UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA

UFS UV

Document name	**General/Human Research Ethics Committee Standard Operating Procedure**
Developed by	**Members of the General/Human Research Ethics Committee**
Date	**November 2022_V1**
Type of document	**Standard Operating Procedures**
Relevant institutional policies/guidelines	**University of the Free State Research Integrity and Ethics Policy**
Status	**APPROVED**
Approved by	**University of the Free State Senate Research Ethics Committee**
Date of approval	**23 November 2022**
Implementation date	**23 November 2022**
Date for next review	**November 2025**

SIGNATURE:

Prof Vasu Reddy

DVC: Research and Internationalisation

Table of Contents

STANDARD OPERATING PROCEDURES (SOP)

1. Roles and responsibilities

The GHREC will function according to the Standard Operational Procedures (SOP) formulated in this document.

Ethical issues in research often require case-by-case deliberation. The ethics review process should not be mechanical and should consider each application on its own merit. Although the consistency of review outcomes for similar studies may be desirable, it is not always possible or appropriate in light of the details of an application.

In making decisions regarding the research proposal under review, the GHREC focuses in particular on:

- actual or potential ethical risks related to research proposals and
- measures to avoid or minimise these risks, among other ethically important considerations

The GHREC review proposals from researchers affiliated with the UFS only, without levying a review fee. The Committee does not conduct reviews for external applicants **except** in cases with an agreeable motivation and an agreement, where a review fee will be applicable.[1] A review fee will be levied as provided in the UFS Research Integrity and Ethics Policy.[2]

The GHREC will be available to render researchers, upon formal request, an expert opinion regarding research ethics (advice regarding application procedures will be addressed on an informal and ad hoc basis by the Directorate: Research Development).

The Directorate Research Development (DRD) is responsible for the Secretariat of the GHREC.

2. Submission and review procedures

The GHREC is tasked with reviewing research proposals **before** the research can commence. The GHREC does not provide retrospective approval.

The responsibility to submit research proposals and applications for ethical review and clearance to the GHREC rests on the individual researcher. In the case of student research, the supervisor takes responsibility.

Requirements for applying for ethical clearance with the GHREC through the electronic online system (RIMS) are available to prospective applicants on the website of the Directorate Research Development.

---

1 ToR para 4.5.
2 UFS Research Integrity and Ethics Policy, SOP para 8.

All research proposals of researchers at the UFS (excluding health research, research using animals and Environmental and Biosafety research) will be reviewed by the GHREC.

Research involving students, staff (employees), alumni of the UFS, or external collaborators must also be submitted for review by the GHREC, irrespective of the level of risk involved. This includes all research done on any UFS premises or in any UFS facilities.[3] It also includes collaborative, multi-institutional, or multi-country[4] studies.

Researchers, supervisors, academic heads of department and faculty / departmental scientific committees have the primary responsibility to ensure that research conducted in their respective disciplines is characterised by methodological rigour and scientific merit and complies with the guidelines of relevant professional bodies and scientific organisations and any applicable or relevant legislation, institutional, national and international ethics guidelines.

2.1 Faculty or departmental scientific and ethics review processes

Scientific review of research proposals takes place at a departmental and/or faculty level. Scientific review and approval are required for student research projects before an application for ethical clearance can be submitted.

After submitting an application for ethical clearance online on RIMS, the Ethics Administrator receives an online notification of a new application. Following the deadline for submissions and in consultation with the Chairperson the ethics administrator sends the application to two committee members of the GHREC with the necessary expertise in the field of study to do a review. Members have ten working days to complete a review. Feedback is submitted online on the reviewer's feedback template on RIMS. Once completed, the reviews route to the GHREC Secretariat and the application is placed on the Agenda for the first next meeting of the GHREC. The GHREC discusses the reviews and makes the final decision during the formal monthly meeting. Only the Chairperson can provide a digitally signed feedback letter. For detailed information on the timelines and how feedback is provided to the applicant, refer to Section 3 of this document.

All research ethics applications and processes are conducted online on RIMS. No paper-based applications will be considered for ethical clearance. Only electronically signed approval letters from the Chairperson of GHREC with a valid approval number will be considered valid and can be used as proof of ethics approval.

Applications must be completed in plain, non-technical language that can be understood by all members of the GHREC, irrespective of their field of specialisation. This includes the layperson. An application should be written in English. Exception can be made for application in other languages based on a strongly motivated reason.

---

[3] See UFS Research Integrity and Ethics Policy, SOP para 3 "Scope".

[4] For a multi-country study, there must be a collaborator in the corresponding country or countries where ethical clearance processes are also followed.

In the review, the application and research proposal, as well as all supporting documents, are considered.

For the criteria considered during the GHREC's ethics review, the Department of Health's guidelines (2015), Chapters 2 and 3 apply.[5]

- Relevance, value and scientific integrity with specific consideration of the research design, aims and objectives;
- Research procedures (which include a review of activities for the participation and data to be collected from participants);
- Risk of harm and likelihood of benefit;
- Reimbursements and inducements for participants;
- Ongoing respect for the dignity of participants, including their privacy and confidentiality interests;
- Process of obtaining informed consent and documents provided to participants
- If applicable, criteria for withdrawing research participants (if applicable) before completion of the research.
- The measures of support provided to participants (if applicable) if they need it during or after the research.
- Fair selection of participants with consideration of the recruitment process. In the assessment of the recruitment of research participants, the following will be considered, as applicable:
    - The characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status, or ethnicity). Special attention will be given to vulnerable individuals and groups (Definition in Appendix A).
    - Inclusion and exclusion criteria for research participants.
- Care and protection of research participants. The following will be considered concerning the protection of research participants, as applicable, taking into account that a wide variety of types of research are conducted that fall within the mandate of the GHREC:
    - The suitability of the investigator(s)'s qualifications and experience for the proposed study, adequacy of supervision of researchers in training involved in the study.
    - The adequacy of psychological or other care to be provided to research participants during and after the course of the research, if applicable, those who reported adverse events, and to participants who voluntarily withdrew from the study
    - provisions to ensure research participants do not incur any financial costs in participating.
    - The compensation for research participants in the event of injury/death attributable to participation in the research.

---

5 See REC: SBE SOP, 2020, chapter 5.

- Protection of research participant privacy and confidentiality. The following will be considered with respect to the protection of research participant confidentiality, as applicable:
    - Measures taken to ensure the confidentiality and security of personal information concerning research participants.
    - A data management plan must be in place, detailing –
        - a description of the persons who will have access to personal data of the research participants (including medical records and biological data, or any other records of a confidential nature), where applicable;
        - how data will be kept (in electronic, hard-copy, or any other format) to ensure safe storage, and to prevent any unauthorised access to it, duration of data storage, destruction, and sharing in compliance with POPIA.
- Informed consent process. The following will be considered concerning the informed consent process, as applicable:
    - A full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent, as it is relevant and appropriate to the research.
    - The adequacy, completeness, and clarity of written and oral information to be conveyed to prospective research participants, and, when appropriate, their legal representative(s).
    - Clear justification of the intention to include in the research individuals who cannot give consent, and a full account of the arrangements for obtaining consent or authorisation for the participation of such individuals.
    - A clear description of the measures taken to obtain permission (i.e. consent (Definition in Appendix A)) from parents/guardians for their children to participate in research.
    - A clear description of the measures taken to obtain assent (Definition in Appendix A) from minors (younger than 18 years of age) to participate in research.
    - A clear description of reasons for any request to waive consent or assent.
    - A clear indication of the assurances given to research participants prior to commencing with the research that their rights, safety, dignity and well-being will be protected.
    - A clear indication that research participants will receive information that becomes available during the course of the research relevant to their participation (including information about their rights, safety, and well-being).
    - The provisions for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project.
    - A full description of how research results will be made available to research participants and, where applicable, the community/communities/groups in the communities where the research was done.

    - A clear description of reasons for not making research results available to participants or the community/communities in which the research was done.
- Guidance on risk and benefit assessment[6]
    - The ratio of risk of harm to the likelihood of benefit should be favourable, i.e. the likelihood of benefit, at least to the category of person involved, should outweigh the risk of harm to the participants as well as to the community or society as a whole.
    - In weighing risk of harm against the likelihood of benefit, the analysis is concerned not only with the participants themselves but also with community or societal interests.
    - The ratio may be analysed by considering whether
        - the harms and benefits are adequately identified, evaluated and described;
        - the harms stated in the proposal match those stated in the informed consent documentation;
        - the risk of harm is reasonable in relation to the anticipated benefit;
        - the risk of harm is reasonable in relation to the importance of the anticipated knowledge to be gained;
        - counselling and support services will be made available if appropriate.[7]
    - Anticipated harms should be minimised by preventing occurrence as far as possible and by implementing appropriate remedial interventions, should the harm occur. The nature of harms will vary in accordance with the type of research under consideration and may include physical, psychological, legal, social (including stigma) and financial harms.
    - The REC should also assess the possibility of harm to the researcher, study or project personnel, e.g. safety concerns.
- Protection of researchers, research partners, research assistants, and/or field workers. The following will be considered concerning the protection of researchers, research partners, research assistants and or fieldworkers:
    - The ethical risks that researchers, research partners, and research assistants are exposed to in the course of the research, and the question of whether appropriate and adequate measures are put in place to avoid or minimise these risks.
- How their interests, e.g., contribution and authorship, are recognised.
- Community considerations. The following will be considered with respect to the impact of research on communities, as applicable:
    - The impact and relevance of the research on the local community.
    - The steps taken to consult with the concerned communities and obtain permission.

---

[6] DoH 2015 para 3.1.6.

[7] E.g. if emotional distress is a likely side effect of research procedures, arrangements to facilitate access to assistance should be made.

- Discussions of potential benefit sharing about, for example, the extent to which the research contributes to capacity building in the community and/or the responsiveness of the research to the community needs, must be conducted.
- The manner in which the research results will be made available to the research participants and the concerned communities, or groupings within them.

2.2 GHREC review meetings

Meetings will be scheduled to be held every month except in December. Meetings are scheduled for the last Thursday of each month or another suitable day as per the Chairperson's decision.

The deadline for submissions by applicants is the 1st business day of each month. The researcher remains responsible for submitting the application within the given timeframes and responding to requested modifications timeously.

No meetings are scheduled for December. The GHREC will attempt to accommodate urgent submissions during December on an ad hoc basis. Clearly motivated applications may be considered for an ad hoc review in exceptional cases (e.g. sponsor deadlines). This is an extraordinary measure and will be accommodated as far as possible at the Chairperson's discretion.

At the last meeting of the current year, members will be notified of the scheduled dates of meetings for the following year. Meeting dates are also published on the RIMS webpage and the Directorate: Research Development (DRD) website to be accessible to all researchers.

The meetings of the GHREC will be minuted.

Minutes of meetings will be included in the agenda of the next meeting of the GHREC for approval and to deal with matters arising.

Approved minutes will be signed by the Chairperson and appropriately filed for record-keeping by the Secretariat.

2.2.1 Review meeting protocol

The GHREC Secretariat compiles an agenda with all the applications submitted and reviewed (responses and re-submissions from applicants) before the agenda closes. The agenda for the meeting closes ten working days before the meeting date.

All applications are captured on RIMS, which committee members have access to.

The GHREC chairperson may co-opt an external expert reviewer for a specific application. This may be done at the Chairperson's discretion if she/he feels that the Committee could benefit from specific expertise to perform an adequate review of the relevant application.

A quorum must be present at the meeting. Thirty-three per cent of the voting members constitute a quorum. Every effort will be made to have at least one of the members who reviewed an application present at the meeting.

Conflict of Interest is a standing item on the agenda. Where a member has a potential conflict of interest due to their involvement in a project on the agenda, they must indicate the conflict

of interest at the beginning of the meeting. A conflict of interest will be handled as provided in Section 5 of this document.

Attendance of applicants: The researcher, supervisor or Academic Head of Department may be invited to present the research proposal or elaborate on specific issues at a meeting of the GHREC or, if applicable, at a special meeting of the GHREC. The final decision will be made in the absence of the invitees. The decision of the committee will be communicated to the applicant as described in Section 4 of this document.

2.3 Rapid reviews

Valid and clearly motivated applications may be considered for a rapid review in exceptional cases, e.g., health emergencies. This is an extraordinary measure and applies to applications which are time-sensitive. All applications for a rapid review must be thoroughly motivated in writing by the researcher or supervisor and approved for rapid review by the Chairperson.

The GHREC can also decide to treat a category of research projects dealing with time-sensitive subject matter in a rapid process.

The rapid review process entails the following:

- The application should have undergone a scientific review (in the case of student researchers).
- The request is directed at the Chairperson, and if the Chairperson approves a rapid process, the application is submitted on RIMS by the usual procedure described in Section 2.1 of this document. The Chairperson allocate two members of the committee as reviewers.
- The reviewers review the application and make a recommendation. The Chairperson then convenes a special meeting of the GHREC to discuss the application and make a decision and feedback is then provided to the applicant as described in Section 4 of this document.
- Every effort will be made to provide feedback within three to five days of receipt of the application.

2.4 Expedited reviews

Expedited reviews are conducted only for minimal risk studies and may include studies employing the method of review of materials available in the public domain, such as:

- Published works, systematic reviews, literature reviews, collective reviews.
- Archived materials that are available in the public domain.
- Newspapers, websites, magazines, public reports, public statements, films, television programs, public performances, public exhibitions, and public speeches.
- A desktop/literature study refers to a study that is carried out exclusively through the use of publicly available data or information. This may be a preliminary study carried out before a more detailed investigation, or it may be a stand-alone study.

Expedited reviews also apply to studies that qualify for exemption from formal ethics review.[8]

All above-mentioned research must be submitted via RIMS using the applicable online application form. The Ethics Administrator verify that the application qualifies for the expedited process. The Chairperson of the GHREC makes the final decision, which may include signed acknowledgement or approval, or an Exco review and final decision.

The final decision of a study's ethics review exempt status can only be made by the GHREC Chairperson and not by the applicant or another third party.

Other types of research that fall under the GHREC mandate (low-risk studies) but do not involve humans, or private information of humans, outside the research team, and do not fit the categories above, may also qualify for exemption at the discretion of the Chairperson. Examples include:

- Simulation studies, where all data is hypothetical and generated by the researchers themselves, possibly using (pseudo) random number generators, and clearly identified as such.
- Studies relying on the generation of mathematical derivations, proofs, algorithms, or computer code.

2.5 Reciprocal review process

The GHREC may, at its own discretion, recognise the prior review and approval of a research proposal by another NHREC-registered committee to avoid duplication of efforts.

When the GHREC recognises prior review in this manner, specific documents must be filed locally. This includes a copy of the approval letter from the other NHREC-registered Committee, research proposal, data collection instruments, information and consent forms, and relevant recruitment material.

The GHREC may revise their decision to do so if justifying circumstances arise. The reasoning supporting a reversal of recognition will be documented.

The above does not prevent the GHREC from initiating its own independent review process of an application for reciprocal approval.

Responsibilities: The GHREC will only be responsible for the sites of which they have oversight and that they approve. The REC of record will remain responsible for the management of the entire study.

2.6 Reviews by multiple UFS RECs

Applications for ethical clearance can be submitted to more than one of the UFS Research Ethics Committees if the study involves research that is governed by more than one Research Ethics Committee.

---

[8] Refer to DoH 2015 Guidelines 1.19.

The GHREC can also, as one of its findings on an application, direct the applicant to also submit the application to another UFS Research Ethics Committee if part of the research in the protocol falls within the mandate and scope of such another committee (for example, when studies involve human participants and animals). In these instances, the GHREC will conditionally approve the study until approval from the referred Committee is provided, after which the study will receive full approval.

3. Decision-making within the GHREC

3.1 Decision-making process

In making decisions on applications for the ethics review of research, the GHREC will make use of the following procedures and considerations: Decisions can only be made at meetings where a quorum is present.

The documents required for a full review of the application should be complete, and they should be considered before a decision is made.

Decisions at meetings of the GHREC are arrived at through discussion and need consensus, where possible. When consensus is not reached, it is recommended that the GHREC members vote. Each member shall have one vote, and the Chairperson will have a casting vote in addition to a deliberative vote. If there is a stay of votes, the Chairperson of the GHREC can cast a deciding vote. Only voting members can participate in decision-making.

Non-binding advice may be appended to the decision of the GHREC

3.2 Committee Decision

The GHREC can make the following decisions, including but not limited to:

- The approval of a research ethics application
- Conditional approval when the project can be approved, but documents such as a letter of permission from an authority or gatekeeper's approval are required.
- Modifications required before approval
- Rejected
- Not approved with major modifications required (This requires a new submission to be made).

3.3 Communicating a decision

The decision or outcome of the GHREC review will be communicated to the applicant in an electronic letter, normally within five working days following the meeting at which the decision was made.

The content of the communication will, at least, include the following:

- The exact title of the research proposal reviewed.

- The precise identification number of the research proposal/protocol/study of the proposed research.
- The name and title of the applicant.
- A clear indication that the decision was taken by the GHREC.
- A clear statement of the decision made.
- Any advice or recommendations by the GHREC.
- In the case of a modification request or a conditional decision, any requirements as indicated by the GHREC.
- In the case of a favourable decision, a statement of the responsibilities of the applicant, for example, submission of continuation/progress report(s); the need to notify the GHREC in cases of protocol amendments or any adverse event (Definition in Appendix A), continuation/progress (when applicable) or final reports.
- Approval is only valid for one year from the date of the clearance letter. If a research project stretches over more than one year, it is the researcher's responsibility to apply for an extension of the approval before the validity of the approval has lapsed.
- In the case of an unfavourable decision on an application, the communication must clearly state the reason(s) for the decision and suggestions to amend the application and/or supporting documents.
- Signature (dated) of the Chairperson of GHREC.

4. Conflict of interest management

Before the commencement of a meeting, the Chairperson must request all present to declare any potential conflict of interest.

The conflicted member must recuse themselves before the discussion of and decision-making on the application. The recusal will not affect the quorum. The declared conflict and recusal must be minuted. The same procedure is followed if the Vice-Chairperson declares a conflict of interest.

If the Chairperson declares a conflict of interest, the Chairperson must withdraw from the meeting for the discussion and decision-making process. In such an instance, the Vice-Chairperson will act as the Chairperson of the meeting for the duration of the discussion and decision process of the relevant application. The Vice-Chairperson will also be responsible for signing the letter advising the relevant applicant of the outcome of the application and all subsequent engagement with the application that the Chairperson would have ordinarily done.

5. Monitoring of research in progress

The frequency and type of monitoring should reflect the degree and extent of risk of harm to participants.

The GHREC may recommend and adopt any other appropriate monitoring mechanism. These could include frequent passive monitoring, random inspection of research sites,

welfare monitoring sheets, data and signed consent forms, and records of interviews. Information and consent materials should indicate that such monitoring may take place. In studies with a high-risk research profile, the GHREC could assume an active monitoring role instead of a passive approach. This could be done in high-risk studies or if the GHREC receives an alert about a study, which includes a report by a whistle-blower. In such cases, the Chairperson will assign a member of the GHREC to investigate the matter and follow an active monitoring process. That member will then report their findings and recommendations to the GHREC. The GHREC will then decide on a further course of action. This should be read with the paragraph dealing with the suspension or termination of studies below.

The GHREC ensures regular monitoring and evaluation of the ethical risks related to ongoing studies approved by the GHREC – particularly in research that entails high ethical risk (Definition in Appendix A).

5.1 Passive monitoring

RIMS should generate online alerts 12 months after the date of approval requesting researchers to submit progress or final reports for studies. This process applies until the finalisation of the research, for which approval was granted. This annual reporting (passive monitoring) will apply to all low- and medium-risk studies.

For studies carrying a high ethical risk, researchers must report every six months for the duration of the study or at shorter intervals if required by the GHREC. The GHREC will minute this status at the meeting where the application is considered. Through the Secretariat, the application will be noted on the RIMS platform so that the necessary alerts can be generated at such times as the GHREC decides.

Ethical clearance is needed for the full period of the study.

If the study is not completed within the approved period of twelve months, a progress/continuation report must be submitted to request an extension of the approval period.

The applicant must submit progress or final reports and other subsequent submissions as required, e.g., Progress/Continuation Report or Amendments.

5.2 Follow-up procedure

The follow-up procedure will take into consideration the following:

- The requirements for follow-up reviews, the review procedure, and the communication procedure may vary from the requirements and procedures for the initial decision on an application.
- The follow-up review intervals are determined by the nature and the events expected in relation to particular research projects. However, each research project should undergo a follow-up review at least once a year.
- The following instances or events require the follow-up review of a study:

  - any protocol amendment likely to affect the rights, safety, and/or well-being of the research participants or the conduct of the study.
  - serious and unexpected adverse events (Definition in Appendix A) related to the conduct of the study or study results and the response taken by investigators, sponsors, and regulatory agencies, when applicable.
  - any event or new information that may affect the benefit/risk ratio of the study.
- A decision of a follow-up review will be issued and communicated to the applicant, indicating a modification, suspension, or termination of the GHREC's original decision or confirmation that the decision is still valid.
- In the case of the premature suspension/termination of a research project that GHREC approved, the applicant should notify the GHREC immediately of the suspension/termination and the reasons for suspension/termination.
- A summary of results obtained in a study prematurely suspended/terminated should be communicated immediately to the GHREC.
- The GHREC should receive notification from the applicant at the time of the completion of a study.

6. Suspension or termination of studies

When circumstances indicate that a project is non-compliant with the approved proposal and the interest of the participants is at risk of harm or impact on human well-being exceeding what has been approved or can be justified, the GHREC may withdraw approval, after due process.

A clear process should be followed that permits swift but proper investigation and decision-making to ensure the protection of participants. This should include interaction with the researcher and other interested parties to ensure a fair and transparent process. If a decision is to withdraw approval, the GHREC should inform the researcher and other interested parties. It should also recommend remedial actions where appropriate. In the case of suspension, the researcher should comply with the recommendations and/or conditions imposed by the GHREC.

7. Subsequent submissions

7.1 Amendments

Amendments are changes to an active study made in advance of the planned date of implementation. Prospective GHREC review and approval are requirements before implementing any changes (amendments in approved research). Approval cannot be granted retrospectively after a change has been made. This applies to all amendments, including those that may appear to researchers to be primarily administrative in nature.

Application for amendments is submitted on RIMS. Amendments may be classified as minor or major (substantive). The proposed amendments must include a justification or rationale for the proposed change(s).

The Ethics Administrator receives an electronic notification once a submission is made, and the Chairperson will determine whether the proposed amendment is a minor or major amendment. Major and minor amendments follow different processes.

7.1.1 Minor amendments

Minor amendments for projects that the GHREC initially approved as low risk may be reviewed by the expedited process rather than a full GHREC meeting. Minor amendments are changes to the proposed research and/or supporting documents considered negligible or non-substantial that would not alter the risk-benefit assessment of the study or increase the potential risk of harm to participants. These may include:

- Negligible changes to the study title, for example, correcting spelling or grammatical errors or reformulating a title for clarity without substantively changing the meaning.
- Small format/typographical/editorial changes to the informed consent documentation, questionnaires or recruitment flyers.
- Changes regarding the inclusion of a small number of additional questions, provided they do not change the meaning or tone of the questionnaire.
- Changes that do not affect the study design, study outcomes and/or the risk level of the project.
- Changes regarding a new site for the research, provided it is not distinctly different from the other research sites.
- Extension of the period over which the research is to be conducted.
- Minor administrative changes (i.e. contact information of the applicant and/or co-investigators).
- An increase or decrease in the proposed number of participants supported by a statistical justification.
- Changes regarding the inclusion of additional participants or informants, provided they are from the same population group as previously agreed to.

Following the Chairperson's determination that the application is a minor amendment, the application is routed to the Chairperson and Exco for a decision. The applicant is advised of the outcome in writing by the Chairperson.

7.1.2 Major amendments

Major amendments are changes to the proposed research and/or supporting documents that are deemed substantial enough to potentially result in an alteration of the risk-benefit assessment of the study or increase the potential risk of harm to participants. These may include:

- Changes in the study design or research methods.
- Changes to how data will be analysed.
- Adding another research activity, study procedure or including another phase of research.

- Changes to study population (i.e. the type of participants required for the research or adding a population group that is exposed to key vulnerabilities in the context of research or requiring specific attention by the REC).
- Changes regarding a new site if the new location is abroad or distinctly different from the previously agreed-upon research sites.
- Major changes to the documentation to be used during the research, including a substantial revision of the informed consent documents, a questionnaire or interview schedule.
- Significant changes to the inclusion or exclusion criteria.
- Change in the principal investigator whilst the project is still active.

Following the determination of the Chairperson that the amendment is classified as major, the ethics administrator sends it to two members of the GHREC for review, preferably those who reviewed the initial application or any two members with the necessary expertise in the field of study to make a recommendation.

The final decision regarding the approval of the amendment(s) is made at the full GHREC meeting. Communication of the decision to the applicant is as described in Section 3.3 of this document.

7.2 Progress / Continuation Report

A Progress / Continuation report must be submitted to the GHREC at the end of the approval period, which is twelve months if the project was not completed before that date. The report must be submitted on the prescribed form and provide details regarding, inter alia, research progress, preliminary findings, subject withdrawal or complaints.[9]

The Ethics Administrator sends it to two GHREC member reviewers with the necessary expertise in the field of study to make a recommendation for an extension of approval for another twelve-month term. The Chairperson of the GHREC makes the final decision. The applicant is advised of the outcome in writing by the Chairperson.

7.3 Final Report

After completion of the project, a final report must be submitted to GHREC via RIMS.

7.4 Adverse event / Unanticipated event report

Reports of incidences that might affect a research participant negatively or increase the risk of harm, or that might jeopardise the research outcome must be reported to the GHREC within seven days (7 days) of the incident. The report must quote the project number, title, the incident, cause, any remedial action taken if necessary, and the potential effect the incident could have on the project's outcome.

---

[9] See para 5 above.

Once a report is received, it is reviewed by Exco for the severity of the incidents. The Exco will then make recommendations to the investigator.

8. Application for gatekeeper's approval

In cases where researchers do not have a current ethics clearance certificate from their own institution or where the external institution is not an NHREC-registered committee, they must apply to the GHREC as an external applicant and complete a full application on RIMS. They are thus subjected to the full application and review process, and the application will not be expedited.

The GHREC reserves the right not to accept the research application for review.

A Researcher not affiliated with the UFS who wishes to use students, staff, or alumni of the UFS as research participants must first obtain ethical clearance. After ethics approval, the researcher must apply for the institutional gatekeeper's permission for the research.

9. Complaints handling procedure

Researchers who have complaints or grievances regarding the decisions of the GHREC must follow the process described in Section 10 below.

In reporting research misconduct or ethical concerns regarding a research study approved by GHREC, the complainant must first direct a complaint in writing to the GHREC Administration.

Within three business days of receipt, the GHREC Administration:

- Provides the GHREC Chairperson with a copy of the complaint; and
- Sends the complainant an acknowledgement of receipt of the complaint.

The GHREC Chairperson reviews the complaint to determine whether an appeal is appropriate. This may include consultation with the Exco to review the complaint.

If the complaint is against the Chairperson, the Vice-Chair will review the complaint to determine the steps to be taken.

The GHREC will exercise discretion on how to handle allegations of misconduct.

In performing the above, the GHREC **can**, after due consideration and consultation, take the following actions, including but not limited to:

- Monitor research.[10]
- Inspect a research site.[11]
- Request an immediate report on the ethical aspects of a research project.
- Temporarily suspend a research project.
- Suspend a research project.

---

[10] Refer Section 5 above.
[11] Refer Section 5 above.

- Investigate a case of a breach of research ethics.

If a complaint is not resolved by the GHREC, complainants may follow the appeal process of the Senate Research Ethics Committee (SREC).

10. Researcher appeals and complaints

10.1 Purpose

This section describes the procedures for appealing a determination by the GHREC. The defined process may be a two-stage process involving first the GHREC against which the appeal has been lodged. If the GHREC agrees or prefers, the matter can be referred to the Senate Research Ethics Committee (SREC) for finalisation. However, to retain the decisional integrity and independence of a REC within the institution, researchers first need to appeal to the GHREC; if not satisfactorily resolved, they may appeal to the SREC.

10.2 Policy

The GHREC may determine that some or all of a proposed research activity cannot be approved or may require the researcher to make changes to the research in order to obtain GHREC approval.

A researcher may appeal to the SREC to do a formal review of a decision according to the SOP of the SREC. The only grounds for requesting a review are the following:

(*a*) There have been multiple unsuccessful efforts by the researcher and the GHREC to resolve a disagreement; and

(*b*) The researcher believes that the GHREC's decision is due to the following:

- Inadequate or inaccurate information;
- GHREC non-compliance with GHREC policy, national and/or international regulations.

See the UFS Research Integrity and Ethics Policy, SOP para 5.1, for details of the process that should be followed.

11. Reporting research misconduct and fraud (whistle-blower policy)

11.1 Purpose

This section describes the policy and procedures the GHREC follows when research misconduct is reported in research studies. The purpose of this procedure is to:

- Enable individuals to raise legitimate concerns relating to research misconduct.
- Make clear to individuals that allegations of research misconduct are taken seriously by the GHREC.
- Provide the opportunity for an individual who has inadvertently breached good practice to declare the problem openly, allowing the process to occur fairly and transparently.

- Provide a process for concerns to be raised, investigated and, where appropriate, acted upon in a fair and transparent manner and in confidence.
- Act as a deterrent to potential perpetrators of research misconduct.
- Strengthen the confidence of all parties (e.g., research funders, the individual making an allegation) that the GHREC maintains the highest standards of research conduct.

11.2 Policy

Researchers should report evidence of fraud and other crimes or scientific misconduct in research to the GHREC. Researchers must report any incident of misconduct, whether this has been witnessed or whether it is suspected. The GHREC expects all approved research to be conducted, observing the highest standards of research practice.

Sources are encouraged to put their name to any allegation they make since part of the purpose of this procedure is to promote openness and discourage fear of reprisals. Allegations made anonymously are far less capable of being addressed effectively but may be considered after taking into account the seriousness of the issue, the credibility of the allegation, the likelihood of being able to investigate the matter and confirm the allegation from alternative sources, and fairness to any individual mentioned in the allegation.

The identity of the person raising the matter will, if required, be kept confidential for as long as possible, provided that this is compatible with an adequate investigation. However, the investigation process may have to reveal the source of the information at some stage, and the individual making the allegation may need to make a statement as part of the required evidence. All allegations made under this procedure will be treated in a confidential and sensitive manner.

Named individuals will be informed of the allegation(s) made against them and the supporting evidence, and this will be confirmed in writing, considering all aspects of confidentiality. The point at which this occurs will depend upon the specific nature of the case.

The named individual will be allowed to respond and, if they wish, can be accompanied by a work colleague or staff representative. The named individual will, in all circumstances where a case has been established and where formal action is to be taken, have the opportunity to put their case forward and respond to the allegations per agreed ethics committee procedures.

Individuals making an allegation found malicious by subsequent investigation, may be subject to disciplinary or other appropriate action.

Suspicions reported in confidence and in good faith which are not confirmed by subsequent investigation will not lead to any action against the person making the allegation.

Investigations will be conducted as speedily as possible, considering the nature and complexity of the allegation. The outcomes of the process will be made known to relevant persons involved, including the person making the allegation and the person against whom the allegation has been made, whilst also maintaining confidentiality wherever possible.

11.3 Procedures

11.3.1 Allegations should be made in writing to the GHREC Chair.

11.3.2 Any individual wishing to make a disclosure, or to give further details as the matter is investigated may be accompanied by a work colleague or staff representative of their choice.

11.3.3 The GHREC Chair shall appoint a sub-committee to lead an initial investigation.

11.3.4 Since the person conducting the investigation should not be the person who would ultimately make decisions based on the outcomes of the investigation, the Chair will not personally conduct the investigation. It remains separate from the investigation to maintain impartiality and fairness in the investigative process.

The GHREC Chairperson shall:

- Decide how an investigation should take place and its form.
- Decide on the seriousness and if it needs to be escalated to the SREC
- Appoint (a) relevant person/s to investigate the allegation;
- Decide whether there are grounds for proceeding further.
- Report / Escalate serious misconduct to the SREC for further investigation (See the UFS Research Integrity and Ethics Policy, para 5.5, for details of the process that should be followed).

If a complaint is received through the Institution's Whistleblowing Hotline, the procedure for handling such complaints will be followed (See Policy of the University of the Free State Whistleblowing Hotline, para 4.9[12]).

11.4 Outcome

The GHREC Chairperson will, when the matter has been investigated, decide whether the matter should be taken further and, if so, how it should be handled. Reporting and or escalating of the allegations or findings of any investigation will depend on the nature of the allegation.

The process of the investigation will be recorded and filed on RIMS.

12. Record keeping

The GHREC must maintain a record of all the research proposals/projects/studies/protocols it considered for ethical clearance. These include information sheets, consent forms and relevant correspondence in the format in which they were approved.

Records will be kept on the Institutional server and are retrievable.

[12] Policy of the UFS Whistleblowing Hotline, 4.9: "The information transcribed to the call sheet will be transmitted to designated recipients at the UFS, who will be responsible for taking action based on the information contained in such a report."

13. Reporting to the Senate (SREC)

The GHREC submits annual reports to the SREC. The report could include but is not limited to matters such as:

- The number and types of projects approved.
- Details of studies monitored.
- Details of studies not approved.
- Adverse events.
- Any complaints or grievances regarding research or decisions of the GHREC.
- Any reports or press releases regarding studies that have been subjected to ethics review
- Administrative or other difficulties being experienced.
- Requirements for staff training on research ethics or details about such training.
- GHREC membership.

14. Adoption of and changes to the Standard Operating Procedure (SOP)

The GHREC must assess the efficacy of its SOP at least once a year, and minute the results of this assessment at one of its ordinary meetings.

Changes to this SOP can be suggested at any ordinary meeting or workshop of the GHREC.

The updating of GHREC SOPs may be initiated by the GHREC Chairperson.

SREC approves the SOP of the GHREC after faculties have been given a reasonable time to comment on the SOP.

Appendix A

Regulatory Framework

Relevant legislation

Examples of relevant Acts, treaties, and conventions include, but are not limited to:

The Constitution of the Republic of South Africa, 1996
The Children's Act 38 of 2005
National Health Act 61 of 2003
Human Tissue Act 65 of 1983
Promotion of Access to Information Act 2 of 2000
Protection of Personal Information Act 4 of 2013.

Policies and Guidelines

In addition to the regulatory framework, the GHREC functions within the framework of and is committed to the ethical principles set out in the following documents:

The University of the Free State Research Integrity and Ethics Policy
National Department of Health (DoH) (2015), Ethics in Health Research: Principles, Processes and Structures
The Universal Declaration of Human Rights (1948)
Belmont Report 1979
Declaration of Helsinki 2013
Global Code of Conduct for Research in Resource-Poor Settings, 2019
Singapore Statement on Research Integrity 2010
The Norwegian Guidelines for Research Ethics in the Social Sciences and the Humanities (2021)

Additional Guidelines

Statement of Ethical Practice for the British Sociological Association http://www.britsoc.co.uk/equality/Statement+Ethical+Practice.htm (March 2002, updated May 2004)
Ethical guidelines and principles of conduct for anthropologists. 2005 *Anthropology Southern Africa*. 28(3&4):142-3. https://www.asnahome.org/about-the-asna/ethical-guidelines.
The Health Professional Council of South Africa (HPCSA), Professional Board For Psychology. Rules of Conduct Pertaining Specifically to Psychology. (http://www.psyssa.com/aboutus/codeofconduct.asp; http://www.hpcsa.co.za/downloads/conduct_ethics/rules/ethical_rules_psychology.pdf)
South African Council for Social Service Professions. Policy Guidelines for Course of Conduct, Codes of Ethics, and the Rules for Social Workers.

Bibliography

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

CSIR Research Ethics Policy.
SREC: 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.
National Department of Health (DoH) (2004), Ethics in Health Research: Principles, structures, and processes.
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.
World Medical Association, Declaration of Lisbon on the Rights of the Patient. Adopted by the 34th World Medical Assembly, Lisbon, Portugal, September/October 1981, and amended by the 47th General Assembly, Bali, Indonesia, September 1995.
Operational Guidelines for Ethics Committees Reviewing Biomedical Research, WHO Geneva 2000
Kruger, M, e.a. Research Ethics in Africa: A resource for Research Ethics Committees: Sun Media, 2014

Glossary

Introduction

Most entries in this Glossary have been adopted verbatim from the Glossary of the DoH 2015 – as a point of reference and with a view to further elaboration in some cases to convey the concept in terms more appropriate to research in the humanities. Definitions marked by an asterisk (*) do not appear in the Glossary of the NHREC**. In using these definitions, please note that there is a wide spectrum of research conducted in the disciplines covered by the GHREC's mandate. A definition that may not apply to a specific field of research may well be applicable to research done in other departments and faculties or disciplines.**

The definitions in this Glossary serve as a guide to interpreting the Terms of Reference and Standard Operating Procedure. Where definitions in the list below differ from or conflict with discipline-specific definitions generally used in your field of research, there is an obligation on researchers to bring the alternatives to the attention of the GHREC. Researchers must

make it explicit in their applications which definitions they use if different from the entries in this Glossary.

The GHREC can update this Glossary on an ongoing basis.

Definitions

Accountability research*

Research about the accountability of politicians, government departments, public officials, professionals, professional bodies, organisations, institutions, corporations, companies, or the providers of services or goods.

Adverse event*

Any undesirable or unintended response or occurrence in a research participant, i.e., a clinical sign, symptom, condition, or psychological reaction, to a research intervention, which does not necessarily have a causal relationship with the intervention being researched.

Elaborated in terms more appropriate to social research*

Any undesirable or unintended response or occurrence that emerges in research, which does not necessarily have a causal relationship with the research process, for example, a research participant disclosing unsolicited information that reveals an emergency situation.

Applicant*

A qualified researcher undertaking the scientific and ethical responsibility for a research project, either on his/her own behalf or on behalf of an organisation/firm, seeking a decision from an ethics committee through the formal application.

Approval (concerning the GHREC)*

The GHREC's affirmation that the research protocol has been reviewed and that the research may be conducted by the applicant according to the constraints set out by the ethics committee, the institution, and legal requirements.

Approval conditions*

Conditions to be met by the applicant prior to the start of the research. Approval conditions are issued by the GHREC with the final letter confirming a favourable ethical opinion. (Note: Approval conditions are distinct from the further information or clarification requested from the applicant when issuing a provisional opinion).

Assent*

Permission to participate in research provided by a minor, or someone under legal guardianship.

Benefit*

That which positively affects the interests or welfare of an individual or group, or the public generally.

Chairperson*

The member of a GHREC appointed to be Chairperson by the appointing authority. Where the Chairperson is unavailable for any reason, their duties should be performed by the vice-Chairperson /Secundus.

Child

Subject to law in the relevant jurisdiction, a child is a minor who lacks the maturity and legal ability to decide whether or not to participate in research.

Community

The "community" may not be characterised by social coherence and stability, but by contestation, conflict, imbalances in power relations, inequality and injustice – pointing to the question, if applicable, whether these characteristics are appropriately acknowledged and responded to in the research design with a view to minimising ethical risks.

Confidentiality

The obligation of people not to use private information – whether private because of its content or the context of its communication – for any purpose other than that for which it was given to them.

Conflict of interest (research)

In the research context: where a person's individual interests or responsibilities have the potential to influence the carrying out of their institutional role or professional obligations in research, or where an institution's interests or responsibilities have the potential to influence the carrying out of its research obligation.

Conflict of interest (GHREC)

A conflict of interest arises when a member (or members) of the GHREC holds interests with respect to specific applications for review that may jeopardise their ability to provide a free and independent evaluation of the research focused on the protection of the research participants. Conflicts of interests may arise when a GHREC member has supervisory, financial, material, institutional, or social ties to the research or the researcher.

Consent

A person's or group's voluntary agreement based on adequate knowledge and understanding of relevant material, to participate in research. Informed consent is one possible result of informed choice; the other possibility is a refusal.

Discomfort

A negative accompaniment or effects of research, less serious than harm.

Ethical/Unethical

Right or morally acceptable, on the one hand, wrong or morally unacceptable on the other. Conforming to the rationally acknowledged norms and standards of behaviour, or failure to conform to such norms and standards.

Ethical review

Review of research proposals/projects by the GHREC or other body prior to commencement of the research. The review ascertains the level of risk a proposed research project/study holds and whether sufficient measures are in place to serve to mitigate the research risks.

Ethical risk [in human research, non-medical] *

An action, procedure, or method used in the research and in its reporting that can compromise the dignity, rights, safety, and well-being of participants in research, or those affected by that research.

Ethics

A branch of moral philosophy concerned with the rational evaluation of the concepts of right and wrong, justice and injustice, virtue and vice, good and bad, and activities to which these concepts apply.

Gatekeeper

Gatekeeper approval could include approval by any relevant institution, including but not limited to national or provincial ministerial departments, companies, local authorities.

GHREC

Body, which has been constituted by the Senate of the UFS and has been authorised and registered by the NHREC, to carry out ethical reviews of research.

GHREC reference number

Reference number uniquely assigned by the GHREC accepting the application for review. This includes a specific project number and year.

Harm

That which adversely affects the interests or welfare of an individual or a group during the research process. Harm includes physical harm, anxiety, pain, psychological disturbance, devaluation of personal worth, and social disadvantage.

High risk (research)

Research in which there is a foreseeable risk of harm and discomfort, which may lead to a serious adverse event, if not managed responsibly.

Elaborated in terms more appropriate to social research*

Research in which potential exists for a level of emotional or psychological distress and/or social stigmatisation, prosecution or persecution where there is a likelihood that harm could be done to the well-being of the participant even if due care is taken and mitigation is provided. (See Addendum 3 for a classification of risk types.)

Inconvenience

A minor negative accompaniment or effect of research, less serious than discomfort.

Individually identifiable data

Data from which the identity of a specific individual can reasonably be ascertained.

Integrity

Honesty and probity as qualities of character and behaviour.

Investigator

A qualified scientist who undertakes scientific and ethical responsibility, either on their own behalf or on behalf of an organisation/firm, for the ethical and scientific integrity of a research project at a specific site or group of sites. In some instances, a coordinating or principal investigator may be appointed as the responsible leader of a team of sub investigators.

Elaborated in terms more appropriate to research done that concerns the GHREC*

The terms "investigator" and "researcher" can be used interchangeably, and it should be noted that research that falls within the mandate of the GHREC may not be site-specific.

Low risk (research)

Research in which the only foreseeable risk is one of discomfort.

Elaborated in terms more appropriate to research done that concerns the GHREC*

Research in which the potential exists for minor emotional discomfort, e.g., the subject matter, may have a low degree of personal, social or political sensitivity that could cause embarrassment to participants. This risk can be easily mitigated by a sensitive approach by the investigator. (See Addendum 3 for a classification of risk types.)

Medium risk

Research in which there is a probable risk of harm or discomfort, but which can be fairly easily managed to pose the minimum risk to the participant.

Elaborated in terms more appropriate to social research*

Research in which the potential exists for a level of emotional or psychological distress and/or social stigmatisation, prosecution or persecution that could be harmful to the participant if due care is not taken by the investigator, and could require mitigation, e.g., counselling or other forms of support. (See Addendum 3 for a classification of risk types.)

Minimal risk

The probability or magnitude of harm or discomfort anticipated in the research is not greater in itself than that ordinarily encountered in daily life.

Elaborated in terms more appropriate to research done that concerns the GHREC*

Research involving the analysis of existing statistics, as well as literature, documents, databases, and information in the public domain, for example, in public libraries, public archives, on websites, newspapers, or newsletters. Any anticipated harm or discomfort to third parties related to this research is no greater than ordinarily encountered in daily life. (See Addendum 3 for a classification of risk types.)

Monitoring (of research)

The process of verifying that the conduct of research conforms to the approved proposal.

No risk research*

See Minimal risk.

Personal information

Information by which individuals can be identified.

Privacy

Privacy implies a zone of exclusivity where individuals and collectives are free from the scrutiny of others. It may also include control over the extent, timing, and circumstances of sharing oneself with others, whether physically, intellectually or in terms of behaviour.

Proposal

A document that provides the background, rationale, and objectives of the research and describes its design, methodology, organisation and the conditions under which it is to be performed and managed.

Provisional clearance

Ethical approval is granted on condition that the researcher provides further information or clarification on specified issues, or submits outstanding documents, prior to the commencement of the research.

Public domain*

Generally, a zone of common, unrestricted access shared by individuals and collectives.

Elaborated in terms more appropriate to intellectual property right on research instruments* "**Public domain information is publicly accessible information, the use of which does not infringe any legal right, or breach any other communal right (such as indigenous rights) or any obligation of confidentiality"**.

Public domain information refers to the realm of all works or objects of related rights, which can be exploited by everybody without any authorisation, for instance because protection is not granted under national or international law, or because of the expiration of the term of protection, or due to the absence of an international instrument ensuring protection in the case of foreign works or objects of related rights."[13]

Research

Includes at least an investigation undertaken to gain knowledge and understanding or to train researchers.

Research Ethics (health)

Review invasive types of research, e.g., intervention studies collecting blood or tissue, drug trials, using surgical procedures, or chart reviews involving biomedical subject areas.

[13] UNESCO definition. Available at http://www.unesco.org/new/en/communication-and-information/information-society/open-source-and-low-cost-technologies/public-domain-information/ (accessed on 9 Feb 2021).

Research misconduct

Includes fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting the results of research, and failure to declare or manage a serious conflict of interest. It also includes failure to follow research proposals approved by a GHREC, particularly where this failure may result in unreasonable risk or harm to humans, other animals, or the environment. It also includes the willful concealment or facilitation of research misconduct by others.

Requirements

In the context of decisions, requirements are binding elements that express ethical considerations whose implementation the ethics committee requires or views as obligatory in pursuing the research.

Revision of application

Any changes made to the terms of an application at the request of the GHREC following the meeting or, following issue of an opinion, before the research has started. Revision is not permitted prior to the GHREC meeting once the application has been validated.

Risk

Within the context of research ethics, risk is the function of the magnitude of harm and the probability that it will occur. Degrees of risk include minimum risk, low risk, medium and high risk. (See Addendum 3 for a classification of risk types.)

SOPs

The standard operating procedures issued by the GHREC

Sponsor

An individual, company, institution, or organisation that takes responsibility for the initiation, management, and/or financing of research.

Voluntary participation

Participation that is free of coercion and pressure.

Vulnerable person/groups

Those whose willingness to volunteer in a research study may be unduly influenced by the expectation of benefits associated with participation.

Elaborated in terms more appropriate to social research*

Individuals or categories of participants can be vulnerable prior to research, or rendered vulnerable because of research, due to factors including, but not limited to:

- Reduced ability to make a voluntary decision, because of factors including, but not limited to age, mental disarray, subordinate position, or impoverished position.
- Reduced ability to make an informed decision because of factors including, but not limited to, lack of familiarity with the scientific method, linguistic barriers, inability to read or write, reticence to ask questions about the research.

- Breaching of confidentiality by the researcher at any stage of the research.
- Exposing participants unfairly to the risks of the research, or bestowing on participants unfairly the benefits of the research.
- Exposing participants or third parties not directly involved in the research, to any complications that may be caused by the research.

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.