



UNIVERSITY OF KWAZULU-NATAL
HUMANITIES AND SOCIAL SCIENCES RESEARCH ETHICS COMMITTEE (HSSREC)
STANDARD OPERATING PROCEDURES

1. INTRODUCTION

These Standard Operating Procedures (SOPs) outline how HSSREC conducts its activities as mandated by the current HSSREC Terms of Reference (ToR).

2. HSSREC MEETINGS

Meetings will be held once a month for 12 months of the year. A schedule of meeting dates and deadlines for submission for any given year will be circulated to Committee Members and placed on the UKZN HSSREC web page by the second week of January each year. The minutes of meetings and the agenda will be 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. THE COMMITTEE

3.1. ROLE OF THE HSSREC COMMITTEE

A basic requirement of HSSREC shall be to conduct independent ethics review to foster confidence that approved research protocols are ethical ('Independent ethics review' means that members of the REC are encouraged to be objective, informed and to act without fear or favour when conducting scientific and ethical reviews). As per the 2024 NHREC Guidelines, the independence of RECs means that the committees must be free to do their work as described in these guidelines and the governing statutory frameworks, without interference from others within the institution or entity. The primary responsibility of each HSSREC member is to ensure that the review of the proposed research aligns with this independence and adheres to exemplary standards in research activities.

UKZN recognizes that HSSREC has a dual governance model, in that it is an institutional committees and is expected to comply with

- 1) with the usual institutional committee reporting lines and
- 2) national compliance in line with statute and associated regulations and national

guidelines.

UKZN is mindful of the need for HSSREC to develop institutional memory amongst the membership as well as to ensure succession planning. Members of HSSREC are appointed formally for periods of three years, renewable once, after which the member should step down for at least one term. Appointments should overlap so that no more than half the committee membership is new at any one appointment time. This practice allows knowledge and experience to be shared appropriately, efficiently and effectively amongst new appointees.

3.2.MEMBERSHIP COMPOSITION

The composition of HSSREC shall be in accordance with the provisions of the National Health Research Ethics Council (2024) South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 3rd ed. National Department of Health of the Republic of South Africa. Pretoria: NDoH (2024 NHREC Guidelines).

To review and evaluate the scientific, legal, psychosocial and ethical aspects of research proposals, HSSREC shall comprise of independent, multi-disciplinary professionals and lay persons with diverse ethnic, cultural and gender representation, with collective qualifications, experience and expertise, including research ethics training, The total number of Committee members must be no less than 10 (ten). HSSREC members and researchers are expected to familiarise themselves with the institutional documentation as well as the national and relevant international research ethics guidelines and should have documented proof of such familiarity e.g., an assessment of training certificate, not a mere attendance certificate.

3.2.1. APPOINTMENT OF THE CHAIRPERSON

The Chairperson of HSSREC, who shall be a member of the University, shall be appointed by and report to the Deputy Vice Chancellor (DVC) of Research for a renewable term of three years. The Chairperson must have experience in research methodology and research ethics, should have at least two years' experience as an REC member and should have leadership experience.

3.2.2. APPOINTMENT OF THE DEPUTY CHAIRPERSON(S)

The Deputy Chairperson(s), who is/are member(s) of the University, shall be elected by the HSSREC members and be expected to assist the Chairperson with responsibilities and inter-meeting matters, as well as to step into the role of Chairperson, when necessary.

3.2.3. APPOINTMENT OF MEMBERS

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.

3.2.4. 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 (ten) members, with a simple majority constituting a quorum;
- Have a chairperson and a deputy-chairperson(s).
- 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.
- All committee members must receive initial and ongoing training in research ethics and committee work.

3.2.5. QUORUM/VOTING

- HSSREC membership should consist of at least 10 (ten) members
- A minimum of nine members with a quorum being a simple majority;
- At least one layperson and at least one member with knowledge of, and current experience in the professional care, counselling, or health-related treatment of people, e.g., a social worker, nurse, psychologist, or medical practitioner, at least one member with professional training and experience in qualitative research methodologies, members with professional training and experience in quantitative research methodologies, a member with expertise in biostatistics, a member with expertise in research ethics, a member who is legally qualified;

- 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.

3.2.6. CONFLICT OF INTERESTS

HSSREC members shall declare any prior information and/or interest /involvement that may lead to potential, actual or perceived conflict of interest in any matter being discussed by HSSREC and HSSREC decision-making, including reviewing of protocols at each meeting. HSSREC members shall not review or make decisions about research protocols which they are involved in personally or financially (including as a supervisor or student). In convened HSSREC meetings the member will be recused from discussion of conflict of interests items.

3.2.7. CONFIDENTIALITY

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).

4. REVIEW PROCEDURES

4.1. PROTOCOL SUBMISSION

In line with the 2024 NHREC Guidelines, HSSREC SOPs clarify the expectation about research submissions. It is important to note that UKZN student researchers must always be supervised by a Supervisor within UKZN. Students from abroad (foreign), registered with UKZN as a student, must also be under the oversight of Supervisor within UKZN. It is the responsibility of the Supervisor to sign off on research protocols and research ethics review applications, accepting responsibility ensuring compliance with research integrity and ethical conduct by the student.

All researchers must ensure that the information about the research is explained in the proposed research in plain local language(s), including ethical implications of the research, to aid a systematic and standardised review process. Research ethics applications must provide adequate evidence of consideration for participant wellbeing, safety and human rights. Within the research environment the attributes of Ubuntu should be pursued, together with the research integrity core values of scientific merit, openness, distributive and social justice, care, beneficence and nonmaleficence. The ethics review and oversight processes must protect the rights, safety and welfare interests of participants involved in research, particularly vulnerable participants; as well as the safety and other interests of researchers. It is expected that all researchers who conduct research within UKZN and in South Africa comply with these guidelines.

The following document/s from the researcher, using a standard checklist before uploading to the UKZN RIG system:

- Current HSSREC application form(s)
- Study protocol(s)
- Research community settings (with evidence of community engagement)
- Written informed consent form(s) (ICF)
- Written information to be provided to participants
- Participant/patient Information sheets (PIC) which anticipates literacy levels and readability
- Research Instruments
- Participant recruitment procedures (e.g., posters, social media posts)
- Safety information
- Gatekeeper letters
- Any other documents that HSSREC may need to fulfil its responsibilities.
- Researchers must disclose potential, actual or perceived conflicts of interest (financial or personal)
- Ethics Training Certificates for researchers and supervisors
- Proof of review of protocol at School level

4.2. PROTOCOL REVIEW

4.2.1. ETHICAL FRAMEWORK FOR REVIEW

In general terms, HSSREC strives for improvements in efficiencies, e.g., streamlining review processes, considering use of new technologies to improve review and approval cycles. The ethical issues in the research application often require case-by-case deliberation, following independent review by more than one HSSREC member and as such is not a tick-box or mechanical process.

The review of protocols will be informed by the ethical principles which guide the planning, designing, and conducting of the research. Emanuel,., Wendler and Grady (2008) identify eight ethical principles, namely, collaborative partnership, social value, scientific validity, fair participant selection, favourable risk-benefit ratio, independent ethics review, informed consent and respect for informants. These principles serve to inform social science research.

4.2.2. REVIEW PROCEDURES

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

4.2.2.1. EXEMPTION FROM ETHICAL REVIEW

It is important to note that research that relies exclusively on information that is publicly available and does not require gate keeper permission, site/platform permission/accessible in terms of legislation or regulation may, need to undergo formal ethics review, depending on ethical considerations relevant to the research.

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 (including virtual) space, or natural environments). However, the researcher

1) must not interact with the individuals/groups; or

2) does not stage any intervention; or

Individuals/groups have a reasonable expectation of privacy. Importantly, if publication of such studies is intended/anticipated/desirable, it is prudent to obtain ethical approval prior to study commencement. RECs cannot grant retrospective ethics approval.

4.2.2.2. EXPEDITED REVIEW PROCESS

It is important to note that expedited review is not that same as rapid review. In principle, HSSREC may use the expedited review procedure in the following circumstances:

- (1) The research is deemed to pose no more than **minimal risk of harm** (Appendix A), where no fewer than two REC members review the protocol and that deliberation in the full REC meeting is waived, unless the reviewers believe there are issues that the full REC should discuss.
- (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 Chairperson or by one or more experienced reviewers designated by the Chairperson 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). The outcomes of the expedited review process must be reported to the full REC, at least by being noted on the agenda, so that the record is complete.

4.2.2.3. 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 HSSREC 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 HSSREC
 - not approved: The research ethics committee requests major revision in the proposed study. A re-submission of the research protocol is required.
 - Rejection: The study is not accepted by the research ethics committee and the ethics application is closed.
- Reasons for provisional approval, non-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.

4.2.2.4. 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.

Considerations when reviewing research protocols involving minors.

When reviewing protocols involving minors (i.e., individuals under the age of 18), HSSREC must ensure that the inclusion of minors (children or adolescents) is both scientifically necessary and ethically justified. Minors (i.e., children or adolescents under the age of 18 years) may not independently choose whether to participate in research. The legal status of a minor and its implications for the informed consent process must not be ignored and reviewed carefully in the research ethics review. The parent or guardian must give permission for the minor to choose. This is because young persons' understanding of key aspects of the research initiative may be compromised and, consequently, they may be exposed to increased risk of harm from specific research procedures, without realising it could happen.

In line with 2024 NHREC Guidelines, minors' participation in research should be approved only if the following key considerations have carefully guided the ethics review process:

Scientific justification for inclusion –

Minors should only be included as research participants when their participation is scientifically indispensable to the research. This means that:

- The research must investigate a problem relevant to minors.
- It follows that where research can be done with consenting adults but nevertheless proposes also to include minors, researchers must provide strong and clear justification for the inclusion of minors. The research protocol must clearly and sufficiently justify the inclusion of minors and provide evidence that their participation is essential to achieving the research objectives.

Risk assessment

Children and adolescents should participate in research only where such research poses acceptable risks of harm. That is, research involving children and adolescents should be approved only if:

- i. the research, **including observational research**, is not contrary to the best interest of the minor (child or adolescent), and
- ii. the research, **including observational research**, places the child or adolescent at no more than minimal risk of harm, where the probability and magnitude of possible harms implied by participation are not greater than those posed by daily life in a stable society or routine medical, dental, educational, or psychological tests or examinations; or
- iii. the research involves greater than minimal risk of harm but provides the prospect of direct benefit for the child or adolescent.

The degree of risk of harm should be justified by the potential benefit; or the research, including observational research, involves greater than minimal risk of harm, with no prospect of direct benefit to the child or adolescent, but has a high probability of providing significant generalisable knowledge. The degree of risk of harm should be justified by the risk-knowledge ratio.

Greater than minimal risk of harm should represent no more than a minor increase over minimal risk.

Permission for minors to participate in research must be obtained from the parents or legal guardian and the minor's assent. 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.

The Protection of Personal Information Act 4 of 2013 (POPIA) applies where information about a minor (under 18 years) is to be processed, permission of a parent or guardian is required before collection (section 35(1)(a)), even when permission of a parent or guardian is not required for the activity that gives rise to the information, e.g., donating blood. A minor aged 16 years or more may donate blood without parental permission, but POPIA requires parental or guardian permission to process the minor's information.

4.2.3. CONTINUING REVIEW PROCEDURES

4.2.3.1. 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.

4.2.3.2. 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.

4.2.3.3. 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.

4.2.3.4. 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 3.2.3.1 above for recertification.

4.2.3.5. 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.

5. MONITORING

HSSREC has the right to monitor the research it approves. Researchers are expected to provide appropriate information to the HSSREC to facilitate monitoring, including alerts and investigator brochures. The frequency and type of monitoring should reflect the degree and extent of risk of harm to participants.

Monitoring types include passive and active measures. Whilst it stands to reason that monitoring can take different forms, active monitoring requires a site visit, whilst passive monitoring is generally paper-based, using reports and other information. A site visit is

expected also for investigation of adverse events, serious adverse events for high-risk research, as well as other occurrences that prompt concerns for HSSREC.

A site visit could include an evaluation of the protocol and investigational plan's adherence to the REC-approved research protocol:

- application of the study selection criteria (inclusion and exclusion criteria)
- documentation of the informed consent process
- type of data collected
- date of enrolment for the study participants
- documentation of adverse and serious adverse events
- evidence of HREC-approved amendments to the study
- any protocol deviations
- date of most recent certification
- application of the data management plan (data security and confidentiality).

Such an evaluation would include criteria for categorising the findings, such as

- excellent
- acceptable; no serious or urgent concerns
- minor concerns requiring attention
- serious concerns about participant safety/animal welfare/protocol adherence

HSSREC shall ensure that appropriate feedback is given to the PI, with an opportunity to address any identified gaps within a negotiated timeline. HSSREC may recommend and adopt any additional appropriate mechanism for monitoring, including random inspection of research sites, welfare monitoring sheets, data and signed consent forms, and records of interviews. Information and consent materials should indicate that such monitoring may take place. HSSREC will inform PIs in writing of concerns arising from such monitoring activities.

6. COMPLAINTS BY INVESTIGATORS

Principal Investigators should seek to resolve complaints with HSSREC procedures or decisions informally through the Chairperson 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/>).

7. WHISTLE BLOWING AND COMPLAINTS

UKZN staff, students, HSSREC members, study participants and any stakeholders who have a reasonable belief that ethics irregularities have occurred or are likely to occur that may negatively affect either the research participants or study outcomes, must report.

Apart from grievances that should be reported following the procedure set out in section 5 above, if a complainant does not wish to direct a complaint through the channels outlined above and would like to remain anonymous this can be reported through the Fraud and Ethics Hotline XXXX which is available to all UKZN stakeholders and allows for anonymous disclosures.

This can be done either:

Telephonically by dialling Toll-free: 0800 203 285

By sending an e-mail to: ukzn@tip-offs.com

Through post by sending the letter to:

Tip-offs Anonymous, FreePost KZN 138, Umhlanga Rocks, 4320 ·

8. RESEARCH MISCONDUCT

(See UKZN Research Ethics Policy V)

Research misconduct encompasses *inter alia*:

- 4.3. Failure to submit a protocol for ethics approval in term of this document.
- 4.4. Fabrication, falsification, plagiarism in proposing, performing, reviewing or reporting of research.
- 4.5. Deviation from or failure to adhere to the approved protocol without prior formal approval from HSSREC.
- 4.6. Misrepresentation of data and/or interests and/or involvement.
- 4.7. Falsification of credentials.
- 4.8. Deception in the research proposal.
- 4.9. Non-approved deception in the carrying out of research.
- 4.10. Piracy of materials.
- 4.11. Failure to follow accepted procedures to exercise due care in avoiding unreasonable harm or discomfort to participants or research staff.
- 4.12. Failure to obtain voluntary and informed consent.
- 4.13. Breach of confidentiality.
- 4.14. 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.

9. 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).

10. SELECTED REFERENCES

Biomedical Research Ethics Committee (BREC) (2010). *Terms of reference and standard operating procedures*. University of KwaZulu-Natal, Durban, South Africa.

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- University of KwaZulu-Natal (2007). *Research Policy V. Research Ethics*.
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- 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).

Vulnerability may be due to limited decision-making capacity, or limited access to social goods, such as health care, education, or social support experienced in varying degrees at different times. **Participants requiring careful consideration** where appropriate, may require additional precautions and protection measures are put into place so that adequate protection of their rights and welfare interests. **Research participants** who fall into one or more of the following categories:

- Minors: Children and adolescents (below the age of 18 years)
- Women: Women and Pregnancy
- Persons with mental disabilities
- Persons who may be legally incapable
- Persons who may be factually incapable or less capable of understanding and processing information to make an informed decision (diminished capacity)
- 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
- Students
- Persons highly dependent on medical care: Intensive care
- Neonatal intensive care
- Terminal care
- Persons with impaired capacity to communicate, or with visual, auditory or mobility impairments
- Unconscious persons
- Elderly persons
- Specific social collectivities
- Persons in indigenous medical systems
- Emergency care research
- Innovative therapy or intervention
- HIV/AIDS clinical and epidemiological research” (Adapted from: BRECSOPs, 2010; SA GCP Guidance, DoH, 2006).

Vulnerable communities means communities which have some or all of the following contextual factors associated with:

- Limited economic development;
- Low levels of formal education or literacy
- 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 and/or access to 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: BRECSOPs, 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.

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.

CONFIDENTIALITY

- 1.3 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.
- 1.4 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)).
- 1.5 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.

GOVERNING LAW

1.6 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:
