Standard Operating Procedures (SOP)
Senate Ethics in Research Committee (EiRC)

Title	Standard Operating Procedure, Senate Ethics in Research Committee (EiRC)
Approval date	05 June 2024, EiRC Q2 meeting
Person(s) responsible for drafting, review and revision	EiRC Chair; ORI Director, ORI Manager, ORI EiRC Servicing Officer.
Next review date	January 2026
Frequency of review	3 years
Status	Committee of Senate, Standard Operating Procedure
Approval route	EiRC
Approving body	EiRC
Relevant related policies, procedures and guidelines	This standard operating procedure should be understood in conjunction with the general rules for procedures for committees, as amended from time to time, and published in the Principal's Circular. These general rules and procedures can be found at: http://governance.uct.ac.za/committees/default.aspx • UCT Policy for Responsible Conduct of Research • UCT Research Ethics Code for Research Involving Human Participants • Register of Ethics Approvals for Research Conducted under the Auspices of UCT • Code for UCT Research Ethics Committee Members • Appeal to Ethics in Research Committee: Standard Operating Procedure • Conflict of Interest Policy • 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 Whistleblowing Policy • EiRC Recommendations: Standard criteria for inclusion in research invitations • UCT Guideline for Risk-Based Ethical Review of Research (Human Participants) • EiRC Guidelines and recommendations for the use of generative artificial intelligence (AI) tools in research • UCT Research Data Management Policy

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Standard Operating Procedures, Senate Ethics in Research Committee

1. Purpose

To ensure the protection of human rights and the well-being of research participants based on ethical and integrity principles and norms, and compliance with the highest ethical standards in social and scientific research, including matters involving authorship and research misconduct, but excluding research involving animals.

2. Delegated authority of the committee

The Committee has the power to act on behalf of Senate

- to resolve, advise on, or otherwise deal with concerns, questions, and disputes about the implementation of the UCT Research Policy and the UCT Research Ethics Code for Research Involving Human Participants and other policies, guidelines and codes of conduct on these matters;
- to hear appeals in terms of the Standard Operating Procedure for Appeals to Ethics in Research committee.

3. Definitions

Conflict of interest/commitment refers to the situation where a member of UCT's interests and his or her professional obligations to UCT diverge so that an independent third party might reasonably question whether the member's professional actions or decisions are determined by considerations other than the maintenance of high ethical standards in research.[1]

Privacy refers to an individual's right to manage access to their personal data, extending to control over their physical body, including the collection of biological samples. It represents a person's capacity to dictate how others perceive, interact with, or acquire information regarding them. [2]

Confidentiality refers to securing private information and only allowing authorized individuals access to said information. This includes confidentiality regarding committee discussions, agendas, and any information shared with the committee.

Informed consent stands as a cornerstone principle of research ethics, aiming to ensure that human participants engage in research voluntarily and with knowledge of the implications of their participation.[3]

Research integrity/responsible conduct of research refers to "the practice of scientific investigation with integrity."[4] It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to research[5].

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[1] Taken from the UCT POLICY FOR BREACH OF RESEARCH ETHICS CODES AND ALLEGATIONS OF MISCONDUCT IN RESEARCH, 2023 (policy not active yet).
[2] Definition found at University of Pittsburgh Human Research Protection Office -
[3] Definition found at Oxford University Research Support
[4] See National Institutes of Health Rules and Policies.
[5] Taken from Policy for the Responsible Conduct of Research with Restitution Statement Addendum.

4. Ethical, regulatory and legal requirements guiding the work of the committee

In addition to the rules, regulations, policies, and guidelines outlined on the cover page of this SOP document, the below regulatory, legal, and ethical requirements, both local and international, should guide the work of the committee.

a. Regulatory and legal requirements guiding the work of the committee:

- South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, 3rd ed. (NDoH 2024)
- National Health Act 61 of 2003

b. Ethical requirements guiding the work of the committee:

- Singapore Statement on Research Integrity
- Cape Town Statement on Fostering Research Integrity Through Fairness and Equity
- The TRUST Code: A Global Code of Conduct for Equitable Research Partnerships
- The Belmont Report
- The Nuremberg Code
- Declaration of Helsinki

5. Procedures

- The Committee must call for Faculty-specific ethics codes to be lodged with EiRC for information and reference purposes, at least once every three (3) years
- The Committee should encourage Inter-Faculty discussion and debate around topics of mutual interest, especially regarding ethics review of interdisciplinary research. This is to assist with clarification and sharing of resources to ensure the maintenance of the highest ethical standards in such research endeavours.
- The Committee should liaise with the Office of Research Integrity to ensure that research ethics training opportunities are made available at least annually.
- The Committee must submit an annual report on its activities to Senate for approval.

6. Meeting procedures

a. Frequency of meetings

The committee shall meet 3 times per year but may convene additional meetings if necessary. In addition, the committee hosts an annual workshop.

Meetings will be scheduled with at least 6 weeks' notice and the Servicing Officer will be responsible for sending calendar invitations to committee members.

It is preferrable that a scheduled of meetings for the year is prepared in advance, and that these meetings are scheduled in calendars well in advance.

b. Format of meetings

The committee will meet in-person. The Servicing Officer shall secure an appropriate venue and communicate the venue in the Outlook meeting invitation and subsequent meeting information.

Committees may choose to run some meetings online, some in-person only and others in a hybrid manner, regardless of which format is chosen, this shall be adequately communicated to the committee members, in advance.

The preferred platform for online and hybrid meetings is Zoom.

c. Quorum requirements

Quorum for committee meetings is 50% +1 of the full membership (not including administrative or support staff or invited guests).

The quorum status of all meetings shall be noted by the Servicing Officer and must be recorded in the set of minutes for the given meeting.

If quorum is not met a meeting may proceed, but any decisions taken in that meeting must be ratified by means of a Chair's Circular.

d. Chair's Circular

A Chair's Circular may be issued to deal with any extraordinary or urgent business that arises in between scheduled meetings that needs urgent attention.

A Chair's Circular may also be issued to ratify any decisions of a committee meeting which was not quorate.

Non-quorate meeting

In consultation with the REC Chair, the Servicing Officer shall prepare the Chair's Circular for review by the Chair. If it is the case that a Circular is issued as a result of a non-quorate meeting, the Circular shall contain:
  i.   The original agenda of the meeting
  ii.   A short summary of each item
  iii. Any decisions taken in the meeting, which need ratification.
  iv.   A commenting deadline.

The Circular shall be sent, via email, to the committee with a commenting deadline 7 days after its distribution. All comments received in the commenting period shall be reviewed by the Chair, and a decision taken. Following the conclusion of the commenting period, and after consultation with the Chair, the Servicing Officer shall confirm that the commenting period has passed and indicate which decisions were ratified and if any have been held to the next meeting.

Extraordinary or urgent business

If it is the case that a Circular is issued as a result of extraordinary or urgent business, the Circular shall contain:
  i.   A summary of the business, including motivation for why it qualifies as extraordinary or urgent.
  ii.   Any supporting documentation.
  iii. An invitation for discussion or comments.
  iv.   A commenting deadline.

The Circular shall be sent, via email, to the committee with a commenting deadline 7 days after its distribution. All comments received in the commenting period shall be reviewed by the Chair, and a decision taken. Following the conclusion of the commenting period, and after consultation with the Chair, the Servicing Officer shall confirm that the commenting period has passed and indicate the outcome of the circular.

e. Declarations of conflicts of interest and/or commitment and confidentiality

Each member will be asked to sign a conflict of interest and/or commitment and confidentiality agreement prior to attendance at a meeting. The declaration reads as follows:

> As a Senate EiRC member, proxy or co-opted staff member, or member of UCT staff, I agree to:
> - Maintain the confidentiality of all discussions, deliberations, records, and other information related to the functions of the EiRC
> - **Not** participate in any case where I have a present or potential personal, professional, or financial conflicting interest or commitment. In such a case, I will be present only to provide information requested by the EiRC and will recuse myself during the discussion.

The business of the EiRC is confidential and should remain within the bounds of the committee. Committee members are expected to maintain the confidentiality of discussions in meetings.

What may be communicated beyond the committee:
  i. Summarised discussions related to policies where Senate bodies, such as the Senate Executive Committee (SEC) have mandated consultation on proposed policy revisions. Specific concerns may be communicated provided that explicit permission has been obtained from the party.
  ii. Overall challenges and experiences of the committee may be reported to SEC at their meetings, to enable and enhance ethics governance and review throughout the institution.
  iii. The EiRC Chair may consult other REC Chairs, other Senate committee Chairs, or the Office of Research Integrity when challenging situations arise.

It is the intention that confidentiality protects the business and independence of an ethics committee and the decisions it is empowered to take. Confidentiality should be seen to extend to other committees, the ORI and experts who may be consulted in order to make an informed, balanced and ethically informed decision on a given matter.

If it is necessary to consult an external, independent, expert on a given matter then a confidentiality or non-disclosure agreement should be signed before extensive consultations take place.

f. Non-attendance of committee meetings

Committee members shall make every effort to attend committee meetings, with a minimum requirement of 75% of the committee's annual meetings (including the workshop).

If a member is not able to attend a committee meeting then that person shall, in advance, send apologies to the Servicing Officer, to be recorded in the meeting minutes. In the formal record this shall be recorded as a member sending apologies for the meeting. However, if the core member is able to nominate someone to attend on their behalf, to represent the Faculty in question, then this would be suitable. This is beneficial in cases where members go on sabbatical or extended leave.

If a committee member is absent (i.e., does not attend a meeting and does not send apologies in advance), for more than 2 meetings in a year, then the Chair may consult with the Dean of the Faculty in question, or the Senate Nominations Committee, to seek a replacement for that member.

g. Preparation and dissemination of meeting agenda

In consultation with the EiRC Chair, the Servicing Officer shall send a call for agenda items to the committee no less than 3 weeks prior to a scheduled meeting.

Agenda items must be sent to the Servicing Officer, in writing, with a short description, any supporting documentation and identification of person responsible for speaking to the item. Agenda items must be sent to the Servicing Officer no less than 2 weeks prior to the scheduled meeting.

In consultation with the EiRC Chair the Servicing Officer shall prepare the agenda for the meeting. The agenda could include:

i. Welcome and apologies
ii. Confirmation of agenda
iii. Confirmation of minutes of the previous meeting
iv. Matters arising (any items that have arisen out of previous meetings, still requiring resolution; if there are no arising matters then this section may be omitted)
v. Matters for noting (any items that committee members should take note of, but which do not require discussion at the meeting, if there are no matters for noting then this section may be omitted)
vi. Matters for discussion (this should include new matters brought to the attention of the committee either between meetings or as a result of the call for agenda items)
vii. Any other business (this section includes any previously unknown matters raised in (ii) above)
viii. Dates of forthcoming meetings
ix. Conclusion (including the time at which the meeting terminated)

The agenda for a meeting shall be distributed to the committee, along with confirmation of format and any venue information, no more than 7 days prior to a scheduled meeting.

h. Recording, circulation and approval of meeting minutes

The Servicing Officer shall be responsible for recording the meeting either by use of the record function in an online or hybrid meeting, or by taking notes in an in-person meeting.

The minutes shall include a statement on whether quorum was met.

The draft minutes will be compiled by the Servicing Officer within 2 weeks of a meeting having taken place. The draft minutes will be sent to the Chair for review. The Chair shall have 1 week to review the draft minutes and recommended any revisions. Once the Servicing Officer has implemented the Chair's recommended revisions, the draft minutes shall be considered ready to be included in the agenda of the next committee meeting, for review, revision and/or approval by the whole committee.

In order to approve the minutes of a previous meeting one member shall nominate that the minutes are approved, and another committee member shall second this nomination. Minutes may be approved subject to agreed changes discussed in the committee meeting.

The Servicing Officer shall note any revisions required by the committee and make those edits, following which the Chair shall sign the minutes.

The signed minutes will be kept on file by the Servicing Officer in the committee's document repository.

7. Authorship and acknowledgement

The template document for Faculty Standard Operating Procedure (SOP) was developed by Mrs Paula Saner (Manager, Office of Research Integrity). Each Faculty has permission to edit and adjust the template to suit faculty needs and practices.

The EiRC Servicing Officer is responsible for populating the content of the document and for regularly reviewing it to ensure it remains up-to-date and relevant.

The National Health Research Ethics Council (NHREC) Ethics in Health Research Guidelines (2024) provided useful information which has been incorporated into this SOP document.

Thanks go to the internal audit team for recommendations for improving ethics governance structures at UCT through strengthening and harmonising (where possible) documentation and processes.