



**TERMS OF REFERENCE FOR THE TUT HUMAN RESEARCH ETHICS  
COMMITTEE (HREC)**

**1. Name of Committee**

Human Research Ethics Committee

**2. Status of the Committee**

The Human Research Ethics Committee (HREC) is a sub-committee of the Senate of TUT. The TUT Human Research Ethics Committee (hereafter referred to as the HREC/Committee) was established under section 73 of the National Health Act (hereafter NHA). The HREC's purpose is to review and approve research proposals that aim to conduct health research, and the HREC also must monitor all research proposals and protocols that it has approved.

All research conducted at and by TUT researchers/scientists as well as students must be of acceptable ethical standards and must be conducted with prior written approval by HREC.

**3. Registration and Accountability of the HREC**

3.1 The National Health Act, 2003 (NHA) (Act No. 61 of 2003) obligates the Minister of Health to establish a National Health Research Ethics Council (hereafter referred to as NHREC) within the National Department of Health (NDoH). The NHREC requires every institution, health agency and health establishment at which health research is conducted to establish or have access to a research ethics committee (REC), which is registered with the NHREC.

3.2 The NHREC Sub-Committee for Norms and Standards revised the second edition of the Guidelines on Research Ethics developed in 2015 and produced a revised third edition titled *South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024 (NDoH 2024)*.

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3.3 These guidelines serve as a minimum national benchmark for norms and standards for conducting responsible and ethical research and as the basis for the HREC's registration with the NHREC, and supersede any other documents or requirements locally and internationally regarding research ethics and RECs in South Africa.

3.3.1 The HREC is registered with the NHREC of South Africa with the registration number REC-220508-008.

3.3.2 The HREC is a standing subcommittee of the Senate, and it accounts to the Senate.

3.3.3 The Chairperson of the HREC must submit quarterly reports to the Senate.

### 4. Functions and Responsibilities of the Research Ethics Committee

4.1 HREC is guided in all its activities by the following documents:

- National Health Act, 2003 (Act No. 61 of 2003);
- National Department of Health Guidelines: South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024;
- Council for International Organisations of Medical Sciences (CIOMS) Guidelines, 2016;
- Declaration of Helsinki, 2013; and
- Belmont Report, 1979.

4.2 The HREC will be responsible for *inter alia*, the following:

4.2.1 Ensuring that humans involved in research are treated with utmost respect and dignity and that their well-being is not compromised.

4.2.2 Ensuring that the research is done with integrity according to high scientific, regulatory, and ethics/ethical standards.

4.2.3 Giving approval where research proposals meet ethics standards and regulatory requirements.

4.2.4 The Committee will review all research involving humans conducted by researchers, as well as students, while ensuring that research conducted will promote responsible conduct.

### 4.3 Secretarial Support

The HREC will have a Secretariat providing administrative support for the HREC, with relevant ethics training, who will be responsible for the following:

- 4.3.1 Receipt of protocols;
  - 4.3.2 Preliminary protocol screening;
  - 4.3.3 Arranging for scientific review of proposals from faculties;
  - 4.3.4 Compiling meeting agendas;
  - 4.3.5 Administrative duties, such as preparing minutes of meetings, record keeping, correspondence, handling queries, approving minor administrative amendments, managing all documentation related to the research studies, and updating the ethics website;
  - 4.3.6 Travel arrangements for members and claims processing; and
  - 4.3.7 All matters reported to the Secretariat regarding HREC submissions are communicated to the Chair, as required, and to the full Committee if indicated. This includes operational issues at research sites that impact on research and participant well-being and safety.
- 4.4 Instruction must be given to researchers to report immediately anything that might warrant reconsideration of ethics approval of the protocol, such as –
- 4.4.1 Serious or unexpected adverse effects on participants;
  - 4.4.2 Proposed changes in the protocol;
  - 4.4.3 Unforeseen events that might affect the continued ethical acceptability of the project, and
  - 4.4.4 Termination or suspension of the project before the anticipated date of completion.
- 4.5 HREC bases its evaluation of applications for ethics approval on the Standard Operating Procedures.
- 4.6 The Committee should monitor all research proposals (passive and active) that it approved. This can be done through annual reporting and ongoing reports from the researcher/PI or by any other appropriate form/activities. The HREC should inform the researcher/PI in writing should concerns arise from the monitoring exercise.

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- 4.7 Constructive engagement with researchers is very important as an educative and supportive role depends on this cordial relationship between the HREC and researchers.
- 4.8 The Code of Conduct for HREC members is outlined in the HREC Standard Operating Procedures.
- 4.9 All research-related institutional ethics fall within the mandate of the HREC.
- 4.10 All matters of research integrity, including research misconduct, fall within the mandate of the Chairperson of the HREC currently, pending the establishment of the Office of Research Integrity and the appointment of a Research Integrity Officer (RIO).

### **4.11 External experts/ consultants**

- 4.11.1 Consultants may be engaged occasionally should there be a need to assist with the reviews of research proposals. This will be done in research proposals requiring some special expertise for ethics review that is not available among HREC members.
- 4.11.2 As an alternative, consultants may be contracted if the HREC members with expertise in a specific complex area all declare conflict of interest in a particular research proposal.
- 4.11.3 Consultants will be expected to declare any conflict of interest they might have, just like HREC members.
- 4.11.4 Engagement with consultants must first be discussed with the DVC: Research and Innovation, who must first grant approval for such a contractual agreement with an expert/consultant.
- 4.11.5 The involvement of a consultant shall not be unreasonably rejected.
- 4.11.6 To avoid the use of a consultant, the HREC may request special training and/or workshops in emerging trends and conceptual aspects of research ethics including research integrity and responsible conduct of research or research methods critical to matters being placed before the Committee. Where resources are required for this purpose, a request should be made to the DVC: Research and Innovation, who should provide approval for this engagement.

## 5. HREC Membership

### 5.1 Composition of HREC membership

5.1.1 The composition of the Committee must be according to the National Department of Health Guidelines: South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, as well as the TUT Human Research Ethics Policy.

5.1.2 The HREC members collectively have all the requisite skills and expertise to review and evaluate the science and ethics of research proposals as submitted to them.

5.1.3 The Faculty Committees for Research Ethics (FCRE) / Higher Education Development and Support (HEDS) will appoint the chairperson and the deputy chairperson to represent the respective faculty discipline at the HREC considering the following criterias:

- Members from diverse age groups and academic (PhD) or professional ranks including experience in supervision.
- Ethnically and culturally diverse members and an appropriate mix of genders.
- Members who have attended training and have expertise in research ethics.
- Staff members who are holding senior positions should not be nominated to serve as FCRE representatives at the HREC.

5.1.4 Researchers are expected to ensure they have the appropriate knowledge, skills, expertise, competence, including discipline-appropriate scientific background and research ethics training to conduct studies involving human participants or the use of animals.

5.1.5 A member should serve for 5 years with the option of renewing their term once, HREC members who resigned or left the Committee before their term ended will be considered to have served for a full term unless it is due to medical reasons or other reasons that deter the member from perform Committee duties.

- 5.1.6 The committee should include sufficient members with the necessary qualifications (PhD) and experience (supervision), including research ethics training, to be able to review and evaluate the science, the health aspects, the ethics of the proposed research, as well as assess the anticipated layperson's perspective.
- 5.1.7 The HREC members and researchers are expected to familiarise themselves with the institutional research ethics documentation as well as the national and relevant international research ethics guidelines and should have documented proof of such familiarity e.g., an training certificate with assessment, not a mere attendance certificate.
- 5.1.8 The HREC appoints members, and the University Senate chairperson signs the letters of appointment to the members after a competitive recruitment process in terms of the Research Ethics Policy. Members serve for five years, which may be renewable for the last term, as determined by the HREC.
- 5.1.9 At least two of the committee members should be external community members.
- 5.1.10 Only external members of the Committee will be remunerated in accordance with the TUT policies.

### **5.1.11 Election of Chairperson and Deputy Chairperson**

#### **5.1.11.1 Background**

The members of the HREC, when duly constituted, elect the Chairperson and Deputy Chairperson from the existing members of the HREC by majority vote. The term of office for the Chairperson and Deputy-Chairperson is five years, and may be re-elected for the second term.

5.1.11.2 The appointment letters of the Chairperson and the Deputy Chairperson of HREC are signed by the TUT Senate Chairperson following the election at HREC.

- 5.1.12 The Committee may seek the expertise of external individuals, as well as TUT researchers with expert knowledge as required. When there are issues of legal concern viewed by the Committee, the legal representative within the Committee will liaise with the Legal Services of TUT to sort out the query.
- 5.1.13 The independence of the Committee is guided by international standards and norms. For example, the **WHO Standard 4: Independence of research ethics committees<sup>1</sup> states:**

*“... to ensure independence of the REC’s operations, in order to protect decision-making from influence by any individual or entity that sponsors, conducts, or hosts the research reviews ... and to ensure that the REC cannot be pressured to approve or disapprove particular protocols, the charter, by-laws, policies and/or procedural rules of the REC provide that:...”*

## 5.2 HREC voting members

- (a) The Chairperson and Deputy Chairperson of each Faculty Committee for Research Ethics (FCRE). Each FCRE must also nominate two secundus who will attend the HREC meeting when the faculty representative cannot do so;
- (b) Two members (one primus and one secundus) who are legally qualified and have an understanding of health research, nominated by the Registrar;
- (c) Two members (one primus and one secundus) who are professional statisticians by training. The HREC will appoint the statisticians who may be nominated from the Directorate of Research and Innovation;
- (d) Two members (one primus and one secundus) with professional training and research experience in qualitative research methodologies. The HREC will appoint the members with professional training and research experience in qualitative research methodologies, who may be nominated from the Directorate of Research and Innovation;

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<sup>1</sup> World Health Organization (2011). Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants.

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- (e) Two members (one primus and one secundus) with professional training and research experience in quantitative research methodologies. The HREC will appoint a member with professional training and research experience in quantitative research methodologies who may be nominated from the Directorate of Research and Innovation;
- (f) Two members (one primus and one secundus) with knowledge of, and current research experience in, professional care, counselling or health-related care of people. Such a member might be – a medical practitioner, psychologist, social worker or nurse. The HREC will appoint the healthcare research experts who may be nominated from the Faculty of Science; and
- (g) Two laypersons who have no affiliation with TUT and are not currently involved in medical, scientific or legal work and are preferably from the community or represent communities where research is conducted or occur. The HREC will appoint the community representatives through advertisement within the TUT community.

HREC members may represent more than one of the above skills categories or categories of personal attributes.

### **5.3 HREC non-voting members**

- 5.3.1 The Secretariat supporting the functions of the Committee will be non-voting members of the HREC and will maintain confidentiality similar to that of the voting HREC members.
- 5.3.2 The HREC may co-opt additional members from relevant interest groups, where the HREC does not have the necessary expertise to evaluate particular research fields, for example, environmental ethics, intellectual property rights, indigenous knowledge systems.
- 5.3.3 The quorum of HREC meetings is 33% as per the NDoH Guidelines, South African Ethics in Health Research: Principles, Processes and Structures, 2024. The total voting membership comprises 25 members; however, 9 members forming a quorum of 33% will be sufficient to pass a verdict.

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<b>Member type<sup>1</sup></b>	<b>Number of members<sup>2</sup></b>
Chairperson	1
Deputy Chairperson	1
Faculty representatives	16
Statistician	1
Community representative	2
Law expert	1
Qualitative research expert	1
Quantitative research expert	1
Professional healthcare expert	1
Co-opted members	Optional
Secretariat (non-voting)	2
Consultants (non-voting)	Optional
<b>TOTAL: Voting members</b>	<b>25 plus Co-opted members</b>
<b>TOTAL: Non-voting members</b>	<b>2 plus Consultants</b>

### 5.4 Resignation and Termination

5.4.1 HREC members may resign if they can no longer serve.

5.4.1.1 Resignation must be submitted in writing to the HREC chairperson, and members are not obliged to disclose the reasons for the resignation.

5.4.1.2 Should an HREC member fail to comply with the contents of the Research Ethics Policy on matters relating to the HREC, or she or he discloses a serious conflict of interest, the member may be requested to resign by the TUT Senate chairperson on a written recommendation by the Chairperson of the HREC.

5.4.1.3 If a member fails to resign as directed in 5.13.1.2, the TUT Senate Chairperson may terminate the member's appointment based on the condition/s given.

- 5.4.1.4 The vacancy should be filled timeously with a person having the same skillset.
- 5.4.1.5 Should the HREC Chairperson need to resign or fail to comply with the contents of the Research Ethics Policy on matters relating to the HREC, or she or he discloses serious conflict of interest, the Chairperson may be requested to resign by the TUT Senate chairperson.
- 5.4.1.6 If the Chairperson fails to resign as directed in 5.13.1.5, the TUT Senate Chairperson may terminate the Chairperson's appointment based on the condition/s given.

## **5.5 HREC Member Training**

- 5.5.1 The HREC members receive training in research ethics right from their commencement and/or assuming the position of HREC member as stipulated in the member's appointment letters. This training can be offered online and/or in a face-to-face, assessable form that will cover the basic ethical principles/theories of research. Health research ethics training is additional to discipline- or profession-specific and must include an assessment to provide evidence of more than mere attendance at training.
- 5.5.2 The training programme is also extended to researchers in their different levels of functioning, such as – senior researchers/scientists, supervisors, and postgraduates (junior researchers/scientists), as well as members of the University at administrative and undergraduate students who are interested in research.
- 5.5.3 After two years of serving at the HREC, members are retrained. The course is called Advanced Ethics Training (Applied Ethics Training), which serves as a “refresher” course on research ethics for HREC members, which is at a higher level of research issues and concepts locally and globally.
- 5.5.4 The HREC Office will cover the above-mentioned training costs for HREC members, where relevant.
- 5.5.5 The TUT faculties will be responsible for their staff training costs.

## **6 HREC Meetings**

### **6.1 Background**

The HREC convenes regularly, preferably ten times per year, to deliberate and review the ethical issues of submitted research proposals and to monitor the progress of ongoing studies for which ethics approval has been granted. The HREC is responsible for monitoring the scientific validity of the proposed research. This requirement includes assessing that the researcher is suitably competent to undertake the research. The HREC must also satisfy itself that, where a substantial expenditure of public funds will be incurred, the importance and potential benefit of the research will be proportionate.

### **6.2 Procedure**

The following agenda issues are dealt with at an HREC meeting:

- 6.2.1 Members present, absent and absent with apology;
- 6.2.2 Supplementary and/or new matters;
- 6.2.3 Approval of the minutes of the previous HREC meeting;
- 6.2.4 Matters arising from the previous minutes;
- 6.2.5 Notification of formal letters sent to researchers;
- 6.2.6 Evaluation of revised project proposals;
- 6.2.7 Evaluation of new project proposals;
- 6.2.8 Evaluation of annual research ethics progress reports;
- 6.2.9 Evaluation of research proposals submitted for external funding (e.g., Medical Research Council and National Research Foundation);
- 6.2.10 Evaluation of project lists submitted by FCRE in respect to research proposals that did not require ethics review;
- 6.2.11 Issues pertaining to the Faculty Research Ethics Committees;
- 6.2.12 Discussion of the Supplementary agenda; and
- 6.2.13 Next meeting dates.

The decisions of the HREC are made according to the following principles:

- 6.2.14 A quorum of at least 33% of members must be present;
- 6.2.15 The decisions of the HREC are based on national and internationally accepted ethics codes and/or guidelines. When strict compliance with

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the letter of a particular requirement of any code/guideline is impossible, the HREC will ensure that the proposed research is nonetheless in keeping with the spirit of those codes/guidelines;

- 6.2.16 The HREC strives to reach decisions by consensus. If consensus cannot be reached, the HREC will vote on the approval of the particular proposal, in which case, a majority vote is appropriate, which should be minuted properly with sufficient detail. The only exception will be when voting is mandatory in terms of research proposals that require strict adherence to the Code of Federal Regulations, 45 CFR 46 (Department of Health and Human Services, United States of America);
- 6.2.17 The HREC will not consider proposals for review if the research project's data collection has already started or has been completed.
- 6.2.18 The HREC may approve, require amendments/revisions to, or reject a research proposal on ethical grounds.

The following HREC decisions are possible:

- Approval with no changes;
  - Provisional Approval - the required changes and/or clarifications can be finalised and approved by the Chairperson without the proposal having to serve before the full HREC again;
  - Referred back - the revised proposal needs to be re-evaluated by a full HREC meeting;
  - Rejected - the specific reasons need to be accurately recorded; and
  - Termination or suspension of prior approval - the specific reasons need to be accurately recorded.
- 6.2.19 The HREC Administration officer records all decisions in the minutes, as well as the method by which they were made. The approved minutes are open for public scrutiny.
- 6.2.20 The HREC Chairperson or Deputy Chairperson have the authority to call a special meeting of the HREC to address urgent matters should they arise.

### 6.3 Post-Meeting Administrative Process

#### 6.3.1 Background

Decisions taken at the HREC meeting with respect to each submitted research proposal are communicated in writing to the researcher and/or study leader. Often, the HREC will request some changes/revisions to the proposal and/or consent form or clarification of certain issues. Only once these requirements are fulfilled will a formal letter of approval be issued. On occasion, a research study may be completely rejected.

#### 6.3.2 Procedure

The following administrative procedures are conducted after the meeting:

- 6.3.2.1 The minutes will be recorded and written up by the HREC Administration officer in consultation with the Chairperson;
- 6.3.2.2 The HREC Administration officer will allocate a unique HREC reference number to all the proposals, including proposals on the FCRE lists, proposals submitted for expedited review and proposals submitted for full HREC review. This reference number should, from then onwards, be quoted in all the relevant research project documentation and communications for ease of reference;
- 6.3.2.3 The HREC Administration officer will send formal letters to all the researchers, study leaders and relevant FCRE chairpersons detailing the HREC's deliberation regarding the submitted research proposals;
- 6.3.2.4 Researchers can address any queries and/or feedback to the HREC Administration officer, who will liaise with the Chairperson to resolve any problems;
- 6.3.2.5 A researcher may lodge an appeal against the HREC's review decision of his/her research proposal to the HREC Chairperson. If the matter cannot be resolved to all the concerned parties' satisfaction, the HREC will refer the appeal to a TUT-recognised independent Ethics Committee/Council in South Africa for review. The HREC will ratify the review report from this Committee/Council

and will be binding on all the concerned parties.

- 6.3.2.6 A researcher may lodge an appeal with the HREC Chairperson against the HREC Standard Operating Procedures that were followed during the review of his/her research proposal. If the matter cannot be resolved to all the concerned parties' satisfaction, the HREC will refer the appeal to the Senate for clarification of proper procedures; and
- 6.3.2.7 It is the responsibility of the researcher and, where applicable, the study leader to comply with all the required revisions and/or clarifications. The revised and/or requested documentation should be submitted to the HREC as soon as possible, but not later than six (6) months, after the relevant HREC meeting.

## **7 Confidentiality**

- 7.1 All matters pertaining to the documents reviewed will be treated as confidential by all members of the Committee and will not be shared and/or distributed to any third party, unless so required by law.
- 7.2 A confidentiality agreement shall be signed by all members upon their assumption of duty as members of the HREC.

## **8 General**

- 8.1 TUT, as an institution, must ensure that the HREC members receive initial and continued training in research ethics and science and are kept aware of current issues and developments in the broad area of research ethics, science, research integrity and the responsible practice of research.
- 8.2 The HREC members must also be aware of the needs for ethics training.
- 8.3 The HREC members are indemnified by the University for legal action and/or suites, e.g., liability consequent upon their decision/approval of research projects as Committee members.
- 8.4 The HREC shall review its own performance and functions annually.

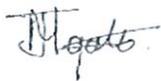
**9. Servicing of the Committee**

- 9.1 The HREC is serviced through the Office of the Deputy Vice Chancellor: Research, Innovation and Engagement with support from the Department of Research & Innovation.
- 9.2 The Administrative support for the HREC resides within the HREC Ethics Office with the reporting line, ideally to the Research Integrity Officer (RIO). However, currently, TUT does not have the Research Integrity Office; consequently, in the absence of an RIO, the Ethics Administrative Officer must report to the Chairperson of the HREC.
- 9.3 The Secretariat shall provide support to the HREC as follows:
  - 9.3.1 Receiving of research proposals.
  - 9.3.2 Preliminary protocols screening.
  - 9.3.3 Liaising with the FCRE, which is responsible for the scientific review of protocols.
  - 9.3.4 Compiling meeting agenda, preparing minutes of the meetings, record keeping, correspondence, handling queries, managing all documentation related to research studies, and updating the research ethics website.
  - 9.3.5 Travel arrangements for members and claims processing.

**10 Review of Term of Reference**

- 10.1 These Terms of Reference will be reviewed occasionally by the HREC and approved by the TUT Senate, as required.

**Confirmation of HREC adoption:**



13/11/2024

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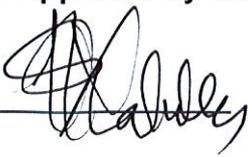
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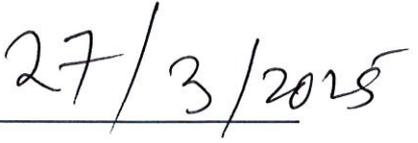
Date

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Confirmation of Approval by Senate:

  
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Prof Tinyiko Maluleke  
Vice-Chancellor and Principal

  
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Date