



**UNIVERSITY OF ZULULAND**

**TERMS OF REFERENCE**

**ON**

**RESEARCH ETHICS COMMITTEE**

## **Terms of Reference**

### **1. Rationale**

The University of Zululand (UniZulu) has in place a faculty-based model for the review of research proposal for qualification and non-qualification research. The University of Zululand Research Ethics Committee (hereafter referred to as UZREC) is a monitoring committee with representatives from all Faculty Research Ethics Committee (FRECs). It operates within the framework of an evolving UniZulu structure that is highly influenced by National Health Research Ethics Council (NHREC). UZREC is registered by the NHREC: registration number (REC-171110-030).

### **2. Identity**

The University of Zululand Research Ethics Committee (UZREC) is mandated to fulfil its function by the Senate of the University of Zululand through the University Research and Ethics Committee, to which UZREC will report annually in writing.

### **3. Objectives**

- 3.1 The UZREC shall promote an environment in which researchers strive to comply with universal standards regarding ethical research and, when and where appropriate, shall advise Senate on matters involving research ethics.
- 3.2 The UZREC shall protect the dignity, rights, safety, and wellbeing of all participants in research and research-related activities through independent ethics-focused review of proposals and research methods, and the monitoring of all research projects within or related to the University.
- 3.3 The UZREC may accept for review research protocols submitted to it by researchers from institutions that are not affiliated to the University.
- 3.4 The UZREC shall ensure that the provisions of this policy are implemented and adhered to.

### **4. Roles**

- 4.1 The UZREC shall have the power to co-opt ad hoc members to deal with particular protocols.
- 4.2 According to the NHREC 2015 guidelines, the UZREC must review the following:
  - Study design (alignment of research topic, research questions, aim, objectives, methodology and research instruments)
  - Risk and benefits
  - Equitable/ Unbiased selection of research participants
  - Identification of research participants and ensuring confidentiality
  - ALL research Instruments (Interview schedule, questionnaire, informed consent process &, etc)

- Qualifications of the researcher
- Clear description of what, who, where, and why?
- Promote community engagement and benefits

4.3 The UZREC shall have the power to assign some of its review tasks to specialist committees established in terms of this policy, but shall at no time abrogate its responsibility to ensure ethical compliance and shall, in particular, not abrogate its responsibility to make the final decision regarding ethical clearance and compliance in any matter.

4.4 The UZREC shall oversee the activities and decisions of all Ethics Committees.

4.5 The UZREC may recommend disciplinary measures where ethical rules and principles are violated.

4.6 When strict compliance with the letter of a particular ethical requirement or guideline is not possible, the UZREC shall ensure that the proposed research is nonetheless in keeping with the spirit of the relevant requirement or guideline and the provisions of this policy.

4.7 UZREC shall attend meetings of Senate, Senate Research Committee, and the Higher Degrees Committee (HDC) as required. This will be through attendance by the Chair or a delegated member of the UZREC.

4.8 Advise Senate, Senate Research Committee, the HDC, and UniZulu Management on matters related to the ethics of research involving humans, animals, and the environment, and on ethics in the broader sense (e.g. plagiarism, conflict of interest, etc.).

## **5.UZREC Membership**

5.1 Members should be people who value morality and demonstrate an awareness of and sensitivity to all humans, animals and the environment. They should defend the continued advancement of science in the interests of society, with particular attention to research needs in South Africa and Africa. The responsibility of a REC member is to review research proposals to determine the safety and well-being of participants before each meeting, by encouraging and promoting research. Making recommendations to ensure that the NHREC guidelines and principles of ethical review are met. Signing a non-disclosure agreement (NDA) in keeping confidentiality on all reviews by the committee is mandatory.

## 5.2 The UZREC comprises the following members:

5.2.1 The Deputy Vice-Chancellor Research and Innovation (Chairperson), Research Director, Research Ethics Administrator/Manager, Deputy Deans Research & Internalization of Faculty or their nominees, Academic members with relevant expertise, member of the community where the institution is operating.

5.2.2 Ordinary membership of the UZREC will be for an initial three-year term, but members may be re-appointed for one additional three-year period. The provisions of this clause may be waived where a person serves on the UZREC in order to fulfil regulatory requirements.

5.2.3 All committee members will be required to sign a confidentiality agreement as well as a code of conduct as part of their appointment process.

5.2.4 The University shall indemnify all committee members in respect of any legal consequences arising from bona fide decisions made as committee members.

## **6 Terms of Reference**

- 6.1** The UZREC shall promote an environment in which researchers strive to comply with universal standards regarding ethical research and, when and where appropriate, shall advise Senate on matters involving research ethics.
- 6.2** The UZREC shall protect the dignity, rights, safety, and wellbeing of all participants in research and research-related activities through independent ethics-focused review of proposals and research methods, and the monitoring of all research projects within or related to the University.
- 6.3** The UZREC may accept for review research protocols submitted to it by researchers from institutions that are not affiliated to the University.
- 6.4** The UZREC shall ensure that the provisions of this policy are implemented and adhered to.
- 6.5** The UZREC shall have the power to co-opt ad hoc members to deal with particular protocols.
- 6.6** The UZREC shall have the power to assign some of its review tasks to specialist committees established in terms of this policy, but shall at no time abrogate its responsibility to ensure ethical compliance and shall, in particular, not abrogate its responsibility to make the final decision regarding ethical clearance and compliance in any matter.
- 6.7** The UZREC shall oversee the activities and decisions of all Faculty Ethics Committees.
- 6.8** The UZREC may recommend disciplinary measures where ethical Rules and principles are violated.
- 6.9** When strict compliance with the letter of a particular ethical requirement or guideline is not possible, the UZREC shall ensure that the proposed research is nonetheless in keeping with the spirit of the relevant requirement or guideline and the provisions of this policy.

## **7. Basic Standard of Conduct**

Members of UZREC shall carry out their responsibilities as prescribed in the policy and guidelines of research ethics designated for the committee. They shall maintain a high standard of integrity, objectivity, confidentiality, commitment and professionalism.

## **8. Operating Procedures**

8.1 The UZREC functions in compliance with, but not limited to, the following documents and guidelines:

8.1.1 The South African National Health Act. No. 61 of 2003.

8.1.2 The South African Department of Health (2015), Ethics in health research: Principles, structures, and processes for National Health Research Ethics Council (NHREC)

8.1.3 South African good clinical practice guidelines (2006).

8.1.4 Declaration of Helsinki (Current version)

8.1.5 The Belmont Report, the US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US).

8.1.6 Department of Health and Human Services- (HHS), 21 CFR 50, 21 CFR 56, CIOMS, ICH-GCP-E6 Sections 1-4.

8.1.7 The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite).

8.1.8 When strict compliance with the letter of a particular requirement of these declarations and codes is not possible, UZREC will ensure that the proposed research is nonetheless in keeping with the spirit of the declarations and codes.

8.1.9 The SOP are thoroughly articulated on the SOP document.