

NELSON MANDELA UNIVERSITY

INSTITUTIONAL REGULATORY CODE (IRC) (Policies, Procedures, Rules etc.)

To be completed by initiator of policy/policy owner:

1. POLICY TITLE:	POLICY ON RESEARCH ETHICS	
2. FIELD OF APPLICATION: (All persons to whom policy applies)	All staff and students engaged in research activities, research associates, external researchers	
3. COMPLIANCE OFFICER(S): (Persons responsible for ensuring policy implementation)	Research project leaders, study leaders, promoters, HODs, Executive Deans, Directors of Research and DVC:RII	
4. STAKEHOLDER CONSULTATION (State the stakeholder group/s consulted during policy formulation/revision)	Senate, RTI Committees, Research Ethics committees	
5. DESIGNATION OF POLICY OWNERS: (Persons responsible for maintaining policy)	DVC: RII/Director: Research Capacity development	

POLICY HISTORY *(To be completed by policy owner)*

Decision Date (Compulsory)	Status (New/Revised/ No Changes)	Implementation Date (Compulsory if "new" or "revised")	Approving Authority (If "new" or "revised". N/A if no changes)	Resolution Number e.g. 07/11- 10.2 (Minute number. N/A if no changes)	Policy Document Number (e.g. D/.../07 N/A if no changes)	Pending date for next revision (Compulsory)
1 Dec 2010	NEW	1 Jan 2011	Council	C10.57.3.2.1. 1	D/739/10(1 2-11- 2010_12h2 9)	1 January 2014

For office use only

SUBJECT (Broad policy field):	Research, Innovation and Engagement
SUBJECT NUMBER:	400
CATEGORY (Policy sub-field):	Research Ethics
CATEGORY NUMBER:	404
IRC NUMBER:	404.02

NELSON MANDELA UNIVERSITY POLICY ON RESEARCH ETHICS

1. PREAMBLE

The Nelson Mandela Metropolitan University acknowledges the need for excellence in research and scholarly endeavour and commits itself to conducting such activities with the utmost integrity. The *Policy on Research Ethics* recognises the inherent academic and intellectual freedom associated with institutions of higher learning which enables the University to fulfill its core mission of generating cutting-edge knowledge. The policy aims to promote awareness of fundamental ethical standards, principles and practices in conducting research with both human and animal subjects.

This policy is to be read in conjunction with the *Code of Conduct for Researchers at Nelson Mandela University* (IRC 404.01).

2. DEFINITIONS¹

- 2.1 'Academic freedom' refers to the right, without constriction by doctrine, to freedom of teaching and discussion, freedom in carrying out research and disseminating and publishing the results thereof, researchers' freedom to express freely their opinion about the institution or system in which they work, freedom from institutional censorship and freedom to participate in professional or representative academic bodies.
- 2.2 'Animal subject' refers to "live sentient non-human vertebrate, including eggs foetuses and embryos that is: fish, amphibians, reptiles, birds and mammals, and encompassing domestic animals, purpose-bred animals, farm animals, wildlife and higher invertebrates such the advanced members from the *Cephalopoda* and *Decapoda*²".
- 2.3 'Ethics' are defined as the rules of conduct recognised in respect to a particular class of human actions or a particular group, and are concerned with how morally accepted outcomes can be achieved in specific situations. Thus, in the context of this policy ethics focuses on the principled actions of the community of researchers at the University who conduct research.
- 2.4 An 'Ethics committee' in the context of this policy refers to an independent review board constituted of a reasonable number of members, who collectively have the qualifications and experience to review and evaluate the science and ethics of proposed research studies.

¹ Unless otherwise stated definitions taken or adapted from UNESCO, *Recommendation concerning the Status of Higher-Education Teaching Personnel*, Paris, 1997, Chapter VI

² South African National Standards Guidelines 2008

- 2.5 'External research' includes any research undertaken among staff and/or students of the Nelson Mandela University where the principal investigator is not an Nelson Mandela University employee or student.
- 2.6 A 'human subject' generally connotes an individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information.
- 2.7 'Institutional research' in the context of this policy refers to research among staff and/or students of the University and includes "a cluster of activities that supports decision-making, policy analysis, quality assurance, effective management, projections and planning in higher education"³.
- 2.8 'Primary responsible person/PRP' refers to the permanently appointed staff member who assumes responsibility for a research protocol or proposed study.
- 2.9 'Principal investigator/PI' refers to the researcher (that is the staff member, research associate, student or external researcher) who is responsible for implementing the research.
- 2.10 'Researchers' includes all persons within the University (staff, undergraduate and postgraduate students) as well as collaborators/partners, research associates, and external researchers who undertake research at and/or through the University.
- 2.11 'Research for degree purposes' connotes all research undertaken by students and staff of the University towards attaining a qualification or degree.
- 2.12 'Research for non-degree purposes' pertains to research undertaken by individuals or collaboratively by groups of researchers and includes contract research, institutional research, and research by external bodies or individuals.
- 2.13 'Staff' refers to all categories of employees of the Nelson Mandela University whether permanently appointed or appointed on contract.
- 2.14 'Stakeholders' includes all parties who have a material interest in the implementation and outcome of research and includes the Nelson Mandela University community, the communities in which we undertake research, the specific participants in a study, sponsors and the broader research community.
- 2.15 'Student' includes all *bona fide* undergraduate students and postgraduate students registered for Honours, Postgraduate Diplomas, Masters by coursework and treatise, Masters by research and Doctoral degrees.
- 2.16 'Vulnerable Persons or Groups' refers to individuals or groups who have "... substantial incapacity to protect their own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical or psychological care or other necessities, or being a junior or subordinate

³ Southern African Association for Institutional Research (SAAIR) website

member of a hierarchical group”⁴. Without restricting the generality of the meaning of ‘vulnerable’ vulnerable groups are defined by the National Health Research Ethics Committee⁵ and CIOMS Guidelines as including, amongst others:

- persons under the age of 18 years (children and adolescents)
- institutionalised persons
- the elderly
- persons with mental or physical incapacity
- persons from a stigmatised or minority group
- groups or communities who are economically or socially disadvantaged
- persons in a dependent relationship (for example, employees, students, patients)
- persons traumatised due to exposure to physical, psychological and/or emotional abuse or trauma).

3. PURPOSE OF THE POLICY

The policy seeks to sustain an environment that supports vibrant research, scholarship and innovation by creating an enabling framework that guides the conduct of staff, students and relevant stakeholders in undertaking research activities. It recognises that sound ethical practice goes hand in hand with scientifically valid research and effective teaching. The purpose of the policy is to:

- inspire researchers at University to maintain shared ethical standards in all research activities at the University
- engender respect for the dignity and rights of all
- articulate ethical norms that transcend disciplinary boundaries
- legitimise discussion of ethical issues
- describe the structures and mandates for the ethical review of research conducted at Nelson Mandela University

4. VALUES AND PRINCIPLES

It is acknowledged that ethics of research are developed and refined within an ever-evolving societal context, elements of which include the need for research and the research community, moral imperatives and ethical principles, and the law. The *Policy on Research*

⁴ Council for International Organizations of Medical Sciences (CIOMS) Guidelines

⁵ National Health Research Ethics Council website <http://www.doh.gov.za/nhrec/norms/ethics.pdf>

Ethics is thus embedded in the values enshrined in the Constitution of the Republic of South Africa (and relevant legislative instruments) and upholds the basic principles and values that pertain to all forms of research.

4.1 **Constitutional Values**

The Bill of Rights (Chapter 2 of the Constitution) enshrines the rights of all people and affirms the democratic values of human dignity, equality and freedom. Section 12 (2)(c) specifies the right of the individual “not to be subjected to medical or scientific experiments without their informed consent”. Section 16 (1)(d) states that individuals have the right to freedom of expression which includes “academic freedom and freedom of scientific research”. Section 24 refers to the rights of individuals “to an environment that is not harmful to their health or well-being; and to have the environment protected for the benefit of present and future generations ...”.

4.2 **Principles and Values of Research**

The fundamental ethical issues and principles in research are common across the social sciences and humanities, the natural sciences and engineering, and the health sciences. The approach taken in this policy framework is to guide and evoke thoughtful actions and ethical decision making based on principles which express acknowledged research values and the integrity of the University research community.

4.2.1 Respect: This principle should permeate the conduct of all researchers and refers to operating in accordance with ethically accepted standards in relation to themselves, their colleagues, the wider scientific and academic community, their human and animal subjects as well as the environment and society. This includes respect for diversity and the specific responsibilities of researchers in their interaction with research participants of different languages, cultures and capacities/abilities, different species, and the environment.

Included in the principle of respect is respect for human dignity which entails ethical obligations toward vulnerable persons or groups (as defined in 2.16). Vulnerable persons are entitled, on grounds of human dignity, caring, solidarity and fairness, to special protection against abuse, exploitation or discrimination. Ethical obligations to vulnerable individuals and groups translate into special procedures to protect their interests.

4.2.2 Free and Informed Consent: Individuals are generally presumed to have the capacity and right to make free and informed decisions. Respect for persons thus means respecting the exercise of individual consent and translates into the dialogue, process, rights, duties and requirements for free and informed consent by the human subject.

By the same token, animal subjects must be treated humanely because they cannot give consent.

4.2.3 Respect for Privacy and Confidentiality: Standards of privacy and confidentiality protect the access, control and dissemination of personal information and help to protect

mental or psychological integrity. They are thus consonant with values underlying respect for privacy, confidentiality and anonymity.

4.2.4 Beneficence and non-malificence: Researchers have an obligation to do no harm (non-malificence) as well as to ensure that their research endeavours aim at overall good (beneficence). In the planning and execution of a study, the researcher should always take into consideration the ethical acceptability and the foreseeable consequences of the research as this indirectly or directly affects human beings and animals. This implies a cost-benefit analysis to ensure a balance between risks and benefits. Such an analysis needs to include human/animal discomfort/risks, and impact on the environment.

4.2.5 Respect for Justice and Inclusiveness: Justice connotes fairness and equity in terms of fair methods, standards and procedures. It is also concerned with the distribution of benefits and burdens/harms of research. On the one hand, this means that no segment of society should be unfairly burdened with the harms of research and on the other hand, imposes duties to neither neglect nor discriminate against individuals and groups who may benefit from advances in research.

4.2.6 Scientific Integrity: Research undertaken should be sound in terms of methodology and scientific validity and be conducted by researchers who are technically competent. Thus, recommendations may be made by the Research Ethics Committee to the PRP with a view to strengthening the quality of a proposed study.

4.2.7 Respect for the Natural Environment: It is acknowledged that research impacts on the natural environment and thus, researchers should evaluate the potential impact of their research on the natural environment, and declare the possible impact, however unlikely. Where remedies are required, such plans should form part of the research design and execution.

5. RESPONSIBILITY FOR ETHICS

- 5.1 It is the responsibility of the University to ensure that there is an accredited structure for the ethical review of research in accordance with relevant legislation.
- 5.2 The University is further responsible for ensuring appropriate and relevant training in respect of the members who serve on its Ethics Committees and within the broader community of researchers (staff and students).

6. STRUCTURES FOR THE ETHICAL REVIEW OF RESEARCH

In order to fulfill its responsibilities regarding the ethical conduct and ethical review of research the formal review of research ethics occurs at two levels at the Nelson Mandela University:

- 6.1 Firstly at the faculty level within the Faculty Research, Technology & Innovation Committees (FRTI) and

- 6.2 Secondly, on the institutional level. At the institutional level ethics review is undertaken by two separate committees namely, the Research Ethics Committee - Human (REC-H) and the Research Ethics Committee – Animal (REC-A). Both are sub-committees of the University's Research, Technology & Innovation Committee (RTI Committee).

7. RESPONSIBILITIES OF ETHICS REVIEW STRUCTURES

The responsibilities of the various committees are as follows:

- 7.1 *Faculty Research, Technology & Innovation Committees (FRTIs)* are responsible for reviewing the proposals/protocols of all research projects whether for academic (degree purposes) or non-degree purposes.
- 7.2 *The Research Ethics Committee (Human) [REC-H]* assumes responsibility for the review of the ethical considerations related to proposals/protocols for research for degree and non-degree purposes involving human subjects which investigate contentious issues or target vulnerable groups as defined in the Committee's Information Document: Process and Codes.⁶ This committee also assumes responsibility for the ethics clearance for institutional and external research involving the staff and students of the University.
- 7.3 *The Research Ethics Committee (Animal) [REC-A]*: is charged with: monitoring the treatment of animals used in research and teaching at Nelson Mandela University, reviewing all protocols involving animal use in order to ensure that they are in accordance with acceptable ethical and scientific standards, and ensuring that all aspects of the care and use of animals in research and teaching comply with national and international standards and norms.

8. MANDATES OF ETHICS REVIEW STRUCTURES

The mandates of the committees listed above are as follows:

- 8.1 To collaboratively develop a policy that promotes the integrity of researchers and complies with relevant national and international regulations and norms for the ethical conduct of research, scholarship and innovation;
- 8.2 To develop appropriate terms of reference that will guide the structuring and functioning of committees as well as the procedures to facilitate the implementation of the *Policy on Research Ethics* at the Nelson Mandela University.

⁶ <http://my.nmmu.ac.za/default.asp?id=539&bhcp=1>

9. **RESPONSIBILITY FOR OBTAINING ETHICS CLEARANCE**

- 9.1 Ethics clearance is required for all research through the appropriate structures outlined above *prior* to the commencement of data collection and *cannot be issued retrospectively*.
- 9.2 All research proposals/protocols and treatises/dissertations/theses should include a section on ethical considerations, where appropriate.
- 9.3 In line with the mandates and the terms of reference of the FRTIs and the RECs, researchers are required to adhere to the procedures set out by these structures and provide all relevant documentation to inform the review of an application for ethics clearance.
- 9.4 The responsibility for the submission of an application rests jointly with the primary responsible person/PRP and the principal investigator/PI.
- 9.4.1 The supervisor/promoter, as PRP, bears responsibility for making the student (as PI) aware of the policy and procedures for obtaining the necessary ethics clearance for research to be undertaken, and for ensuring that the student is deemed competent to undertake the proposed research.
- 9.4.2 The PI is responsible for completing and submitting the relevant documentation as per the rules and procedures of the University with the approval of the research supervisor/PRP. The PI is furthermore responsible for his/her conduct in relation to the final implementation of the research process for which approval has been granted.
- 9.4.3 In the event of any deviation from the approved protocol, it is the joint responsibility of the PRP and PI to bring such amendments to the attention of the relevant REC or FRTI Committee. Failure to do so would constitute misconduct.

ACKNOWLEDGEMENTS

The *Belmont Report* can be found at <http://ohsr.od.nih.gov/guidelines/belmont.html>

The Constitution of the Republic of South Africa. 1996. Act 26 of 1996. Pretoria: Government Printers.

Council for International Organizations of Medical Sciences (CIOMS). www.cioms.ch

The *Declaration of Helsinki* can be found at www.wma.net/e/policy/b3.html

Ethics in Health Research: Principles, Structures and Processes. (Department of Health) Published April 2005 (you can search for this document on the Department of Health web site at <http://www.doh.gov.za/search/index.html>)

Medical Research Council. *Guidelines on Ethics for Medical Research*. Books 1-5. MRC SA (refer <http://www.sahealthinfo.org/ethics/ethics.htm>)

Guide for the Care and Use of Laboratory Animals, Institute for Laboratory Animal Resources, National Research Council, National Academy Press

International Committee for Medical Journal Editors: Guide to Authorship. <http://www.icmje.org/index.html#author>

South African Bureau of Standards. South African National Standard: The Care and Use of Animals for Scientific Purposes. SANS 10386: 2008.

Southern African Association for Institutional Research (SAAIR). <http://www.ukzn.ac.za/dmi/saair/>

Stellenbosch University, *Framework Policy for the Assurance and Promotion of Ethically Accountable Research*, March 2009.

B. Glass, The Ethical Basis of Science, *Science*, Vol. 150, pp. 1257-1258, December 1965.

UNESCO, *Recommendation on the Status of Higher-Education Teaching Personnel*, Paris, 1997.

University of the Western Cape, *Research Policy*, November 2009

Vancouver Protocol. Accessed 22 May 2010.

http://www.authorder.com/index.php?option=com_content&view=article&id=28&Itemid=47