Inter-Faculty Human Research Ethics Committee (IFHREC)

Terms of Reference

(Last edited 31 January 2024, approved via PC02/2024)

Purpose

The IFHREC is a centrally based UCT Research Ethics Committee that will review and approve certain projects from all faculties and UCT-affiliated research institutes, centers, and units, except for all projects from the Faculty of Health Sciences. This committee's mandate is drawn from both the overarching **UCT Policy on Responsible Conduct of Research** (current approved version) and the **UCT Research Code for Research Involving Human Participants** (current approved version).

The purpose of this committee is twofold. First, the committee will review and approve health research originating outside of the Faculty of Health Sciences and which requires approval from the National Health Research Ethics (NHREC) registered ethics committee as per the requirements laid down in Chapter 9, Section 71-73 of the National Health Act No.61. 2003 (henceforth the NHA). Second, this committee will review and approve research that is not adequately accommodated by Faculty RECs (See details under Scope).

More broadly, the committee will ensure that research involving human participants proceeds according to UCT policies and complies with applicable national and international regulatory and funder requirements.

The IFHREC will be registered with both the National Health Research Ethics Council (NHREC) and the Office for Human Research Protections (OHRP) in the United States.

Definitions (non-alphabetic)

Inter-, multi- and trans-disciplinary research These terms are often used quite interchangeably, and different disciplines interpret the differences differently. The Oxford Dictionary does define the terms very similarly:
Interdisciplinary: Of or pertaining to two or more disciplines or branches of learning; contributing to or benefiting from two or more disciplines.
Transdisciplinary: Of or pertaining to more than one discipline or branch of learning; interdisciplinary.
Multidisciplinary: Combining or involving several separate disciplines
Within a research context the following definitions are regularly cited (Stember, Marilyn. Advancing the Social Sciences through the interdisciplinary enterprise. The Social Science Journal. 1991, 28(1):1-14)
• *Intradisciplinary: working within a single discipline.*
• *Crossdisciplinary: viewing one discipline from the perspective of another.*
• *Multidisciplinary: people from different disciplines working together, each drawing on their disciplinary knowledge.*

• Interdisciplinary: integrating knowledge and methods from different disciplines, using a real synthesis of approaches.
• Transdisciplinary: creating a unity of intellectual frameworks beyond the disciplinary perspectives.

Human research is any research that involves human participants or their personal data. Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalisable knowledge.

Health research. *'Health research' per the NHA* (National Health Act. No 61.2003) *may be understood to include, but is not limited to, research that contributes to knowledge of*
• biological, clinical, psychological, or social processes as regards humans
• the causes and effects of and responses to disease
• effects of the environment on humans
• methods to improve health care service delivery
• new pharmaceuticals, medicines, interventions and devices
• new technologies to improve health and health care…

…. 'health research' has both a broad and narrow meaning. In the narrow sense, it refers to research carried out in a health care environment, usually with patients, whether in a hospital, clinic or home-based. In the broad sense, it refers to research conducted outside a health care environment, usually not with patients. (Ethics in Health Research: Principles, Structures and Processes. Department of Health. 2015 p.8)

Much social science research is 'health research' in a broader sense. Researchers should use a 'reasonable person' understanding of 'health research' as well as an ethic of responsible research conduct to decide whether or not their research falls under the jurisdiction of the NHA. For example, if research targets specific groups of participants because of their relationship to a specific illness or health-related condition, then it is likely that they are conducting health research and their project requires approval by a NHREC-registered ethics committee. Another indicator that the research is 'health research' is if gatekeeper permission is required from a health facility such as a clinic or hospital. Regardless of the above, if a member of the research group is from the Faculty of Health Sciences, the application must be submitted to the Faculty of Health Sciences human research ethics committee. Where individuals from the Faculty of Health Sciences join a project after its initial approval, this would be regarded as an amendment requiring further approval as well as possible referral to the Faculty of Health Sciences Research Ethics Committee.

Biomedical research. For the purposes of these Terms of Reference, Biomedical research is defined narrowly as research involving humans that is clinical or involves patients. (This is to distinguish between health research that must be submitted to the Human Research Ethics Committee (HREC) of the Faculty of Health Sciences and health research in a broader sense, that is suitable for submission to IFHREC). In this context Biomedical research seeks to improve health care by developing new drugs, interventions, and diagnostic modalities, or by obtaining new information such as in the case of genetic and genomic research. Biomedical research is likely to have originated in the Faculty of Health Sciences. It will often involve the collection of personal health data and/or biological specimens and may include health

systems research and epidemiological studies. At UCT this research should be submitted to the Faculty of Health Sciences Human Research Ethics Committee (FHS-HREC) for review and approval.

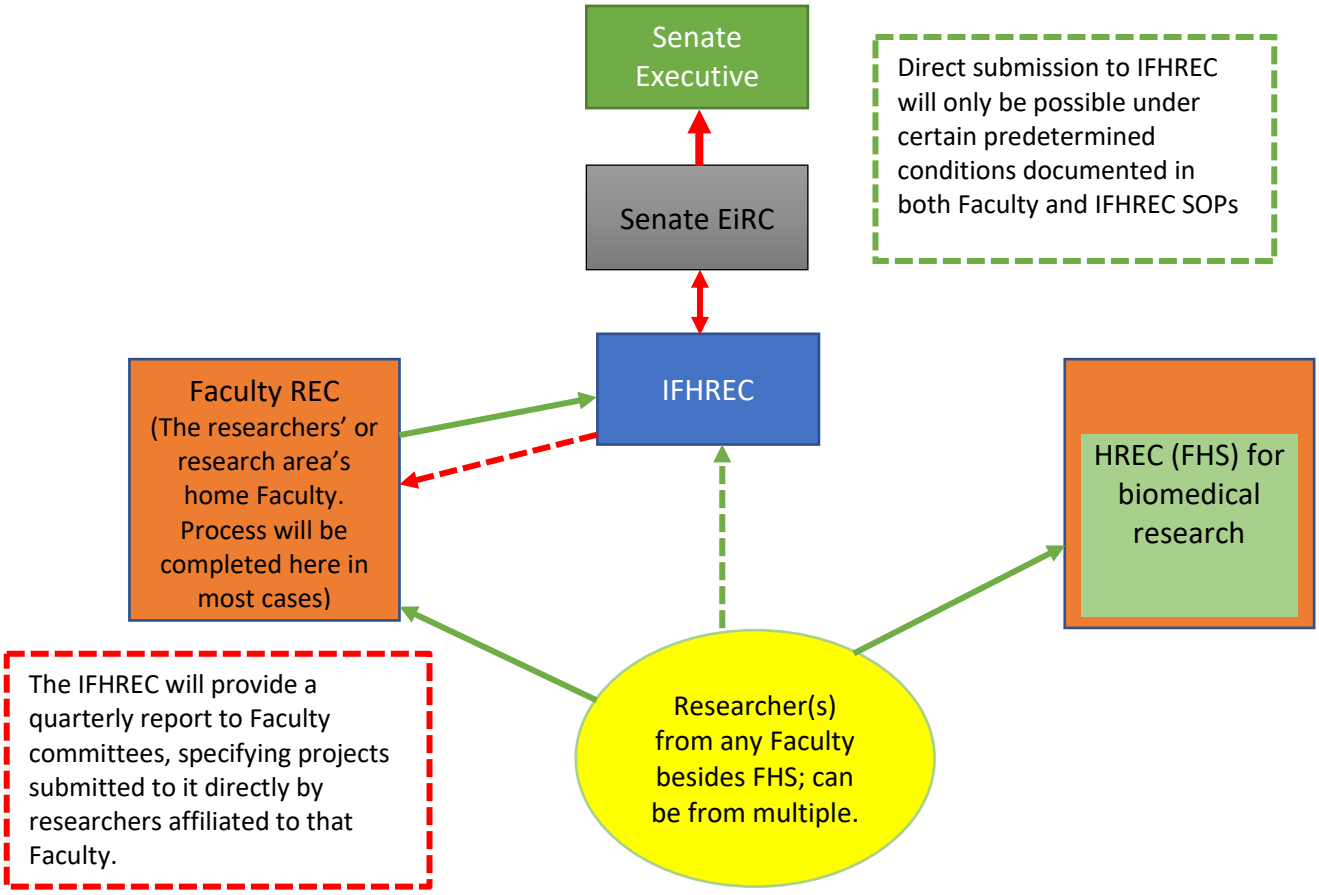
Institutional Responsibility and Reporting.

The IFHREC will report directly to the Senate Ethics in Research Committee (EiRC) and then to Senate, via the Senate Executive Committee. Its Terms of Reference (ToR) must be approved by the Senate, while its Standard Operating Procedure (SoP) must be approved by the EiRC. The IFHREC will, as an NHREC registered committee, must report annually to the NHREC as per their standard reporting format. This committee will thus also be subject to external audit from time to time, where audit results are made publicly available.

The IFHREC will be supported administratively by the Office of Research Integrity, a Directorate in the Research Office.

IFHREC members are expected to abide by the **Code for UCT Research Ethics Committee members.**

Application and reporting flow



Application flow 

Scope

The IFHREC is a UCT-wide ethics committee that will consider projects referred to it by Faculties, or submitted to it by researchers, within the limitations defined below.

Review of Health Research

Projects originating outside of the Faculty of Health Sciences that require approval by a NHREC registered and audited committee, as per the legal requirements of the National Health Act No. 61 of 2003, must be submitted to the IFHREC.

The NHA (s 72(1))requires that proposals to conduct 'health research' must undergo independent ethics review before the research is commenced. Ethics review of proposed 'health research' must be conducted by an REC or AREC that is registered with the NHREC (s 73(2) of the NHA). (Ethics in Health Research: Principles, Structures and Processes. Department of Health. 2015 p.11).

As already stated in the Definitions section above, a 'reasonable person' standard should be applied when deciding whether a project constitutes health research or not. Biomedical research is a subset of health research that, where projects must be submitted to the Faculty of Health Sciences REC. Furthermore, where any of the investigators on the project are members of the Faculty of Health Sciences, applications must be made to the Faculty of Health Sciences REC.

Review of specific categories of projects that do not involve health research

The IFHREC will also consider the following forms of projects, which can either be submitted directly by the investigator, or be referred from a Faculty REC as per Faculty SOPs and in accordance with the IFHREC SOPs:

- Projects that Faculty RECs identify, as per their own SOPs, to carry particularly high ethical complexity and/or risk, resulting in the need for review by the IFHREC, and which are therefore referred to it. (See the UCT Ethical Risk Guidelines for further information on categories of risk.)
- Projects originating outside of, and falling outside of the remit, of FHS HREC, but where funders or collaborators require approval from an externally registered (NHREC and/or OHRP) REC (e.g., the NIH and all US federal agencies, and the NRF in some instances).
- Research conducted by external researchers that requires access to UCT staff and/or students in order for them to serve as study participants, or where external research requires access to UCT staff or student data.

- Trans/multidisciplinary research projects that require review by a multi-disciplinary ethics committee (as discussed above under Purpose). Co-Investigators from different faculties can decide themselves to apply directly to the IFHREC. If the project is primarily informed by a particular discipline, it should typically be submitted to the relevant Faculty's REC rather than to the IFHREC.

In summary, researchers can submit directly to IFHREC (after registration of the project with the Faculty)[1] only if one or more of the following conditions are met:

1. 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 all the named researchers are not staff in the Faculty of Health Sciences.
2. An external funder requires ethics approval from a committee with a US Federal Wide Assurance or SA NHREC registration.
3. Collaborating lead investigators are in different Faculties, and where the research project is not ideally suited to review by one of the originating Faculties.
4. The investigator is from another institution and wishes to conduct research at UCT involving staff and/or students, and/or access to data on staff/students.

Other projects may be referred to the IFHREC via Faculty RECs at their discretion, in accordance with their own SOPs, where the project meets any of the conditions listed above.

Membership

Committee members will be nominated by the Senate Ethics in Research Committee and/or the DVC: Research and Internationalisation, in consultation with Faculties, and approved by Senate. Membership should be ethnically and culturally diverse, include members with disability where possible, consist of an appropriate mix of genders, and collectively comprise a membership with experience and understanding of research integrity as well as research methodology. Both early career as well as senior researchers should be included.

Additional expertise can be co-opted onto the committee if needed for specific projects, and researchers can request the inclusion of *ad hoc* reviewers to assist IFHREC for the review of projects where this is considered necessary or desirable. The co-opted expert will not have voting rights on the IFHREC and would be expected to contribute to the project review until such a time as the IFHREC has made a determination on the project application.

The Chairperson will be appointed by the DVC: Research and Internationalisation, following consultation with the IFHREC. A Deputy Chairperson will be elected by the committee. Membership will consist of the following categories of persons, with overlap allowed.

[1] The IFHREC will utilise the Converis eRA system to register and process all projects. The Faculty registration process should be accommodated as part of this process so as to avoid delays and added burdens for applicants, and provision will need to be made for external researchers to have access to the eRA system.

1. Two representatives from each faculty
2. A legal representative
3. At least three persons with expertise in qualitative research methodology
4. At least three persons with expertise in quantitative research methodology
5. A person experienced in conducting trans-disciplinary research
6. A biostatistician
7. A person with a formal qualification in research ethics
8. A person "with knowledge of, and current experience in, the professional care, counselling or health-related treatment of people. Such a member might be e.g. a medical practitioner, psychologist, social worker or nurse" (Department of Health 2015 Guidelines)
9. At least two non-affiliated persons[2].

Members will normally serve a four-year term, in alignment with Senate and Council terms, with the possibility of two renewals. A member can be re-appointed after having stood down for one or more terms.

Training

All IFHREC members must agree to undergo training in research ethics and the ethical review of research projects on an annual basis, including completing the relevant Responsible Conduct of Research (RCR) modules on the SuccessFactors platform. All members, including new members, are required to complete the following 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

Proof of member training is required for annual NHREC reporting, and members will be requested to provide certificates of completion for these modules. Additional training can take the form of appropriate online training or attendance of workshops, seminars, or conferences.

Succession Planning

The IFHREC will engage with Faculty Ethics structures to inform them of the nature and scope of the IFHREC on an annual basis, and request that they (including in devolved groups such as

[2] At least one of these persons should come "from local communities in which research is likely to be conducted" (a Department of Health ethics guideline (2015) requirement). Such members could be drawn from community-based NGOs; from other institutions, or any person deemed suitable to serve in this capacity by the committee.

Departmental Ethics Committees) nominate staff to the IFHREC, and a database of names will be retained to fill vacancies as they arise. All incoming members, whether mid-cycle appointments or not, will be required to complete the training detailed above. Departing members will be encouraged to provide the new member with an overview of their responsibilities within the committee, and the ORI will provide all necessary documentation such as the process manual for ethics applications and the governance documents for the committee.

Framework Operating Procedures

1. The IFHREC will be supported administratively by the Office of Research Integrity
2. Guiding policy documents, process manuals for applications, and relevant links to e.g., the application portal will be made available via a web page.
3. Agenda closure dates and meeting dates will be published annually.
4. The committee will meet quarterly face-to-face, excluding July and December.
5. The Quorum will consist of 50%+1 of the committee members and must include at least 1 representative per Faculty.
6. Each project will be allocated to a minimum of two reviewers, and all projects and outcomes of approval applications will be reported to the full committee.
7. Screening questions will be incorporated into the IFHREC application form to assist with assessment of ethical risk as per UCT Ethical Risk Guidelines.
8. Detailed Standard Operating Procedures (SOP) will be developed by the IFHREC and will require the approval of the Senate EiRC. This SOP will include review principles and guidelines, criteria for expedited review and full committee review, dispute resolution and appeal mechanisms, informed consent templates, etc.
9. The committee will register with both the NHREC AND OHRP, and adhere to relevant reporting requirements.
10. Appropriate training opportunities will be made available to members via the IFHREC secretariat.