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TITLE: Inter-Faculty Human Research Ethics Committee (IFHREC) Standard Operating Procedures

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IMPLEMENTATION RESPONSIBILITY:
IFHREC Chairperson; Director: Research and Innovation; Deputy Vice Chancellor: Research, Partnerships and Innovation

STRUCTURE APPROVED BY: Senate Research Ethics Oversight Committee (SREOC)

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TO BE READ IN CONJUNCTION WITH THE FOLLOWING Documents:

- University Research Ethics Policy
- IFHREC Terms of Reference
- UFH Code of conduct for Research Ethics and Biosafety Committees
- National Human Research Ethics Council Guidelines
- National Department of Health Guidelines

APPROVED BY:

2024.10.29
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DESIGNATION: Chairperson of UFH Senate Research Ethics Oversight Committee (SREOC)

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Inter-Faculty Human Research Ethics Committee (IFHREC)

IFHREC SOP 001: Recruitment and Appointment of REC Members

(Version: 29 August 2024)

1. Purpose

The purpose of this standard operating procedure (SOP) is to provide a standard way of recruiting and appointing members of IFHREC in accordance with NDoH 2024 Guidelines.

2. Scope

The SOP applies to IFHREC members who are:

2.1 Employees of UFH

2.2 Non-employees of UFH

3 Recruitment and appointment of members

3.1 Call for applications to be considered to become members of IFHREC should be disseminated widely for a minimum of two weeks before selection process commences.

3.2 Members of the IFHREC are appointed for a period of up to four years, renewable once, after which the member should step down for at least one term.

3.3 Appointments of new IFHREC members should overlap so that no more than half the committee membership is new.

3.4 The committee must have a minimum number of nine (9) members with a quorum of simple majority (50% + 1).

3.5 If the number of IFHREC is more than 15, the quorum should be 33%

3.6 IFHREC should increasingly reflect the demographic profile as well as the gender balance of the population of the Republic of South Africa.

3.7 IFHREC composition should have:

3.7.1 At least one layperson who is from the communities in which the University is located or conducts its research and who is not currently involved in medical, scientific or legal work.

3.7.2 At least one member with training and experience in qualitative research methodologies.

3.7.3 At least one member with training and experience in quantitative research methodologies.

3.7.4 At least one member with expertise in biostatistics.

3.7.5 At least one member with expertise and experience in research ethics.

3.7.6 At least one member with a legal background and has knowledge in research ethics.

3.8 IFHREC may co-opt members for specialist inputs.

3.9 A member may voluntarily step down from the committee, and should give at least 3-months- notice through the Chair of IFHREC in order to enable a replacement to be appointed

3.10 Applications for membership shall be tabled before a full IFHREC meeting for nomination of candidates to be recommended for submission to the UFH Senate Research Ethics Oversight Committee (SREOC) for approval.

3.11 Approved nominations shall be appointed through an appointment letter signed by the Chairperson of SREOC.

4 Cost of participation of non-UFH members shall be covered by UFH

4.1 The University of Fort Hare shall cover costs of participation of IFHREC members who are not employees of UFH.

4.2 A sitting allowance of R950 per meeting or workshop that an external member participates in shall be paid to cover pertinent costs that include data, airtime, fuel for local travel, printing and refreshments.

4.3 The sitting allowance is not remuneration; it covers costs that external members have to incur to take part in IFHREC activities.

4.4 The allowance applies to face-to-face meetings and virtual meetings.

4.5 The University of Fort Hare shall cover costs associated with IFHREC activities, such as flights, accommodation, car hire, per diem, training

costs, and other relevant and costs that are permitted by UFH policies.

4.6 The amount of sitting allowance per meeting per external member shall be reviewed every two years by IFHREC and approved by SREOC.

5. Attendance of Meetings and Termination of Membership

5.1 IFHREC members shall be expected to attend IFHREC meetings to enable the requirement for quorum to be met.

5.2 If a member will not be able to attend an upcoming IFHREC meeting, they must submit an apology to IFHREC secretariat at least 3 days before the scheduled meeting. The reason for failure to attend (e.g. away on sick leave, clash with a scheduled teaching responsibility, etc.) should be stated when an apology is submitted.

5.3 If a member does not attend a scheduled meeting and does not submit an apology as per point 5.2 above, they shall be recorded as being "absent" in the minutes of the meeting.

5.4 One's IFHERC membership shall be terminated if one:

(a) Is absent from at least four (4) scheduled IFHREC meetings per year without apology.

(b) Fails to attend 75% (three quarters) of scheduled IFHREC meetings per year (including special meetings), with and /or without apology. For example, if there are 12 scheduled IFHREC meetings in a year and a member fails to attend nine (9) of the 12 meetings, then the membership shall be terminated because the failure to attend the majority of IFHREC meetings in a year implies that the member's work schedule does not permit them to attend most of IFHREC meetings.

(c) Brings the name of IFHREC and UFH into disrepute through such acts as violating the UFH Code of Conduct for Research Ethics and Biosafety Committees and other types of misconduct.

5.5 The condition that membership shall be terminated if a member fails to attend 75% (three quarters) of scheduled IFHREC meetings per year (including special meetings) shall not apply if a member is not able to attend scheduled meetings due to:

(a) Illness (sickness) supported by official sick leave

(b) Sabbatical leave

(c) Official leave of absence (e.g. being on a fellowship abroad)

(d) Any other reason that IFHREC committee deems to be valid and justifiable

5.6 To terminate membership for reasons stipulated in point 5.4 above, the IFHREC Chairperson shall:

(a) Include termination of membership on the IFHREC agenda for formal deliberation by IFHREC and capturing in minutes of the IFHREC meeting.

(b) Table the termination of the membership before Senate Research Ethics Oversight Committee (SREOC) for ratification. A formal letter informing the member of termination of IFHREC membership shall be issued and signed by SREOC Chairperson.

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Inter-Faculty Human Research Ethics Committee (IFHREC)

IFHREC SOP 002: Appointment of Chairperson and Deputy Chairperson

(Version: 29 August 2024)

1 Purpose

The purpose of this standard operating procedure (SOP) is to provide a standard way of nominating and appointing Chairperson and Deputy Chairperson of IFHREC in accordance with NDoH 2024 Guidelines.

2 Scope

The SOP applies to IFHREC Chairperson and Deputy Chairperson.

3 Nomination and appointment of IFHREC Chairperson and Deputy Chairperson

3.1 IFHREC shall nominate a Chairperson and Deputy Chairperson from its members.

3.2 Chairperson must have experience conducting research and should have at least two years' experience in Research Ethics. Leadership qualities and experience are also important.

3.3 Nominations of Chairperson and Deputy Chairperson shall be tabled before the Senate Research Ethics Oversight Committee for ratification and formal appointment.

3.4 The Chairperson and Deputy Chairperson shall be appointed for a period of 3 to 5 years.

3.5 It shall be permissible to nominate and appoint an external person who is not UFH employee as Chairperson.

3.6 For external members, costs of participation in IFHREC activities shall be covered by UFH:

3.6.1 The University of Fort Hare shall cover costs of participation of IFHREC members who are not employees of UFH.

3.6.2 A sitting allowance of R950 per meeting or workshop that an external member participates in shall be paid to cover pertinent costs that include data, airtime, fuel for local travel, printing and refreshments.

3.6.3 The sitting allowance is not remuneration; it covers costs that external members must incur to take part in IFHREC activities.

3.6.4 The allowance applies to face-to-face meetings and virtual meetings.

3.6.5 The University of Fort Hare shall cover costs that associated with IFHREC activities, such as flights, accommodation, car hire, per diem, training costs, and other relevant and costs that are permitted by UFH policies.

3.6.6 The amount of sitting allowance per meeting per external member shall be reviewed every two years by IFHREC and approved by SREOC.

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Inter-Faculty Human Research Ethics Committee (IFHREC)

IFHREC SOP 003: Induction of New Members

(Version: 29 August 2024)

1 Purpose

This standard operating procedure (SOP) gives a standard way of carrying out induction of IFHREC members upon appointment.

2 Scope

The SOP applies to IFHREC members, Chairperson and Deputy Chairperson.

3 Induction

3.1 IFHREC Chairperson shall go through the UFH Code of Conduct for Research Ethics Committee with the new IFHREC member.
3.2 After going through the code of conduct and asking any questions to understand the code, the members shall sign the code of conduct.
3.3 The IFHREC Chairperson shall conduct induction training which shall cover the following:
3.4 The role of ethics committee members.
3.5 The composition of the committee.
3.6 Introduction to the SOPs and Terms of Reference.
3.7 Introduction to DoH2024 guidelines.
3.8 Introduction to the National Health Research Ethics Council processes.
3.9 Introduction to the review process.
3.10 Introduced to how to manage conflicts of interest.
3.11 Tell them about training (assessed and non-assessed training)

3.12 Members will be given an induction package either hard copies or electronic versions of all ethics related documents prior the induction day.

3.13 The induction of new members is the responsibility of the Chairperson and the secretariate.

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Inter-Faculty Human Research Ethics Committee (IFHREC)

IFHREC SOP 004: IFHREC Meeting Procedures

(Version: 29 August 2024)

1. Purpose

This standard operating procedure (SOP) gives procedures of convening IFHREC meetings that shall be followed.

2. Scope

The SOP applies to ordinary scheduled meetings and special meetings of IFHREC.

3. Procedures for ordinary scheduled meetings

3.1 IFHREC shall convene one ordinary full committee meeting per month.

3.2 The monthly meeting shall be in the last week of each month, but the date can be shifted if need be.

3.3 At the beginning of the year, IFHREC secretariat shall provide members with dates of the scheduled meetings for the year after consultation with the Chairperson. The dates should avoid clashes with meetings of institutional statutory committees that include

Senate Subcommittees, Senate Executive Committee, Senate, Extended Management Committee and Council.

3.4 The agenda for the meeting shall be sent to members at least 2 weeks before the date of the meeting.

3.5 Minutes of the previous meeting shall be included in the agenda of the next meeting.

3.6 Meetings shall only be conducted when a quorum is met. The quorum is fifty percent plus one (50%+1), or thirty three percent (33%) if the committee has more than fifteen (15) members.

3.7 IFHREC members attending meetings must sign declarations regarding confidentiality and conflict of interest for each meeting

3.8 On invitation or request, IFHREC meetings may be attended by non-members that include registered students, researchers, and other interested parties as non-voting observers, subject to the signing of declaration regarding confidentiality and conflict of interest and subject also to being excluded from certain agenda items as determined by the Chairperson.

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

3.10 The meetings of IFHREC shall be recorded by means of minute-taking and electronic recording.

3.11 If a member is absent from a meeting for four (4) consecutive meetings without an apology or valid reason, the Chairperson shall address their absence verbally and in writing to the specific member. Then, the IFHREC Chairperson, in consultation with the committee, shall make a recommendation to terminate membership to Senate Research Oversight Committee (SREOC).

4 Procedures for convening special meetings

4.1 If an urgent need for a full IFHREC meeting arises, the Chairperson shall announce a date and convene the special meeting.

4.2 A special meeting must be focused on and limited to the agenda item(s) for which it was convened.

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Inter-Faculty Human Research Ethics Committee (IFHREC)

IFHREC SOP 005: Expedited Review

(Version: 29 August 2024)

1. Purpose

The purpose of this standard operating procedure is to provide a standard way of determining applications that are eligible for expedited review and how the expedited review must be conducted.

2. Scope

This SOP applies to requests for expedited review of applications submitted by researchers. IFHREC and researchers must use this SOP to guide them on research projects that are eligible for expedited review.

3. Eligibility for Expedited Review

3.1 A new research study may be considered suitable for a "fast track" ethical review process only if it involves "minimal risk" research.

3.2 An expedited ethical clearance process may be followed in the following instances:

3.2.1 Where the research involves desktop or library work only.

3.2.2 Where secondary data will be collected.

3.2.3 In exceptional cases, where it is in the public interest to expedite the process.

3.2.4 Minimal risk research, for the purposes of a degree or diploma (under or postgraduate)

4 Process of Expedited Review

4.1 Applications for expedited review shall be submitted to the IFHREC and shall be recorded in the usual manner.

4.2 The chairperson of IFHREC shall constitute an ad hoc committee comprising at least three (3) members of IFHREC who do not have any conflict of interests, and have relevant expertise, to assess whether or not the application process could be expedited.

4.3 The constituted ad hoc committee shall appoint a chairperson to the ad hoc committee.

4.4 Where the ad hoc committee finds the application suitable for expedited review, the committee must conduct the expedited review.

4.5 Where an ad hoc committee member objects to a matter being expedited the objection should be recorded, with a full motivation provided.

4.6 Irrespective of the objection recorded, the expedited review must proceed.

4.7 The ad hoc committee's majority decision on the expedited review is final

4.8 Based on the decision made by the ad hoc committee, the IFHREC Chairperson must within two days issue an ethical clearance certificate.

5 Report to IFHREC for noting

IFHREC chairperson must report to IFHREC members on all expedited reviews in the next full ordinary IFHREC meeting

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Inter-Faculty Human Research Ethics Committee (IFHREC)

IFHREC SOP 006: Definitions of risk and risk-benefit ratio

(Version: 29 August 2024)

1. **Purpose**

   The purpose of this standard operating procedure is to provide definitions of risks and risk-benefit ration in the context of research.

2. **Scope**

   The SOP covers all research projects reviewed, approved and monitored by IFHREC.

3. **Definitions of Risks**

   3.1 **Minimal risk:** Minimal risk is risk that is potential risk that is not greater than potential risk that is ordinarily encountered in ordinary day-to-day life in terms of the magnitude of harm or discomfort and likelihood or probability of occurring.

   3.2 **Medium (or moderate) risk:** Medium or moderate risk is greater than minimal risk in terms of magnitude of harm or discomfort and the likelihood or probability of occurring, but the risks can be mitigated or reduced through measures put in place by the researchers.

   3.3 **High risk:** High risks can cause serious harm that can lead to hospitalization, disability or death. Research involving or exposed to a high level of danger. Research involving very sensitive topics and/or participation of vulnerable individuals or groups such as

children, institutionalized people, marginalized groups, etc. is associated with potential high risks that need adequate measures to mitigate the high risks.

4. Risk-benefit Ratio

Risk-benefit ratio is a comparison of potential risks versus potential benefits. An acceptable risk-benefit ratio of a research project is when potential benefits of the research project outweigh potential risks associated with the research project. To approve research, IFHREC shall assess the risk-benefit ration of the proposed research and shall ensure that the following requirements are satisfied:

4.1 Risks to participants are minimized:

4.1.1 Using procedures which are consistent with sound research design, and which do not unnecessarily expose participants to risk, and

4.1.2 Whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.

4.2 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, IFHREC 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).

4.3 If applicable, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants

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Inter-Faculty Human Research Ethics Committee (IFHREC)

IFHREC SOP 007: Conflict of Interest

(Version: 29 August 2024)

1. Purpose

This standard operating procedure provides a standard way of handling conflict of interest.

2. Scope

The SOP applies to all members of IFHREC, and any persons invited to be part of IFHREC meeting.

3. Conflict of Interest

Members of the IFHREC are expected to make decisions in an independent manner, free from bias and undue influence. IFHREC members may not be involved in activities that could be perceived as conflicting with their IFHREC responsibility because their objectivity may could be compromised. The integrity of the IFHREC review process can be compromised if such conflicts of interests are not disclosed and managed properly.

3.1 IFHREC members are required to declare if they have any conflict of interest in relation to any issue being handled by the committee.

3.2 If a member has declared a conflict of interest linked to any issue, they should be recused from the meeting during deliberations and decision-making that pertain to that issue.

3.3 Some examples of conflict of interest are:

3.4 If a member of IFHREC is an applicant for ethical clearance of their research project, then there is conflict of interest.

3.5 If IFHREC member is a supervisor or co-supervisor of an applicant whose application is to be reviewed by the committee, then there is conflict of interest.

3.6 Having a relationship with an applicant whose application is tabled for review by IFHREC. For example, if a member is a parent, spouse or relative of an applicant.

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Inter-Faculty Human Research Ethics Committee (IFHREC)

IFHREC SOP 008: Passive Monitoring

(Version: 29 August 2024)

1. Purpose

The purpose of this standard operating procedure (SOP) is to provide a standard and consistent way of passively monitoring research projects approved by IFHREC.

2. Scope

The SOP applies to all research projects that were reviewed and approved by IFHREC.

3. Passive Monitoring

3.1 Passive monitoring is mandatory, and IFHREC must determine if the Principal Investigator (PI) is conducting approved research in accordance with the ethical standards and the approved proposal.

3.2 Passive monitoring occurs through submission of annual progress reports to IFHREC by the PI.

3.3 IFHREC may request more frequent reports than annual reports, for example, quarterly or 6-monthly reports depending on the nature of the research being conducted.

3.4 The report should include, inter alia, the following:

3.5 Title of the approved research project

3.6 Research objectives that have been accomplished and the results obtained

3.7 Outstanding research objectives

3.8 How collected research samples, data and documents are being kept.

3.9 Any ethical or methodological challenges being encountered, and if any, measures being taken to mitigate the challenges.

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Inter-Faculty Human Research Ethics Committee (IFHREC)

IFHREC SOP 009: Active Monitoring

(Version: 29 August 2024)

1 Purpose

The purpose of this standard operating procedure (SOP) is to provide a standard and consistent way of actively monitoring research projects approved by IFHREC.

2 Scope

The SOP applies to all research projects that were reviewed and approved by IFHREC.

3 Active Monitoring

3.1 IFHREC has a mandate to conduct onsite monitoring of research to ensure active validation of compliance with ethical standards and approved research project.

3.2 Active monitoring involves physical inspection of a research project on site by IFHREC

3.3 IFHREC shall select research projects to be visited/monitored

3.4 IFHREC may undertake the monitoring by itself and/or appoint an ad hoc team to monitor a particular project

3.5 IFHREC shall provide the monitoring team, be it an ad hoc team or IFHREC itself, with a brief expressly stipulating the areas of focus, the monitoring instrument, and a list of the documents to be assessed by the monitoring team on site.

3.6 The inspection can be either announced or unannounced

3.7 It is mandatory for researchers to supply documents requested by a monitoring team. Some of the documents that may be requested from the investigator's study file are, inter alia:

- 3.7.1 Signed copy of the final proposal and any amendments
- 3.7.2 Signed informed consent forms
- 3.7.3 Participant screening list
- 3.7.4 Participant recruitment log
- 3.7.5 Participant identification record
- 3.7.6 Copies of serious adverse events
- 3.7.7 Specimen diary card, questionnaires, etc.
- 3.7.8 Dated, signed CVs of all study site personnel
- 3.7.9 Specimen of signatures of site staff
- 3.7.10 Responsibilities list
- 3.7.11 Correspondence and communication with funders, and other authorities e.g. Provincial government authority
- 3.7.12 Audio recordings of qualitative data
- 3.7.13 Equipment calibration log

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Inter-Faculty Human Research Ethics Committee (IFHREC)

IFHREC SOP 010: Suspension and Termination of Ethical Approval

(Version: 29 August 2024)

1 Purpose

The purpose of this standard operating procedure is to provide standardised processes for IFHREC for suspending or terminating ethical approval and implementation of research projects that it reviewed and approved.

2 Scope

The SOP covers all research projects reviewed and approved by IFHREC.

3 Suspension of Ethical Approval by IFHREC

IFHREC has the authority to suspend ethical approval and implementation of a research project that it approved if:

3.1 The researcher(s) conducting the research project violate ethical standards that pertain to the research project and were part of the research proposal that was reviewed and approved by IFHREC. Examples include, inter alia, the following:

3.1.1 Enrolling participants into the research project without obtaining valid informed consent.

3.1.2 Collecting research data that was not included in the approved research proposal.

3.1.3 Poor record keeping of research information.

3.1.4 Failure to implement measures to practically mitigate any potential risks.

3.2 The decision to suspend a research project shall be taken by a IFHREC through a full committee meeting which may be ordinary scheduled meeting, or a special meeting convened by the Chairperson specifically for that purpose.

3.3 The suspension shall be for a period of not more than three months.

3.4 IFHREC must indicate in a suspension letter written by IFHREC Chairperson to the Principal Investigator (PI) what action must be taken by the PI to rectify the shortcomings that warranted the suspension.

3.5 IFHREC must indicate in the suspension letter to the PI the deadline for submission of a report by the PI to IFHREC through the secretariat.

3.6 After the PI has submitted a report on measures taken to rectify the shortcomings, IFHREC shall assess if the measures taken by the PI are satisfactory.

3.7 If the report is satisfactory, IFHREC shall write a letter to the PI indicating that the suspension has been lifted and indicating the date the lifting of the suspension comes into effect.

3.8 If the report is not satisfactory, IFHREC has the authority to extend the suspension or to terminate the approval and implementation of the research project through a process stipulated in point number 4 below.

4 Termination of Ethical Approval by IFHREC

4.1 IFHREC has authority to terminate approval and implementation of a research project that it reviewed and approved if there are serious ethical shortcomings that include, inter alia, the following:

4.1.1 Unsatisfactory report submitted by the PI after suspension of ethical approval and implementation of the research project.

4.1.2 If a researcher does not submit annual progress reports and continues conducting the research project.

4.1.3 If the researcher does not apply for an extension of an ethical clearance before it expires and continues to conduct the research project without a valid ethical clearance.

4.1.4 Serious violation of ethical standards that significantly affect the risk-benefit ratio of the research project and make it a high-risk research project that seriously expose participants to serious harm. For example, including vulnerable participants when the proposal did not indicate that vulnerable participants will be involved, asking very sensitive questions that were not in the data collection tool that was approved by IFHREC and without approval for an amendment to add the additional sensitive questions, etc.

4.1.5 Serious misconduct that compromises the welfare of participants and poses a serious public health risk. Examples include, inter alia:

4.1.5.1 fabrication of critical research documents such as informed consent

4.1.5.2 fabrication of research data

4.1.5.3 falsification of data

4.1.5.4 flowed methodological procedures that compromise the welfare of participants and the integrity of the research findings

4.2 The decision to terminate ethical approval and implementation of a research project shall be taken by a IFHREC through a full committee meeting which may be ordinary scheduled meeting, or a special meeting convened by the Chairperson specifically for that purpose.

4.3 IFHREC must inform the PI of the termination of approval and implementation of the research project through letter written by IFHREC Chairperson based on a resolution by a full IFHREC meeting.

4.4 If the PI is a student, the termination letter must be copied to the supervisor.

4.5 If the PI is a postdoctoral fellow, the letter must copied be copied to the researcher hosting the fellow.

4.6 If the PI is a staff member or any researcher officially affiliated with UFH, the termination letter must be copied to the Dean and/or HOD of the Faculty and/or Department where the staff member or researcher is based.

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Inter-Faculty Human Research Ethics Committee (IFHREC)

IFHREC SOP 011: Application Process

(Version: 29 August 2024)

1. Purpose

The purpose of this standard operating procedure (SOP) is to provide a standard way of applying of ethical clearance.

2. Scope

2.1 The SOP applies to all applications submitted to IFHREC. Research that is eligible to be reviewed and approved by IFHREC include:

2.1.1 Secondary Data Analysis

2.1.2 Qualitative research involving humans

2.1.3 Surveys

2.1.4 Desktop research

2.1.5 Desktop research

2.1.6 Laboratory research that involves non-pathogenic materials

2.1.7 Field-based research (e.g. Agricultural research (crop science, soil science, etc.), botanical research, microbiological research involving non-pathogenic microorganisms, Molecular Biology research, etc.

2.2 The SOP does not include:

2.2.1 Clinical or medical research,

2.2.2 Research involving animals or animal samples

2.2.3 Research involving biohazardous materials that include genetically modified organisms (GMOs), release of GMOs into the environment, recombinant DNA (rDNA), RNA derived from rDNA, human pathogens requiring biosafety level (BSL) 2 labs or higher BSL and radioactive materials.

3. Application Process

3.1 A fully completed Research Ethics Application Form dated and signed by the Researcher and Supervisor (if applicable); and

3.2 The Application Form should include:

3.2.1 A summary, synopsis, or diagrammatic representation of the research process.

3.2.2 Research instruments (i.e. Interview schedules, questionnaires and observation schedules intended for research participants) and, if applicable, should be translated into other languages relevant to the research.

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

3.2.4 Templates provided by IFHREC must be used.

3.2.5 A statement describing any incentives for participation in the research (if any).

3.2.6 A description of the arrangements to ensure that there will be no unauthorized access to research data (i.e. how the data will be kept safe).

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

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Inter-Faculty Human Research Ethics Committee (IFHREC)

IFHREC SOP 012: Amendments

(Version: 29 August 2024)

1. Purpose

This standard operating procedure (SOP) provides a standard way of handling amendments from approved proposal.

2. Scope

The SOP applies to any deviation from the proposal that was approved by IFHREC.

3. Minor Amendments

3.1 Minor amendments do not change the risk-benefit ratio of the study, in other words, the amendment does not increase the potential risks associated with the study.

3.2 Examples include:

3.2.1 Change of title,

3.2.2 Administrative changes,

3.2.3 Adding an investigator,

3.2.4 Changing the wording used in the information sheet and consent such as editorial changes.

3.2.5 Changes in background information or update of literature review

3.2.6 Other changes that do not affect study design and will not affect study outcomes or results

4 Major Amendments

4.1 These are changes that may affect the risk-benefit ratio by increasing the severity and / or number of risks associated with the study.

4.2 Examples include:

4.2.1 Inclusion of vulnerable groups in a study

4.2.2 Increasing the duration of study procedures

4.2.3 Adding some sensitive questions, etc.

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Inter-Faculty Human Research Ethics Committee (IFHREC)

IFHREC SOP 013: Extension of Ethical Clearance

(Version: 29 August 2024)

1. Purpose

This standard operating procedure (SOP) provides a standard and consistent way of handling applications for extension of ethical clearance for research projects that were approved by IFHREC but have not been closed-out because they have not been completed. A research project that has not been completed and has not been closed-out through submission of a final report must be covered by a valid ethical clearance.

2. Scope

The SOP covers research conducted by UFH staff members, postdoctoral fellows, students and UFH affiliates that is still ongoing and will not be completed by the date of expiry of the ethical clearance that was issued by IFHREC.

3. Procedure

The procedure to be followed shall be as follows:

3.1 The applicant shall complete an annual progress report indicating progress made in the project, outstanding research objectives, any challenges that may have been experienced and expected completion date.

3.2 The applicant shall indicate that extension of the ethical clearance is required.

3.3 IFHREC shall review the annual progress report, assessing if the research project has been conducted as per the approved proposal.

3.4 IFHREC shall assess if the risk-benefit ratio has not changed, and it still permits the study to be conducted.

3.5 If the annual progress report is not satisfactory, IFHREC shall provide feedback to the applicant and request them to address the identified shortcomings and resubmit the annual progress report.

3.5.1 If the annual progress report is satisfactory, IFHREC shall issue the ethical clearance certificate valid for 12 months from the date of approval.

3.6 The annual progress report shall form part of passive monitoring that is to be conducted by IFHREC.

4. Template

IFHREC shall provide a template for annual progress report that is linked to request for extension of ethical clearance.

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Inter-Faculty Human Research Ethics Committee (IFHREC)

IFHREC SOP 014: Rejection of retrospective application for ethical clearance

(Version: 29 August 2024)

1. Purpose

The purpose of this standard operating procedure (SOP) is to provide a standard way of rejecting any application for retrospective ethical clearance certificate. Under no circumstances shall research conducted at the University of Fort Hare by staff members, postdoctoral fellows, students or any persons affiliated with UFH 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, and 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 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.

2. Scope

The SOP applies to all University of Fort Hare (UFH) staff members, postdoctoral fellows, students and any persons affiliated with UFH.

3. Process of rejecting application for retrospective ethical clearance

3.1 Processing of application

3.1.1 If an application submitted to IFHREC is found to be for retrospective approval at the submission stage, it should still be tabled before IFHREC for review in accordance with the standard operating procedures for processing applications.

3.1.2 The application should be part of the agenda of a regular scheduled IFHREC meeting.

3.1.3 IFHREC members who review the application should present their comments to the committee, clearly explaining evidence from the application that indicates that the data were collected without valid ethical approval and the application is therefore for retrospective ethical approval.

3.2 Communicating the rejection of retrospective application for ethical clearance certificate

3.2.1 The decision of IFHREC shall be an outright written rejection of the application for retrospective approval.

3.2.2 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.

3.2.3 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.

3.2.4 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.

3.2.5 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.)

4 Possible consequences of conducting research without ethical clearance

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

4.2 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.

4.3 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.

4.4 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.

4.5 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.

5 Revising and resubmitting rejected application is not permitted

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

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.

University of Fort Hare
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Inter-Faculty Human Research Ethics Committee (IFHREC)

IFHREC SOP 015: Informed Consent

(Version: 29 August 2024)

1 Purpose

The purpose of this standard operating procedure is to provide a standard way of obtaining voluntary informed consent for participation in research.

2 Scope

The SOP covers all research projects reviewed, approved and monitored by IFHREC.

3 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 forms 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 documents 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.

Information Sheet and consent must include the following:

3.1 The qualification/s and contact details of the researcher/s
3.2 Participants' responsibilities
3.3 Purpose of the research, including the uses to which data will be put
3.4 Any risks and benefits to participants
3.5 Duration of study
3.6 Confidentiality considerations
3.7 A statement that participation is voluntary and that non-participation will not result in any penalty
3.8 A statement that ethics approval for the study was obtained from IFHREC with the ethics clearance certificate number
3.9 Contact details and name of IFHREC administrator
3.10 Contact details and name of the person overseeing research ethics matters at the UFH should there be any research related injury or harm
3.11 Information and consent must be written in simple language.

4 Translation of Information sheet and informed Consent documents

Multilingualism could pose challenges 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.

4.1 Information and consent documents should be available in the language(s) understandable to the participants. The applicant(s) should state the language(s) spoken by potential participants in the study area.

4.2 Documents are submitted to IFHREC 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.

4.3 In their annual progress reports, the researcher(s) shall report on translations done.

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

5 Research Involving Children/Minors

5.1 A "Child" is defined as someone younger than 18 years in the Constitution of the Republic of South Africa, 1996

5.2 Research with children must comply with DoH 2024

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

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

5.4.1 Research not involving greater than minimal risk to the children

5.4.2 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child participants involved in the research

5.4.3 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

5.4.4 Research that IFHREC 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.

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

5.6 Where parents and legal guardians are not available, IFHREC 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.

6 Non-therapeutic research involving minors: Ministerial Statement and Form A

6.1 Section 71(3)(a)(ii) of the National Health Act (NHA) stipulates that 'non-therapeutic' health research with minors requires approval of the Minister of Health.

6.2 'Non-therapeutic' research is defined as "research that does not hold out the prospect of direct benefit but holds out the prospect of generalizable knowledge".

6.3 Thus, in the context of minors, non-therapeutic research does not have exclusive benefits for minors and is not specific to minors, which means that it could be conducted with adults to generate the same generalizable knowledge.

6.4 Researchers who intend to conduct non-therapeutic research with minors must download a form prescribed by the Department of Health (Form A), complete it and upload it for submission to the Ministry of Health by the IFHREC.

6.5 IFHREC must submit the completed Form A application together with all the required documents to the Ministry.

7 Community-based research

7.1 In the case of research that involves communities IFHREC must ensure that those communities' traditions and values are respected.

7.2 This applies particularly to the process of obtaining consent to participate in the research.

7.3 Permission to enter the communities should be obtained from the relevant community leaders in accordance with the community's culture and traditions.

7.4 However, permission given by a community's leader does not absolve the researcher from also obtaining the informed consent of each individual participant.

8 Prison-based research

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

8.1 The application is submitted to the Department of Correctional Services Research Ethics Committee.

8.2 The researcher has complied with the conditions specified in the South African DoH 2024 Ethical Guidelines

8.3 The proposed research involving prisoners comply with relevant South African legislation and regulations.

University of Fort Hare
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Inter-Faculty Human Research Ethics Committee (IFHREC)

IFHREC SOP 016: Complaints

(Version: 29 August 2024)

1 Purpose

The purpose of this standard operating procedure is to provide a standard way of handling complaints that pertain to ethical issues surrounding research approved by IFHREC.

2 Scope

The SOP covers all research projects approved by IFHREC.

3 Complaints from applicants

3.1 Complaints from applicants may arise due to their dissatisfaction that may arise when IFHREC:

3.2 Rejects ethical clearance application

3.3 Terminates a study due to serious ethical issues or violations

3.4 Requires additional protections for participants or conditions before approving a proposal

3.5 Makes a decision that the researcher(s) may be unhappy with

4 Complaints from members of the public

Complaints from community members may arise where:

4.1 Proper consent (as defined in Section 1) is alleged not to have been obtained.

4.2 Risks are alleged not to have been addressed, or not addressed adequately

4.3 There is allegation of breach of confidentiality and privacy

4.4 There is allegation of lack of compliance with undertaking to disseminate research findings to participants

4.5 There is allegation of lack of transparency

4.6 Researcher is alleged to have committed some research misconduct

5 Procedure of handling complaints

5.1 The complaint must be submitted in writing, together with supporting information

5.2 IFHREC shall consider and determine the substance of the complaint.

5.3 Where the application raises a complaint that is not serious, IFHREC shall deal with it.

5.4 Where the application constitutes a complaint of a serious nature, the IFHREC chairperson, in consultation with IFHREC members, shall set up an ad hoc committee.

5.5 Membership of the ad hoc committee must consider the relevant field of study and expertise underpinning the complaint.

5.6 The ad hoc committee shall revisit the substance of, and/or investigate, the complaint.

5.7 The ad hoc committee must provide a report to IFHREC.

5.8 After deliberations on the report, IFHREC group make a decision, taking into account the report from the ad hoc committee.

5.9 Complainants are entitled to pursue IFHREC decisions through other means.

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Inter-Faculty Human Research Ethics Committee (IFHREC)

IFHREC SOP 017: Record Keeping

(Version: 29 August 2024)

1. Purpose

This standard operating procedure (SOP) is intended to provide a standard way of keeping records of IFHREC.

2. Scope

The SOP applies to all records of IFHREC generated through applications, review process, meetings, ethical clearances and monitoring.

3. Record Keeping

3.1 Applications

3.1.1 IFHREC reference number is allocated to all new applications. This number is recorded on all correspondence and additional attachments/amendments.

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

3.1.3 Copies of all research study related documents and correspondence are filed according to their reference numbers.

3.1.4 Records of all communication between investigators and the IFHREC office are recorded and filed using this reference number.

3.2 Meetings

Written minutes of IFHREC meetings will be recorded in sufficient detail to show:

3.2.1 Attendance at the meetings.

3.2.2 All actions taken by the IFHREC.

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

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

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

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

3.3 Other Records

3.3.1 IFHREC membership

3.3.2 Signed declarations to maintain confidentiality

3.3.3 Signed declarations of Conflict of Interest

3.3.4 Training records

3.3.5 Passive monitoring reports

3.3.6 Active monitoring reports

3.3.7 Audit information

3.3.8 IFHREC SOPs

3.3.9 Other IFHREC Documents (e.g. IFHREC Terms of Reference, Code of Conduct, NDoH 2024 guidelines, etc.).

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Inter-Faculty Human Research Ethics Committee (IFHREC)

IFHREC SOP 018: Whistle Blowing

(Version: 29 August 2024)

1. **Purpose**
   The purpose of the standard operating procedure (SOP) is to provide a mechanism for submission of information about wrongdoing related to research, which is whistleblowing, and a mechanism for acting on the submitted information.

2. **Scope**
   The SOP applies to a wide range of wrongdoing related to research, which shall be referred to herein as research misconduct, that include but is not limited to the following:
   2.1 Conducting research that involves humans without ethical clearance.
   2.2 Not obtaining informed consent from people recruited into a research project.
   2.3 Recruiting minors without parental consent.
   2.4 Undue inducement during recruitment of research participants.
   2.5 Fabrication or creation of research data.
   2.6 Falsification or manipulation of research data. This may include manipulating research materials, equipment, or processes, or changing or omitting data or results to suit a desired outcome.
   2.7 Misuse of research funds.
   2.8 Plagiarism.

3. **Procedure**

3.1 The whistleblower shall complete a form for reporting research misconduct which is provided by IFHREC
3.2 The whistleblower shall submit the completed form to the IFHREC Chairperson or IFHREC administrator.
3.3 Upon receipt of the completed whistleblowing form, the IFHREC Chairperson shall set up an ad hoc committee to investigate the alleged misconduct.
3.4 The ad hoc committee may conduct site visits and interviews to gather and or verify information.
3.5 Details of the alleged misconduct and the identity of the accused person shall be kept private and confidential throughout the process, in accordance with the South African Protected Disclosures Act (PDA) 26 of 2000, amended by the Protected Disclosures Amendment Act, Act 5 of 2017.
3.6 If the committee does not find evidence that supports the allegations, the IFHREC Chairperson shall explain the findings to the whistleblower and no action shall be taken against the accused person.
3.7 If the committee finds that there is a prima facie case, appropriate action (which could be disciplinary action) shall be recommended to the institution and the findings shall be explained to the whistleblower by IFHREC Chairperson.

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Inter-Faculty Human Research Ethics Committee (IFHREC)

IFHREC SOP 019: Material Transfer Agreement

(Version: 29 August 2024)

1 Purpose

The purpose of the standard operating procedure (SOP) for material transfer agreements (MTA) is to provide a standard framework for sharing materials that are to be used for research purposes in a collaborative research project that involves researchers from the University of Fort Hare (UFH) and researchers from other universities and / or organisations.

2 Scope

The scope of the SOP covers research that involves sharing of research materials for research conducted by UFH staff members, postdoctoral fellows, students and UFH affiliates in collaboration with researchers from other universities and /or organisations. The SOP covers the UFH Inter-Faculty Research Ethics Committee (IFHREC) that shall be responsible for ensuring that applications for ethical clearance of collaborative research that involve sharing of research materials include a completed and duly signed MTA, or in instances where it has not yet been duly signed, a statement indicating progress made in ensuring that the MTA is duly signed.

3 Procedure

The procedure to be followed shall be as follows:

3.1 IFHREC shall not accept an application for ethical clearance of research that involves sharing of research materials that does not have MTA

3.2 IFHREC shall ensure that the MTA covers the following:

3.2.1 Name of the university/organization that will provide the research materials
3.2.2 First name, surname and national identification number of the researcher leading the collection and sending of the materials that will be provided to the other university/organization.
3.2.3 Name of the university/organization that will receive the research materials
3.2.4 First name, surname and national identification number of the researcher that will receive the materials at the receiving university/organization.
3.2.5 Description of the research materials
3.2.6 Number and / or quantity (e.g. weight, volume, etc.) of the research materials that will be shared.
3.2.7 Explicit purpose that is based on the research proposal.
3.2.8 If research materials are to be sent to several partner universities/organisations, there must be a separate MTA for each receiving university/organisation.
3.2.9 A receiver shall not be permitted to share the research materials with any other university/organisation (third party). It is only the provider of the research materials that can enter into an agreement to share the research materials with specific universities/organisations.
3.2.10 First name, surname and position of the legal representative of the university /organization that will provide the research materials
3.2.11 First name, surname and position of the legal representative of the university /organization that will receive the research materials.

4 Duration

4.1 The MTA shall cover sharing of materials during the life span of the approved research project and shall not authorize transfer of research materials after the expiry of the ethical clearance of the research project.
4.2 Any left-over research materials must be disposed of appropriately and must not be used for any other purpose after the approved research project has ended.

5 Responsibilities

5.1 It shall be the responsibility of the provider and receiver of the shared research materials, through their universities or organisations, to obtain all pertinent permits or approvals for the export, import and /or shipment of the shared research materials.

5.2 IFHREC has the mandate to monitor (passively and / or actively) compliance with MTA of research projects that it approved.

6 Template

6.1 IFHREC shall provide MTA template for UFH researchers to use

6.2 Other MTA templates shall be acceptable to IFHREC provided they cover the minimum details specified in this SOP.

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Inter-Faculty Human Research Ethics Committee (IFHREC)

IFHREC SOP 020: Data Transfer Agreement

(Version: 29 August 2024)

1 Purpose

The purpose of the standard operating procedure (SOP) for data transfer agreements (DTA) is to provide a standard framework for sharing data that are to be used for research purposes in a collaborative research project that involves researchers from the University of Fort Hare (UFH) and researchers from other universities and / or organisations.

2 Scope

The scope of the SOP covers research that involves sharing of research data for research conducted by UFH staff members, postdoctoral fellows, students and UFH affiliates in collaboration with researchers from other universities and /or organisations. The SOP covers the UFH Inter-Faculty Research Ethics Committee (IFHREC) that shall be responsible for ensuring that applications for ethical clearance of collaborative research that involve sharing of research data include a completed and duly signed DTA, or in instances where it has not yet been duly signed, a statement indicating progress made in ensuring that the DTA is duly signed.

3 Procedure

The procedure to be followed shall be as follows:

3.1 IFHREC shall not accept an application for ethical clearance of research that involves sharing of research data that does not have DTA

3.2 IFHREC shall ensure that the DTA covers the following:

3.2.1 Name of the university/organization that will provide the research data

3.2.2 First name, surname and national identification number of the researcher leading the collection and sending of the data that will be provided to the other university/organization.

3.2.3 Name of the university/organization that will receive the research data

3.2.4 First name, surname and national identification number of the researcher that will receive the data at the receiving university/organization.

3.2.5 Description of the research data

3.2.6 Number and / or quantity (e.g. weight, volume, etc.) of the research data that will be shared.

3.2.7 Explicit purpose that is based on the research proposal.

3.2.8 If research data are to be sent to several partner universities/organisations, there must be a separate DTA for each receiving university/organisation.

3.2.9 A receiver shall not be permitted to share the research data with any other university/organisation (third party). It is only the provider of the research data that can enter into an agreement to share the research data with specific universities/organisations.

3.2.10 First name, surname and position of the legal representative of the university /organization that will provide the research data

3.2.11 First name, surname and position of the legal representative of the university /organization that will receive the research data.

4 Duration

4.1 The DTA shall cover sharing of data during the life span of the approved research project and shall not authorize transfer of research data after the expiry of the ethical clearance of the research project.

4.2 Raw research data must be disposed of appropriately and must not be used for any other purpose after the approved research project has ended.

5 Responsibilities

IFHREC has the mandate to monitor (passively and / or actively) compliance with DTA of research projects that it approved.

6 Template

6.1 IFHREC shall provide DTA template for UFH researchers to use.

6.2 Other DTA templates shall be acceptable to IFHREC provided they cover the minimum core information required by IFHREC.

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Inter-Faculty Human Research Ethics Committee (IFHREC)

IFHREC SOP 021: International Collaborations and Partnerships

(Version: 29 August 2024)

1 Purpose

This standard operating procedure (SOP) is for research projects that are to be conducted by University of Fort Hare (UFH) and researchers in collaborative partnerships with researchers from from other international universities and / or organisations.

2 Scope

The scope of the SOP covers research that involves UFH staff members, postdoctoral fellows, students and / or UFH affiliates conducting research in collaborative partnership with researchers from other international universities and /or organisations. The SOP covers the UFH Inter-Faculty Research Ethics Committee (IFHREC) that shall be responsible for ensuring research that involves international collaborative partnerships is conducted ethically in accordance with the NHREC guidelines of 2024.[1]

3 Procedure

The procedure to be followed shall be as follows:

3.1 IFHREC shall not accept an application for ethical clearance of research that involves international collaborative partnership that

[1] 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. 137p. ISBN 978-0-621-52027-9.

does not have a partnership Memorandum of Understanding or Agreement (MOU or MOA)

3.2 IFHREC shall ensure that the MOU/MOA covers the following:

3.2.1 Names of the partnering universities (UFH and the other party)

3.2.2 Details of the collaborative partnership that include, inter alia, the following:

3.2.2.1 Purpose of the collaborative partnership

3.2.2.2 Expected deliverables

3.2.2.3 Responsibilities of each party

3.2.2.4 Sharing of research materials (accompanied by MTA if applicable)

3.2.2.5 Sharing of research data (accompanied by DTA if applicable)

3.2.2.6 Publications and co-authorship

3.2.2.7 Financial management

3.2.2.8 Dispute resolution procedure

3.2.2.9 Duration of the MOU/MOA

3.2.2.10 Intellectual Property ownership, possible commercialization and sharing

3.2.2.11 The MOU/MOA shall be vetted by the UFH Legal Office, Registrar's Office, prior to the submission to the Vice Chancellor's Office for approval and signing off.

4 IFHREC Ethical Clearance

4.1 IFHREC shall give ethical clearance that is within the duration of the duly signed MOU/MOA for the research project concerned.

4.2 IFHREC shall recognize ethical clearance issued by an accredited REC.

University of Fort Hare
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Inter-Faculty Human Research Ethics Committee (IFHREC)

IFHREC SOP 022: Protection of Personal Information

(Version: 29 August 2024)

1 Purpose

The purpose of this standard operating procedure (SOP) is to provide a standard way of protecting personal information without preventing ethically and legally permissible access to information that does not compromise protection of personal information. This enables IFHREC to achieve a balance between the Protection of Personal Information Act (POPIA) and the Promotion of Access to Information Act (PAIA).

2 Scope

The scope of the SOP covers all information received, processed and kept by IFHREC administrators and IFHREC members.

3 Procedure

The procedure to be followed shall be as follows:

3.1 IFHREC members shall sign a code of conduct that covers the obligation to uphold privacy and confidentiality of REC information.

3.2 IFHREC minutes shall only be accessed by REC members, Senate Research Ethics Oversight Committee and other official authorities (e.g. court of Law).

3.3 To comply with POPIA, IFHREC reports that will be accessible in the public domain must not have any personal identifiers of

applicants and research participants that include, but not limited to, the following:

3.3.1 Names
3.3.2 Date of birth
3.3.3 Addresses
3.3.4 Telephone numbers
3.3.5 Email addresses
3.3.6 etc.

3.4 To uphold PAIA, information that does not have personal identifiers and general information and statistics may be provided in the form of reports.

3.5 Requests from third parties for information of any nature shall be considered by the Chairperson of IFHREC.

3.6 The Chairperson shall approve any information that is to be shared with third parties.

University of Fort Hare
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Inter-Faculty Human Research Ethics Committee (IFHREC)

IFHREC SOP 023: Training

(Version: 29 August 2024)

1. **Purpose**

   The purpose of this standard operating procedure (SOP) is to provide guidance in terms of training that IFHREC should ensure that it is implemented to enable it to function effectively and in accordance with the National Health Research Ethics Council (NHREC) guidelines.

2. **Scope**

   The SOP applies to IFHREC members, staff members, postdoctoral fellows, students and UFH affiliates. It applies to mandatory as well as non-mandatory training.

3. **Training**

   3.1 Training for IFHREC members

   3.1.1 Induction upon joining IFHREC

   3.1.1.1 Upon joining IFHREC, members shall undergo an induction facilitated by the Chairperson

   3.1.1.2 The induction training shall cover the following:

   3.1.1.2.1 National Health Research Ethics Council guidelines

   3.1.1.2.2 UFH Research Ethics Policy

   3.1.1.2.3 Composition and accreditation of IFHREC by NHREC

   3.1.1.2.4 UFH Research Ethics Committees Code of Conduct

3.1.1.2.5 Mandate of IFHREC
3.1.1.2.6 IFHREC Terms of Reference
3.1.1.2.7 IFHERC Standard Operating Procedures (SOPs)
3.1.1.2.8 IFHREC Templates that include application form, Information Sheet, Informed Consent Forms (for adults, for parental concent, assent forms), Material Transfer Agreements (MTAs), Data Transfer Agreements (DTA), etc.
3.1.1.2.9 Ethical review process
3.1.1.2.10 Passive and active monitoring

3.1.2 Training on Research Ethics and Ethical Review

3.1.2.1 Ethical principles that include principles of beneficence, non-maleficence, autonomy and distributive justice.
3.1.2.2 Research integrity and research misconduct
3.1.2.3 Vulnerable groups
3.1.2.4 Risk-benefit ratio analysis
3.1.2.5 At least one assessed training with certificate to indicate that the candidate passed the assessment

3.1.3 Other Training Activities

IFHERC members shall be encouraged to participate in any other training that is related to research ethics; the training may be workshops, seminars, conferences organized internally or externally.

3.2 Training for IFHREC Administrators

3.2.1 Training on ethical review process
3.2.2 Developing agenda for meetings
3.2.3 Writing minutes of meetings
3.2.4 Providing feedback from IFHREC to applicants
3.2.5 Record keeping

3.3 Training for researchers

3.3.1 Research Ethics topics
3.3.2 Research misconduct

3.3.3 Ethical principles and research integrity
3.3.4 Risk-benefit ratio analysis

4 Responsibilities

4.1 The University of Fort Hare shall provide resources for training for IFHREC members, IFHREC administrators and UFH researchers.
4.2 IFHREC shall organize training activities for the various target audience
4.3 IFHREC members, IFHREC administrators and UFH researchers shall be expected to create time to undergo training.