

**TERMS OF REFERENCE AND STANDARD OPERATING PROCEDURES FOR
THE HUMANITIES AND SOCIAL SCIENCE RESEARCH ETHICS COMMITTEE
AT UKZN**

**HUMANITIES AND SOCIAL SCIENCE RESEARCH ETHICS COMMITTEE
TERMS OF REFERENCE AND STANDARD OPERATING PROCEDURES**

1. DEFINITIONS

Terms set in bold in this document are defined in Appendix A

2. TERMS OF REFERENCE

2.1 The Humanities and Social Science Research Ethics Committee (hereafter referred to as "HSSREC") is mandated to fulfil its function by the Senate of the University of KwaZulu-Natal through the University Research Ethics Policy V and the Research Strategy Group (RSG), to which HSSREC will report annually in writing.

2.2 The essential purpose of HSSREC is to protect the dignity, rights, safety and well-being of all human participants in non-biomedical, human participant research. HSSREC will do this through independent, prospective and ongoing ethics review of all social science and humanities research projects undertaken by members of staff, registered students and affiliates of the University. Research to be reviewed will be in accordance with the provisions of the National Health Act (Act 61 of 2004).

2.3 A significant proportion of the Humanities and Social Science research conducted at the University constitutes *Health Research* (as defined by The National Health Act, Act 61 of 2004), and it is therefore appropriate that the HSSREC is registered with and accredited by the National Health Research Ethics Council (NHREC). Once accredited by the NHREC, HSSREC may advise the University Dean of Research to initiate disciplinary steps against investigators who violate either national or the HSSREC's own ethical guidelines as outlined in UKZN Research Ethics Policy V.

2.4 The overarching ethics guidance for the HSSREC will be the SA Department of Health (2004) *Ethics in health research: Principles, structures and processes*. Where relevant major international guidelines (including, but not restricted to: The Declaration of Helsinki, current version; The Belmont Report; and The CIOMS Guidelines) will apply. When strict compliance with the letter of a particular requirement of these declarations and codes is not possible, HSSREC will ensure that the proposed research is nonetheless in keeping with the spirit of the declarations and codes.

3. STANDARD OPERATING PROCEDURES

3.1 HSSREC MEETINGS

Meetings will be held once a month for 11 months of the year (excluding January). A schedule of meeting dates and deadlines for submission for any given year will be circulated to Committee Members and placed on the HSSREC web page by the second week of January each year; with the minutes of meetings and the agenda being circulated to members at least 7 days prior to the meeting. A special meeting may be called at any time by the Chairperson of HSSREC.

3.2 THE COMMITTEE

3.2.1 COMPOSITION

The composition of HSSREC will be in accordance with the provisions of the Department of Health (2004) *Ethics in health research: Principles, structures and processes* and (2006) *South African Good Clinical Practice Guidelines*. Members of HSSREC should collectively have the qualifications, experience and expertise to review and evaluate the scientific, legal, psychosocial and ethical aspects of research proposals. The total number of Committee members must be no less than 10.

The Chairperson of HSSREC shall be appointed by and report to the Deputy Vice Chancellor of Research for a renewable term of three years. HSSREC members shall be appointed by the HSSREC Chairperson (in consultation with committee members, and the Dean of Research) for a term of 3-years, renewable. A vice-chairperson, who shall be a member of the University, will be elected by HSSREC from the committee membership.

3.2.2 MEMBERSHIP

The committee shall:

- Be representative of the communities it serves and, increasingly, reflect the demographic profile of the population of South Africa.
- Include members of both genders, with no more than 70% of members being of one gender.
- Have at least 10 members, with a simple majority constituting a quorum;
- Have a chairperson and a vice-chairperson (or persons).
- Include at least two members of academic staff from each of the Colleges serviced by the Committee/major Schools (i.e. Humanities; Health Sciences; Law and Management Studies).
- Include at least two lay persons who: have no affiliation to the institution; are not currently involved in social science/humanities, scientific, or legal work; and are competent to provide an informed view on the concerns, interests and well-being of vulnerable communities.
- Include at least one member with knowledge of, and current experience in,

areas of research that are likely to be regularly considered by HSSREC.

- Include at least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people. Such a member might be, for example, a medical practitioner, psychologist, social worker or nurse).
- Include at least one member who has professional training in both qualitative and quantitative research methodologies.
- Include at least one member who is legally trained.
- Ensure that the membership is equipped to address all relevant considerations arising from the categories of research likely to be submitted to it.
- Ensure that it is adequately informed on all aspects of a research protocol, including its scientific and statistical validity, that are relevant to deciding whether the protocol is both acceptable on ethical grounds and conforms to the principles of this document.
- HSSREC may co-opt expert members and other representatives as voting members as required by particular protocols. Voting status is to be confirmed by HSSREC in advance on a case by case basis.
- On invitation or request, HSSREC meetings may be attended by *bona fide* students, researchers and other interested parties as non-voting observers, subject to the signing of a confidentiality undertaking and subject also to being excluded from certain agenda items as determined by the Chair.

3.2.3 TRAINING

All committee members must receive initial and ongoing training in research ethics and committee work.

3.3 CONFLICT OF INTERESTS

HSSREC members shall declare any prior interest and/or involvement in any matter being discussed by HSSREC to avoid conflict of interest in HSSREC decision-making, including reviewing of protocols. In convened HSSREC meetings, the Chair shall determine whether the member be recused for items of discussion, or be allowed to remain and address questions when asked to do so, but not vote or participate in final decision-making on the matter in question.

3.4 CONFIDENTIALITY

In order to assure the protection of **confidential information** (Appendix A), all HSSREC members, support staff and observers shall sign a standard confidentiality agreement on appointment to HSSREC (see Appendix B).

3.5 QUORUM/VOTING

The Committee will make its decisions at scheduled or extraordinary meetings at which a quorum of members is present. Meetings will only be conducted when a quorum is present. Decisions will be determined by consensus (general agreement). In situations where consensus cannot be achieved, the decision will be arrived at by

vote. Minutes taken at HSSREC meetings will be of sufficient detail to show attendance at the meetings; actions taken by HSSREC; if applicable, the vote on these actions including the number of members voting for, against and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of disputed issues and their resolution.

3.6 RESEARCH REQUIRING ADDITIONAL ATTENTION

HSSREC will pay special attention to protecting the welfare of participants from **vulnerable populations** (Appendix A) and/or **participants requiring additional attention** (Appendix A), with the HSSREC needing to satisfy itself that consent obtained from such respondents is both adequately informed and voluntary.

Research involving children (i.e. individuals under the age of 18 years) may only be approved if:

- The research involves no more than minimal risk.
- The research involves more than minimal risk but provides direct benefit to the child which is commensurate with the level of risk (i.e. a favourable risk-benefit ratio).
- The research involves no more than a minor increase over minimal risk, with no direct benefit to the child, but the research has a high probability of providing significantly generalisable knowledge (i.e. a favourable risk-knowledge ratio).

Consent for children to participate in research must be obtained from the parents or legal guardian. HSSREC must ensure that adequate steps are outlined in protocols to obtain the child's assent when, in the opinion of the HSSREC, the child is capable of providing such assent.

3.7 REVIEW PROCEDURES

3.7.1 PROTOCOL SUBMISSION

The Committee will obtain the following document/s from the researcher, using a standard checklist:

- Current HSSREC application form(s)
- Study protocol(s)
- Written informed consent form(s)
- Information sheets
- Participant recruitment procedures (e.g. advertisements)
- Written information to be provided to participants
- Safety information

Any other documents that HSSREC may need to fulfil its responsibilities.

3.7.2 PROTOCOL REVIEW

3.7.2.1 ETHICAL FRAMEWORK FOR REVIEW

The review of protocols will be informed by the ethical framework developed by Emanuel et al. (2008) which can be summarised in terms of eight ethical principles: collaborative partnership, social value, scientific validity, fair participant selection, favourable risk-benefit ratio, independent ethics review, informed consent and respect for informants. This framework has been adapted for social science research (Wassenaar and Mamotte, 2012).

3.7.2.2 REVIEW PROCEDURES

In the first phase of the review, all protocols will be triaged by the HSSREC Chair into one of three mutually exclusive categories:

3.7.2.2.1 EXEMPTION FROM ETHICAL REVIEW

HSSREC may grant exemption from ethical review for research which does not involve **human participants** (Appendix A) and carries no risk for the well-being of individuals or groups of individuals (e.g. research which is restricted to the secondary analysis of data sources which are in the public domain or observations of behaviour which is in the public domain).

3.7.2.2.2 EXPEDITED REVIEW PROCESS

The HSSREC may use the expedited review procedure in the following circumstances:

- (1) The research is deemed to involve no more than **minimal risk** (Appendix A);
- (2) To approve minor changes in previously approved research during the period for which approval is authorised; and/or
- (3) HSSREC will consider “Class approvals” for expedited review in circumstances where the usual criteria for expedited approval are met, in addition to the following: (a) where an investigator wishes to do exploratory research involving several lines of inquiry on retrospectively collected data, or (b) where an investigator needs to repeat a specified research exercise, for teaching or training purposes.

Under an expedited review procedure, the review may be carried out by the HSSREC chair or by one or more experienced reviewers designated by the chair from among members of the HSSREC. In reviewing the research, the reviewers will exercise all the authority of the HSSREC except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedures set out below. Members of HSSREC will be informed at committee meetings of all protocols that have been approved using the expedited review process since the last committee meeting (Adapted from: 45 CFR 46 110(b); BREC, 2010).

3.7.2.2.3 FULL COMMITTEE REVIEW

Research which is deemed to constitute a minor increase over minimal risk will be reviewed by the full HSSREC. The review process for protocols categorised as *for full committee review* will be as follows:

- Protocols received at least 10 days prior to a scheduled HSSREC committee meeting will be tabled at the next committee meeting, with feedback on the committee's conclusions being provided to the Primary Investigator within five working days of the committee meeting.
- Each protocol will be discussed at a convened quorate HSSREC meeting at which a majority of the members of the HSSREC are present, including at least one member whose primary concerns are in non-scientific areas.
- For all non-expedited reviews, all committee members will receive copies of the HSSREC application form and the protocol.
- Each non-expedited application and protocol will be reviewed in advance of a convened HSSREC meeting by all HSSREC members. A primary and secondary reviewer, and where necessary, an expert reviewer will be allocated to review each such application.
- The primary and secondary reviewer (and expert reviewer, where applicable) will, at the HSSREC meeting, initially provide an evaluation of the positive and negative aspects of the proposed research, with other committee members present at the meeting subsequently being afforded an opportunity to provide their evaluations.
- Apart from the scientific input, opinions from members representing the community must also be taken into account.
- Decisions are reached either by consensus or by a vote.
- HSSREC's review of a protocol will lead to written confirmation to the applicant of either:
 - final approval
 - provisional approval conditional to modifications required by the Committee
 - rejection
- Reasons for provisional approval and rejection will be furnished to the researcher in writing.
- HSSREC must document its views in writing, clearly identifying the study, the documents reviewed, and the dates for the following:
 - approval;
 - modifications required prior to resubmission for approval;
 - rejection; and
 - termination or suspension of any prior approval.

3.7.3 CONTINUING REVIEW PROCEDURES

3.7.3.1 RECERTIFICATION AND CONTINUING REVIEW

HSSREC should decide the frequency of continuing review for each study protocol necessary to ensure the continued protection of the rights and welfare of research participants, to be done on either a tri-annual, a bi-annual or not less than an annual basis. In conducting continuing review of research not eligible for expedited review, all HSSREC members should at least receive and review the HSSREC recertification application form containing essential study information including a protocol summary and status report on the progress of the research.

3.7.3.2 ADVERSE EVENTS

Reports on adverse events and serious adverse events (AEs and SAEs) should be reported in writing to HSSREC, the study sponsors, and any regulatory authority (where appropriate), within 7 working days of the occurrence for local sites and one month for all other South African sites. Protocol violations and deviations shall also be reported in the same manner.

3.7.3.3 SUSPENSION/TERMINATION OF APPROVAL

HSSREC may suspend or terminate approval of a study that is not being conducted in accordance with prevailing HSSREC or South African Department of Health Ethical requirements. The primary justification for suspension or termination of approval should be the safety of participants or others. Such suspension or termination of approval must be authorised by the HSSREC chair in minuted consultation with a HSSREC subcommittee and/or other co-opted parties as soon as possible but not more than seven days after receipt of relevant information by the chair. Such action must be reported to HSSREC at the next quorate meeting, and to the University Dean of Research.

3.7.3.4 PROTOCOL AMENDMENTS

Unless urgently required to protect the safety of participants, all amendments to research protocols (including changes to key study personnel/supervisors, etc.) require prior written approval from the HSSREC. The review procedures for protocol amendment shall be the same as those outlined in 3.7.3.1 above for recertification.

3.7.3.5 RECORDS

All HSSREC documentation and communication is dated, filed and archived. All records (electronic and hard copies) are stored securely to safeguard the information and ensure confidentiality. Staff are appropriately trained to ensure optimal record-keeping, retrieval and confidentiality.

3.8 COMPLAINTS BY INVESTIGATORS

Investigators should seek to resolve complaints with HSSREC procedures or decisions informally through the Chair in the first instance. If complaints remain unresolved investigators may lodge a formal complaint with the University Dean of Research, and/or directly to the National Health Research Ethics Council at the National Department of Health (<http://www.doh.gov.za/nhrec/>).

3.9 RESEARCH MISCONDUCT (See UKZN Research Ethics Policy V)

Research misconduct encompasses *inter alia*:

- Failure to submit a protocol for ethics approval in term of this document
- Fabrication, falsification, plagiarism in proposing, performing, reviewing or reporting of research
- Deviation from or failure to adhere to the approved protocol without prior formal approval from HSSREC
- Misrepresentation of data and/or interests and/or involvement
- Falsification of credentials
- Deception in the research proposal
- Non-approved deception in the carrying out of research
- Piracy of materials
- Failure to follow accepted procedures to exercise due care in avoiding unreasonable harm or discomfort to participants or research staff
- Failure to obtain voluntary and informed consent
- Breach of confidentiality
- Negligent management of data security.

Incidents of research misconduct will be reported to the University Dean of Research and managed in accordance with applicable University rules and procedures. The identity of the individual who raises awareness of research misconduct will be protected and will be made known to the Chair and members of the University Research and Ethics Committee and HSSREC only. Protocol violations are to be tabled and discussed at quorate meetings of HSSREC.

3.10 CHANGES TO HSSREC TERMS OF REFERENCE, STANDARD OPERATING PROCEDURES, AND/OR MEMBERSHIP

Any changes to HSSREC Standard Operating procedures and/or Terms of Reference, will need to be approved by the Research Strategy Group (RSG), the Senate of the University of KwaZulu-Natal, and the SA National Health Research Ethics Council (NHREC).

4. SELECTED REFERENCES

- Biomedical Research Ethics Committee (BREC) (2010). *Terms of reference and standard operating procedures*. University of KwaZulu-Natal, Durban, South Africa.
- Council for International Organizations of Medical Sciences (CIOMS) (2002). *International ethical guidelines for biomedical research involving human subjects*. Geneva.
- Department of Health (2004). *Ethics in health research: Principles, structures and processes*. Pretoria.
- Department of Health, Education, and Welfare (1979). *Belmont Report: Ethical principles and guidelines for the protection of human subjects of research. Report of the National Commission for the protection of human subjects of biomedical and behavioral research*. Washington.
- Emanuel, E.J., Wendler, D., & Grady C. (2008). An ethical framework for bioethical research. In: Emanuel et. al., *The Oxford textbook of clinical research ethics* (pp. 123-135), New York: Oxford University Press.
- Human Sciences Research Council (HSRC) (n.d.). *Research Ethics Committee Terms of reference*.
- Medical Research Council: (2000). *Guidelines on ethics for medical research: General principles*. Cape Town.
- University of KwaZulu-Natal (2007). *Research Policy V. Research Ethics*.
- US Federal Regulations: 45 CFR 46. Available from <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>
- Wassenaar DR., & Mamotte N. (2012). Ethical issues and ethics reviews in social science research. *The Oxford Handbook for international psychological ethics*. (pp. 268- 282). New York: Oxford. Online: Nov12. DOI: 10.1093/oxfordhb/9780199739165.001.0001
- World Health Organisation (2011). *Standards and operational guidelines for ethics committees that review biomedical research*. Geneva: WHO.
- World Health Organisation (2011). *Standards and operational guidance for ethics review of health-related research with human participants*. Geneva: WHO.

APPENDIX A

Confidential Information means certain proprietary, personal, clinical or protocol-specific information which the HSSREC member acknowledges to be confidential. Such information includes all protocols relating to research with human participants and associated documentation. The Confidential Information may be conveyed in written, graphic, oral or physical form including (but not limited to) scientific knowledge, skills, processes, inventions, techniques, formulae, products, business operations, patient requirements, biological materials, designs, sketches, photographs, drawings, specifications, reports, studies, findings, data, plans or other records, and/or software (BREC SOPs, 2010)

Human subject means :

(1) “A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with an individual; with the term *intervention* including both physical procedures whereby data are gathered and manipulations of the subject or the subject’s environment that are performed for research purposes, and the term *interaction* including communication or interpersonal contact between researcher and subject; or (2) A living, or deceased, individual about whom an investigator (whether professional or student) conducting research obtains information that is both identifiable and private; with information being *identifiable* if the identity of the individual is, or may readily be, ascertained by the investigator, or associated with the information, and *private information* including information about behaviour that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record)” (Adapted from 45 CFR 46.102).

Minimal risk means “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” (45CFR 46.101).

Participants requiring additional attention means “participants who fall into one or more of the following categories:

- Minors: Children and adolescents
- Women: Women and Pregnancy
- Persons with mental disabilities
- Persons with substance abuse related disorders
- Persons in dependent or subservient relationships (e.g., students where the investigator is directly involved in their training; employees where the investigator has line authority over them).
- Prisoners
- Persons highly dependent on medical care:
 - Intensive care
 - Neonatal intensive care
 - Terminal care

- Persons with impaired capacity to communicate
- Unconscious persons
- Specific social collectivities
- Persons in indigenous medical systems
- Emergency care research
- Innovative therapy or intervention
- HIV/AIDS clinical and epidemiological research” (Adapted from: BREC SOPs, 2010; SA GCP Guidance, DoH, 2006).

Vulnerable communities means “communities which have some or all of the following characteristics:

- Limited economic development;
- Inadequate protection of human rights and discrimination on the basis of health status;
- Inadequate community or cultural experience with the understanding of scientific research;
- Limited availability of health care and treatment options;
- Limited ability of individuals in the community to provide informed consent;
- Culturally marginal groups
- Persons involved in illegal activities or livelihoods” (Adapted from: BREC SOPS, 2010; SA DoH, 2004; UNAIDS, 2000; 2007).

APPENDIX B

HSSREC Confidentiality Agreement

CONFIDENTIALITY AGREEMENT

FOR MEMBERS OF THE

UKZN HUMANITIES AND SOCIAL SCIENCE RESEARCH ETHICS COMMITTEE (HSSREC)

I the undersigned _____ (hereinafter referred to as “the HSSREC Member”) with physical address at _____

HEREBY AGREE TO THE FOLLOWING:

- A. The UKZN HSSREC is a body constituted by appropriately qualified professionals tasked with the reviewing of novel proposals for research which is to be conducted on/or with human participants and/or animals.
- B. The work of the UKZN HSSREC is the scientific evaluation and systematic review of the ethical status of the research related actions of researchers and/or clinicians within the framework of health care.
- C. The Members of the UKZN HSSREC, supporting Administrative staff and ad hoc attendees hereby agree to be bound by the provisions of this Agreement for the duration of their service to and on the UKZN Research Ethics Committee as well as beyond the confines of the HSSREC Member’s obligations to the UKZN HSSREC and without limit in time.

1. INTERPRETATION

Unless the context indicates the contrary:

- 1.1 “Confidential Information” shall mean certain proprietary or confidential information which the UKZN HSSREC member acknowledges to be confidential. Such information relates to all trial protocols relating either to research on human participants, and associated documentation. The Confidential Information may be conveyed in written, graphic, oral or physical form including (but not limited to) scientific knowledge, know-how, processes, inventions, techniques, formulae, products, business operations, patient requirements, designs, sketches, photographs, drawings, specifications, reports, studies, findings, data, plans or other records, biological materials, and/or software.
- 1.2 “Results” shall mean all results obtained and conclusions reached during the contingency of the Project and the Main Agreement.

2. CONFIDENTIALITY

- 2.1 The HSSREC Member undertakes in favour of the others that he/she will treat as confidential all information labelled as confidential information including all results generated from any proposal and/or project, including any and all information whether of a technical or scientific nature or otherwise relating to all research proposals reviewed by the UKZN HSSREC as a whole or communicated to him/her hereunder or otherwise in connection with the HSSREC Member's role on the UKZN HSSREC. The HSSREC member agrees that he/she will not disclose such information to any person, any legal entity, or to the media, and will not use such information other than for the purposes of this Agreement, subject to any prior specific written authorization by the other members to such disclosure or use.
- 2.2 Confidential information shall not include:
- (a) Information which at the time of disclosure is published or otherwise generally available to the public, or later becomes generally available to the public otherwise than through any act or omission on the part of the HSSREC Member; or
 - (b) Information which the HSSREC Member can show by written records and to the satisfaction of the Disclosing Party, was in his/her possession at the time of disclosure and which was not acquired directly or indirectly from the Disclosing Party; or
 - (c) Information rightfully acquired from a *bona fide* third party who did not obtain it under pledge of secrecy to the disclosing Party; or
 - (d) Information which is or had been independently generated or developed by the HSSREC which can be shown by written records and to the satisfaction of the Disclosing Party; or
 - (e) Information which is required to be disclosed by law or a valid order of a court of competent jurisdiction or the request of any governmental or other regulatory authority, in which event the parties hereto shall use their best endeavours to seek confidential treatment of such information.
 - (f) Information released to specified parties by or after consultation with the Chair of HSSREC and any other relevant parties (e.g., Dean of Research, DVC (Research)).
- 2.3 The confidentiality obligations contained in this Agreement shall endure beyond the confines of the HSSREC Member's obligations to the UKZN HSSREC and without limit in time.

3. GOVERNING LAW

3.1 This Agreement shall be governed by the law of the Republic of South Africa. Any disputes under this Agreement shall be resolved in a court of competent jurisdiction in Durban, South Africa.

Thus read, signed and agreed:

Signed at _____ on the _____ day of _____ 201____

Full names:

Signed: UKZN HSSREC Member