University of Fort Hare
Together in Excellence

TITLE: STANDARD OPERATING PROCEDURES: University Research Ethics Committee (UREC) Inter-Faculty Research Ethics Committee (IFREC)			
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IMPLEMENTATION RESPONSIBILITY: Director: Research and Innovation; Deputy Vice Chancellor: Research, Partnerships and Innovation			
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TO BE READ IN CONJUNCTION WITH THE FOLLOWING Documents: • University Research Ethics Policy; • University Research Ethics Committee (UREC) Terms of Reference • Inter-Faculty Research Ethics (IFREC) Terms of Reference			

APPROVED BY:

Name: Prof. Sakhela Buhlungu

9 December 2022
Date

DESIGNATION: Vice Chancellor and Senate Chair
UNIVERSITY OF FORT HARE

1. INTRODUCTION

The overarching objective of these Standard Operating Procedures (SOPs) is to ensure that ethically responsible research is conducted at the University of Fort Hare (UFH), including in the humanities, social, behavioural, economic and educational sciences. The specific objective of these SOPs is to set out the procedures for consistency and quality in reviewing and responding to all applications for ethical clearance in research by the University Research Ethics Committee (UREC) [excluding those submitted to the Animal Research Ethics Committee (AREC) and the Health Research Ethics Committee (HREC)]. This document also sets out the SOPs for the Inter-Faculty Research Ethics Committee (IFREC), which is a sub-committee of UREC with Senate-approved delegated authority[1].

2. DELEGATION OF AUTHORITY

The Senate has, in establishing IFREC, granted UREC the authority to delegate certain authority to IFREC. IFREC will operate as a sub-committee of UREC.

UREC is the registered authority with the National Health Research Ethics Council (NHREC) and will be the authority that issues ethics clearance certificates.

The NHREC registration number for UFH UREC is REC-270710-028.

3. THE PURPOSE OF UREC and IFREC

3.1 The Purpose of UREC

The purpose of UREC, which is a standing committee of Senate, is to protect the dignity, rights, safety, and well-being of all human participants in research. UREC will do this by ensuring that independent, prospective and ongoing research ethics reviews take place for all research projects undertaken by members of staff, registered students and by affiliates of UFH (excluding research ethics applications submitted to HREC and AREC).

3.2 The Purpose of IFREC

To facilitate efficient, independent, competent, and timely reviews of the ethical risks related to research proposals. Senate has approved delegation of authority to a sub-committee of UREC, namely the Inter-Faculty Research Ethics Committee (IFREC), to review and

[1]Senate delegation approved 5 September 2019

process all applications for ethical approval from the Faculties of Humanities and Social Sciences; Education; Law; Science and Agriculture; and Management and Commerce on behalf of UREC. IFREC (functioning alongside AREC and HREC), derives its authority from UREC, and can recommend measures aimed at mitigating ethical risks and can also require that certain measures be taken by researchers to minimise or avoid potential ethical risks in theirresearch.

IFREC's purpose is to centralise the research ethics review processes to ensure quicker turnaround times for ethics approvals. The three ethics committees, IFREC, together with the independently accredited AREC and HREC, comprehensively provide for all research at UFH to undergo ethics approval processes. IFREC may refer difficult/problem research ethics cases to UREC; and IFREC decisions which are appealed, will be tabled and considered by UREC; as will amendments to previously approved research protocols.

4. SCOPE OF UREC AND IFREC

These standing operating procedures (SOPs) apply to any research undertaken by students or staff of the University and must be submitted for research ethics review to UREC (except for applications for research ethics approval submitted to HREC and AREC). However, by virtue of Senate delegated authority from UREC to IFREC, IFREC serves as the central ethics application body of UREC for the Faculties of Humanities and Social Sciences; Education; Law; Science and Agriculture; and Management and Commerce as well as UFH affiliated centres, units or institutes.

UREC will review applications for ethical clearance referred by IFREC, appeals, amendments to previously approved research protocols; and review applications from external researchers intending to conduct research in the University.

The responsibility to submit research proposals to UREC via IFREC, lies with the researcher, supervisor and departmental head, and where relevant, the faculty in which the research originates.

These SOPs apply, irrespective of the levels of ethical risks and vulnerability of researchparticipants involved.

When reviewing research proposals, special attention will be given to research that includes certain individuals or categories of participants who may be vulnerable to undue influence and/or duress (for example, the poor and the marginalised, pregnant women, children,

people with disabilities, people in prison, refugees, the elderly, people in hospital, people attending a clinic).

5. CONSTITUTING UREC AND IFREC

5.1 The Composition of UREC

The composition of UREC is in accordance with DoH 2015 Guidelines as far as is relevant to the humanities and social sciences.

Members of UREC should collectively have the qualifications, experience and expertise to evaluate the scientific, legal, psychosocial and ethical aspects of research proposals and appeals received from the IFREC.

The Deputy Vice-Chancellor: Research, Partnerships and Innovation is appointed by the Senate as Chairpersonof UREC. The Chairperson of UREC reports to the Senate. The following applies in the composition of UREC:

- Members of the UREC are appointed for a period of five (5) years;
- Members of the UREC can be re-appointed for a second (2^{nd}) and subsequent third (3^{rd}), five (5)-year term consecutively;
- UREC must have one layperson who is from the communities in which the university is located or conducts its research and who are not currently involved in medical, scientific or legal work.
- UREC should increasingly reflect the demographic profile of the population of the Republic of South Africa;
- Both male and female members are required, the ultimate goal being not to have one sex holding more than70% representation
- The total number of members must be no less than 10, including the Chairperson;
- It is permissible for the University of Fort Hare to pay external members of the committee sitting allowances if that is necessary to ensure compliance with the mandatory minimum composition stipulated by the Department of Health 2015 Guidelines and by the National Health Research Ethics Council. The amount to be paid as sitting allowance per external member shall be determined by the three UFH Ethics Committees and approved by UREC. The sitting allowance shall be reviewed annually taking into account budgetary

implications for UFH and rates prevailing at other institutions.

Membership of UREC

- Deputy Vice Chancellor: Research, Partnerships and Innovation (Chairperson)
- Chairperson of the Inter-Faculty Ethics Committee (IFREC) – Director: Research and Innovation
- Chairpersons of HREC and AREC or their nominees
- The Faculty Deans / Deputy Deans (Research) (or nominee) (6)

- At least one (1) layperson from the community where the University is located or conducts its research
- Two (2) senior academic members of staff nominated by Senate with knowledge of, and current experience in, areas of research that are likely to be regularly reviewed by the IFREC and ratified by UREC as the overseer of Research Ethics at the University
- One (1) member with knowledge of, and current experience in, the professional care, counselling or treatment of people. (For example, a medical practitioner, psychologist, social worker or nurse.)
- At least one (1) member who has professional training in both qualitative and quantitative research methodologies
- One (1) member who is legally trained

UREC has the authority to appoint, from time to time, a standing or ad hoc subcommittee to investigate or finalise certain matters under its jurisdiction, in compliance with applicable norms, rules and regulations.

5.2 The composition of IFREC

IFREC members are appointed through a transparent and inclusive recruitment process by UREC. UREC will put out a call for nominations for IFREC. In constituting IFREC, criteria such as research standing, research ethics experience and ethics training as well as diversity in member are to be considered. Both males and females are required, the ultimate goal being not to have one sex holding more than 70% representation.

The chairperson of IFREC, who is the Director of Research and Innovation, reports to the chair of UREC (Deputy Vice-Chancellor: Research, Partnerships and Innovation, with responsibility for the University research portfolio).

Members of IFREC are appointed for a period of five years. Members can be re-appointed for a second (2nd) and subsequent third (3rd), five-year term consecutively.

If a member wants to step down from the committee, s/he should give at least 3-months-notice through the Chair of IFREC in order to enable a replacement to be appointed,

Membership of IFREC

- The Director of Research and Innovation (Chairperson)
- One (1) representative nominated from each of the following Faculties: Humanities and Social Sciences; Law; Education; Science and Agriculture; and

Management and Commerce. (Each Faculty to nominate a representative and an alternate)

- One (1) layperson from the community where the university is located or conducts its research
- A member with legal training
- At least one (1) member who is professionally trained in qualitative and quantitative methodologies

IFREC may co-opt members for specialist inputs, provided any such members are first approved by UREC.

5.3 Appointment of Members of UREC and IFREC

The members of UREC are appointed by Senate as per approved composition set out in the UREC Terms of Reference.

Members of IFREC are appointed by UREC according to the approved composition set out in the IFREC Terms of Reference.

Members of UREC or IFREC will have undergone research ethics training. Deans or Deputy Deans (Research) may nominate appropriate alternate members from their Faculty if they do not have the requisite research ethics training.

6. FUNCTIONING OF UREC AND IFREC

In executing its duties UREC and IFREC will ensure that standard practices and procedures are followed to mitigate bias and undue influence that could compromise its independence in decision-making.

In its structure and functioning, and in the execution of their duties, UREC and IFREC willfollow:

- the principles and guidelines stipulated in the National Health Research Ethics Council (in so far as it is relevant to research in the social sciences and humanities); and
- any official documents of professional bodies, scientific organisations or relevant legislation, regulations and guidelines, including international guidelines and standards in so far as they are applicable to research in the social sciences and humanities.

6.1 Meeting Procedures for UREC

6.1.1 UREC will make its decisions at scheduled meetings once each quarter, as an Ordinary meeting, and as a Special meeting, if required, as per Senate rules.

6.1.2 Meetings will only be conducted when a quorum is present. The quorum is a simple majority.

6.1.3 Decisions will be determined by consensus (general agreement). Where general agreement does not exist, decisions will be arrived at by majority vote.

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

6.1.5 If a member is absent from a meeting for four (4) consecutive meetings without an apology, his or her absence will be addressed by the Chairperson verbally and in writing to the specific member, after which the Chairperson can make a recommendation, and in this context, has the authority to remove a member reported as non-attending. The official recruitment process will be followed to recruit a replacement for the remainder of the disqualified member's term. Such appointment is to be made by Senate.

6.1.7 Disengagement from the UREC can be initiated by the respective Chairpersons or any other member of the UREC and must be in writing. Such disengagement from UREC must be reported to Senate;

6.1.8 Upon appointment to the UREC, new members must sign a confidentiality agreement.

6.1.9 On invitation or request, UREC meetings may be attended by registered students, researchers and other interested parties as non-voting observers, subject to the signing of confidentiality undertaking and subject also to being excluded from certain agenda items as determined by the Chairperson.

6.1.10 At the last meeting of the current year members will be notified of the scheduled dates of meetings for the following year and this information will also be placed on the website of GMRDC.

6.1.11 The meetings of UREC will be recorded by means of minute-taking and electronic recording.

6.1.12 Minutes of meetings will be included in the agenda of the next meeting.

6.2 Meeting Procedures for IFREC

6.2.1 IFREC will make its decisions at scheduled meetings once every three (3) weeks. Depending on the volume of applications for ethical clearance, it may meet more frequently.

6.2.2 Meetings will only be conducted when a quorum is present. The quorum is a simple majority.

6.2.3 Decisions will be determined by consensus (general agreement). Where general agreement does not exist, decisions will be arrived at by majority vote.

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

6.2.5 If a member is absent from a meeting for four (4) consecutive meetings without an apology, his or her absence will be addressed by the Chairperson verbally and in writing to the specific member, after which the Chairperson can make a recommendation, and in this context, has the authority to remove a member reported as non-attending. The official recruitment process will be followed to recruit a replacement for the remainder of the disqualified member's term. Such appointment is to be made by UREC;

6.2.6 Disengagement from the IFREC can be initiated by the respective Chairperson or any other member of the IFREC and must be in writing. Such disengagement from IFREC must be reported to UREC;

6.2.7 Upon appointment to the IFREC, new members must sign a confidentiality agreement.

6.2.8 On invitation or request, IFREC meetings may be attended by registered students, researchers and other interested parties as non-voting observers, subject to the signing of a confidentiality agreement and subject also to being excluded from certain agenda items as determined by the Chairperson.

6.2.9 At the last meeting of the current year members will be notified of the scheduled dates of meetings for the following year and this information will also be placed on the website of the Research Office.

6.2.10 The meetings of the IFREC will be recorded by means of minute-taking and electronic recording.

6.2.11 Minutes of meetings will be included in the agenda of the next meeting. Once confirmed they will be forwarded to UREC for tabling on the UREC Agenda.

6.3 Induction and Training

6.3.1 All new UREC and IFREC members are required to familiarise themselves with the contents of the University's Govan Mbeki Centre for Research and Development Centre (GMRDC) Website where they can access the policies, SOPs and any other relevant documentation of the UREC and IFREC;

6.3.2 All UREC and IFREC members will be required to have continuous personal development in research ethics as stipulated by the National guidelines.

7. APPLICATION REQUIREMENTS FOR UREC AND IFREC REVIEW

Applications for research ethics reviews will be conducted by IFREC on behalf of UREC.

UREC will review applications for ethical clearance which are referred from IFREC, as well as consider appeals on IFREC decisions. UREC will also review applications for ethical clearance from external researchers seeking to undertake research in the University.

Requirements for submitting an application to the UREC or IFREC include the following aspects.

For an ethical clearance application to be reviewed, the following documentation is required:

- A fully completed Research Ethics Application Form dated and signed by the Researcher and Supervisor (if applicable); and
- A research proposal together with supporting documents.

The Application Form should include:

7.1 A summary, synopsis, or diagrammatic representation of the research process;

7.2 Research instruments; (i.e. Interview schedules, questionnaires and observation schedules intended for research participants and, when required), should be translated into other languages relevant to the research;

7.3 An overview of the process that will be used to recruit potential participants, when applicable (i.e. how, where and by whom will prospective participants be approached).

7.4 A description of the process as set out in *Ethics in Health Research: Principles, Processes and Structures* (2015) be used to obtain and document free and informed consent (required when human research participants, institutions or organisations are involved), taking into account that:

- Written and other forms of information for potential research participants in the language(s) understood by the potential research participants and, when relevant, in other languages;
- Informed Consent Form in the language(s) appropriate to the potential research participants and, when relevant, in other languages;

7.5 A statement describing any incentives for participation in the research;

7.6 A description of the arrangements to ensure that there will be no unauthorised access to research data (i.e. how the data will be kept safe); and

7.7 A description of what will happen to the data after completion of the research, including any archival storage, in an appropriate medium.

8. THE FULL UREC AND IFREC REVIEW

8.1 Elements of the Review

Reports on ethics applications received, reviews which have been conducted by IFREC and decisions made are recorded and the confirmed minutes of IFREC meetings will be tabled by the Chairperson of IFREC at UREC meetings.

All research protocols to be reviewed by IFREC must be submitted to the designated administrators in the Govan Mbeki Research and Development Centre (GMRDC) offices at least three (3) weeks before the IFREC meeting.

8.1.1 The IFREC Processes:

- Two (2) IFREC administrators from the Research Office shall receive and co- ordinate all applications for ethical clearance and do an initial screening for completeness of documents
- The IFREC committee will meet once every three weeks
- For an application to be considered at an IFREC meeting, it must be received by members at least 7 working days before a meeting
- Prior to making a recommendation, IFREC will review ethical clearance applications, research proposals, research instruments, consent forms, conflict of interest forms and/or any other relevant research documentation.
- Ethics clearance for a particular project will not be considered without the completed protocol and the research proposal; but where other documents are not submitted, IFREC if satisfied with the applicant's reasons for not submitting the required documentation, may consider granting provisional clearance pending the submission of particular documentation.

- IFREC will determine one of the following outcomes for a research ethics application:
    a) Grant clearance;
    b) Recommend that clearance be granted subject to certain specified conditions;
    c) Decline to make a recommendation and refer the application back to the applicant, with reasons for the decision and suggested amendments on how to meet the requirements of this policy;
    d) Decline to grant clearance (reject an application), with valid reasons for the rejection;
    e) Require a project to be monitored in a specific manner; or
    f) Refer the application to UREC for a decision, if- the committee is not able to make a decision.
- All IFREC decisions/recommendations must be recorded in its minutes and the Chairperson must within 5 working days complete, in respect of each application, an ethical clearance application cover sheet which records the outcome/decision.
- The decision signed by the chairperson of IFREC should be sent electronically to the applicant within 7 working days of the date of the IFREC meeting.
- An ethical clearance certificate should be prepared in respect of each successful application for the IFREC and UREC Chairpersons' signatures; and sent to applicants within 14 working days of the IFREC decision.
- The GMRDC administrators tasked with the administration of IFREC shall forward the signed ethical clearance certificates to the applicants and, where applicable, supervisors. (Principal investigators have the right to re-apply for ethics approval in instances where applications have been refused, withdrawn or suspended, which will be considered by UREC)
- Where a matter has been referred back and an applicant is unable to agree to the IFREC recommendations, or where an applicant wishes an IFREC decision to be reviewed, the matter shall be referred for appeal to the UREC, whose decision shall be final.
- Any applicant aggrieved by a decision of IFREC may appeal to UREC.
- Should any member of the IFREC disagree with a majority decision, that fact should be recorded and made known to the UREC; and any dissenting member may provide the UREC with reasons for such dissent
- IFREC shall record and retain on file all documentation submitted to and/or considered by the IFREC.
- IFREC must utilise approved documentation (application forms, guidance documents, information and consent documentation, etc. as per Appendices) to facilitate processing of applications and in responding to applicants.

- IFREC shall table review reports and minutes at meetings of UREC.

8.1.2 The UREC Processes

- A dedicated Committee Officer in the Office of the Registrar will be tasked with the administration of meetings of UREC and shall coordinate all documents received from IFREC. The Committee Officer will receive training in the ethics review procedures and work closely with the IFREC administrators in GMRDC.
- UREC will deal with any cases referred from IFREC and external applications. UREC will review ethical clearance application, research proposals, research questionnaires, consent forms, conflict of interest forms and/or any other relevant research documentation.
- UREC will consider appeals submitted in relation to IFREC decisions
- Ethical clearance for a particular project will normally not be considered without the completed protocol, the research proposal and request/recommendation from IFREC.
- The UREC will make one of the following decisions:
    a) Grant ethical clearance
    b) Grant ethical clearance subject to certain specified conditions
    c) Decline granting of ethical clearance and refer the application back to the applicant, with reasons for the decision and suggested amendments on how to meet the requirements of this policy
    d) Request Principal Investigators to make representations to the UREC in order to provide information which may assist UREC in making an informed decision about the proposed research protocol
    e) Specify methods of reporting progress.
- All UREC decisions must be recorded in its minutes.
- The UREC administrator must within seven (7) days of a UREC decision:
    a) Communicate in writing with the applicant and, where applicable the supervisor, as well as the Chairperson of the IFREC to inform them of the UREC decision, and the reasons for that decision.
    b) Prepare an ethical clearance certificate in respect of each successful application/appeal for the UREC Chairperson's signature.
    c) The UREC administrator shall forward the signed ethical clearance certificates to the applicants and, where applicable, supervisors.
- The UREC Committee Officer shall retain on file all documentation submitted to and/or considered by the UREC, as well as records of all UREC decisions.

8.2 Criteria for review of projects

8.2.1 Social and scientific value of project

UREC and IFREC must consider the research project to have relevance to the community involved and/or the greater South African and African community.

8.2.2 Scientific validity

UREC and IFREC must ensure that the proposed research is scientifically valid. (Research participants and volunteers may not, ethically, be exposed to potential risks and burdens where the project will not generate the intended knowledge). This requirement includes ensuring that the researchers are suitably qualified to undertake the research.

8.2.3 Risk-benefit ratio of project

In order to approve research covered by this policy, IFREC shall determine that all of the following requirements are satisfied:

- Risks to participants are minimised:
    - Using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and
    - Whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
- Risks to participants must be reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, IFREC shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research). IFREC shall not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among the research risks that fall within the purview of its responsibility.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants

8.2.4 Fair selection of research participants

- Selection of participants is equitable. In making this assessment IFREC shall take into account the purposes of the research and the setting in which the research will be conducted and shall be particularly cognisant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women,

mentally disabled persons, or economically or educationally disadvantaged persons.

- When some or all of the participants are likely to be vulnerable to undue influence or coercion, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants.

8.2.5 Informed consent processes

- Informed consent will be sought from each prospective participant or the participant's legally authorised representative, in accordance with, and as required by Section 7 of this document.
- Informed consent will be appropriately documented, in accordance with, and as required by the University Research Ethics policy.

8.2.6 Respect for participants

- The research protocol demonstrates respect for participants throughout the course of the project e.g. there are adequate provisions to protect the privacy of participants and to maintain the confidentiality and security of data. Participants may withdraw from the study at any time without prejudice etc.

8.2.7 Respect for communities

- The proposed research demonstrates respect for communities by appropriate community interaction and feedback of results.

Additional points of note:

- All international collaborative research will have a local PI.
- Studies that have a clinical component, where the PI is not a clinician, s/he should appoint an HPCSA-registered clinician as a co-investigator to the study.

8.3 Expedited Review

- A new research study may be considered suitable for a “fast track” ethical review process only if it involves “minimal risk” research: Minimal risk means the probability and magnitude of harm or discomfort anticipated in the research, is 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.
- An expedited ethical clearance process may be followed in the following instances:
    a) Where the research involves desktop, library work or laboratory work only.

b) Where data will be collected but not from human participants or animals.
c) In exceptional cases, where it is in the public interest to expedite the process.
d) Minimal risk research, for the purposes of a degree or diploma (under or post graduate)
e) When an investigator specifically motivates for and justifies a "fast track" approval process.
f) Any minimal risk project identified as suitable by the chairperson or any other person delegated by the chairperson for this purpose.

- Expedited reviews may not be followed where the research involves human health related matters and/or animals, children and/or individuals identified as vulnerable.

Process

a) Applications for expedited review shall be submitted to the IFREC and shall be recorded in the usual manner.
b) The chairperson of IFREC shall assess with a minimum of two IFREC members from faculties (other than the faculty from where the requests emanates) whether or not the application process could be expedited. The latter could be done electronically by round robin. If there is a lack of consensus, they shall request a ruling from the UREC Chairperson.
c) Where an expedited process is appropriate, the IFREC administrators will forward electronic versions of the application to members of IFREC and a decision can be made via round robin.
d) The final outcome/decision can be made by a simple majority of members.
e) Should an IFREC member object to a matter being expedited, the Chairperson shall record that objection and the reasons therefore and thereafter may:
    ✓ Hold the matter over and place it on the agenda of the next IFREC meeting.
    ✓ Submit the matter to the UREC for a decision.
f) Upon the required majority having been attained, the IFREC Chairperson shall within two days complete an ethical clearance application cover sheet and submit it and any additional documentation considered by the IFREC to the Research Office administrators responsible for IFREC.
g) IFREC shall record and retain on file all documentation submitted to and/or considered by the IFREC.
h) The decision should be recorded and reported on to UREC at the next meeting of UREC.
i) Upon the required majority having been attained, the IFREC Chairperson shall notify the IFREC administrators of the decision and ensure that the ethical clearance

certificate to be processed in the normal manner and the applicant informed of the decision.

j) All IFREC decisions made electronically shall be placed on the agenda of the committee meeting following that decision and formally noted in the minutes of that meeting.

The following projects are considered by UREC and IFREC to be not suitable for fast track review and should (except in exceptional circumstances) be reviewed by a full committee:

- Multi-institutional collaborative research project
- International grant funded research

9. ACTION AGAINST APPLICATION FOR RETROSPETIVE ETHICAL CLEARANCE

Under no circumstances shall research conducted at the University of Fort Hare by staff members or students be given ethical clearance retrospectively. Ethical clearance of any research project to be conducted at the University of Fort Hare must be obtained before implementation of the research project commences.

Conducting research at the University of Fort Hare without ethical clearance upfront is a research misconduct, and appropriate action against researchers who commit such a research misconduct shall be taken by relevant structures of the University.

The requirement for research to be reviewed and approved before commencement is aimed at protecting the welfare and interests of research participants, communities, animals and or the environment. This requirement applies even if the proposed research poses minimal or no risks; it is the prerogative of the relevant Ethics Committee to determine the level of risks and grant approval accordingly. If the level of risk that a research study poses is only determined after it has already been started or completed, then the participants (humans or animals) or the environment would have already been exposed to potential harm, and in the case of human participants, their autonomy would have been compromised and or their rights violated. Therefore, retrospective approval of research not only undermines the legitimacy of the Ethics Committee concerned, but also poses reputational risk for the institutions (like universities) where the Ethics Committees are based. Thus, there should never be retrospective approval, as approval must be in advance, and any research (including laboratory-based research) conducted before valid ethics approval is granted is unethical. Hence, granting retrospective ethical approval would also be unethical.

Action: research misconduct

9.1 Definitions

9.1.1 **Standard Operating Procedure:** This is a set of written instructions that give a step by step process of performing a specific activity.

9.1.2 **Valid Ethics Approval:** This is approval granted by a properly constituted and duly registered Ethics Committee before a research study is started. The Ethics Committee can be at any organisation, institution and or in another country.

9.1.3 **Application for Retrospective Ethics Approval**: An application is considered to be for retrospective Ethics approval if data were already collected for research purposes but without valid ethics approval that was granted by a duly established Ethics Committee. Ethics approval is not required for generating or gathering data for non-research purposes (e.g. data gathered during routine operational activities or processes), but use of such data for research purposes (retrospective research or secondary data analysis) requires ethics approval before utilising the data as well as permission from the relevant owners or custodians of the data.

9.1.4 **Pilot study**: a pilot study is a small study aimed at testing the appropriateness of planned methods and data collection tools of the intended larger study. A pilot study should be part of a research proposal that is submitted to an Ethics Committee and should not be undertaken before ethics approval is granted. Conducting a pilot study before obtaining ethical approval exposes participants (humans or animals) or the environment to potential risks, regardless of the fact that the study is on a smaller scale than the intended study. In the research proposal it should be stated that the methods and/or data collection tools may be amended on the basis of the findings from the pilot study, and details of such changes should be submitted to the Ethics Committee as an application for amendment.

9.1.5 **Literature review**: Literature review is a review or appraisal of research findings that are already published and are available in the public domain. Literature review is not research in itself because it is not meant to answer a research question or research questions; it is background information that highlights gaps in existing knowledge that still need to be ‘plugged’ through research. Hence, it sets the scene for the rationale for conducting the proposed research. Since most published research findings emanate from research that would have been granted ethical clearance before being conducted, and most publishers request proof of ethical clearance before publishing research findings, literature review does not have require ethical clearance before it is done.

9.1.6 **Systematic Literature Review**: Systematic Literature review is aimed at answering specific research question(s), hence it is research in its own right. The systematic literature review is a methodological approach used to answer specific research questions, hence ethical clearance must be obtained before conducting systematic literature review because it is research.

9.1.7 **Outright rejection of an application**: Outright rejection of an application for ethics approval means that the application cannot be revised and resubmitted since the rejection is on the basis of violation of the ethical principle of obtaining ethical clearance before commencing research, and not about how the application was written up.

9.2 Processing of application for retrospective ethical clearance

9.2.1 If an application submitted to the Ethics Committee is found to be for retrospective approval at the submission stage, it should still be reviewed and tabled before the Ethics Committee in accordance with the standard operating procedures for processing applications.

9.2.2 The application should be part of the agenda of a regular scheduled Ethics Committee meeting.

9.2.3 Ethics Committee members who review the application should present their comments to the committee, clearly explaining evidence from the application that indicate that the data were collected without valid ethical approval (as defined in 2.2 above) and the application is therefore for retrospective ethical approval.

9.3 Decision of the Ethics Committee and Communicating the outcome

9.3.1 The decision of the Ethics Committee shall be an outright written rejection of the application for retrospective approval.

9.3.2 If the applicant is a student, the written rejection should be sent to the student, the supervisor(s) of the student, the Deputy Dean (responsible for research) and the Dean of the Faculty where the applicant is registered as a student.

9.3.3 If the applicant is a postdoctoral fellow, (a) the written rejection should be sent to the postdoctoral fellow, the supervisor(s) of the postdoctoral fellow, the Deputy Dean (responsible for research) and Dean of the Faculty where the postdoctoral fellow is based, OR (b) the written rejection should be sent to the postdoctoral fellow, the supervisor(s) of the postdoctoral fellow, the Research Leader (e.g. Director) of the Research Unit, Research Centre, Centre of Excellence or Research Institute where the postdoctoral fellow is based.

9.3.4 If the applicant is an academic staff member, the written rejection should be sent to the applicant and the Deputy Dean (responsible for research) and Dean of the Faculty where the applicant is based.

9.3.5 If the applicant is a non-academic professional staff member, the written rejection should be sent to the staff member and the relevant line manager of the staff member (e.g. Director, DVC, etc.)

9.4 Possible Consequences

9.4.1 If the applicant is a student, the Deanery of the Faculty where the student is registered should take appropriate action (a) against the student in line with relevant disciplinary procedures for students that are in place at the University of

Fort Hare, and (b) against the supervisor(s) of the student in accordance with relevant disciplinary procedures for staff members that are in place at the University of Fort Hare.

9.4.2 If the applicant is a postdoctoral fellow, the structure of UFH that is hosting the postdoctoral fellow should take appropriate action (a) against the postdoctoral fellow, and (b) against the supervisor(s) of the student in accordance with relevant disciplinary procedures for postdoctoral fellows and staff members, respectively, that are in place at the University of Fort Hare.

9.4.3 If the applicant is an academic staff member, the structure of UFH where the staff member is based should take appropriate action against the staff member in accordance with relevant disciplinary procedures for academic staff members that are in place at the University of Fort Hare.

9.4.4 If the applicant is a non-academic staff member, the structure of UFH where the staff member is based should take appropriate action against the staff member in accordance with relevant disciplinary procedures for non-academic staff members that are in place at the University of Fort Hare.

9.5 Resubmission of an amended version of the same research proposal that was rejected by the Ethics Committee is not permissible

9.5.1 The same research project that was conducted without valid ethical approval and was rejected by the Ethics Committee must not be submitted again for ethical approval even after revising it.

9.5.2 Revising the application to remove evidence that the study was started or completed without advance ethical approval is not permissible as it is tantamount to concealing the fact that the research study was already started or done unethically.

10. INFORMED CONSENT PROCEDURES AND DOCUMENTATION

All research approved involving human participants must have a letter of information and consent compiled according to the guidelines of the Information Sheet and Informed Consent form of UFH. Each participant or, where necessary, the participant's legally authorised representative, must be given sufficient time to read the information sheet and informed consent document and have the opportunity to ask questions.

There should be no coercion or undue influence and the participant should be given the option to opt out at any point. The information sheet and informed consent document should be in a language understandable to the participant or representative, allowing them to make an informed decision to participate in the research. Only then may the participant or representative sign the letter of information and consent. In the case where the participant is illiterate, verbal consent may be given in the presence of a literate independent witness who will verify and sign the letter of information and consent on behalf of the participant,

indicating that informed verbal consent was given.

The letter of information and consent must include the following:

- The qualification/s and contact details of the researcher/s
- Participants' responsibilities
- Purpose of the research
- Any risks and benefits to participants
- Duration of study
- Confidentiality considerations

- A statement that participation is voluntary and that non-participation will not result in any penalty
- A statement that ethics approval for the study was obtained from IFREC/UREC with the ethical clearance number
- Contact details of UREC / IFREC administrator
- Contact details of the person to contact should there be research related injury or harm

The letter of information and consent must be written in simple language.

10.1 Translation of Information sheet and informed Consent document

Multilingualism is a challenge for any research involving human participants in the South African context. In a country that has 11 official languages, the task of translating and effectively communicating information to, and obtaining consent from participants in several languages is daunting.

The principle of justice in research requires that potential research participants of all local language groups should be afforded the opportunity to participate in research.

10.1.1 In the Eastern Cape, information and consent documents should be available in three languages, namely Xhosa, English and Afrikaans. An exemption from this requirement must be specifically requested and justified and approved by IFREC.

10.1.2 Documents are submitted to IFREC for approval, in English. Once the original document in English is approved, it is the responsibility of the researcher to arrange for translations of the forms, if appropriate.

10.1.3 Once completed, the translations must be returned to the IFREC administrator accompanied by either a certificate of translation or letter from the PI declaring that the translation is an accurate reflection of the approved English version.

10.1.4 IFREC will acknowledge receipt of translations. However only the original English version will be officially approved.

10.1.5 IFREC reserves the right to check translations and delay approval of the study, if the translations are deemed to differ significantly from the approved documents in language quality and meaning.

10.1.6 Investigators and sponsors are encouraged to ensure that Information and Consent documents are translated where appropriate.

10.2 Research Involving Children/Minors

10.2.1 A “Child” is defined as someone younger than 18 years in the Constitution of South Africa.

10.2.2 Research with children must comply with DoH (2015) (see section 3.2.2).

10.2.3 Research involving children must conform to ethical guidelines and the law.

10.2.4 Unless contrary to South African laws and regulations, research involving children should be determined by IFREC as falling into one of the following categories:

a) Research not involving greater than minimal risk to the children
b) Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child participants involved in the research
c) Research involving greater than minimal risk and no prospect of direct benefit to the individual child participants involved in the research, but likely to yield generalisable knowledge about the participant’s disorder or condition provided that the risk represents a minor increase over minimal risk
d) Research that IFREC and UREC believes does not meet the conditions above but finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

10.2.5 Adequate provision should be made for obtaining assent of the children and consent from their parents or legal guardians.

10.2.6 Where parents and legal guardians are not available, IFREC and UREC shall be guided by applicable laws and guidelines, the merits of the study and expert opinion on legal and technical points concerning the proposed study.

10.2.7 US DHHS funded research with children must comply with US 45 CFR 46.404-407 in addition to relevant South African legislation and regulations.

10.3 Community and Prison based Studies

IFREC must ensure that, particularly with regard to research involving communities, those communities’ traditions and values are respected. This applies particularly with regards to obtaining consent to participate in the research. However, permission given by a community's leader does not absolve the researcher from also obtaining the informed consent of each individual participant.

When reviewing non-expedited studies involving prisoners, IFREC must ensure that

- The application is submitted to the Department of Correctional Services Research Ethics Committee;
- The Investigator has complied with the conditions specified in the South African DoH (2015) Ethical Guidelines (Section. 3.2.8); and
- Studies with prisoners comply with relevant South African legislation and regulations.

11. RECORD KEEPING

Legal and ethical requirements regarding human research participant protection require that records be retained in an orderly and easily accessible manner for future reference and for audit purposes for a minimum period of five years.

11.1 Research Projects

11.1.1 A UREC/IFREC reference number is allocated to all new applications. This number is recorded on all correspondence and additional attachments/amendments.

11.1.2 A research ethics data base is used to capture project information such as name of investigators, title of project etc.

11.1.3 Hard copies of all research study related documents and correspondence are filed according to their reference numbers.

11.1.4 Hard copy records of all communication between investigators and the UREC/IFREC office are recorded and filed using this reference number.

11.2 Meetings

Written minutes of UREC and IFREC meetings will be recorded in sufficient detail to:-

11.2.1 Show attendance at the meetings.

11.2.2 All actions taken by the UREC and IFREC.

11.2.3 Whether or not a decision was reached by consensus or voting.

11.2.4 If by voting, then the number voting for, against and abstaining.

11.2.5 The basis for requiring changes to, or rejection of research ethics application.

11.2.6 A written summary of the discussion of controversial issues and their resolution.

11.3 Record of membership

An up-to-date list of UREC and IFREC members identified by name; earned degrees; representative capacity; indication of experience sufficient to describe each member's chief anticipated contributions to Institutional Review Board deliberations; and any employment or

other relationship between each member and the institution will be retained at the UREC office.

12. AMENDMENT TO RESEARCH PROTOCOLS

UREC/IFREC approves the study protocol ensuring that the research will be conducted using sound ethical principles. However, amendments to, and deviations from, approved protocols can be required.

Protocol amendments

Amendments, sub-studies or addendums to studies are planned changes to a study protocol, made in advance. The following points apply to all planned changes to approved study protocols:

12.1 Changes to research protocols should be submitted to the UREC as a requested "study amendment" using the application form for substantial/major amendments and should not be implemented prior to UREC approval.

12.2 An exception to this would be where it is necessary to eliminate an immediate hazard to, for example, trial participants or when the change involves only administrative or logistical elements e.g. change of telephone number.

12.3 UREC or a person delegated this authority by the UREC Chairperson, will decide if the amendment has minor or major implications for the study and its participants.

- If the change is minor, it may be seen through expedited review.
- If the change is major, it will serve at a full committee meeting.

12.4 Minor amendment - does not change the risk-benefit profile of the study, e.g. change of title, administrative changes, adding an investigator, changes that do not affect study design and outcomes, small changes to letter of information and consent such as editorial changes. Examples of typical minor amendments:

- Additional Investigators or study sites
- Small changes in the Informed Consent
- Change in background information or update of literature review
- Extension of period of study
- Other changes that do not affect study design and will not affect study outcomes or results
- Administrative changes

- Stricter inclusion or exclusion criteria.

12.5 Major amendment - does change the risk-benefit profile of the study, e.g. change in study aims and objectives, alterations to study procedure, changing inclusion criteria to make study more accessible, changes to letter of information and consent. Examples of major changes:

- Change in study aims, objectives or design
- Resulting changes to consent documents
- Additional study procedures
- Easing of inclusion or exclusion criteria

Protocol deviations

A protocol deviation is a “once off” instance when, for some reason, the protocol is not followed e.g. the protocol states that only people over the age of 18 will be enrolled. However, a participant, aged 17 years and 6 months meets all admission criteria and is deliberately enrolled in this study. Protocol deviations can also occur when mistakes are made e.g. the wrong follow up-date is given and thus follow up occurs outside of a specified time frame.

Significant protocol deviations that are likely to adversely affect participant well-being or data integrity should be reported to the UREC within a maximum of 15 days. Minor protocol deviations can be listed with the annual progress report.

13. GUIDELINES FOR ROUTINE CONTINUAL REVIEW AND ANNUAL RE-CERTIFICATION

All research approved by the UREC / IFREC will be subject to substantive, meaningful and focused continuing review to determine that the risks and benefits of the study have not changed, that there are no unanticipated findings involving risks to participants and/or others, and that any new information regarding risks and benefits are provided to the participants. The review will occur annually, unless the level of risk requires more frequent review. UREC may withdraw approval of a protocol previously approved. The responsibility for the application for recertification lies with the researcher and supervisor.

13.1 Ethics approval is valid for one year only.

13.2 A progress report is an application for renewal of ethics approval and must be submitted annually, at least 2 months before the ethics approval expiry date, so that the progress report can be reviewed and the project re-approved prior to the expiry date. No research may continue without this process and re-approval. Six monthly progress reports may occasionally be requested if UREC deems the project to be of particularly high risk.

13.3 The progress report must be submitted on a UREC progress report form.

13.4 The progress report should contain sufficient information to allow the reviewer to conduct a substantive and meaningful review of the progress of the project, including any challenges or problems encountered.

13.5 For multi-centre studies the information in the progress report must pertain specifically to UFH sites. A site-specific progress report must be submitted annually, for ethics re-approval, using a UREC progress report form.

13.6 An updated complete protocol, incorporating all approved amendments should be submitted approximately every three years unless there have been no, or minimal changes to the project. Main points to be included are:

a) the number of participants recruited;
b) a summary of any unanticipated problems and available information regarding adverse events (in many cases, such a summary could be a simple brief statement that there have been no unanticipated problems and that adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document and any investigator brochure)
c) a summary of any withdrawal of participants from the research since the last Research ethics committee (UREC) review;
d) a summary of any complaints about the research since the last UREC review; a summary of any recent literature that may be relevant to the research and any amendments or modifications to the research since the last UREC review; any relevant multi-centre trial reports;
e) any other relevant information, especially information about risks associated with the research; A copy of the current informed consent document and any newly proposed consent document.

13.7 The above information will be distributed to all UREC members prior to each meeting for discussion and renewal of approval.

13.8 The minutes of the UREC meeting will document separate deliberations for each protocol undergoing continued review.

13.9 UREC has the authority to place restrictions on, suspend, or terminate any study in which the investigator fails to comply with the review process OR where such actions are deemed appropriate and justified by UREC.

13.10 If a project was eligible for expedited review when initially approved, the continuing review may occur via an expedited process. However if the project was not eligible for expedited review then the continuing review must occur at a convened meeting.

13.11 A study is considered active while analysis of any data collected or resulting from the study is on-going.

Progress reports are required annually until such time as the investigator submits a final study report or a notice of termination of the study.

14. SUSPENSION/TERMINATION OF APPROVAL

14.1 Suspension or termination by UREC

UREC may suspend or terminate approval of a study that is not being conducted in accordance with prevailing UREC or South African Department of Health Ethicalrequirements. 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 UREC chairperson in minuted consultation with a UREC subcommittee and/or other co-opted parties as soon as possible but not more than seven days after receiptof relevant information by the chairperson. Such action must be reported to UREC at the nextquorate meeting.

14.2 Suspension or termination by researcher

In the case where a research project is prematurely suspended/ terminated the principal investigator/researcher must notify UREC in writing of the reasons for suspension/termination and give a summary of the results obtained in a study thus far.

15. COMPLAINTS PROCEDURE

Appeals arise because the IFREC rejects a research proposal, adjudges a protocol deviation or violation to be sufficiently serious to merit calling a halt to the research, or requires additional protections or conditions before approving a protocol and the PI objects to the decision of the IFREC and wishes to appeal.

In such cases:

- An appeal must be directed to the chairperson of UREC. A researcher may not appeal directly to any members of UREC.
- Complaints arise because of alleged IFREC or UREC procedural irregularities, breach of researcher confidentiality, unacceptable delays or conflicts of interest.

Complaints should be directed, in the first instance, to the chair of the UREC.

The researcher retains the right to appeal or complain to the National Health Research Ethics Council, if the research falls under the jurisdiction of this council i.e. fulfils the definition of Health Research as defined in the National health Act No.61.2003.

15.1 Appeal Process (UREC level)

- Where a PI is dissatisfied with a UREC decision, he or she has the right to obtain from the UREC written reasons for its decision and should exercise this right before launching an appeal.
- UREC will have a mechanism whereby a PI may appeal UREC's decision. The chairperson of the UREC must appoint a subcommittee to revisit the substance of the application together with any additional information put forward by the PI. The subcommittee must obtain at least one independent, external, expert review of the research project and the substance of the appeal. Additional reviews should be obtained if deemed appropriate. The subcommittee may have the same powers asthe UREC, if so constituted by the UREC concerned.
- The appeal is usually considered on the grounds of written submission only. However the chairperson of the appeal subcommittee may invite the PI to provide an additional oral submission to the subcommittee and answer questions.
- After deliberation of all the information placed before it, the subcommittee must either
  a) Uphold the appeal
  b) Reject the appeal
- In the event of an (a) or (b) outcome, the decision of the UREC is final.
- Researchers conducting 'health research' retain the right to complain or appeal to the National Health Research Ethics Council in the event that they remain dissatisfied with the outcome of the appeal.

15.2 Complaints Process

15.2.1 All complaints against UREC, for matters as described above, should be submitted directly to the UREC chairperson, who should make every effort to investigate the complaint thoroughly, resolve the issue and communicate the outcome of the investigation to the complainant.

15.2.2 The chairperson of the UREC shall appoint an ad-hoc committee to investigate the complaint and report back to the full UREC at a forthcoming meeting. Where necessary the subcommittee may need to interview the complainant, the chairperson and/or other persons.

15.2.3 UREC shall compile a report of its findings and recommended action. The report shall be submitted to the Deputy Vice-Chancellor: Academic Affairs, the chairperson of the UREC

15.2.4 The PI shall be notified of the outcome of the UREC investigation.

16. CONFLICT OF INTERESTS

16.1 For Investigators

A conflict of interests (COI) occurs when professional judgement regarding an interest e.g. research, or patient care, is unduly influenced by another interest e.g. financial gain or gain in personal status. Admitting to a conflict of interest is not an indication of moral failure but an honest appraisal of the potential influence of secondary interests on one's judgement and actions. Conflicts of interests are an inherent and unavoidable part of the academic research environment and can be effectively managed by disclosure and transparency.

Investigator conflicts of interests are of particular importance when an unacknowledged or undisclosed interest, financial or otherwise, may negatively affect the well-being of research participants. It is this aspect of Conflicts of Interests that is of concern and relevance to the UREC and IFREC. Therefore,

- Investigators must consider the potential effects that a financial relationship of any kind may have on the research or on interactions with research participants;
- All investigators are obligated to sign the Conflict of Interest Declaration that is part of the Investigator declaration;
- In particular investigators should disclose the following potential conflict of interests to the UREC and IFREC
    a) Equity or stock holding in a sponsor company;

b) Proprietary interests in product- patent holding, intellectual property rights, trademark, and licensing agreements;
c) Grants paid speaking arrangements, retainers for on-going consultations, sitting on “Pharmaceutical Advisory Boards” etc.;
d) Travel/conference sponsorship;
e) Recruitment fees or other personal payments that are linked to study outcome, in any way
f) Co-authorship of articles, where the co-author’s input has been minimal.
g) Funding for additional staff and facilities, especially if not directly linked to the research project;
h) Equipment for use in a study that will then belong to the department;
i) Donation of equipment unrelated to study, and
j) Contributions to a departmental budget not directly related to project expenses.

These may be potential but not actual conflicts of interest and after particular set of circumstances.

16.2 Applicable to UREC and IFREC Members

Members of the UREC and IFREC are expected to make decisions and conduct their oversight responsibilities in an independent manner, free from bias and undue influence. UREC and IFREC members (and members of their immediate families) may not be involved in activities that could be perceived as conflicting with their UREC and IFREC responsibility. The integrity of the UREC and IFREC review process can be compromised if such conflicts of interests are not disclosed and where necessary, avoided.

17. AUDITS OF RESEARCH PROTOCOLS

In cases where an audit is decided upon by UREC, the audit team will examine the structure of the PI’s research organisation and their standard operating procedures to determine whether he/she complies with the ethical standards and regulatory requirements governing research involving human subjects.

In the case of audits in response to a complaint, the audit team will be supplied with an Audit Brief, which may outline the complaint and indicate specific focus areas for the audit.

In the case of random audits, the audit team reviews records maintained by the PI, including site-monitoring notes where applicable, for the duration of the study.

The main focus of the audit team is to ensure that the research is being conducted in an ethical manner and that participant's interests are fully recognised, represented and protected.

Some or all of the following documents may be examined by the audit team during the audit process, depending on the nature of the audit and the nature of the study. (NB: Some of the documents listed here may not be applicable)

Investigator's Study File:

- Confirmation of Regulatory Approval
- Signed funding agreement and copies of receipts or financial correspondence (where applicable)
- Signed copy of the final protocol and any amendments
- Specimen diary card, questionnaires, etc.
- Dated, signed CVs of all study site personnel
- Specimen of signatures of site staff
- Responsibilities list
- Correspondence and communication with funders, and other authorities e.g. Provincial government authority
- Record relating to equipment loan during the study
- Equipment calibration logs

17.1 UREC Compliance

- Any correspondence with the UREC
- List of Committee members
- Letter of UREC approval and approval of any protocol amendments or other changes
- 6-monthly/annual progress report to UREC
- Annual re-approval from UREC
- Notification of end of study
- Insurance statement (if applicable)
- Signed indemnity letter (if applicable)
- Any advertisement used for subject recruitment
- Specimen subject information consent forms

- Signed consent forms
- Participant screening list
- Participant recruitment log
- Participant identification record
- Copies of serious adverse events

17.2 Reporting of Audit and Follow-up

- The audit team will compile an audit report, which is submitted to the Chairperson of the UREC and/or to the PI.
- The PI will be requested to respond formally in writing to the audit report and address each point. The PI's report should also include a corrective action plan, if appropriate.
- The audit team or the UREC then reviews the report, identifying irregularities in the statements and/or documents, summarising the issues that justify or refute the reasons for the initial complaint, where applicable and proposing a plan or corrective action if appropriate.
- The auditor/team may arrange a formal meeting between the PI, audit team, representatives from the UREC where appropriate, to discuss any findings of the audit including any findings of non-compliance. This meeting is formal and should be minuted in detail.
- The Audit Report, PI's written response and minutes of the follow up meeting are confidential and will usually be tabled at a forthcoming UREC meeting.

17.3 UREC deliberations and decisions

UREC reviews the audit team's summary report, the PI's written response and the minutes of the follow up meeting report, where applicable. UREC will decide either by consensus or by vote to:

- Accept the audit findings and PI's written response as acceptable with no cause for further action. A final letter will be sent to the PI, briefly summarising the outcome and declaring the matter satisfactorily resolved.
- Request the PI to provide additional information, or take some other form of corrective action, which may even, involve a suspension of approval of the research study involved until proof of corrective action has been provided.
- Withdraw study approval AND/OR
- Refer the matter to line management for further investigation and action where appropriate.

- All correspondence between the UREC, auditor and PI will remain confidential except in cases of serious research non-compliance in which instance the report may be forwarded to external regulatory bodies or funders as deemed appropriate after discussion with the Chairperson of the UREC and other relevant stakeholders.

NB. When an audit is initiated in response to a 3rd party complaint about a researcher or research study, deviations from the above procedure may occur. This will depend on the nature, seriousness and context of the complaint.

18. ADOPTION OF, AND CHANGES TO, THIS STANDARD OPERATING PROCEDURE

Changes to this Standard Operating Procedures can be made and should go through the institutional approval process that leads to approval by Senate. The SOPs should be reviewed in the fifth year of every 5-year cycle.

19. AUDITING AND ACCREDITATION OF UREC

UREC is registered with the National Health Research Ethics Council (NHREC).

The registration number of UREC is REC-270710-028.

UREC will be regularly audited by NHREC.

20. REGULATORY FRAMEWORK

This UREC functions within the framework of all relevant promulgated Acts of Parliament and international treaties and conventions to which the Republic of South Africa is a signatory, interpreted in a manner appropriate to research in the humanities, (i.e. the social, behavioural, economic and educational sciences). Examples of relevant Acts, treaties and conventions include, but are not limited to: t

- The Constitution of South Africa, Act 108 of 1996:

- The Children's Act, Act 38 of 2005;
- National Health Act, Act 61 of 2003;
- Promotion of Access to Information Act, Act 2 of 2000; and
- Protection of Personal Information Act, Act 4 of 2013.

21. POLICIES AND GUIDELINES

In addition to the regulatory framework, the UREC functions within the framework of the following documents:

- National Department of Health (DoH) (2004),
- Ethics in Health Research: Principles, Structures and Processes; and
- National Department of Health (2015) Ethics in Health Research: Principles, Processes and Structures.

22. DEFINITIONS

- **Ethics review** –review of research proposals or protocols by RECs prior to commencement of the research.
- **Accountability** – the measure by which it can be demonstrated that responsibilities have been or are being fulfilled; it may involve reporting upwards in a hierarchical structure.
- **Adolescent** – a child between 12 and 17 years of age.
- **Autonomy** – the capacity to understand information; to act on it voluntarily; to use own judgement to make decisions about own actions, including whether to participate in research.
- **Coercion** – extreme form of undue influence, involving a threat of harm or punishment for failure to participate in research; see Undue influence.
- **Confidentiality** – the responsibility to protect information entrusted to researchers for research purposes from unauthorised access, use, disclosure, modification, loss or theft.
- **Conflict of interests** – incompatibility of duties, responsibilities or interests (personalor professional) of a person or an institution as regards ethical conduct of research so that one cannot be fulfilled without compromising another.
- **Consent** – indication of agreement to participate in research, based on adequate knowledge and understanding of relevant information, and freely given.

- **Harm** – anything that has a negative effect on participants' welfare, broadly construed; its nature may be physical, emotional, psychological, social or legal
- **Minor**– a person under 18 years (s 17 Children's Act).
- **Vulnerability** – diminished ability to fully safeguard one's own interests in the context of a specific research project; may be caused by limited capacity or limited access to social goods like rights, opportunities and power

23. REFERENCES

In the compilation of this Standard Operating Procedure the following documents were consulted:

- Code of Federal Regulations CFR Title 21 Food & Drugs revised as of April1 2003
- Code of Federal Regulation CFR Title 45 Public Welfare as of April 2003
- Council for International Organizations of Medical Sciences (CIOMS) Council for International Organizations of Medical Sciences. Geneva 2016
- HSRC Research Ethics Committee: Standard Operational Procedures.
- Department of Health, Education, and Welfare, Office of the Secretary, Protection of Human Subjects. Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Report of the National Committee for the Protection of Human Subjects of Biomedical and Behavioural Research. DHEW Publication No. (OS) 78-0013 and No. (OS) 78-0014. 18 April 1979.
- Dept of Health and Human Services. Financial relationship and Interests Involving Human Subjects: Guidance for Human Subject Protection. Published in Federal Register May 12th 2004.
- Department of Health, 2006. Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa. Department of Health: Pretoria, South Africa (South African Good Clinical Practice Guidelines).
- Ethics in Health Research. Principles, processes and structures (2015)
- International Conference on Harmonisation of Technical requirements for registration of pharmaceuticals for human use (ICH Guidelines for Good Clinical Practice) 1996.
- Guidelines on Ethics for Medical Research: General Principles. MRC- SA 4th Edition
- National Department of Health (DoH) (2004), Ethics in Health Research: Principles, structures and processes

- Stellenbosch University: Faculty of Health Sciences Standard Operating Procedure (2011)
- University of Kwazulu Natal: Research Ethics Policy
- University of Zululand: Standard Operating Procedure
- University of Free State: Standard Operating Procedure
- University of Western Cape: Research Ethics Policy
- University of Witwatersrand Standard Operating Procedure
- World Medical Association, Declaration of Helsinki: Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects. Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964. Amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975; the 35th World Medical Assembly, Venice, Italy, October 1983; the 41st World Medical Assembly, Hong Kong, September 1989; and the 48th General Assembly, Somerset West, Republic of South Africa, October 1996, Helsinki, August 2008

24. APPENDICES

(1) UREC/ IFREC Research Ethics Application Form

(2) Completion of study form

(3) IFREC Confidentiality Agreement (NEW)

(4) Focus Group Information and Consent Form (18 year+)

(5) UREC Renewal Approval Letter

(6) Request for Permission to Conduct Study

(7) Application for Approval of Amendment

(8) Ethical Clearance Certificate

(9) UREC Confidentiality Form

(10) Conflict of Interest Form (UREC and IFREC)

(11) Parents Information and Consent Form

(12) Assent to Participate in a Study Form (12-17 Years)

(13) UREC Individual Consent Form

(14) IFREC Renewal Letter (NEW)

(15) UREC Progress Report Form