Rules for the management of research ethics at the North-West University

1 Introduction

1.1 Motivation for a management process for research ethics

Research ethics deals with the way in which research is planned, conducted and executed, in order to ensure that the entire process conforms to rules, standards or norms for conduct as agreed upon by the research community at large. Naturally, this is dependent on the field of study and the research methodologies that are deemed acceptable within that field.

There are many aspects and challenges involved in different research fields, and hence many reasons to consider the ethical aspects of such research. The following is a small selection of examples to illustrate the point:

- Research involving human participants or animal subjects: The rights and welfare of such participants/subjects must be safeguarded, the relationship between researcher and participants must be considered;
- Data-intensive research: Aspects involving the collection, use and interpretation of data must be acceptable;
- Research plans: Aspects such as formulating, review, reporting, communication of findings, affordability to execute and complete research
- Research teams: Competence and authorisation of team members to perform tasks and ability take necessary responsibility;
- Relationships within research teams: Who will publish or co-publish, first-author agreements, travel and conference attendance, issues related to affiliation, conflict resolution.
- Relationship with the community: Responsibility to perform and communicate research such that it remains responsive to community needs and aspirations, keeping the community engaged, aware and informed.

From a normative perspective, there are several reasons to adhere to solid ethics standards, such as:

- Ensuring honesty in all aspects of research;
- Ensuring that researchers can be held accountable when conducting research;
- Ensuring a high level of professional courtesy and fairness in working with others;
- Ensuring good stewardship of research on behalf of others.

It is hence imperative that all researchers at the NWU must agree on a shared set of ethics guidelines, and that management measures be put in place to ensure that all research is conducted within the boundaries of these guidelines. These guidelines will be derived from the Research Ethics Policy of the NWU.

1.2 Overview of management process

1.2.1 Code of Conduct

The NWU has adopted a Research Ethics Policy which lays down the ethics principles for research at the university. These principles were further expanded into an approved Research Code of Conduct, which must be signed by all researchers to indicate their acceptance of these principles. All management structures of the NWU will ensure that all research conducted under the auspices of the NWU must adhere to these principles.

1.2.2 Structure

In order to give effect to the Research Ethics Policy of the NWU, a committee structure will be set up to manage the Research Ethics processes of the NWU. An **Institutional Research Ethics Regulatory Committee (IRERC)** will be responsible for the governance issues, and a number of **Research Ethics Committees (REC)** functioning within the faculties will be responsible for the operational management of the

process. Each faculty will have at least one REC, but can have more than one such REC depending on discipline-specific needs.

Each REC will function in close alignment with the various research committees in the Faculty e.g. the research entity's Scientific/Proposal Committee and the Faculty Research Committee. The REC will have the same status and reporting responsibility as the Faculty Research Committee.

1.2.3 Statutory requirements for external registration of REC

The National Health Act was first published in 2003. Chapter 9 of the Act deals with National health research and information. A large portion of that chapter is in fact dedicated to health research ethics. Section 72 mandates the establishment of the National Health Research Ethics Council (NHREC), and stipulates that all RECs dealing with health research must be registered by the NHREC. The gazetted regulation relating to research with human participants of 2014 and the document Ethics in Health Sciences: Principles, Processes and Structures of 2015 expand on this and refer to *health and health-related research*. The latter document is intended to provide the minimum national benchmark of norms and standards for conducting responsible and ethical health and health-related research, including research with animals. In the latter case, the SANS 10386:2008 provides the minimum benchmark to ensure ethical and humane care of animals used for scientific purposes.

It can easily be envisaged that other groupings can follow this example set by the Department of Health, i.e. that the research ethics within various contexts can in some form or way be governed by a statutory body. Hence, these rules must make provision for a variety of RECs that are registered with some statutory body, which prescribes guidelines that must be adhered to.

All RECs that are approved by the NWU, irrespective of it being registered with an external regulatory body or not, will have the same status within the NWU.

1.2.4 Risk Level Descriptors

A risk can be seen as "the probability of harm occurring as a result of participation in research" or "an unexpected negative consequence of unethical actions". Therefore, risk needs to be assessed prior to conducting research. A risk level descriptor (RLD) is therefore the specification of the magnitude of the risk and probability of such risk occurring. It forms the basis of RECs' decision-making regarding ethical clearance of research.

Research Ethics Risks can be classified in the following four categories: (**Note:** The definitions given here, with minor changes, are quoted from the document "Regulations relating to research on human subjects"[1] derived from the National Health Act of 2003, and **may not be directly applicable to all contexts**).

1. **No Risk**: There is no possible risk that the research may lead to any undesirable effects or unexpected negative consequence.
2. **Minimal, Low or Negligible Risk**: The probability, magnitude or seriousness of unexpected negative consequences, harm or discomfort anticipated in the research is **negligible** and not greater than that ordinarily encountered in daily life ("Daily life" as a benchmark should be that of daily life experienced by the average person living in a safe "first world" country). Research in which the only foreseeable risk is one of **minimal unexpected negative consequences, discomfort or inconvenience**.
3. **Medium Risk**: Research in which there is a potential risk of unexpected negative consequences, harm or discomfort, but where appropriate steps can be taken to mitigate or reduce overall risk. Remedial interventions can be undertaken should harm occur.
4. **High Risk:** Research in which there is a real and foreseeable risk of unexpected negative consequences, harm and discomfort, and which may lead to serious adverse consequences if not managed in a responsible manner.

There are various other ways of classifying risk. For instance, risk for research with animals is usually classified according to the impact on animal wellbeing, ranging from no impact on animal wellbeing to very severe impact, requiring extraordinary motivation and control measures.

By their very nature, these RLDs are discipline-specific. Hence, each REC needs to formulate its own definitions and examples for the various risk levels described above. These examples of RLDs must be reviewed and approved by the NWU IRERC.

[1] Regulations relating to research on human subjects, Department of Health, Government Gazette #36508, 29 May 2013.

1.2.5 Application for Ethics Clearance

Before any research may be conducted scientific clearance must be granted for a project by the relevant scientific/proposal committee. The process of application for ethics clearance will be based on the RLDs applicable to the specific discipline and produced by the relevant REC.

A typical ethics clearance process would include that a research proposal with supporting documents as well as an ethics checklist (determined by discipline specific RLDs) first be submitted to a scientific/proposal committee for scientific review. This committee will make a preliminary assessment of the risk levels of the application based on an ethics checklist, and refer the application to an appropriate REC for a final review. The REC must also determine the context of the research: if the context is health or health-related, the application must be referred to a committee registered with the NHREC, in the format specified by the registered REC.

After proper review by the relevant REC, the committee will communicate their decision to the researcher and/or the IRERC for further action.

1.2.6 Training

Knowledge regarding research ethics has evolved greatly over the course of the past few years. More specifically in South Africa research ethics, which originally focused on health research due to Chapter 9 of the National Health Act 61 of 2003, has developed to reveal other important ethical aspects within non-health disciplines, as motivated in 1.1 above. With this evolution new research ethics issues have come to the fore as well as misconceptions with regard to what is ethical research behaviour and what is not. To stay informed and up to date with current developments within research ethics, training of researchers and research ethics committee members needs to be done on a continuous basis (at least once every three years).

In the sections following this Introduction, this document makes provision for the following:

- Rules for the establishment of the IRERC that provides governance leadership for research ethics at the NWU;
- Rules for the establishment of NWU RECs;
- Rules for the functioning of such RECs;
- Rules which makes provision for some of the NWU RECs to register with external regulatory bodies, and which allows these registered RECs to also satisfy the requirements of the external regulatory body;
- Rules to establish a mechanism and guidelines in order to ensure that research ethics applications are considered by the correct and appropriate REC.

2 Terms of Reference: Institutional Research Ethics Regulatory Committee (IRERC)

2.1 Purpose of the IRERC

The IRERC is established for matters concerning research ethics. These matters include ethics planning, and the ethics policy framework. This committee is meant to support the Senate in this regard.

2.2 Responsibilities of the IRERC

Governance: Formulates the Research Ethics Policy of the NWU, and ensures that all research conforms to this policy by

- Formulating a research ethics code of conduct to be signed by all researchers;
- Formulating generic minimum rules for all RECs at the NWU;
- Facilitating the establishment of appropriate research ethics committees (REC) within the NWU;
- Approving the specific operational rules, RLDs and codes of conduct where applicable for each REC;
- Ensuring that every REC performs its duties in line with its approved operational rules;
- Ensuring that the members of each REC are appropriately trained and qualified;
- Being co-responsible for ensuring that, when appropriate, registered RECs comply with the rules of the external governing body.

Support: Provides the necessary support (via the Research Support office) to RECs, in terms of:

- Providing and maintaining an efficient research ethics management system (InfoEd);

- Providing a research ethics awareness program for new staff;
- Creating awareness with line managers to ensure that RECs are provided with the necessary resources in the normal budgeting process in order to fulfil its Terms of Reference;
- Recordkeeping (via the research ethics management system) of all activities of each REC, including the recording of ethics approval numbers and the issuing of ethics certificates.
- Refering to the appropriate REC, any request from an outside entity to conduct research within the NWU, for review.

Reporting and Monitoring: Considers the annual reports of RECs, and reports on ethics activities to ICRI and Senate.

- Reviews the activities of each REC annually, by considering the annual report of the REC in consultation with the Chairperson of the REC. The IRERC will also conduct regular on-site reviews of all RECs. This review must satisfy the IRERC that the proper procedures as approved by the NWU are followed by the REC. In cases where the REC is registered with some external body, this review will be combined with external reviews conducted by the external body, and will serve to ensure that the conditions of that body are satisfied;
- Requests an appropriate REC to comment on particular ethics aspects if requested by an outside entity;
- Through ICRI, provide Senate with an annual report on research ethics matters.

2.3 Authority of the IRERC

The IRERC is a standing committee of the Senate of the NWU, and advises Senate on research ethics governance matters. The IRERC must report continuously to the DVC: Research and Innovation, or as determined by the Senate.

2.4 Membership of the IRERC

The IRERC consists of:

- A chairperson **appointed by Senate** for an appropriate period from the ranks of the DVCs;
- The DVC: RIT *(ex officio)*
- The Director: Research Support of the NWU *(ex officio)*;
- A member of the Institutional Legal Office or an expert from one of the Law Faculties of the University, **appointed by Senate**;
- The Chairperson(s) or his/her delegate of each REC of the NWU *(ex officio)*;
- A member of the Research Support Office, who provides support as specified in 2.2 above *(ex officio)*;
- A committee secretary from the department of Institutional Governance and Secretarial Services.
- The IRERC may from time to time co-opt additional members as needed, such as the Head of the Faculty of Health Sciences Research Ethics office..

All members of the IRERC have voting rights.

2.5 Meeting arrangements of the IRERC of the IRERC

Frequency	Twice per annum; the first meeting of the year will deal mainly with reports from RECs, while the second will deal mainly with governance matters.
Extraordinary meetings	If and when necessary
Quorum	The quorum of the meeting will be half (50%) plus one of all the members, excluding vacant positions.
Notice	At least 14 days before the meeting date, the Secretariat electronically notifies of the time and place where the meeting is to be held. At least 2 days before an extraordinary meeting, the Secretariat electronically notifies, provides the reason for an extraordinary meeting, as well as the time and venue.
Agenda	At least 7 days prior to the meeting, the Secretariat provides the complete

	agenda pack electronically to all members.
Reporting	The IRERC reports to Senate via the ICRI. The minutes of each meeting serves at ICRI for discussion and approval.
Decision-making process	Matters are decided by means of general consensus. The Chairperson might however decide when a decision should be taken by means of a voting procedure. The Chairperson may decide that voting must be by secret ballot, provided that voting for persons must always be by secret ballot. The Chairperson has an ordinary vote, but must in addition exercise a casting vote in the event of an equality of votes on any matter. The number of votes in favour of or against any proposal is not recorded in the minutes, unless the Chairperson so decides.
Conflict of Interest	A member may not take part in the discussion of or vote on any matter in which the member has a direct financial or other interest, unless the members first discloses the nature and extent of the interest and obtains the leave of the meeting to take part in the discussion or to vote.
Point of Order	A point of order, clarification or information may be raised against any member, in which instance the ruling of the Chairperson is binding. The ruling of the Chairperson is binding and cannot be challenged. Should the above point of order, clarification or information be immediately challenged by a member, the ruling is put to the meeting for determination – without it being discussed, and the decision of the meeting is final.
Disrespectful / Disorderly conduct	Anyone attending a meeting who, after having been requested to refrain from disrespectful or disorderly conduct, continues to disobey a ruling from the Chairperson, must be requested to leave the meeting. If that person does not leave the meeting immediately, such a person could be removed from the meeting with the assistance of Protection Services.
Apology	Members absent from the meeting, with apology prior to the meeting, are allowed to participate. The views of a member who is unable to attend a meeting may be submitted in writing.
Round Robin Process	The Chairperson may electronically submit urgent matters in between scheduled meetings. The Secretariat will assist in this process. At least two thirds of the members have to electronically confirm their involvement in the process by giving feedback, approval or non-approval. When a majority of members reaches agreement it is taken as a resolution. Such resolution is equivalent to a resolution of the committee and must be recorded in the minutes of the next meeting.
Resources and Budget	A centralised budget regarding the matters of this committee is managed within Institutional Research Support.
Records management	All records of the committee (terms of reference, membership list, agendas, attendance register, correspondence, etc.) will be kept electronically (on *Share*)

2.6 Approval and Review

The following documents guide the operations of the IRERC:

Document	Status	Authority	Date
Research and Innovation Policy	Approved	Council	20 September 2013
Research Ethics Policy	To be approved		

Policy for the Management of Research and Innovation Contracts and External Investment/Stake holding	Approved	Council	23 November 2012
Policy on Joint and Double Degrees at Masters and Doctoral Level with Foreign Universities	Approved	Council	31 July 2015
Rules for the Classification of Thesis and Dissertations	Approved	Council	20 June 2014

3 Terms of Reference: Research Ethics Committees (RECs)

These terms of reference provides a minimum standard for the operational management of the research ethics process within the NWU. All RECs approved by Senate, including REC registered with some external regulatory body, will function within these terms of reference.

3.1 Purpose of the REC

The REC provides operational management of the research ethics process at faculty level within its field of research expertise.

3.2 Responsibilities of the REC

The IRERC, in its governance role, stipulates that each REC will, within its specific field of research expertise:

- The REC will function within a strict code of conduct as appropriate for the specific research field and approved by the IRERC, and will ensure confidentiality of all information revealed to it;
- Ensure that researchers have a proper understanding of research ethics as applicable to the specific research field of expertise by providing subject-specific training;
- Ensure that all researchers working within its research field of expertise sign the NWU research ethics code of conduct;
- Formulate and seek approval from the IRERC for a set of operational rules for ethics applications within the specific research field of expertise;
- Formulate and seek approval for a set of research field-specific examples of Risk Level Descriptors, in line with the IRERC guidelines, to make a suitable classification of research ethics proposals.
- Provide feedback on specific ethics matters as requested by the IRERC;
- Receive applications for research ethics approval from researchers via the provided research management system;
- Consider these applications at its regular meetings, and communicate and minute the RECs decision regarding applications to the applicants;
- Approve the issuing of research ethics certificates for approved projects;
- In cases where the REC cannot come to a conclusion, or some other conflict arises within the REC, follow the general NWU rules for conflict resolution;
- Consider and act appropriately on the annual reports of approved projects;
- Consider applications to change any of the details of the research project as specified in the original proposal;
- Consider and act appropriately in cases of ethical misconduct by researchers
- Report via the approved Faculty structures to the relevant Dean;
- Report to the IRERC on an annual basis, using the prescribed reporting template.

3.2.1 Minimum standard for the ethics application procedure:

The IRERC will, with the support of the Research Support Office, maintain and manage the research ethics management system (e.g. InfoEd). All ethics applications (ethics checklist, relevant application forms and supporting documents) must be captured and managed on this research management system, where after all decisions regarding applications must be captured on this system.

The ethics application procedure shall include at least the following steps:

1. A completed research proposal as well as an ethics checklist (as developed by the relevant ethics committee in line with its RLD) must be submitted to the relevant Scientific/proposal Committee for

review.

2. The Scientific/Proposal Committee decides (based on the information in the research proposal and checklist) whether ethics clearance is required and refers the application to the relevant REC if necessary.
3. The REC will handle each application for ethics clearance according to the rules and operating procedures of the involved REC.
4. If deemed necessary or if required a REC may refer an application to a suitable registered committee.

3.3 Authority of the REC

The REC functions as a sub-committee of the Faculty board and in close collaboration with the Faculty Research Committee and Scientific/Proposal Committee. Each REC functions within a specific research field of expertise. Hence, any faculty could establish one or more RECs, depending on factors such as the number of research fields active within the faculty or statutory requirements.

The REC derives its authority from the governance rules formulated by the IRERC. As such, the establishment of an REC must also be approved by the IRERC. If an REC is dissolved by its faculty, this must be reported to the IRERC.

3.4 Membership of the REC

Members of an REC are recommended to, and approved by the relevant Faculty board for a period of five years, in accordance with the governance rules of the IRERC. Members are recommended based on their expertise within the specific research field, as well as their general research ethics expertise. Upon appointment, a formal Letter of Appointment will be issued by the IRERC. This appointment must reflect in the annual task agreement of the staff member.

3.4.1 Composition of the REC

The REC will consist of ***at least*** the following:

- A minimum of two members who are specialists in the particular research field,
- One member who is not a staff member of the North-West University (lay person).
- The research director of the research entity responsible for the research field of expertise (if practical; in large faculties this may not be the case).
- One member should be an expert in the field of statistics if applicable to the application;
- Ad hoc attendees can be nominated for meetings.

The composition of RECs registered with an outside regulatory body might be prescribed by that body. Even if this is the case, the minimum membership will be as described above.

3.4.2 Appointment of members

Members are approved by the relevant faculty board, and formally appointed by the IRERC, in its role as subcommittee of Senate.

3.4.3 Appointment of Chairperson and acting Chairperson

The Faculty Board appoints a chairperson in consultation with the REC. An acting chairperson can be appointed by the REC, to act for a limited period.

3.4.4 Co-opted members, observers and visitors

The REC co-opts members as and when needed. Since the REC functions within a strictly confidential environment, observers and visitors will only be allowed in exceptional cases and for a specific purpose. Researchers can be invited for the discussion of their application and to be present to clarify any uncertainties.

3.4.5 Voting rights

All members will have voting rights, while co-opted members, observers and visitors will not have such rights.

3.4.6 Secretariat

The relevant Faculty will ensure that appropriate secretarial services are provided.

3.5 Meeting arrangements

The following meeting arrangements apply:

Frequency	A **minimum** of twice per annum preceding the two meetings of the IRERC. These meetings should preferably be face-to-face meetings, but can also be held via electronic media where practical. The timing of meetings should be such that research projects are not delayed unnecessarily while waiting for ethics clearance.
Extraordinary meetings	If and when necessary
Quorum	The quorum of the meeting will be at least half (50%) plus one of all the members, excluding vacant positions.
Notice	At least 14 days before the meeting date, the Secretariat electronically notifies of the time and place where the meeting is to be held. At least 2 days before an extraordinary meeting, the Secretariat electronically notifies, provides the reason for an extraordinary meeting, as well as the time and venue.
Agenda	At least 5 days prior to the meeting, the Secretariat provides the complete agenda pack electronically to all members.
Reporting	A report of the RECs activities, excluding confidential information, serves at the appropriate faculty board for discussion and approval. An annual report must be submitted to the IRERC in the prescribed format.
Decision-making process	Matters are decided by means of general debate and consensus. The Chairperson might however decide when a decision should be taken by means of a voting procedure. The Chairperson may decide that voting must be by secret ballot, provided that voting for persons must always be by secret ballot. The Chairperson has an ordinary vote, but must in addition exercise a casting vote in the event of an equality of votes on any matter.
Conflict of Interest	A member may not take part in the discussion of or vote on any matter in which the member has a direct financial or other interest, unless the members first discloses the nature and extent of the interest and obtains the leave of the meeting to take part in the discussion or to vote.
Point of Order	A point of order, clarification or information may be raised against any member, in which instance the ruling of the Chairperson is binding. The ruling of the Chairperson is binding and cannot be challenged. Should the above point of order, clarification or information be immediately challenged by a member, the ruling is put to the meeting for determination – without it being discussed, and the decision of the meeting is final.
Disrespectful / Disorderly conduct	Anyone attending a meeting who, after having been requested to refrain from disrespectful or disorderly conduct, continues to disobey a ruling from the Chairperson, must be requested to leave the meeting. If that person does not leave the meeting immediately, such a person could be removed from the meeting with the assistance of Protection Services.
Apology	Members absent from the meeting, with apology prior to the meeting, are allowed to participate. The views of a member who is unable to attend a meeting may be submitted in writing.
Round Robin Process	The Chairperson **may** electronically submit urgent matters in between scheduled meetings. The Secretariat will assist in this process.[2]

[2] In the case of NHREC registered RECs, there is a requirement that all meetings are to be held in a face-to-face environment.

	At least two thirds of the members have to electronically confirm their involvement in the process by giving feedback, approval or non-approval. When a majority of members reaches agreement it is taken as a resolution. Such resolution is equivalent to a resolution of the committee and must be recorded in the minutes of the next meeting.
Resources and Budget	The Chairperson submits a budget to the appropriate faculty as part of the annual budgeting process.
Records management	All records of the committee (terms of reference, membership list, agendas, attendance register, correspondence, etc.) will be kept electronically on the research ethics management system (InfoEd).

4 RECs registered with external regulatory bodies

There is currently only one such external regulatory body, namely the National Health Research Ethics Council.

4.1 Registration with the NHREC

The National Health Act was first published in 2003. Chapter 9 of the Act deals with National health research and information. A large portion of that chapter is in fact dedicated to health research ethics. Section 72 mandates the establishment of the National Health Research Ethics Council (NHREC), and stipulates that all RECs dealing with health research must be registered by the NHREC. The gazetted regulation relating to research with human participants of 2013 (See footnote 1 above) and the document *Ethics in Health Sciences: Principles, Processes and Structures*[3] of 2015 expand on this and refer to *health and health-related research*. The latter document is intended to provide the minimum national benchmark of norms and standards for conducting responsible and ethical health and health-related research, including research with animals, as specified in paragraphs 1.4.1 and 1.5.1 of the document in footnote 3. In the latter case, the SANS 10386:2008 provides the minimum benchmark to ensure ethical and humane care of animals used for scientific purposes.

Health research is defined as

Health research *– contributes to knowledge of biological, clinical, psychological, or social welfare matters including processes; causes and effects of and responses to diseases; effects of environment on humans; methods to improve health care delivery; new pharmaceuticals, medicines, interventions and devices; new technologies to improve health and health care*

Each REC dealing with research that complies with this definition of Health or Health-Related Research must be registered with the NHREC. After registering with the NHREC, the REC must, in addition to the minimum rules for REC as stipulated by the IRERC, also comply with the rules of the NHREC.

It can easily be envisaged that other groupings can follow this example set by the Department of Health, i.e. that the research ethics within various contexts can in some form or way be governed by a statutory body. Hence, these rules must make provision for a variety of RECs that are registered with some statutory body, which prescribes procedures that must be adhered to.

4.2 Exclusions

The importance of ethical behaviour in all scientific endeavours cannot be denied. This is especially true when the health and well-being of humans and animals are at stake. There is a general school of thought that the National Health Act and its associated publications provide a minimum national benchmark of norms and standards for conducting responsible and ethical research in **all** research fields. This school of thought is based on statements made in the Foreword of the document referred to in footnote 3.

The following ***verbatim extract*** from *Ethics in Health Research: Principles, Processes and Structures (Second Edition), 2015,* provide guidelines to better understand the context within which the document must be interpreted, and hence where the principles as specified in the document are applicable. (See also Appendix 1 of the document for definitions. Where any confusion or misinterpretation can arise, the definitions are also given here in footnotes.)

1.4.1 The National Health Act (NHAs 72(6)(c)) gives authority to the NHREC for setting norms and standards for ***health and health-related*** *research that involves humans.* (Authors emphasis)

[3] See: Ethics in Health Research: Principles, Processes and Structures (Second Edition), 2015, Published by the Department of Health, Republic of South Africa

*1.5.1 The National Health Act (NHA) gives authority to the NHREC for setting norms and standards for **health research** that uses animals (NHA s 72(6)(c)).* (Authors emphasis)

1.1.6 These guidelines do not advocate the so-called 'medical model' of ethics review, especially not for social science, behavioural or humanities research.

1.1.7 The core ethical principles outlined in these guidelines apply to all forms of research that involve living human participants and use of animals, placing their safety, welfare and interests of both humans and animals as paramount. The principles also apply to research that involves use of human biological materials and data collected from living or deceased persons, including human embryos, foetuses, foetal tissue, reproductive materials, and stem cells.

1.1.8 Research that relies exclusively on publicly available information or accessible through legislation or regulation usually need not undergo formal ethics review. This does not mean that ethical considerations are irrelevant to the research.

1.1.9 Research involving observation of people in public spaces and natural environments usually need not undergo formal ethics review, provided that

- the researcher does not interact directly with individuals or groups
- the researcher does not stage any intervention
- the individuals or groups do not have a reasonable expectation of privacy
- dissemination of research findings does not identify individuals or groups

1.1.10 Research that relies exclusively on secondary use of anonymous information[4] or anonymous human biological materials usually need not undergo formal ethics review, provided that no identifiable information is generated. See 3.3 below for further information regarding human biological materials.

1.1.11 Quality assurance and quality improvement studies (audits), programme evaluation activities and performance reviews usually do not constitute research and thus usually do not undergo formal ethics review. It should be noted, however, that if publication of such studies is desirable, it is prudent to obtain ethics approval before the study begins. RECs may not grant retrospective ethics approval.

1.1.12 These guidelines express the view that the core ethical principles apply to all forms of research that involve humans or use of animals, insofar as the welfare and safety interests of both humans and animals are paramount. Health and safety issues include those that may arise in the environment of research e.g. viruses, parasites, bacteria, as well as the air, water and land.

1.1.13 This document is intended to be as inclusive as possible, so that all researchers who involve human participants or use animals in their research will find assistance in these guidelines. In other words, although this document derives its authority from the National Health Act, the National Health Research Ethics Council (NHREC) intends it to address research more broadly to achieve the specific goal of providing guidance for researchers so that all research involving human participants or animals may be conducted in accordance with the highest ethical norms and standards.

From the above, it is clear that the aim of the document is to **provide guidelines** to ensure the **welfare and safety interests** of human participants or animals used in **health or health-related research** (section 1.1.12). The document states clearly that it **does not wish to enforce** a "medical model" of ethics review for research in **social science, behavioural or humanities research.** Sections 1.1.8, 1.1.9 and 1.1.10 makes it clear that in cases where **anonymous data** is collected through means **not involving direct contact** with live humans, ethics clearance as specified for health or health-related research is not necessary. It also **excludes quality assurance** and quality improvement studies, **program reviews** and **performance reviews** from ethical clearance.

Section 1.4.1 also states that the NHREC derives its authority from the National Health Act, and hence can set norms and standards for health and health-related research that involves humans. In other contexts, the NHREC can provide guidelines, but cannot be prescriptive.

4.3 Referring an ethics application to a registered REC

It must be emphasized that research involving live humans or vulnerable groups of people must be done with the utmost care and consideration of ethical principles. Therefore, if any doubt exists, applications for ethical clearance involving live humans must be referred to an REC registered with the NHREC.

However, it is also clear that the NHREC regulations could be interpreted in a way that seriously complicates and sometimes even compromises research projects. The REC must therefore give careful consideration to

[4] See Ethics in Health Research: **Anonymous data or specimen**–data or biological materials without any overt identifying information or link to a specific donor

such applications before referring it to a NHREC-registered REC. In the deliberations of the REC, the following two questions must be considered:

1. If the research project involves live humans or animals, is the research done in the health or health-related context?
    a. If YES, do any of the exclusions above apply? If yes, the REC may proceed to question 2 below, otherwise the application is referred to a registered REC qualified to deal with the application.
    b. If NO, the REC may proceed to question 2 below.
2. Is there any possibility of unexpected negative consequences, harm or discomfort as a result of unethical behaviour? Based on the RLD's as approved for this specific REC, a risk classification is made and the application is dealt with in terms of the rules as approved for this REC.

The answer to question 1 above is not a simple matter, and requires the members of the REC to apply their minds. A simple statement like "If it involves humans, it is health" is obviously not the answer. Turning to the definition of health research given above, one must consider whether the research will contribute towards a better understanding of

- biological, clinical, psychological, or social welfare matters.
- causes and effects of and responses to diseases;
- effects of environment on humans;
- methods to improve health care delivery;
- new pharmaceuticals, medicines, interventions and devices;
- new technologies to improve health and health care

If the answer is YES, then it is research within the health or health related context. If one of the exclusions as discussed above applies, then it is not required to get ethical clearance. Otherwise, ethical clearance from a registered REC is compulsory.

To answer the second question is again not a simple matter. A simple statement like "there is no risk, since the research does not involve live humans" is again not conclusive. There is for instance a serious risk of harm to the reputation of the NWU due to unethical behaviour in virtually every research project.

The final message here is that a very careful assessment of each research project in in the context of its field of research must be made to decide on the appropriate REC.

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