UNIVERSITY OF CAPE TOWN (UCT)

INTER-FACULTY HUMAN RESEARCH ETHICS COMMITTEE (IFHREC)

STANDARD OPERATING PROCEDURES (SOP) FOR PROTOCOL SUBMISSION, REVIEW AND APPROVAL

Title	INTER-FACULTY HUMAN RESEARCH ETHICS COMMITTEE (IFHREC): STANDARD OPERATING PROCEDURES (SOP) FOR PROTOCOL SUBMISSION, REVIEW AND APPROVAL
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Approving body	IFHREC
Relevant related policies, procedures, and guidelines	• UCT Policy for Responsible Conduct of Research • UCT Research Ethics Code for Research Involving Human Participants • Code for UCT Research Ethics Committee Members • Appeal to Ethics in Research Committee: Standard Operating Procedure • Authorship Practices Policy • Conflicts of interest: principles, policy and rules • Policy and Standard Operating Procedure: Ethics Clearance and Permission to Engage UCT Staff and/or Students or their Data in Research • UCT Policy and Procedures for Breach of Research Ethics Codes and Allegations of Misconduct in Research • UCT Policy Statement on Safeguarding in Research • Whistleblowing policy • Academic Misconduct Policy • UCT Research Data Management Policy • UCT Open Access policy • UCT Guideline for Risk-Based Ethical Review of Research • IFHREC Terms of Reference

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UNIVERSITY OF CAPE TOWN (UCT)

INTER-FACULTY HUMAN RESEARCH ETHICS COMMITTEE (IFHREC)

STANDARD OPERATING PROCEDURES (SOP) FOR PROTOCOL SUBMISSION, REVIEW AND APPROVAL

1. PURPOSE

a. To provide guidelines on appropriate procedures for the review and approval of health research originating outside of the Faculty of Health Sciences, and which requires approval from the National Health Research Ethics Committee.
b. To provide guidelines on appropriate procedures for the review and approval of research that is not adequately accommodated by faculty Research Ethics Committees (RECs).
c. To support and promote research integrity at UCT, within a context of recognising disciplinary variations; and premised on an awareness that principles related to research integrity, including definition of possible harms to research participants, must be considered with sensitivity to relevant social, historical, and epistemic contestation.

2. SCOPE

This Standard Operating Procedure (SOP) addresses the procedures; required documentation for review and approval; and the potential outcomes of ethics application submissions. In addition, this SOP seeks to define the types of ethics applications that will be considered or escalated to the IFHREC.

Applications can be escalated to the IFHREC directly from a Faculty REC as per Faculty SOPs, or if the Faculty identifies it to be of high ethical complexity and/or risk, and thus more suitable for review by an inter-disciplinary REC. See UCT Guideline for Risk-Based Ethical Review of Research for further information.

Researchers may submit directly to IFHREC only if one or more of the following apply:

1. An external funder or collaborator requires ethics approval from an externally registered (NHREC[1] and/or OHRP[2]) REC. (e.g., NIH[3] and all US federal agencies, NRF[4] in some instances).
2. Collaborating lead investigators are in different UCT faculties (except FHS, where projects involving FHS members must be submitted to the FHS Research Ethics Committee), and where the project does not clearly fall under the ambit of any of the individual faculties they represent; and/or where the project employs a mixed methods approach and would therefore benefit from review by a multi-disciplinary ethics committee.
3. The investigator is from another institution and wishes to conduct research at UCT involving staff and/or students.
4. The project involves health research (and is thus subject to the legal requirement of obtaining ethics approval from an NHREC registered and audited REC), and where no member of the research group represents the Faculty of Health Sciences. (FHS).

[1] National Health Research Ethics Committee (NHREC)
[2] Office for Human Research Protections (OHRP)
[3] National Institutes of Health (NIH)
[4] National Research Foundation (NRF, South Africa)

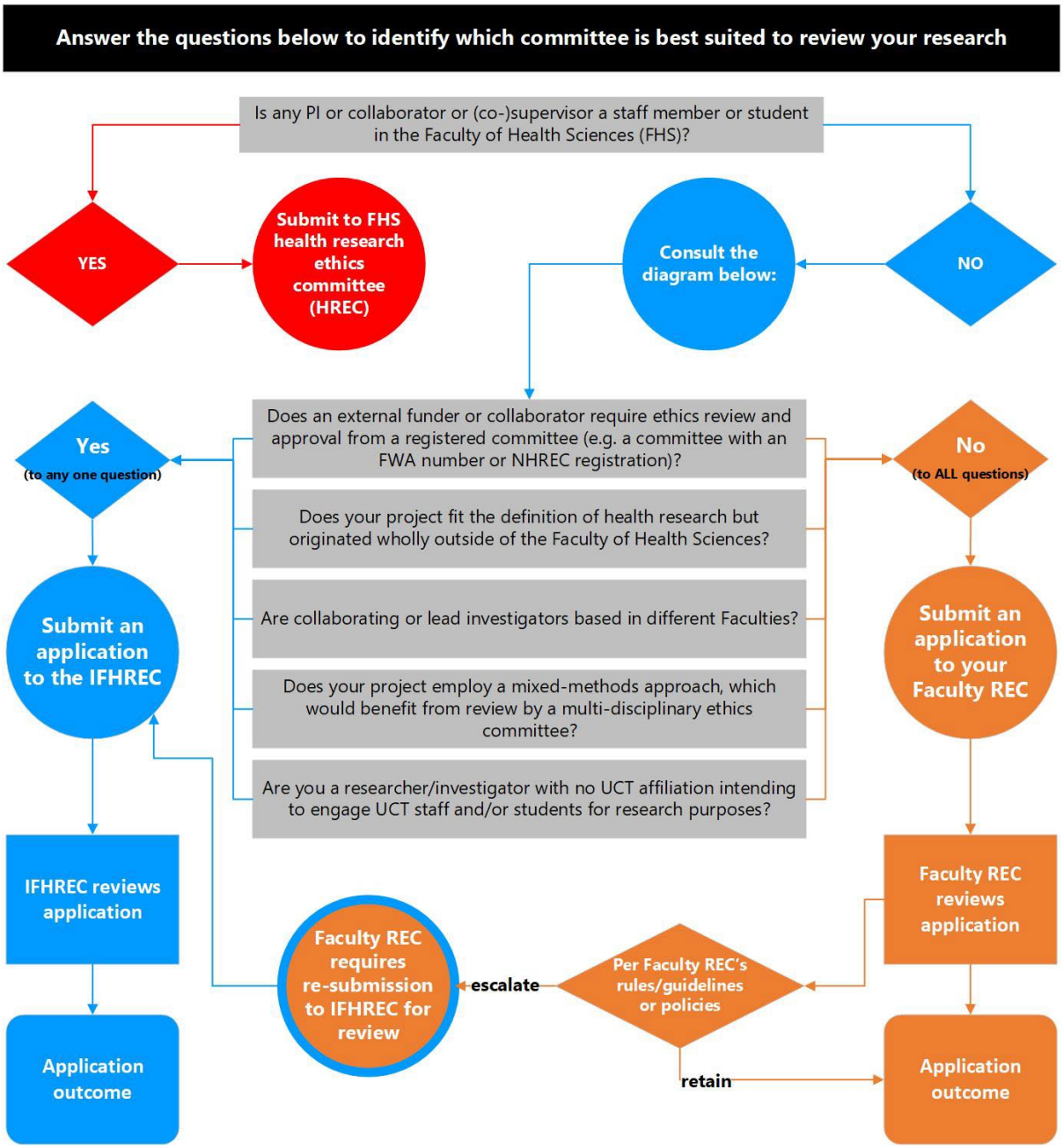


Figure 1: Determining which committee will review research.

1. *IFHREC relationship to UCT Ethics committees*
   - The IFHREC is constituted to be at the same 'level of authority' as the Faculty RECs. The IFHREC and the Faculty RECs will collaborate by means of referrals as outlined in Figure 1 (page 4).
   - The IFHREC will provide quarterly reports to the Faculty RECs regarding applications originating from staff and/or students in their faculty who have made direct applications to the IFHREC.
   - Faculty RECs can escalate applications received directly by Faculty committees if they judge that it would be better served by review from the IFHREC, as per the limitations defined in Section 2

above. The Faculty RECs have the authority to make this determination and/or escalation in line with their own policies and/or procedures.

- The IFHREC retains the right to reject referrals from Faculty committees in accordance with its scope.
- The IFHREC may receive applications directly from applicants, as outlined in Figure 1 (page 5) and defined in Section 2 of this SOP.
- The IFHREC will provide an annual report to the Senate Ethics in Research Committee (EiRC), in the same manner as all Faculty RECs are currently required to provide.
- The Chair of the IFHREC will sit on the EiRC as a regular member, in the same manner as the Faculty REC Chairs currently hold membership of the EiRC.

3. COMMITTEE MEETINGS, QUORUM AND MEMBERSHIP

The committee will meet quarterly, except for July and December. If there is no business for the committee to consider then a Chair's Circular may be issued to notify the committee of any applications which may have received approval in the interim, including a summary motivation for any such approvals.

If an urgent meeting is needed, outside of the quarterly meetings, the committee administrator will liaise with the members to schedule the meeting. Urgent business may also be conducted via a Chair's Circular and where a scheduled meeting's agenda comprises matters of a routine/uncontroversial nature, a Circular can be issued in place of said meeting.

The quorum for a meeting is at least 50%+1 of the committee members and must comprise at least 1 representative per Faculty. Faculty members shall liaise with each other to ensure sufficient representation at a given meeting. If it is the case that a meeting is not quorate, the meeting will be rescheduled.

When matters need to be resolved by a committee vote, motions will carry when supported by a simple majority of members in a quorate and properly constituted meeting.

1. Members

Committee membership is detailed in the Terms of Reference (ToR) document. Members are appointed for a period of 4 years, aligned with Senate/Council cycles, renewable for two terms, where joining the IFHREC mid-cycle will not contribute to a term. Members are nominated to the committee by Faculty Deans, Research Ethics Committees, the Deputy Vice-Chancellor (DVC) for Research, or can be self-nominated. The nominees are considered by the Senate Ethics in Research Committee (EiRC), with consideration of any relevant institutional rules for committee membership, while also seeking to maximise breadth of knowledge, experience, and diversity of representation. The EiRC then publishes the proposed membership for approval by Senate, who are the appointing body.

a. Chair

The IFHREC Chair is appointed by the Deputy Vice Chancellor (DVC) Research and is issued with an appropriate letter of appointment from their office.

b. Deputy Chair

The Deputy Chair will be elected by the committee, and this will be recorded in the committee minutes. The Deputy Chair will assume the role of Chair if the Chair is unable to attend a given meeting or has a conflict of interest.

c. Executive Committee (EXCO)

The EXCO shall consist of the Chair, the Deputy Chair, and at least two additional IFHREC members. The EXCO membership must include a non-affiliated member, as well as a member from FHS (or who has experience with biomedical research).

4. FINANCIAL COMPENSATION FOR MEMBERS

No financial compensation (remuneration) is permitted for external IFHREC members (e.g., travel expenses, loss of income for any professionals, etc.).

5. CONFLICTS OF INTEREST/COMMITMENT AND CONFIDENTIALITY

Conflicts of interest/commitment are governed by the relevant institutional policies. At the start of each convened meeting, members of the committee will be given the opportunity to declare any conflicts of interest/commitment pertaining to items on the agenda (either on a register for an in-person meeting, or via a poll in an online meeting)

- If no conflicts are declared, then the meeting will continue as planned.
- If conflicts are declared, then the nature of the conflict must be disclosed, and the affected member shall recuse themselves from the discussion of that specific item if the committee agrees that the member is conflicted. If deemed to be conflicted, the member may be permitted to provide supporting information related to the item and/or contribute to discussion on the item, but they will not be permitted to cast a deliberative vote on said item and may be asked to leave the room while a decision is being finalised.

The business of an ethics committee is confidential, and committee members will be asked to sign a declaration at the start of each meeting, agreeing to uphold its confidentiality.

6. TRAINING OF COMMITTEE MEMBERS

All committee members must agree to undergo training in research ethics and the ethical review of research projects on an annual basis. This training can take the form of appropriate online training or workshop attendance. Proof of ongoing member training will be required for annual NHREC reporting.

Training will be provided by the ORI and will take a blended learning approach, combining online asynchronous learning modules as well as in-person, synchronous seminars and/or workshops. The ORI offers Responsible Conduct of Research (RCR) training and development sessions throughout the university, and IFHREC members can attend and then register these sessions as meeting their IFHREC training requirements.

The ORI will also provide training in the topics of research using human participants and the ethical review of research projects.

All members, including new members, are required to complete the first five training modules on research integrity that are offered on the UCT SuccessFactors online learning platform:

- Module 1: Introduction
- Module 2 - Misconduct and Questionable Research Practices
- Module 3: Authorship and Publication
- Module 4: Research involving Research Participants

- Module 5: Managing and Sharing Human Research Data

From 2024 new members will also attend a face-to-face training sessions facilitated by the ORI, which will be communicated to members.

1. Training of secretariat and administrative staff

Secretariate and administrative staff will be required to complete the online RCR modules, as described for committee members, and to attend a face-to-face workshop at least once every three years. Additionally, administrative staff will also be required to complete Good Clinical Practice Training (GCP) in line with GCP regulations, once every three years, as well as the Southern African Research & Innovation Management Association (SARIMA) Ethics and Integrity course.

7. SUBMISSION PROCEDURES

The IFHREC will utilise the Converis eRA (electronic Research Administration) for applicants to submit their ethics application for review. The documents listed below are needed when completing an online application (disclaimer: *documents may change with the nature of the project, ongoing development of the system, or as per the review requirements of the committee*):

1. Cover letter motivating why the application has been submitted to, and should be reviewed, by the IFHREC.
2. Full research proposal
3. Participant informed consent document(s)
4. Copies of all research instruments
5. Gatekeeper permission document (if available at the time of application)
6. CVs or bio sketches of investigators and supervisor(s) (in the case of student projects)
7. Supervisory agreements, if needed in the case of student projects.
8. Copies of any research ethics training certificates for investigators and supervisors.
9. Signed letter of participation if there is a co-supervisor involved (in the case of student projects).
10. Data management plan and related files
11. Information about previous ethics applications related to the current one.
12. Any other supporting documentation

8. RECIPROCAL REVIEW

UCT researchers frequently collaborate with researchers from other universities both in South Africa and globally. In some instances, the lead investigator may come from another university, and multi-site projects could involve several universities. Obtaining ethics full ethics approval from every university involved in a project can be time consuming, result in delays, and result in the research being approved by one university and not one or more of the other relevant bodies. To minimise the likelihood of these outcomes, the following principles apply:

Research with South African collaborators: RECs registered with the National Health Research Ethics Council can agree to work with a REC at another institution (if that REC is also registered with the NHREC) and agree that only one institution will conduct a full review of the project. If that REC is not at UCT, the UCT IFHREC will recognise the validity of that review and approval process. This would typically mean that the IFHREC approves the project without a full review. However, this decision is at the discretion of the Chairperson and committee. In some instances, particularly if the project is deemed to be of a higher ethical risk, IFHREC may choose to conduct a full independent review.

Research with international collaborators:

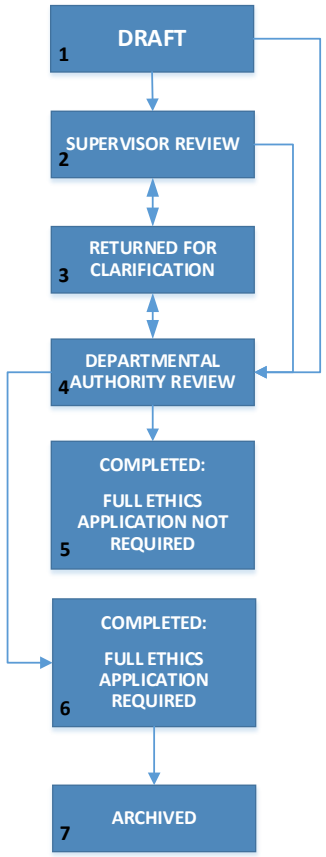
NHREC and the National health Act require that all human research conducted within the borders of South Africa is reviewed and approved by a South African REC. If a UCT researcher is collaborating directly with one or more researchers external to South Africa, with no other South African university involved, then IFHREC must conduct a full review of the project. If there are other South African researchers involved from other South African institutions than reciprocal review, as described above, can apply if appropriate.

Process: Researchers should contact the IFHREC secretariat and submit the ethics approval letter from the external institution and a project synopsis. The IFHREC secretariat will inform the researcher via email if an application via the eRA system will be required or not, and whether any other documentation or motivation is required.

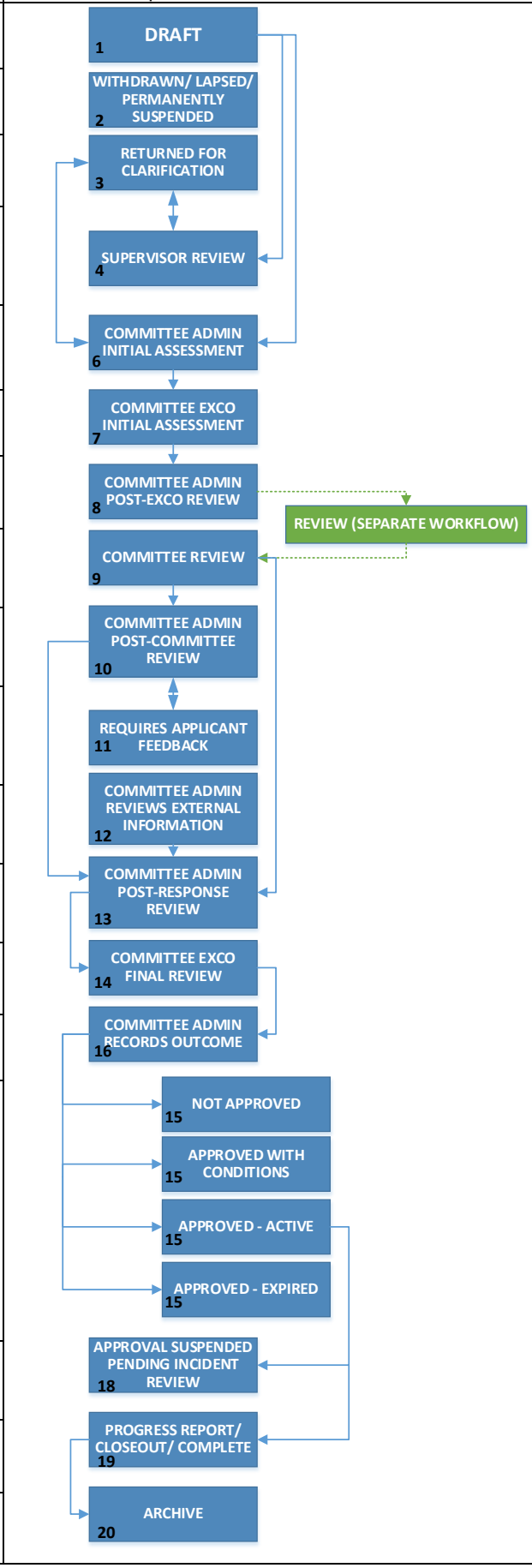
9. REVIEW PROCEDURES

1. Outline of process

The IFHREC will make use of a pre-screening questionnaire (PSQ) to determine if full review by a REC is required. Additionally, the IFHREC will use the responses to the PSQ as a tool to flag areas of potential concern where a full ethics application has been submitted. The PSQ process is as follows:

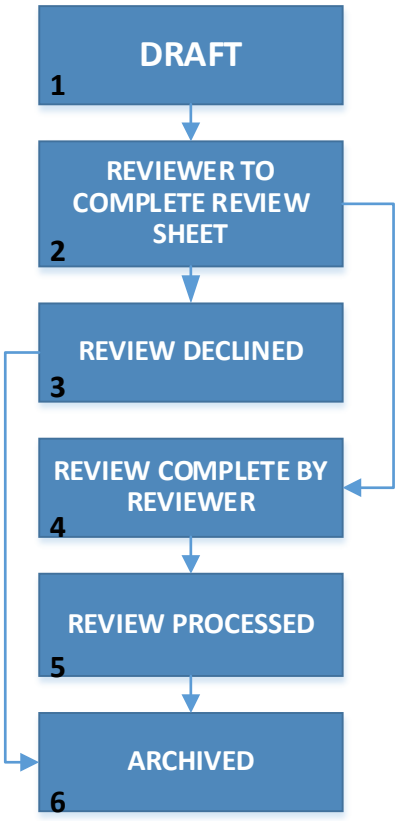
Item description	Workflow step
Draft PSQ application that applicant is working on, on the eRA system.	
In the case of a student project, an application will be first directed to the supervisor for review and approval.	
The questionnaire is returned to the applicant if clarification is required.	
The Chair (using the departmental authority role) reviews the submission, and determines if exempted or not	
Possible outcome: Project is exempted from a full ethics application.	
Possible outcome: The Chair indicates that a full ethics application is required.	
Used once decision is made and can be archived for history data storage.	

IFHREC will review the submission to determine if it will remain under the jurisdiction of the IFHREC, or whether it should be reviewed by a specific Faculty REC (see Figure 1 on page 5 for determination of whether applications should be reviewed by a Faculty REC or the IFHREC). Should the protocol remain with the IFHREC, then the relevant IFHREC processes will follow.

Item description	Workflow step
Draft application that applicant is working on, on the eRA system	
System status for ethics approval which have lapsed or been withdrawn	
Step which allows a committee administrator, departmental authority, or supervisor to return the application to the applicant	
In the case of a student project, an application will be first directed to the supervisor for review and approval.	
Next an application is escalated to a committee administrator (CA) for an administrative review. The CA can either return it for clarification or send if forward to the EXCO.	
The committee EXCO does a rough review of the application and recommends reviewers.	
The CA sends requests to the recommended reviewers and moves the application into the review workflow.	
Once the application is returned by the reviewers it is added to an agenda for a forthcoming meeting (in the case of a full committee review) or is redirected to step 13 (in the case of an expedited review).	
If the committee request additional information or modifications to the project, from the applicant it is recorded in this step by the CA.	
This step allows applicants to supply additional information and documents.	
After the applicant submits additional or outstanding documentation, the CA reviews that the information supplied is in line with what had been requested and notes this on system.	
The CA escalates the updated application to the Chair and/or EXCO.	
The Chair and/or EXCO review the application and additional documentation and make a final decision on the application outcome.	
The CA records the final recommendation of the Chair/EXCO on system.	
Final application outcomes options: • NOT APPROVED • APPROVED WITH CONDITIONS • APPROVED (Active) • APPROVED (Expired, used for applications which were approved by which have now exceeded the time limit of their approval and need to submit a renewal application or annual report) Applicants can download an outcome letter on the eRA system.	
Used for applications where an incident has been reported to the committee. The committee will investigate the incident and either reactivate the study following remedial actions taken or close the study.	
Used when an applicant submits an annual progress report or a notification that the study has been completed.	
Used once projects are no longer active and can be archived for history data storage.	

2. *Review procedures*

- Each project will be allocated to a minimum of two reviewers. The Chair and/or EXCO can nominate reviewers, but they will typically be assigned by the committee administrator (CA) using the eRA system, mindful of both disciplinary expertise and an even distribution of reviewer workload. The CA will assign the recommended reviewers using the eRA system.
- Reviewers will receive a system notification informing them of the request to review an application. A reviewer may accept or decline the invitation within 3 days of the invitation having been sent to review on the eRA system.
- Should a reviewer decline an invitation to review, the Chair and/or EXCO shall nominate an alternate reviewer.
- Reviewers will be asked to complete their review within 2 weeks of accepting the invitation to review.
- Reviews shall take place on the eRA system using the workflow described below. Reviewers will be prompted to address specific questions to assist with the assessment of the ethical risk and review of an application. Reviewers will be asked to make a recommendation regarding a possible outcome for the application, which the committee will review either at a convened meeting or through an expedited process, whichever applies. See outcome recommendation options below.

Item description	Workflow step
Status used while committee administrator (CA) is setting up the review form.	
Invitation sent to the reviewer(s) by the CA	
If reviewer declines to review the application, they save it in this step and the CA then archives the request. The CA would need to allocate an alternative reviewer based on the recommendation of the Chair/EXCO.	
If the reviewer accepts the invitation to review the application, they note this status on the system and complete the review of the application. This status is used by the reviewer to alert the CA that the review is complete.	
This step allows the CA to integrate the review feedback into the main application form and move the application into further steps in the main process.	
This step is used by the CA to archive a review that is no longer needed.	

3. *Declining an invitation to review and application.*

A reviewer must formally decline an invitation to review on the eRA system, so that an alternative reviewer may be sought.

A reviewer may decline an invitation for the following reasons:

- Conflict of interest or commitment,
- Insufficiently experienced in the type of research being proposed (either methodologically or based on their own disciplinary background),
- Insufficient time to complete the review in the given timelines.

In the case of a reviewer declining an invitation to review an application, the Chair and/or EXCO shall nominate an alternative reviewer, and this shall be captured by the CA.

10. GUIDELINES FOR REVIEWERS

1. Review principles

IFHREC members are required to familiarise themselves with the UCT Guideline for Risk-Based Ethical Review of Research, as well as to adhere to the training requirements specified in Section 6 above.

A risk-based approach to review and approval of research means that research projects assessed as being of low ethical risk can be reviewed in an expedited manner, whereas projects assessed to be of higher ethical risk are reviewed and discussed in more detail, typically at a convened meeting. Discussion and debate of the ethical aspects of projects at convened meetings is a critical skills development factor in the context of research ethics.

When RECs evaluate the risk of a project their main concern is evaluating risks to participants, although risks to e.g., institutions, or researchers themselves, will also be considered. The following categories of risk all need to be carefully considered in an overall project risk assessment:

- Risk to participants.
- Risk to researchers, especially inexperienced student researchers or projects taking place in unsafe environments.
- Risk to stakeholders other than participants, including communities from which participants are drawn - this includes risk of stigmatisation or legal risks.
- Risk to the institution, which may include risks to reputation.

Types of potential harm to participants in social and behavioural research

- Psychological
- Social or economic
- Legal
- Loss of privacy and/or confidentiality

It is important to note that a project risk assessment must be made independently of steps taken to mitigate risk, such as compensation of participants time, or payment of travel costs. These actions do not alter the assessment of level of risk, but they may favourably alter the overall risk-benefit evaluation of the project.

2. eRA review worksheet

The eRA review worksheet will assist reviewers in completing the review. All submitted documents should be reviewed including informed consent documentation; advertisements, recruitment material or letters of invitation to participants; and research instruments.

Ethics review should include both administrative and substantive components. The administrative review ensures that all required documents or permissions are in place (e.g. assent forms for a project that involves children and consent forms for parents).

The substantive review should cover the following broad considerations:

- Potential social and scientific value.
- Scientific validity: While this is not the primary concern of an ethics committee it is important to note that projects that have methodological problems or appear to lack scientific rigour are

ethically problematic as they waste resources, including those of participants, and can result in unreliable information becoming part of the scientific record.
- Suitability of research population: for example, avoiding selections based primarily on convenience, or targeting of certain groups without adequate justification.
- Adequacy of recruitment material and informed consent information and processes.
- Respect for participants throughout the course of the study by ensuring ability to withdraw if requested without consequences; that data privacy and security are adequately maintained; that additional study-related information is provided if such becomes relevant during the study, adequate debriefing if the study involves partial disclosures, etc.
- Favourable, or at least neutral, balance of risks and potential benefits.
- Researcher competency (or supervision by a competent researcher for the given methodology).
- Community engagement throughout the course of the project if applicable, including dissemination of project outcomes.
- Review of plans for ongoing ethics reflection by the research team, during the project, if applicable.

11. CRITERIA FOR FULL COMMITTEE REVIEW AND RAPID REVIEW

1. Determining full committee review (FCR) versus rapid review (RR)

National ethics guidelines allow for the rapid review of low-risk projects. The committee confirms that the Chair has the delegated authority to finalise projects that are evaluated as low ethical risk in the following cases:

- Projects found to be of low ethical risk by **all** reviewers do not require discussion at a convened IFHREC meeting.
- Projects found to be of medium or high risk by **one** reviewer but of low risk by other reviewers can either be expedited or discussed by the full committee. This decision is taken by the IFHREC Chair or EXCO.
- Projects evaluated as medium or high risk by **more than one** reviewer should be placed on the agenda of the next meeting and discussed by the full committee. The reviewers will lead this discussion.

2. Full Committee Review (FCR)

The ToR of the IFHREC specify that the committee must ensure that research involving human participants, not originating in the Faculty of Health Sciences, or falling within other specified categories[5], proceeds according to UCT policy, and complies with applicable national and international regulatory and funder requirements.

In the context of a FCR, "*The primary role of the REC is to protect the interests (rights and welfare) of the research participants who volunteer to take part in scientifically sound research. Consequently, the primary responsibility of each REC member is to decide independently whether the proposed research protects the interests of participants adequately and keeps to exemplary standards in research activities*". (Ethics in Health Research: Principles, Processes and Structures. Department of Health. 2015 p.40).

- When an application to IFHREC is deemed appropriate for FCR, it will be placed on the agenda for the next meeting for consideration and discussion.
- Applicants should submit their applications approximately 4 weeks before a scheduled meeting. Submission dates will be published on the IFHREC website.[6] This will allow the administrator

[5] As described in section 2 (scope) of this SOP.

[6] A calendar of meeting dates along with submission dates will be published on the ORI/IFHREC website at the start of a calendar year.

enough time to check that the application has been completed correctly and includes all necessary attachments. If any further information is needed, the administrator will contact the applicant for additional information or documentation.

- Once the administrator is confident that the application is ready for review, the committee administrator will, under advice from the Chair and/or EXCO, assign an application to two reviewers (who are members of the committee but, in extra-ordinary cases may be experts external to the committee).
- Reviewers will be given 2 weeks to review an application, submit comments and make a recommendation to the committee administrator.
- Committee members will have a week prior to the meeting to review all applications for a particular meeting. The full applications, reviewer comments and recommendations will be made available to the committee at the next quarterly meeting via the meeting agenda.
- At the committee meeting the reviewers will present a summary of the application, along with their recommendation and reasons for the recommendation.
- The committee will review and discuss each application and assign it a status.
- A formal letter can be downloaded by the applicant on the eRA system. Applicants can consult page10 of this SOP for a link to a how-to document.

3. Rapid Review (RR)

If a researcher indicates in the online eRA application that they would like a rapid review, the Chair must proceed as outlined in Section 10.1, above, which can allow for a final decision without convening a meeting. Ethical urgency is defined as an ethics application needing to be approved urgently, where a delay in consideration would put the research participant at risk of harm.

In completing their allocated reviews, reviewers indicate their assessment of the ethical risk entailed by the project, and where the project is of low ethical risk, final approval outside of IFHREC meeting cycles is permissible under the limitations of Section 10.1.

Applicants can expect a response from the IFHREC for projects that have undergone an rapid review process within 4 weeks of application.

12. OUTCOMES

IFHREC will issue an outcome to applicants, and approval letters will be downloadable from the eRA system. The approval letters will contain the findings of the ethics review, as well as any recommendations made, as well as any conditions specified, by the committee and/or reviewers. At the committee meeting, each protocol that is reviewed may be assigned one of the following statuses:

- **Approved**: Project can start.
- **Approved with condition(s)**: The project is approved, but there are additional requirements (for example, but not limited to, gatekeeper permission), that must be fulfilled before the project can start. It is the responsibility of the applicant to ensure these conditions are met before the project begins, and to provide the IFHREC with outstanding documents as needed. In some instances, additional information will need to be supplied to the REC.
- **Not approved**: The project may not commence.

The committee administrator will capture the committee's comments on the eRA system and move the application to a final status. This will allow the applicant to generate an outcome letter. Thereafter, the applicant will receive a notification, advising that they should log on to the eRA system and download the outcome letter. If an application is approved, the outcome letter is the clearance for the researcher

to commence with the study. If an application is not approved, additional information will be supplied in the outcomes letter and the applicant may submit a new and/or revised application which includes measures to address deficiencies or concerns raised by the committee and/or reviewers.

See guide for downloading an outcome letter on the eRA system.

13. PROJECT AMENDMENTS

Any change to the IFHREC approved research project requires the submission of an amendment request, using the eRA system.

Minor amendments: do not change the risk profile of the project and include changes to research sites; investigators, especially the lead investigator; and minor changes to research methodology, such as adding an additional research instrument. Minor amendments will generally be reviewed and approved via an expedited process involving either the Chairperson, or member(s) to whom this task is delegated.

Major Amendments: involve substantive changes to the project that may alter the ethical risk profile of the research, as described in the "UCT Guideline for Risk-Based Ethical Review of Research". Major amendments will be reviewed as new proposals, and allocated to three reviewers who can either approve the amendment when supported by two or more reviewers or refer it for full committee review in other cases.

Applicants can expect a response from the IFHREC for minor amendments, that have undergone an expedited review process within 4 weeks of application. Timelines for major amendments are the same as for new applications i.e. within 6-8 weeks.

14. ONGOING REVIEW OF ACTIVE PROJECTS

IFHREC has the authority to conduct annual reviews of approved research in order to determine whether renewal of approval is justified. The ongoing review process must be thorough, with a focus on whether the balance of risks and benefits for a particular study has changed, whether there have been any unexpected findings involving risks to participants, and whether participants should be given any new information about risks and benefits. Unless the Committee deems that review should take place more regularly, reviews must take place within a year of the last approval date. Ongoing review will consist of either active or passive monitoring, depending on the risk level of the project.

Authority for auditing and monitoring projects derives from the Department of Health Guidelines mandating risk-related levels of monitoring, including 'random inspection of research sites, data and signed consent forms'.[7] Research audits may be performed as part of a quality improvement and educational strategy or in response to a report or allegation of an unanticipated problem involving serious risks to participants, serious and continuing non-compliance, suspension or termination of a study, or a complaint from a third party such as a sponsor or a research participant.

Depending on its purpose, an audit may include any or all of the following:

- Reviewing investigators' records
- Interviewing investigators, staff and research participants
- Observing the consent process from initiation to documentation of participants' consent

[7] Department of Health (2015). Ethics in Health Research: Principles, Structures and Processes. 2nd edition. See 4.5.1.10 Pg 44.

1. Active and Passive Monitoring

The NHREC, to whom the IFHREC must report for an annual audit, defines Active and Passive monitoring of approved projects as follows:

Active monitoring Refers to active validation of compliance to the ethical aspects of the approved study, including an onsite inspection of the execution of a study.

Passive monitoring Refers to regular (typically annually) written reporting by the principal investigator about research involving human participants, describing research progress and any problems encountered in conducting the research that have a bearing on research integrity.

The IFHREC will engage in active monitoring for projects identified as high risk through measures including onsite inspections, and/or scheduled consultations with the project investigators, throughout the course of the project. Medium and low risk projects will typically not be subject to active monitoring. (Active monitoring is covered in more detail, including a template of an active monitoring form as Annexure 1, on page 22 of this SOP document)

When performing ongoing reviews, the Committee should proceed under the assumption that the previously approved version of the research meets the required standards. The Committee should concentrate on determining whether any new information obtained from the investigator or otherwise made available to the Committee would change its previous conclusions, particularly regarding its earlier assessment of the possible advantages or risks to participants.

Low-risk projects will be presented for approval in summary form by the Chair but can be approved by the Executive Committee of IFHREC on an expedited basis. High-risk projects will be presented to the IFHREC, and approval for renewal requires the support of a majority of members at a quorate meeting. In cases where the committee raises concerns or requests changes, the IFHREC will communicate whether any requirements must be met before an investigator can carry out specific research activities linked, to those concerns, when it approves research on a conditional basis at the time of continuing a review.

If the Committee does not authorize the continuation of a study. The lead researcher will be informed of the considerations leading to that decision and will be invited to respond in writing with an explanation or a proposal to alter the protocol. The main investigator's current appeal would not affect the prior approval's expiration date or the effects of a lapse in that approval. The IFHREC must ensure that any appeals are heard fairly if challenged and must co-operate with the dispute-resolution procedures outlined below.

A more detailed account processes related to active monitoring is provided in Annexure 1.

15. ANNUAL AND CLOSE-OUT REPORTING

Project renewals/extensions will require submission of annual reports, due for submission on eRA when applying for an extension, prior to the expiration of the existing approval. All approved projects that have been concluded, regardless of their duration, must be recorded as such on eRA via the submission of a close-out report. This report could also serve the function of the annual report for projects that conclude in the same period as that in which the annual report is due. A template for annual and/or close-out reporting is available for downloading on the IFHREC website.

16. DISPUTE RESOLUTION AND APPEAL MECHANISMS

1. Dispute resolution

When a researcher is not satisfied with a decision or does not agree with a decision made by the IFHREC, they have a right to dispute the decision. An appeal can be requested for procedural or substantive reasons. The responsibility to justify the grounds for the appeal rests with the researcher. Such appeals must be made, in writing, within ten (10) calendar days of receiving the outcome of their ethics application.

Acceptable grounds for appeal include demonstrable procedural errors and substantive challenges to the justification for the decision.

2. Appeal mechanisms

Researchers who wish to appeal the decision of the IFHREC must provide a detailed account of any procedural errors and/or argument against the decision. The motivation must be submitted via email to the CA, who will include it in the agenda of the next IFHREC meeting. If the committee needs further clarification from the researcher, the Chair (through the CA) will invite the researcher to attend the next scheduled meeting. The researcher's participation will be beneficial if the research itself is complex and needs further explanation.

17. APPEALS, COMPLAINTS AND WHISTLEBLOWING

This section of the SOP has been adapted mostly verbatim from the Faculty of Health Sciences SOP on the same topic, with permission from the Chairperson of the FHS HREC.

1. Appeals

A researcher may submit an appeal directly to the IFHREC if any aspect of the proposed research is rejected. This includes decisions relating to non-compliance findings against researchers.

2. Process for an appeal

The appeal process must initially involve the IFHREC in the first instance. If the IFHREC agrees or prefers, the matter may be referred to the Senate Ethics in Research Committee (EiRC) to be finalised. However, to retain the decisional integrity and independence of the IFHREC within its own institution, PI's may not appeal directly to the EiRC.

If the PI is not satisfied with the IFHREC's decision; he/she/they may then appeal to the Senate EiRC for relief. The researcher also retains the right to appeal to the National Health Research Ethics Council (NHREC), if the research falls under the jurisdiction of the NHREC (that is, fulfils the definition of 'health research' as defined in the National Health Act 61 of 2003 (NHA). The NHREC has been given the mandate by the NHA to investigate and manage complaints related to the review and approval of 'health research' as defined in the NHA, by research ethics committees. With respect to US federally funded or supported research, no-one at the University may approve a study that the Inter-Faculty Human Research Ethics Committee has disapproved (45 CFR 46.112; 21 CFR 56.112).

As a first step where a PI is dissatisfied with an IFHREC decision, he or she has the right to obtain from the IFHREC written reasons for its decision. The PI should exercise this right before launching an appeal. If still not satisfied; a PI may appeal the IFHREC's decision through submitting an appeal in writing to the IFHREC secretariat. Once the appeal has been finalised at IFHREC level and the PI is still not satisfied,

an appeal can be made to the Senate EiRC by notifying the IFHREC secretariat. The IFHREC Chairperson is required to refer the appeal to the Senate EiRC within seven days of receipt.

3. Complaints

Complaints fall into two broad categories:

- Against the IFHREC for procedural irregularities, breach of confidentiality, unacceptable delays, or failure to address conflict of interest adequately.
- Complaints from external parties about the conduct of research over which the IFHREC has jurisdiction.

4. Process for Complaints

1. Complaints against the IFHREC

Complaints against the IFHREC would typically be submitted directly to the Chairperson, who will investigate the matter. Only complaints that cannot be resolved effectively by the IFHREC Chairperson; that are deemed to be irresolvable by either the researcher or IFHREC Chairperson; or where the IFHREC's impartiality in assessing the complaint stands in reasonable doubt should be submitted to the Senate EiRC.

The Senate Ethics in Research Committee (Senate EiRC- the overarching Senate level policy and procedures committee that can as per its Terms of Reference adjudicate appeals and complaints) Chair shall notify the IFHREC Chairperson that a complaint has been made against the IFHREC; inform the IFHREC Chairperson of the nature and substance of the complaint; and request that the IFHREC Chairperson responds in writing to the complaint in sufficient detail to allow for its assessment. The Senate EiRC Chairperson shall then appoint an ad-hoc sub-committee of the Senate EiRC to investigate the complaint and report back to the full EiRC at a forthcoming meeting. Where necessary the subcommittee may need to interview the complainant, the IFHREC Chairperson and/or other persons. The EiRC shall compile a report of its findings and recommended action, with the IFHREC Chairperson excluded from any deliberations and/or voting that might take place in formulating the findings and recommendations. The report shall be submitted to the Deputy Vice-Chancellor of Research, the IFHREC Chairperson, the complainant and other parties if deemed necessary by the EiRC. As previously stated, researchers conducting 'health research' retain the right to lodge complaints to the National Health Research Ethics Council (NHREC) if they remain dissatisfied with the outcome of this complaints process.

2. Complaints about projects that have been approved by the IFHREC

Complainants should submit complaints to the IFHREC secretariat. The complaint will be investigated by the IFHREC, and sanctions or other remedial action taken as appropriate. The IFHREC can, if considered warranted, initiate a research misconduct complaint against a researcher, which would then be investigated as per the UCT Research Misconduct policy.

Concerned parties may raise complaints or issues related to the conduct of the IFHREC or of a project approved by the IFHREC in accordance with the UCT Policy for Breach of Research Ethics Codes and Allegations of Misconduct in Research (colloquially called the Research Misconduct Policy), or the Whistleblowing Policy.

5. Reporting under the research misconduct policy

Annexure 1 (page 8) of the Research Misconduct Policy describes procedures for a complainant:

> *1.1. A person who suspects research misconduct should take responsible action in terms of this policy and procedure and contact the faculty research integrity advisor (F-RIA) or the ORI, to either seek confidential advice or to indicate that they wish to lodge a complaint.*

1.2. *In some instances, an informal discussion may be sufficient to resolve the matter. However, the F-RIA must ensure that potentially valid concerns are not dismissed or minimised.*

6. Reporting under the whistleblowing policy

Section 7.1. (page 6), of the Whistleblowing Policy describes an internal route for a complaint as follows: *"Any concerns or disclosures shall preferably first be made to the line manager or responsible University official, or their superior, unless the whistleblower is for some reason not comfortable taking this reporting route. As an alternative, a report can be made directly to the UCT Risk, Compliance and Relationship Management Director or the Internal Audit Director. The advantage of internal reporting is that it facilitates effective communication between university officials and the whistleblower, and this in turn enables the efficient and effective investigation and resolution of matters. In making a report internally, a whistleblower may request that their identity remain confidential amongst only those with a legitimate need for the information. In this case, the whistleblower must equally make every effort to ensure that they do not themselves cause their identity to become common knowledge."*

1. Protection of whistleblowers

UCT's Whistleblowing Policy states as follows:
" The University of Cape Town (UCT) intends to maintain a culture of integrity in all its work and dealings. As a large and complex institution that engages and deploys significant resources, unlawful and irregular activity can cause significant harm to the University. This means that the risk of unethical activity to UCT resources and to its reputation must be a cause for ongoing vigilance. More specifically, potential and actual wrongdoing needs to be promptly identified in order for any arising loss to be minimised, and that measures to deter recurrence can be instituted. This requires that all stakeholders are aware of and able to discharge their duty to bring any suspicions and knowledge of unethical activity to the attention of the University. Accordingly, UCT has established and maintains channels for the reporting of wrongdoing by all stakeholders, both internal and external. As an employer, the University is committed to enabling its staff and contractors to fulfil their legal obligation to report suspicions or knowledge of fraud, corruption or other malpractice within UCT without fear of retaliation. The effective deterrence, detection and remediation of wrongdoing at UCT is the overriding objective of this Policy. Its implementation plays a key role in ensuring that the University fulfils its obligations in terms of the regulatory framework within which it operates, and in terms of its duties to the communities and society that it serves." (Whistleblowing Policy, page 2)

Should anyone wish to raise concerns about a research project approved by the IFHREC, they may do so in accordance with the whistleblowing policy. Please consult page 7 of the aforementioned policy for routes to report concerns. **Calls should be made to 0800 650 000, which is toll-free from landlines. Alternatively, an SMS can be sent to 33490 and a whistleblowing hotline information agent will call back.** There are other routes to report concerns described in the policy document.

18. SERIOUS ADVERSE EVENTS

In accordance with national and international ethical and regulatory standards, the IFHREC must have written procedures to ensure prompt reporting of unforeseen issues, including serious adverse events that could put human research participants at an increased risk of physical, psychological, economic, or social harm, to the Committee, sponsors, and appropriate regulatory agencies.
A serious adverse event (SAE) is any event in research that results in any of the following:

- Death.
- A life-threatening incident.
- Hospitalization.

- Disability.
- Congenital abnormality.
- Requires medical or surgical intervention to prevent permanent impairment or damage.
- Disclosure of confidential information if there is a risk to a participant (domestic or child abuse).

Reports of serious adverse events, submitted to the IFHREC must include the following:

- Appropriate identifying information for the research protocol, such as title, investigator's name, and eRA reference number.
- A description of the adverse event/incident/experience/outcome.
- An explanation for determining that the adverse event/incident/experience/outcome indicates an unanticipated problem.
- A description of any proposed changes and corrective actions that will be taken in response to the unanticipated problem.

The principal investigator's competence is relied upon by the IFHREC in order to determine the problem's or event's cause, seriousness, and if it was anticipated. Additionally, researchers must advise whether a modification to the protocol is required to reduce participant risks, whether the consent form needs to be updated to reflect this risk, and whether people in the study need to re-consent considering this risk.

If there are immediate risks to participants, the Chair or Deputy Chair may take one or more of the following actions:

- Suspend IFHREC approval to ensure the safety of participants.
- Call an emergency IFHREC meeting to act on the report.
- Request additional information from the principal investigator or others.

Serious adverse events reported that are not serious and do not require immediate action will be reviewed by the IFHREC Chair or Deputy Chair using an expedited procedure. If serious adverse events are reported that are serious and require immediate action, the Chair or full committee may request further information or require the following remedial actions:

- Revise the protocol.
- Modify inclusion or exclusion criteria to mitigate the newly identified risks.
- Suspend enrolment of new participants.
- Suspend procedures in currently enrolled participants.
- Modify informed consent documents to include a description of newly identified risks.
- Provide additional information about newly recognized risks to previously enrolled participants.
- Suspend approval.
- Terminate approval.

These documents must be submitted as amendments and approved by the IFHREC before being implemented.

1. Time frame for reporting and evaluation of SAEs

Unforeseen Issues:

- Researchers are required to promptly notify the IFHREC within seven calendar days upon becoming aware of any unforeseen problems that increase the potential risk of harm to participants or others.
- Serious events such as serious injury or an unexpected death of a participant, injury, death or a safety incident involving research staff should be reported immediately if possible or within 48 hours of the event.
- All studies involving drugs, devices or other physical interventions must be reviewed and approved by the FHS HREC.

19. INFORMED CONSENT

The UCT Research Support page provides numerous resources related to research integrity, including informed consent. Generic templates (for example, Cornell University's template for Social and Behavioural Research Projects) can offer useful guidance, but researchers would nevertheless need to adapt any such template to ensure compatibility with any particulars of their research project.

In general, *minimal* requirements for informed consent should ensure that:

- participants are given a full and accurate summary of their expected commitments, for the lifespan of the research project;
- where participants are minors, that a legal guardian has provided consent;
- the purpose or goal, as well as possible costs and benefits, of the research is made clear;
- participants are aware of the manner in which the data might be published, including considerations such as the identifiability of participants);
- participants have clear information regarding the extent of their access to publications resulting from their participation, as well as contact details if future engagement is required;
- the nature of any future access to research outcomes is provided;
- participants are aware of their right to withdraw from the research at any time;
- participants are provided contact details for relevant support channels, where necessary.

20. INVITATIONS TO POTENTIAL RESEARCH PARTICIPANTS

The EiRC Recommendations for Standard criteria for inclusion in research invitations offers recommendations regarding the content of invitations to potential research participants, to allow for an informed choice by potential participants.

21. REFERENCES

- Department of Health (2015). Ethics in Health Research: Principles, Structures and Processes. 2nd edition.
- University of Cape Town Guideline for Risk-Based Ethical Review of Research, February 2021.
- University of Cape Town. Faculty of Health Sciences. Human Research Ethics Committee. Standard Operating Procedures. Version 7.0. October 2019.
- Inter-Faculty Research Ethics Committee Terms of Reference, September 2022.
- Office for Human Research Protections. Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events. January 15, 2007.
- Cornell University Informed Consent Templates - https://researchservices.cornell.edu/forms/irb-consent-form-templates

This document was compiled by the Office of Research Integrity on behalf of the IFHREC.
Version 13, April 2025

ANNEXURE 1: UCT IFHREC ACTIVE MONITORING SOP AND TEMPLATE

1. Medium to High-risk projects, general provisions

The nature and extent of active monitoring will be determined by the risk inherent in the project, alongside any information or reports received that give rise to particular concerns related to research integrity. In some instances, active monitoring could simply entail a requirement to submit more frequent progress reports or request a response to a particular concern that has arisen. For-cause audits are the most rigorous form of monitoring and are detailed separately below.

Monitoring of high-risk projects will be conducted in a collegial yet critical manner, but where investigators must accept that the IFHREC's responsibilities and authority might necessitate incurring additional reporting burdens on the investigators, as well as access to additional documentation and resources.

The principal investigator must allow unimpeded access to any required documentation, as well as to any other investigators on the project. These documents could include, but are not limited to:

- All protocol submissions, grant award letters, research instruments, informed consent letters and recruitment materials.
- All IFHREC correspondence, including Committee action letters, investigator's responses, progress reports and/or amendments requested, and final approval letters.
- Serious adverse event and protocol deviation reports.

The monitoring team will collect data relating to compliance with regulatory requirements and commitment to research integrity, and will conduct interviews with study team members, and occasionally participants, where confidentiality and any other considerations allow for this.

A final report will be compiled, focusing on strengths and recommendations on how shortcomings, if any, can best be addressed, with reference to national and international ethics and regulatory guidelines and best practices. If problems are identified, the final report will include appropriate follow-up measures to ensure corrective actions are implemented. This might include additional auditing and monitoring. However, this report could also recommend the suspension or even termination of the project, in cases where significant concerns arise in the course of monitoring the project.

Once the principal investigator has reviewed the final report, they will be given two weeks to consider and respond to the recommendations and/or resolutions expressed in the report. Any corrective actions undertaken, or planned for rapid implementation, must be documented in this response to the Chair of the IFHREC. If the investigator's responses are accepted, the audit is closed, and the project can continue under a routine monitoring protocol for a project carrying the relevant level of risk.

Any final report arising from such instances is confidential and will only be shared beyond the Committee with the investigator's permission, unless the audit uncovers problems requiring further attention and possible consideration by others.

2. High risk projects and for-cause audits

Definition

A for-cause audit is an in-depth examination of all components of a research study, including all records and documents, observation of research procedures, and interviews with investigators, research staff members and possibly participants, to determine if participants' rights, safety, and welfare are being upheld according to national and international ethical and regulatory standards.

Following a complaint or an allegation of a serious problem in a study, the Chair will decide whether the study should be:

- Suspended immediately due to immediate risks to participants or others
- Placed on administrative hold
- Allowed to continue until the for-cause audit is complete

If the Chair decides there are no immediate or serious risks to participants, an audit may be requested prior to placing immediate restrictions on the study. The Chair, in consultation with the Deputy-Dean of Research and/or the Senate Ethics in Research Committee, may appoint a sub-committee or an independent auditor, on a per-project contract basis, to conduct the for-cause audit.

3. Pre-audit Preparation

The Chair will inform the principal investigator of the reasons for the audit, whether any restrictions have been placed on the study, and any other relevant details relating to the auditing process. In cases necessitating, and allowing for, input from participants, the principal investigator will be asked to submit a list of participants (ID numbers) enrolled in the study or studies from which a percentage will be randomly selected for review. Only files of selected participants will be reviewed, unless a more comprehensive review is called for based on the discovery of further problems.

1. Researcher submission of a pre-audit report

In instances where a research project has been selected for audit (active monitoring) the researcher will be required to prepare a summary and status pre-audit report for the auditors to consider. The pre-audit report shall include the following items and be submitted in a narrative format.

i. Number of participants engaged in the research.
ii. Number of participants who withdrew.
iii. A summary of any complaints or concerns about the research.
iv. A summary of any relevant recent literature, interim findings, and amendments or modifications to the research since submission of the most recent annual progress report.
v. Any other relevant information, especially about risks associated with the research. Inculding a reflection on whether the risks and benefits have been consistent with those originally anticipated, or whether different or unanticipated risks have arisen.
vi. Changes in sponsors or funders.
vii. Changes in research personnel.
viii. A copy of the current informed consent documents, including and translations if applicable.
ix. A summary of any unanticipated problems and available information regarding adverse events.[8]

In many cases, such a summary could be a brief statement that there have been no unanticipated problems and that adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document.

The researcher shall have 7 days from the date of notification to submit this summary to the audit team.

4. Audit Procedures

A review of documentation related to various aspects of the project can be required in a full audit of a research project, including but not limited to those listed above. The audit team may also conduct individual interviews with the principal investigator and/or key research staff to determine if additional

[8] This list is borrowed, with permission from the UCT HREC SOP (pg. 67). The list has been adapted to suit the needs of the IFHREC.

problems, not already examined during the document review, have occurred and to clarify any other issues.

The audit team may assess the informed consent process, including considerations such as:

- Was the environment in which the consent process took place conducive to rational, thoughtful, and unpressured decision-making?
- Was the length of time devoted to the consent process sufficient?
- Was the participant given adequate opportunity to ask questions?
- Was the participant given an adequate explanation of the research using appropriate simplified language?
- Did the participant show a reasonable level of understanding before signing the consent form?

Informed consent forms thus need to state that research may be audited by the Inter-Faculty Research Ethics Committee. Further, participants need to be informed that their confidentiality will be maintained in the event of any such audit.

5. Preparation of Audit Report

Once the audit is complete, the audit team will compile a written report which is sent to the principal investigator, the Chair of the IFHREC, the full committee at its next meeting, and the Deputy Dean of Research. The principal investigator is required to respond in writing to each of the findings. The principal investigator's response is then presented to the full committee, and a final decision taken based on knowledge of the facts including the additional findings gathered by the audit team.

The Inter-Faculty Research Ethics Committee may conclude that any precautionary suspension be lifted, including the possibility of determining that the project can only continue following the implementation of specific remedial actions. The IFHREC may also recommend further follow-up visits or investigations by the audit team, to ensure corrective actions have been implemented and/or that the investigator and research staff undergo specific training in ethical and regulatory issues. The principal investigator will be notified of the final decision made by the IFHREC.

6. Follow-up and appeal

The principal investigator may submit a written request asking the IFHREC to reconsider its decision. The request must specify the facts in dispute or a perceived procedural error, and provide supporting evidence for any such claims. A full committee will decide via consensus or vote whether to leave its decision unchanged or to reopen its review.

If an appeal reveals confirmatory evidence of an unanticipated problem, or further evidence of a known problem, related to serious or continuing non-compliance which threatens the safety, rights and welfare of participants, the full committee may decide to suspend or terminate the study.

Additionally, in the case of federally-funded or -supported research, the Chair must report findings of serious non-compliance to the Office for Human Research Protection Reports of serious non-compliance leading to termination of a study will also be forwarded to the Dean of the principal investigator's Faculty, the investigator's Head of Department, and funding bodies or sponsors as may be required. The IFHREC will forward the report to the identifiable line-managers where the principal investigator is not employed by UCT.

All documentation generated by the audit is filed with the protocol in the IFREC office, as well as with the Office of Research Integrity.

7. Investigators' Input to the Inter-Faculty Human Research Ethics Committee

Whether or not their project is the subject of an audit or active monitoring of any sort, investigators may submit general comments, suggestions, or concerns, including dissatisfaction with the IFHREC review process or operations, via the following mechanisms:

- The Dean of their Faculty if the investigator is a student or staff member at UCT.
- The Deputy Dean of Research
- The Chair of the IFHREC

Principal investigators will be informed of the outcome of these submissions.

Jacques Rousseau: Chair, Inter-Faculty Human Research Ethics Committee

14 November 2025

IFHREC Active monitoring template and checklist

(Excluding all clinical trials or studies i.e GCP requirements not applicable)

Study PI	
Faculty(s)	
Department(s)	
Title	
IFHREC approval date	
IFHREC Number	

Was a complaint received about this project? If yes please summarise here.			
Item	Yes/No	Comments	Recommendations
Study Team			
Do key personnel have a copy of the final IFHREC-approved proposal			
Is the study team aware of UCT policy on safeguarding? Has there been training?			
Is there a delegation list/ list of roles and responsibilities			
Have field staff/ research assistants received adequate training?			
Are they adequately supervised?			
How are research activities tracked or logged?			
Adherence to the approved proposal			
Is there evidence of deviation from the approved proposal? If yes have these been report or an amendment requested?			
Have all commitments in the proposal been met? e.g. gate keeper permission, community/stakeholder engagement.			
Are there study related SOPs that can be reviewed?			
Has participant recruitment taken place in line with the proposal? Have there been problems with recruitment?			
Informed Consent			
Who has been responsible for obtaining informed consent?			
Where was consent obtained?			

Was each participant provided with a copy of the consent form/study information?			
Is there a complete record available of informed consent for each participant that correlates with a participant recruitment log? (Signed if written, witnessed if verbal)			
Have there been any reported problems or complaints from participants relating to informed consent processes?			
Privacy, confidentiality, and data security			
Have there been any concerns or complaints received about privacy?			
Is data being managed according to an approved DMP?			
How is raw data collected and stored, especially if multiple data collectors involved? Is this in accordance with the approved proposal?			
Risk and benefit			
Has the risk level of the study changed since approval? Have additional risk mitigation interventions been required?			
Is compensation of participants, if any, still occurring in line with what was approved			
Have there been any unexpected incidents related to the study? Were these reported timeously?			
Additional study concerns not captured above			
(expand block as needed)			
Final Comments and Recommendations			
(expand block as needed)			

References

1. Ethics in Health Research: Principles, Processes and Structures 2nd Edition, Department of Health, Republic of South Africa, 2015.