotional in nature, and it could arise in regard to a subject’s rights to, among other things, privacy, anonymity, and full disclosure.

**8 BASIC RIGHTS OF SUBJECTS IN RESEARCH, AND HOW THESE RIGHTS AFFECT THE CONDUCT OF RESEARCH**

It is important to remember that Section 16(1)(d) of the Bill of Rights (Chapter 2) in the Constitution of the Republic of South Africa of 1996 provides for the right of everyone to *academic freedom and freedom of scientific research* (Emphasis added). Researchers’ rights are therefore embedded in the above-mentioned subsection of the Constitution of 1996. However, the Bill of Rights also contains a general limitation clause, which provides that the rights in the Bill of Rights may be limited only in terms of law of general application, to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality, and freedom, taking into account a number of listed and relevant factors. The right to academic freedom and freedom of research can thus also be limited. A researcher that oversteps the boundaries of academic freedom and freedom of research could thus expose themselves to legal action.

Within the context of research ethics, Mouton (2001, 243-246) lists some of the most basic rights of subjects in research, and indicates how these rights affect the conduct of research. These rights are

1. the right to privacy (including the right to refuse to participate in research),
2. the right to anonymity and confidentiality,
3. the right to full disclosure about the research (informed consent), and
4. the right not to be harmed in any way (physically, psychologically, or

emotionally).

In addition, “vulnerable” groups (such as children, the aged, and the mentally disabled) may have additional specific rights that should be taken note of. These would all be subjective rights of the subjects, as well as fundamental rights contained in the Bill of Rights, and they fall within the contractual obligations of the person undertaking the research.

**8.1 The right to privacy (including the right to refuse to participate in research)**

Human-Vogel and Coetzee (2011, 178) analysed ethics reviews and found that the majority of researchers stated in their applications that the research did not provide any direct benefit to the participants at all, but that they neglected to state this in the letter of informed consent, presumably because it could have adversely affected participation. It can be argued that researchers can still behave unethically even if there is an acceptable letter of informed consent and an ethics review. In legal terms, negligence by a researcher to disclose absence of benefits associated with participation in a research project could have serious implications for the researcher, as it could negatively impact on the relationship of trust that should exist between the researcher and the subject.

Mouton (2001, 243) points out that in an increasingly public and transparent world, researchers have to be extremely watchful in respecting the right of subjects to privacy. This right to privacy in the field of research is expressed more concretely in the following “rules”: the right to refuse to be interviewed, the right to answer or not to answer telephonic or email questionnaires, the right to refuse to answer any question, and the right not to be interviewed at meal times or at night, or for long periods of time. A delictual violation of these rules could lead to legal action against a researcher.

**8.2 The right to anonymity and confidentiality**

Informants have the right to remain anonymous. This right should be respected both where it is promised explicitly and where no clear understanding to the contrary has been reached (Mouton 2001, 243). While anonymity refers to the principle that the identity of the individual is kept secret, the principle of confidentiality refers to the information gathered from subjects. Such information should be protected even if it enjoys no legal protection or privilege (Mouton 2001, 244).

**8.3 The right to full disclosure about the research (informed consent)**

In section 6 above, I discussed the necessity of informed consent, which is widely acknowledged in research. The fact that researchers may disagree as to the best way of obtaining informed consent was discussed. It was also indicated that from a modernist perspective, informed consent is viewed as a contract or a requirement that is dispensed with at the start of a study. In general, postmodernist researchers experience problems with informed consent, because it can be viewed as a quality of the emerging relationship between the researcher and the participant.

I would argue that as far as informed consent is a contractual requirement, it remains part of the contract (the entire research process) from start to finish, and can be revoked at any time (Mouton 2001, 244).

If the researcher fails to abide by the agreement of full disclosure required for informed consent, they will be in breach of contract, and may face legal action. In section 3 above, attention was drawn to the fact that breach of contract constitutes another form of wrongful conduct in private law in South Africa. As with a delict, breach of contract is normally an act by one person (a contracting party), which, in a wrongful and culpable way, causes damage to another person (another contracting party). The primary remedy for breach of contract is directed at enforcement, fulfilment, or execution of the contract; claiming for damages as a remedy plays only a secondary role.

**8.4 The right not to be harmed in any way (physically, psychologically, or emotionally)**

The process of conducting research must not expose the subjects to substantial risk of personal harm. Informed consent must be obtained when the risks of the research are greater than the risks of everyday life. Even where modest risk or harm is anticipated, informed consent must be obtained. Experimentation of any kind is usually associated with a greater risk of potential harm to subjects. Potentially harmful experimentation would include

1. physiological or psychological experiments,
2. procedures that are intrusive, and
3. steps involving responses to an abnormally stressful stimulus or activity

(stressful beyond the normal experience of the subject, including personal embarrassment) (Mouton 2001, 245).

For the purposes of informed consent, where experiments involve a risk of potential harm to the subject, this must be disclosed to the subject, and if the subject does not have legal status (*locus standi in iudicio*) to grant permission for the experiment to be conducted (as in cases where the subject is a child), consent should be obtained from the person who is legally responsible for that subject (Mouton 2001, 245).

Should any harm occur resulting in loss or damage, as pointed out earlier (with reference to the case of *Kruger v Coetzee*), for *the purposes of liability*, *culpa* (fault) 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,

(ii) and would take *reasonable steps* to guard against such occurrence,

(b) and *the defendant failed to take such steps*.

In this regard, special mention should be made of the rights of vulnerable groups of persons to protection. Examples of such groups are children, mentally disabled persons, the aged, prisoners, psychiatric patients, and so on. This could also apply to illiterate persons, persons who have low social status, or persons who are unfamiliar with social research (Mouton 2001, 245). In terms of current children’s legislation, certain conduct towards children during research may even constitute a criminal offence.

**9 CONCLUSION**

It appears that ethics reviews do not offer as much protection against legal action in terms of the law of delict to researchers and their employers or sponsors or funders as they would like to believe. It is probably not good enough to say that an ethics clearance certificate cannot prevent unethical conduct resulting in harm to the subjects in research.

An employer such as a university can be held vicariously liable for unethical research conducted by its employees. Although it is not possible to estimate what the magnitude of legal action resulting from unethical research conduct might be, it would seem that ethics reviews need to be revisited, and they need to address issues of possible liability for researchers. More attention needs to be given to training on how to conduct ethically irreproachable research that will only in the most exceptional and unforeseeable of cases attract legal liability.

Consideration needs to be given to ways and means of improving preparation of researchers, so that they can develop sound ethics review applications. More important though is support for and supervision of researchers “in the field”, for that is where risky unethical conduct takes place.

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