POLICY ON HUMAN RESEARCH ETHICS

Policy Owner:	DVC: Research, Innovation and Engagement
Responsible Executive Office:	Research, Innovation and Engagement
Policy Type:	Council (Academic Related) Policy

This Policy and its rules, guidelines and procedures replace all previous policies and/or circulars on human research ethics.

1. POLICY STATEMENT

It is the Policy of the Tshwane University of Technology (TUT) to evaluate independently, approve, and monitor research that involves humans' general health, as well as the environment, within a framework of generally accepted research ethics guidelines.

2. DEFINITIONS

In this document, unless otherwise indicated –

"Animal Research Ethics Committee (AREC)" means the subcommittee of the Senate that deals with the use of animals in research and teaching at the Tshwane University of Technology;

"Artificial Intelligence (AI)" means the automated tasks performed by computers through the use of encoded algorithms to imitate human intelligence. AI technology includes machine learning applications based on statistical and mathematical modelling techniques used to define, describe and analyse data[1];

"Conflict of Interest (COI)" means a situation in which someone has competing professional or personal interests such that these competing interests can make it difficult to fulfil their duties impartially;

"Environment" means the combination of external physical conditions that affect and influence the growth, development and survival of organisms;

[1]for ethics review
NDoH, 2024. 3rd ed. Chapter 3: Norms and operational processes for ethics review, p. 62

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"Faculty Committee for Postgraduate Studies (FCPS)" means the faculty-based subcommittee of the Senate Committee for Postgraduate Studies of the Tshwane University of Technology;

"Faculty Committee for Research Ethics (FCRE)" means the faculty-based subcommittee of the Research Ethics Committee;

"Generative AI", sometimes called GEN AI, means artificial intelligence (AI) that can create original content such as text, images, video, audio or software code in response to a user's prompt or request;

"Health research" means research that contributes to knowledge of, among other concerns, biological, clinical, psychological or social welfare matters. Furthermore, health research refers to processes that investigate the causes and effects of and responses to disease, the impact of the environment on humans, methods to improve healthcare service delivery, new pharmaceuticals, medicines, interventions and devices, and new technologies that aim to improve health and healthcare;

"Human Research Ethics Committee (HREC)" means the subcommittee of the Senate that deals with research ethics-related matters at the Tshwane University of Technology;

"National Health Research Ethics Council (NHREC)" refers to a statutory body that was established under the National Health Act No. 61 of 2003. The Act mandates the Minister of Health to establish the Council, and it sets out the NHREC's functions. The NHREC's functions include providing guidelines and direction concerning ethical issues relating to health and conducting research involving humans and animals;

"Non-therapeutic research" refers to research designed primarily to generate knowledge that benefits individuals or groups other than the research participants. Although the participant may not receive any immediate or direct benefits, the study contributes to a broader scientific understanding and potential future societal, clinical or policy benefits;

"Research" means the creative investigation conducted systematically to validate previous research findings, contribute to new knowledge and increase scientific and technological knowledge and expertise;

"Researcher" means an individual engaged in a systematic process of inquiry involving the collection, analysis, and interpretation of data or information using methods appropriate to their discipline. This includes undergraduate and postgraduate students, postdoctoral fellows, and staff (academic or non-academic) who conduct research activities. A researcher must

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possess relevant competencies or work under suitable supervision to ensure scientific rigour, ethical integrity, and compliance with institutional and national research ethics standards;

"Research Ethics" refers to the analysis of ethical issues that arise when humans, animals and/or the biosphere are involved in the research. Furthermore, research ethics relate to the moral rules and professional codes of conduct associated with the act of conducting research;

"Research Ethics Review" means the critical reflection and application of internationally and nationally accepted criteria, norms, and values for conducting research involving human participants, animals and the environment;

"Research Ethics Training" refers to a module, workshop, or programme that focuses on teaching the principles associated with research ethics to researchers, postgraduate students or other interested persons;

"Research Ethics Committee (REC)" refers to both ARECs and HRECs;

"Research Proposal" means a document, inclusive of relevant annexures, that clearly outlines the proposed research and its scientific rationale, prepared according to the TUT Framework for Research Proposals, or a Faculty Framework or any other funding agency proposal guidelines (e.g., the National Research Foundation proposal guidelines, Medical Research Council guidelines);

"Risk" means the probability of harm, disrespect and injustice to participants and vulnerable communities where physical, psychological, social and economic harm may occur as a direct or indirect result of the inclusion in a research;

"Screening" means an evaluation of the document/s submitted by an applicant to assess its suitability and/or completeness;

"Senate Committee for Postgraduate Studies (SCPS)" means the subcommittee of the Senate that deals with matters related to postgraduate studies of the Tshwane University of Technology;

"Similarity index" refers to a high-level screening of the quantity of matched content in research-related documentation;

"Therapeutic research" refers to research conducted with the primary aim of benefiting the individual participant, usually by evaluating the effectiveness, safety, or potential improvement of a treatment, intervention, or medical procedure. This type of research is often

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undertaken in clinical settings and is directly associated with health-related outcomes for participants; and

"University" means the Tshwane University of Technology (TUT), as duly constituted in terms of the provisions of the Higher Education Act, 1997 (Act No. 101 of 1997), as amended.

3. ACRONYMS

AI	-	Artificial Intelligence
AREC	-	Animal Research Ethics Committee
COI	-	Conflict of Interest
DCPS	-	Departmental Committee for Postgraduate Studies
DRC	-	Departmental Research Committee
FCPS	-	Faculty Committee for Postgraduate Studies
FCRE	-	Faculty Committee for Research Ethics
FFP	-	Fabrication, Falsification and Plagiarism
GEN AI	-	Generative Artificial Intelligence
HEDS	-	Higher Education Development and Support
HREC	-	Human Research Ethics Committee
ICMJE	-	International Committee of Medical Journal Editors
ICT	-	Information and Communication Technology
LLM	-	Large Language Models
NDoH	-	National Department of Health
NHREC	-	National Research Ethics Council
PI	-	Principal Investigator
REC	-	Research Ethics Committee
SCPS	-	Senate Committee for Postgraduate Studies
SCRI	-	Senate Committee for Research and Innovation
SOP	-	Standard Operating Procedures
TUT	-	Tshwane University of Technology

4. RULES: HUMAN RESEARCH ETHICS COMMITTEE

4.1 Reporting line

4.1.1 The Human Research Ethics Committee (HREC) is a standing subcommittee of the Senate of the Tshwane University of Technology (TUT). The HREC functions as an independent research ethics committee that evaluates/reviews, and approves research proposals, monitors, and disapproves them as needed. All quarterly and annual reports are sent directly to the Chairperson of the Senate and the DVC: Research, Innovation and Engagement (the Institutional Official).

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4.1.2 The HREC shall evaluate its activities annually by means of a yearly report to the National Health Research Ethics Council (NHREC). The HREC annual report will also be submitted to the Institutional Official on behalf of the Senate for notification.

4.2 Scope

The National Health Act No. 61 of 2003 instructs that ethics review and approval must be done by a registered research ethics committee for:

4.2.1 Health research;

4.2.2 Biomedical research;

4.2.3 Humanities, social and behavioural sciences research, except for research, excluded in terms of the National Department of Health Guidelines: South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024 (NDoH, 2024), subsections 1.1.8 to 1.1.11;

4.2.4 Any other research that may create ethical concerns, cause political or social tensions or have an impact on cultural values;

4.2.5 Research involving the use of human biological materials and data collected from living or deceased persons, including human embryos, fetuses, fetal tissue, reproductive materials and stem cells.

4.3 Application

4.3.1 The HREC is responsible for the research ethics review of all human, general (e.g., laboratory work, environmental research, or information and communication technology (ICT) matters, non-therapeutic research, therapeutic research and health-related research at TUT.

4.3.2 The HREC shall independently review research proposals referred to it by a Faculty Committee for Research Ethics (FCRE) and other relevant environments within TUT.

4.3.3 A FCRE, a subcommittee of the HREC, is responsible for the initial screening of research proposals and protocols originating from academic faculties. This screening ensures that submissions meet the required academic, scientific

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and preliminary ethical standards before being forwarded for formal review and approval by the HREC.

4.3.4 For research proposals originating from non-academic environments, such as support or administrative departments, initial screening must be conducted by the Higher Education Development and Support (HEDS) Research Ethics Committee before submission to the HREC for independent review.

4.3.5 The HREC shall independently review research proposals submitted by non-TUT researchers to collect data within the TUT environment.

4.3.6 The Human Research Ethics Committee (HREC) shall independently review research proposals submitted by non-TUT researchers whose affiliated institutions do not have a registered Research Ethics Committee (REC). In such cases, the HREC serves as the responsible ethical review body, ensuring that all research involving human participants complies with national and institutional ethical standards.

4.3.7 Whereas the primary function of the HREC is to evaluate ethical matters, the Committee may comment on issues such as language and methodology, among others, if it is deemed detrimental to the quality of the proposal, including its adherence to ethical standards.

4.3.8 This Policy also applies in the event that researchers from other institutions have requested the HREC to review their research due to the absence of another suitable registered HREC.

4.4 Recognition of a registered Research Ethics Committee

4.4.1 The HREC will recognise any registered REC, provided it is registered with the National Health Research Ethics Council (NHREC).

4.4.2 The TUT Committee may accept prior review and approval provided by another registered REC, provided that the researcher and/or principal investigator (PI) submits applicable relevant documents required by the HREC as per the HREC checklist, which should at least include the approved version of the proposal, as well as all supporting documents submitted to the REC, and include a copy of the approval letter from the other registered

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REC. The TUT HREC shall thoroughly review the submission and may raise additional ethical concerns for clarification, where necessary.

4.4.3 This mutual recognition should not in itself be construed by researchers to mean that they are at liberty to use it as an alternative route to avoid submitting research proposals to the HREC.

4.4.4 The HREC serves as the point of entry for submitting a proposal when recognition of approval by another registered REC is being sought. However, investigators do not need to reformat their proposals to correspond to the standard TUT HREC submission format. Instead, they should submit the proposal in the same format approved by the other registered REC.

4.5 Publication Ethics

4.5.1 Publication is an essential component of the research process. It enables the dissemination of knowledge, promotes scholarly dialogue and makes meaningful contributions to societal advancement. Within the framework of research ethics, the publication of research findings must embody the principles of honesty, integrity, accountability and transparency.

4.5.2 The HREC supports and encourages the broad dissemination of research outcomes through ethical and responsible publication practices. Researchers are expected to publish in ways that uphold the integrity of the research process and respect the academic values of the Institution.

4.5.3 The imperative to publish is recognised as an integral aspect of academic scholarship, often contributing to career progression, access to funding and professional standing. However, this imperative must not take precedence over established ethical standards. Ethical concerns in the context of publication may arise from, but are unlimited to, the following practices:

4.5.3.1 Failure to give appropriate credit to the work of others: This includes plagiarism, inadequate citation and the omission of significant contributors.

4.5.3.2 Taking undue credit in collaborative work: Researchers must not claim authorship beyond their actual contributions, nor exclude those who have made significant inputs.

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4.5.3.3 Overuse or fragmentation of a limited body of work ("salami slicing"), republishing or slicing the same research into multiple outputs for the purpose of inflating publication records is ethically unacceptable.

4.5.4 Researchers must remain vigilant in ensuring that the pursuit of publication does not compromise their academic and ethical integrity. All research outputs should comply with relevant institutional policies, journal guidelines and international standards for responsible research conduct.

4.6 Redundant publication (duplicate publication)

4.6.1 This occurs when an author republishes the same data, findings or significant portions of previously published work without proper acknowledgement or justification. This practice is considered unethical in academic and scientific research because it distorts the research record, wastes editorial resources, and can mislead readers regarding the novelty or volume of research outputs.

4.6.1.1 Duplicate publication: The author(s) republishes the same paper (or nearly identical content) in more than one journal without acknowledgement or permission.

4.6.1.2 Salami slicing (salami publication): The author(s) breaks down a single research study into several smaller publications to increase the number of publications.

4.6.1.3 Augmented publication: The author(s) reuses significant parts of a previous publication with added data or analysis, without proper citation or explanation.

4.6.1.4 Translated publication without disclosure: The author(s) republishes a previously published article in another language without disclosing the original version.

4.6.1.5 Overlapping publication: The author (s) submits or publishes papers that contain considerable overlap in text, data, or findings, without cross-referencing.

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4.6.1.6 Covert republishing in conference proceedings or book chapters: The author(s) republishes a journal article in a conference proceeding or edited volume without clear attribution or disclosure.

4.7 Authorship

4.7.1 Authorship is both a responsibility and a recognition of intellectual contribution to a research project. Ethical authorship practices ensure that credit is fairly given and that all individuals listed as authors are accountable for the content of the publication.

4.7.2 Ethical Principles of Authorship

4.7.2.1 The HREC authorship principle and definition is guided by the International Committee of Medical Journal Editors (ICMJE).

4.7.2.2 All those designated as authors should meet all four of the following criteria for authorship:

4.7.2.2.1 Only individuals who have made a significant intellectual or practical contribution to the conception, design, execution, analysis or interpretation of the research should be listed as authors. Contributions limited to funding acquisition, general supervision or administrative support do not qualify for authorship.

4.7.2.2.2 Authors should be involved in drafting the manuscript or critically revising it for important intellectual content.

4.7.2.2.3 All listed authors must approve the final version of the manuscript before submission.

4.7.2.2.4 Authors must be able to identify which parts of the work they are responsible for and be accountable for the integrity of those contributions.

4.7.2.2.5 Postgraduate students are encouraged to publish collaboratively with their supervisors. Supervisors and postgraduate students should formalise authorship expectations and responsibilities within their supervision agreements approved at FCPS, ensuring that roles and

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contributions to publications are discussed, documented and reviewed throughout the research process.

4.8 Research misconduct

4.8.1 The HREC recognises the importance of maintaining high standards of integrity, honesty and accountability in the conduct of research. Researchers at the TUT are expected to uphold these values throughout the research process. Research misconduct, including but unlimited to fabrication, falsification, and plagiarism (FFP), is viewed as a serious concern that can compromise the credibility of research and erode public trust (as outlined by the U.S. Department of Health and Human Services, Office of Research Integrity and in alignment with the Singapore Statement on Research Integrity).

4.8.1.1 Fabrication is the act of creating or falsifying data or results and then recording or reporting them as real.

4.8.1.2 Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results, such that the research is inaccurately represented in the research records.

4.8.1.3 Plagiarism is the appropriation of another person's ideas, processes, results or words without giving appropriate credit.

4.8.1.4 Other unethical practices include (implicitly discouraged by the Singapore Statement):

4.8.1.4.1 Misrepresentation of contributions (e.g., false authorship).

4.8.1.4.2 Undisclosed conflicts of interest.

4.8.1.4.3 Improper handling of human or animal research subjects.

4.8.1.4.4 Withholding or selectively reporting results.

4.8.1.4.5 Retaliation against whistleblowers.

4.8.1.4.6 Obstruction of the peer review process.

4.8.2 Research misconduct excludes honest error or differences of opinion.

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4.9 Peer Review

4.9.1 The HREC affirms that peer review is a foundational element of ethical and credible research practice. All researchers engaged in the development, evaluation or dissemination of research are expected to participate in and uphold the principles of objective, constructive and confidential peer review.

4.9.2 Researchers must ensure that peer review processes are conducted with due regard for scientific validity, methodological rigour, and ethical compliance. The HREC supports the use of peer review as a mechanism to promote research excellence, maintain accountability and safeguard the integrity of scholarly communication.

4.9.2.1 Sound methodology and scientific validity are essential entry points for ethical research. Poorly designed studies not only compromise results but also waste valuable resources.

4.9.2.2 Peer review enhances the quality and credibility of research, helping to ensure ethical compliance. Researchers are encouraged to submit their work for peer review and to engage actively in reviewing the work of others.

4.9.3 The HREC supports and encourages its members to participate in this vital process, which is conducted under confidential and privileged conditions.

4.10 Plagiarism

4.10.1 Plagiarism means the intentional or unintentional act of representing the published/unpublished idea, writing, work, or inventions of others as the products of one's original intellectual endeavours without adequately acknowledging the author, creator or source (University of Johannesburg, 2012). Plagiarism includes directly copying or paraphrasing content generated by large language models (LLMs) or other generative artificial intelligence (GEN AI) content and using the output of LLMs to produce academic, professional, or any other form of original work. Suppose explicit permission is not granted to use AI-generated content for an assignment or assessment. In that case, it is plagiarism if this content is presented without appropriate acknowledgement of the AI tools used (TUT Policy of Plagiarism, 2025). The HREC will provide detailed guidelines on the ethical use of AI within research activities, as outlined in the HREC Standard Operating Procedure.

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4.10.2 Careful attention must be given to properly acknowledging all sources in any research output. To support this, the use of plagiarism detection tools is strongly encouraged at all stages, including draft manuscripts and final research publications.

4.10.3 All research must be conducted in strict adherence to the Tshwane University of Technology (TUT) Policy on Plagiarism (2025), ensuring the highest standards of academic integrity and ethical scholarship are maintained.

4.10.4 The HREC may utilise plagiarism software, such as Turnitin, among others, to evaluate and guard against high similarity indexes that could serve as grounds for accusations of plagiarism. All similarity indexes and originality reports need to be examined within the specific field and study context, as outlined in the TUT Policy on Plagiarism.

4.10.5 While all similarities must be reviewed for potential plagiarism, a similarity score exceeding 20%, unless a different threshold is specified by the Faculty, will be deemed unacceptable and the document must be revised.

4.11 Collaborative research outside the Republic of South Africa

4.11.1 In cross-border collaborative research, TUT researchers conducting research beyond the South African borders must get research ethics approval for the research from the country in which data will be collected, as well as from the HREC.

4.11.2 Where a suitable Research Ethics Committee has given research approval in another country, TUT researchers must submit the approved version of the proposal, all attachments, and the letter of approval to the HREC.

4.11.3 The proposal must undergo the process of scientific review by the relevant committees (DRC, FCPS and FCRE). The HREC may request additional information if the level of detail required by the approving ethics committee in another country is insufficient to meet South African standards of ethical review.

4.11.4 The HREC may seek expert opinions on unresolved ethical matters where a final majority decision cannot be reached. The committee will defer to relevant institutional structures or committees on matters related to cultural considerations, budgetary issues, research site access approvals and specific consent form requirements.

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4.11.5 The Standard Operating Procedures (SoP) for international collaborations (Section 18) should be consulted.

4.12 Rights and Responsibilities of Funders, Clients and Sponsors

4.12.1 Funders, clients, and sponsors must provide a clear, written research mandates formalised by a legal contract detailing the research scope, deliverables, timelines, and intellectual property rights. They have the right to request progress information but must not interfere in ways that compromise scientific integrity or participant welfare. They should be informed of, and respect the Institution's Research Ethics Policy, ensuring all research complies with ethical standards. Even when acting as gatekeepers to participants, they cannot replace the researcher's duty to obtain informed consent and protect participant rights.

4.13 HREC Roles and Responsibilities

4.13.1 The HREC shall operate without limitation within the scope of the National Health Act and shall be guided by the National Department of Health's *Ethics in Health Research: Principles, Processes and Structures* (NDoH, 2024), as well as other relevant legal and regulatory frameworks, guidelines, policies, and procedures outlined in this Policy on Human Research Ethics Policy.

4.13.2 The HREC should be provided with sufficient resources and an appropriate annual budget by TUT to perform the responsibilities outlined within this Policy on Human Research Ethics, including, but unlimited to, HREC membership and training.

4.13.3 The Chairperson of the HREC is responsible for managing the annual budget allocated to the HREC.

4.13.4 The HREC must safeguard the protection of, and promote the autonomy, rights, dignity, and welfare of the research participants who volunteer to take part in research that has been assessed to be scientifically and ethically sound.

4.13.5 In research involving humans, the HREC is expected to independently decide on whether or not the proposed research protocol protects the rights (respect for autonomy, dignity and welfare) and interests of participants sufficiently and displays proper norms and standards of research with integrity.

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4.13.6 The HREC is mandated by the National Department of Health Guidelines: South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024 (NDoH, 2024) to also play an educative and supportive role by arranging research ethics training for HREC members, supervisors and researchers.

4.13.7 The HREC will monitor the progress of the approved research, from the time of approval to the closing/termination of the study through annual progress reports and/or site visits as outlined in the HREC SOP (Section 15).

4.13.8 Where research proposals involve the use of vertebrate animals, the proposals must be referred to the Animal Research Ethics Committee (AREC), which is registered with the NHREC and is a standing subcommittee of the Senate, for evaluation and approval.

4.13.9 For non-animal research proposals with minimal risk, and/or undergraduate, advanced and postgraduate diploma research not involving human participants, the proposals are reviewed by the relevant FCREs, which are standing subcommittees of the HREC, for evaluation and recommendation to the HREC. The FCREs review research proposals within the context of their respective Faculty/Higher Education Development and Support (HEDS). The HREC will evaluate the FCRE review, and the final approval will be granted. The HREC has the mandate to override or withdraw a decision made by the FCRE if the HREC deems a study to present ethical risks to participants, researchers, institutions or the environment.

4.14 Established HREC

4.14.1 The HREC is established in line with the mandate of the National Health Research Ethics Council (NHREC) consistent with the National Health Act (2003), Section 73(1), which states that "...every organisation/institution, health agency and health establishment at which health and health-related research involving human participants is conducted, must establish or have access to a registered Research Ethics Committee".

4.14.2 The HREC shall function within the confines of the Act, the Guidelines, CIOMS Guidelines (2016), the Belmont Report (1979), and the Declaration of Helsinki (2013).

4.14.3 The HREC aims to review research involving human participants while exercising due diligence, ensuring that the rights and welfare of research

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participants are safeguarded, meaning autonomy, respect, dignity, safety and well-being.

4.14.4 The HREC will give approval only when research proposals meet both the ethics principles, research integrity norms and standards and regulatory requirements. It is every HREC member's primary responsibility to decide independently whether the proposed protocol protects the interests of participants adequately and keeps to exemplary standards in research activities.

4.14.5 Triage review by an *ad hoc* HREC subcommittee may be instituted on some proposals. The HREC subcommittee will consist of the HREC Chairperson and two other members of the committee who will be subject experts and/or ethicists, who will determine whether a research proposal requires full or expedited ethics review (see TUT SOP, Section 7.7) or is eligible for a waiver.

4.15 HREC Membership

4.15.1 In general, RECs shall be independent, multi-disciplinary, and multi-diverse and broadly reflect the demographic profile of the South African population.

4.15.2 Membership should include as many disciplines, sectors and professions as possible, appropriate to the remits of the TUT Committee.

4.15.3 The HREC Terms of Reference should be consulted for details regarding the composition and the rules of HREC membership.

4.15.4 All HREC members should comply with the Terms of Reference and Code of Conduct.

4.15.5 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. A confidentiality agreement shall be signed by all members upon their assumption of duty as members of the HREC.

4.16 Conflict of Interest (COI)

4.16.1 The HREC members must declare any conflicts of interest they may have (real and potential) to the committee. Conflicts of interest include financial, material and political concerns. They include benefits, such as research

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funding, or indirect benefits, for example, the provision of materials or facilities, or the support of individuals, including the provision of travel or accommodation expenses to attend conferences and political favours.

4.16.2 The HREC members are required to sign conflict of interest agreement. Any member who declares conflict of interest with a submitted protocol must recuse himself/herself from the meeting when discussions and decision-making occur on the protocol in which a member is directly involved as an investigator. Members may not use their membership to elicit an advantage.

4.16.3 A declaration of interest by all members will be completed at each meeting and managed accordingly. A member who is directly involved in a study conducted by their faculty/department will not be part of the decision-making on the study. When a study from a member's department/faculty is discussed, they are considered to have a direct involvement. Offering clarification will not necessarily give that application an unfair advantage, as any researcher may be invited to meetings to provide clarification. Clarification will be managed openly and transparently.

4.16.4 Members serving in HREC, even though they are employees of TUT, serve the committee in their capacity to protect research participants' human rights.

4.17 Scientific Review

4.17.1 Research proposals must undergo scientific review before submission to the HREC for ethical review to ensure that sound and valid scientific methods have been applied to the study.

4.17.2 Scientific review falls under the mandate of the Faculty Committee for Postgraduate Studies (FCPS), which comprises discipline-specific experts. The committee and reviews proposals that have undergone initial scientific evaluation by a Departmental Research Committee (DRC).

4.17.3 A copy of the scientific review form, containing the reviewers' comments, the researcher's response thereto, and the reviewers' approval, will be part of the documents submitted to the HREC. This will facilitate the process and allow the HREC to focus on the ethical aspects, knowing that an in-depth scientific review has been conducted and the protocol stands up to the scientific scrutiny appropriate to the relevant discipline.

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4.17.4 The HREC may initiate additional scientific review where necessary, in line with Chapter 3, Section 3.1 of the National Department of Health Guidelines: South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024 (NDoH, 2024).

5. RULES FOR THE FACULTY RESEARCH ETHICS COMMITTEES (FCRE)

5.1 FCREs are standing sub-committees of the TUT HREC.

5.2 The FCRE is responsible for screening proposals and submitting recommendations to the HREC.

5.3 The FCRE screening includes an evaluation of the proposal's risk level as outlined in the HREC Standard Operating Procedures.

5.4 The HREC recommends that the FCPS and FCRE hold joint monthly meetings to review both scientific aspects and ethical screening concurrently. Members of both the FCPS and FCRE must receive and/or sign a confidentiality agreement, be provided with specific Terms of Reference (ToR) and Standard Operating Procedures (SOPs) relevant to their respective committees and undergo appropriate induction and training.

5.5 **The membership of the FCRE is composed of the following framework:**

5.5.1 The Faculty/HEDS representative on the HREC is the Chairperson of the FCRE, or as determined by the Faculty;

5.5.2 Duly nominated persons serve on the FCRE;

5.5.3 Only persons who are appropriately qualified to evaluate postgraduate proposals (e.g., have completed postgraduate studies or hold pertinent expertise) and have completed or are in the process of completing research ethics training should serve on the FCRE;

5.5.4 Furthermore, members with full voting rights may be co-opted by the FCRE from relevant interest groups, where the FCRE does not have the necessary expertise to evaluate particular research fields (e.g., environmental ethics, statistics, qualitative research);

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5.5.5 An administration officer, appointed by the Executive Dean of the Faculty, who is a non-voting member.

6. ETHICS REVIEW

6.1 TUT is committed to conducting research that has integrity with the responsible practice of research and is obligated to promote ethically sound research. This calls for a cordial working relationship between the HREC and researchers to carry out an exhaustive and open assessment of the ethical implications of the proposals to ensure the safety of participants and researchers.

6.2 The Committee will review proposals prospectively, making sure that they are ethically acceptable, i.e., meeting ethical norms and standards before research begins.

6.3 Ethics reviews and approvals shall be based on the NDoH Guidelines, South African Ethics in Health Research: Principles, Processes and Structures, 2024, including provisions in the Standard Operating Procedures of the HREC for expedited reviews and reciprocal recognition of reviews.

7. THE STANDARD OPERATING PROCEDURES, AS APPROVED BY THE HREC, SHOULD BE CONSULTED FOR MORE INFORMATION REGARDING:

7.1 Application for Ethics Review

7.2 Ethics Review Process

7.3 Complaints and Suspension or Discontinuation of Projects

7.4 Appeals

8. THE TERMS OF REFERENCE OF THE HREC, AS APPROVED BY THE SENATE, SHOULD BE CONSULTED FOR MORE INFORMATION REGARDING:

8.1 Composition of the HREC

8.2 HREC Member Training

8.3 HREC Meetings and Secretarial Support

8.4 External experts/ consultants

9. TUT'S RESPONSIBILITY TOWARDS THE HREC:

9.1 Provision of facilities and resources to enable the Committee to fulfil its mandate

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9.2 Funding for continued research ethics training and research integrity training for researchers and HREC members, as appropriate.

10. RESEARCHERS' RESPONSIBILITIES TOWARDS THE HREC:

10.1 Researchers are responsible for complying with this Policy and its associated SOPs and related legislations, regulations, policies and guidelines.

11. REGISTRATION OF THE HUMAN RESEARCH ETHICS COMMITTEE:

11.1 In keeping with the NHA Section 71, the HREC must at all times have valid and active registration with the NHREC.

12. REPORTING AND AUDITING

12.1 The HREC must report annually to the NHREC on their activities on or before 28 February of each year.

12.2 The HREC should make relevant records available for inspection and auditing by the NHREC (or its delegates) upon request.

12.3 The HREC must submit quarterly reports to the Senate Committee for Research and Innovation (SCRI) and/or Senate Committee for Postgraduate Studies (SCPS) for tabling at the Senate meetings.

13. DOCUMENTS

The Policy should be read in conjunction with:

13.1 Policy on Postgraduate Studies
13.2 Policy on Plagiarism
13.3 Policy on Staff Ethical Behaviour
13.4 Policy on Contract Research
13.5 Policy on Postdoctoral Research Fellows
13.6 Declaration of Helsinki, World Medical Association
13.7 International ethics guidelines for biomedical research involving human subjects, Council for International Organisations of Medical Sciences

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13.8 Department of Health, Republic of South Africa: 1) Ethics in health research: Principles, structures and processes; and 2) Guidelines for good practice in the conduct of clinical trials with human participants in South Africa.
13.9 Annexure A: Research Ethics Committee Terms of Reference
13.10 Annexure B: Research Ethics Committee Standard Operating Procedures
13.11 Legislation:
- 13.11.1 Children's Act No. 38 of 2005
- 13.11.2 Constitution of the Republic of South Africa, Act No. 108 of 1996
- 13.11.3 Hazardous Substances Act No. 15 of 1973
- 13.11.4 Health Professions Act No. 56 of 1974
- 13.11.5 National Health Act, Act No. 61 of 2003
- 13.11.6 National Environmental Management Act No. 107 of 1998
- 13.11.7 National Health Laboratory Act No. 37 of 2000

13.12 Regulatory Frameworks and Guidelines
- 13.12.1 South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, (V3.1) (NDoH 2024). Accessible at: health.gov.za/wp-content/uploads/2025/07/SA-Ethics-in-Health-Research-2024.pdf.
- 13.12.2 Guidelines on Ethics for Medical Research Books 1-5, SAMRC. Available at: http://www.mrc.ac.za/research/ethics/guideline-documents.
- 13.12.3 The South African Medical Research Council Guidelines on the Responsible Conduct of Research (2017).

13.13 International Treaties and Conventions

- 13.13.1 The Belmont Report (1979) Accessible at: http://www.hhs.gov/ohrp/policy/belmont.html
- 13.13.2 CIOMS (2016). International Ethical Guidelines for Health-related Research Involving Humans. Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO). Accessible at: http://cioms.ch/ethical-guidelines-2016/WEB-CIOMS-Ethical-Guidelines.pdf
- 13.13.3. Declaration of Helsinki (2013). Accessible at: http://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
- 13.13.4 The Montreal Statement on. Research Integrity in Cross-Boundary Research Collaborations (2013). Accessible at: http://www.wcri2030.org.
- 13.13.5 The Singapore Statement on Research Integrity. Accessible at: http://www.singaporestatement.org.

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14. SIGNATURES

V MOWENYA (Adv)
CHAIRPERSON OF IPDC

24/04/2026
Date

T MALULEKE (Prof)
CHAIRPERSON OF EMC AND SENATE

24/04/2026
Date

I Ka-MBONANE (Mr)
CHAIRPERSON OF COUNCIL

24/04/2026
Date

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15. POLICY DATES

Date Issued:	1	**Consultation Dates:** – **Stakeholder(s)** – **Webmail**	2025/10/06
Issue Number:	1	**Date checked by:** – **Legal Services** – **Language Editing Services**	2025/11/10 2025/11/12
Date Reviewed:	2025	**Date approved by Responsible Executive Officer:**	2025/09/30
Effective Date:	2026	**Date approved by:** – **IPDC** – **EMC** – **Senate** – **Council**	2025/11/10 2026/01/20 2026/03/02 2026/04/24
Scheduled Review Date:	2031	**Date posted on the Policy Repository:**	April 2026

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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)*.

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 Unforseen 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.

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[1] states:**

"... to ensure independence of the REC's operations, in order to protect decision-[2]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;

[1] World Health Organization (2011). Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants.

(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.

Member type[1]	Number of members[2]
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
TOTAL: Voting members	**25 plus Co-opted members**
TOTAL: Non-voting members	**2 plus Consultants**

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

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

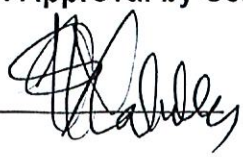
10.1 These Terms of Reference will be reviewed occasionally by the HREC and approved by the TUT Senate, as required.

Confirmation of HREC adoption:

13/11/2024

Chairperson :HREC **Date**

Confirmation of Approval by Senate:



27/3/2025

Prof Tinyiko Maluleke
Vice-Chancellor and Principal

Date

Tshwane University
of Technology

We empower people

TSHWANE UNIVERSITY OF TECHNOLOGY

HUMAN RESEARCH ETHICS COMMITTEE

STANDARD OPERATING PROCEDURES

Table of Contents

1 Authority

1.1 The Tshwane University of Technology (TUT) Human Research Ethics Committee (HREC) is established based on the provisions in both its Human Research Ethics Policy and the Terms of Reference.

1.2 The National Health Research Ethics Council conferred the authority to the HREC to independently review human research ethics, ensure participant protection, monitor studies, and enforce compliance with ethics standards.

2 Role of HREC

2.1 The HREC (hereafter, Committee) is tasked to review, approve and monitor all research proposals involving human participants. The strategic oversight contributes to safeguarding the rights, dignity, safety, and well-being of all research participants, while ensuring research goals do not supersede participants' best interests. The Committee is committed to ensuring high-standard scientific and ethical research by TUT, which protects the professional interests of the researchers as well. The HREC's focus is to provide independent, comprehensive, and timely reviews of the ethics of proposed studies conducted by TUT researchers (senior scientists, junior scientists, undergraduate and postgraduate students). Monitoring of approved research projects/proposals is carried out annually (passive) and ongoing (active) reporting.

3 Meetings

3.1 The HREC will hold a minimum of 10 meetings annually. Additional meetings will depend on the needs of the faculty members in consultation with the HREC Chairperson. These meetings may be conducted face-to-face or virtually. A meeting schedule for the year can be accessed through the HREC Office and the TUT Core Calendar.

3.2 The quorum of HREC meetings is 33% as per the NDoH's South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024.

At the discretion of the Chairperson, in consultation with the Committee members, and subject to their observing the confidentiality of the meeting, applicants may be requested to attend the meeting to provide clarity on their proposals but will not be present when decisions are made by the committee regarding the acceptability or unacceptability of the proposal.

3.3 Poor meeting attendance impacts on the quorum, and this can result in a meeting being cancelled. Committee members are expected to attend meetings regularly and be punctual to ensure timely and efficient review and approval of research proposals.

3.4 The meeting agenda will list the proposals, major amendments, annual status reports, serious adverse events reports, and responses to queries to be discussed. They will be sent to members, together with the study documents.

The Ethics Office must send the final agenda to all members of the HREC at least ***five*** working days before the meeting.

3.5 Additional information regarding the process of HREC meetings is provided in the HREC Terms of Reference.

4 Application for ethics review and approval by the HREC

4.1 The Constitution of the Republic of South Africa, 1996 (the Constitution) emphasises the inherent human dignity, equality, and the advancement of human rights of every individual living in South Africa. The Constitution states unambiguously that human rights must be respected, promoted, and protected. Section 27 (1) guarantees the right of access to health care services, while Section 12(2) of the Bill of Rights in the Constitution protects against research abuse by providing that:

> *"Everyone has the right to bodily and psychological integrity, which includes the right –*
>
> *(a) To make decisions concerning reproduction.*
> *(b) To security in and control over their body; and*

(c) Not to be subjected to medical or scientific experiments[1] without their informed consent".

4.2 Against this background, all human-related research conducted under the auspices of TUT must be submitted to the HREC for review and approval before the study commences.

4.3 The Research Ethics Office will make available a comprehensive checklist (which will be revised from time to time) to guide the researchers when submitting their proposals. The researchers must submit written applications for ethics clearance and provide relevant supporting documents as stipulated-

- TUT ethics declaration, TUT ethics checklist, research proposal, and annexures, such as participant information sheet, informed consent, and questionnaire. One electronic copy of these documents must be submitted to the HREC Administrative Office.

4.4 All documentation must be submitted to the Research Ethics Office 14 working days (excluding public holidays and recess)[2] before the scheduled date of the Committee meeting.

4.5 A research proposal must include:

4.5.1 A statement of the ethics/ethical considerations involved in the proposed study. The Committee must be content that the research proposal offers appropriate consideration to the environment and/or participants' rights, beliefs, values, customs and cultural inheritance.

4.5.2 An outline of a clear community engagement showing how stakeholders and community members will be consulted and involved in the entire research process, where applicable.

4.5.3 Researchers are obligated to provide the process of obtaining informed consent and assessing the participants' understanding of the consent information, and this must be included in the research proposal. Special

[1] **"The term 'experiments' originates from Article 7 of the International Convent on Civil and Political Right – UN 1966 and echoes the Nuremberg Code**; in the constitutional context, it is intended to mean 'research'.

[2] HREC Draft SOPs 2024

attention should be paid to participants' understanding and appreciation of the information given before deciding to participate in the research.

4.5.4 Research conducted for doctoral and master's degrees' must first undergo scientific and subject assessment. Only after receiving this provisional approval can the research project proceed to the HREC for final ethics review and approval.

4.5.4.1 Research projects for staff and internal researchers will serve at the Faculty Committee for Research Ethics (FCRE) for screening and subsequent submission to the HREC, and external research projects will be submitted directly to the HREC.

4.5.4.2 Processes for review and approval of external research projects:

The following documents need to be included in the submission of an external research project for approval by the HREC:

- Approved, full project proposal. Evidence must be submitted regarding the relevant institutional approval of the project. Also, the HREC requires a full proposal that *inter alia* clearly describes the following aspects: rationale, research design, sample selection, sampling strategy, data collection strategy, data analysis, ethics, budget and time schedule. A proposal summary is insufficient for a full review by the HREC.
- Data collection instruments and recruitment material. Copies of the data collection instruments, such as an interview guide, and questionnaire, as well as an indication of the actual format, for example, hard copy, electronic, online, that will be used during the study must be submitted. Evidence of permission to use standardised instruments, such as copyright protected instruments, must be provided where applicable. Also, copies of recruitment material, such as flyers, posters, and invitation-to-participate letters, where applicable, must be submitted.

- Information Leaflet and Informed Consent document. The relevant information leaflets, informed consent documents and/or survey cover letters that will be used must be submitted for review.
- Ethics Approval from the relevant institution where applicable. Evidence must be submitted regarding ethics approval by the relevant Research Ethics Committee.

External research proposals will be charged R2 500 per proposal for review and approval. The fee will be reviewed as required by the HREC. In this context, "External review" is defined as any proposal or project submitted by a researcher without any affiliation to an institution or organisation with a REC that can provide the relevant ethical review and approval. This also encompasses an institution or organisation where the associated REC has been suspended by NHREC or their accreditation with NHREC has been withdrawn.

4.5.4.3 HREC oversight of Faculty Committees for Research Ethics:

I. FCREs are standing sub-committees of the HREC.

II. They provide feedback to researchers regarding decisions taken at Faculty meetings on research projects, and Faculties are well aware that their role is to ensure the science or subject soundness of the research proposal and that the final decision of the ethical acceptability rests with the HREC.

III. The FCREs review and/or screen research proposals in the context of their respective faculty and/or Higher Education Development and Support (HEDS).

i. "Low or minimal risk" research projects can be defined as the probability and magnitude of harm or discomfort anticipated in the research not being greater than that ordinarily encountered in daily life in a stable society or routine medical, dental, educational or psychological tests or examinations;

ii. In this document, "undergraduate" will be defined as the following levels of studies: bachelor's degrees, diplomas and postgraduate

diplomas. Undergraduate, low-risk studies not involving human participants (4.5.5 below) are reviewed and approved by FCREs. In this case, the FCREs will issue a letter indicating that subject/scientific clearance was granted to the applicant's study, which will be signed/co-signed by the HREC chairperson.

iii. Postgraduate and academic staff research will be screened and reviewed by a fully constituted FCRE meeting and then be referred to the next fully convened HREC meeting for presentation and review.

iv. The HREC must indicate to all researchers that all research projects, including low-risk studies, will be subjected to an ethics review or ratification by the Committee.

v. The Human Research Ethics Committee will ratify FCREs' decisions on condition that all decisions are included in the HREC minutes and approved by the Committee.

4.5.5 Ethical clearance of undergraduate bachelor's degree, diploma, postgraduate diploma and structured master's degree research projects that have strict timelines for completion are managed as follows:

4.5.5.1 Students' research projects are evaluated in terms of risk level.

4.5.5.2 HREC will regard the course supervisor as the 'principal investigator (PI), who assumes ultimate responsibility for the project and its ethical components:

i. The scope and ethical sensitivity of a research project should be carefully considered, and it is strongly encouraged that only minimal risk research be conducted in order to comply with the time-sensitive requirements of these academic degrees.

4.5.5.3 The student and supervisor shall discuss the potential ethical issues of a research proposal.

4.5.5.4 The research project shall be submitted to the FCRE, which may approve low or minimal-risk studies **without any human participants**.

4.5.5.5. Applicants are notified in writing of the FCRE review decision and may commence with their research if their application has been approved, on condition that any additional recommendations or feedback required and communicated to the applicants by HREC following the next full meeting at which the review decision ratified will be adhered to and implemented by the applicant with immediate effect.

4.5.5.6 Studies that are low risk with human participants involved or that pose medium-to-high risk shall be submitted to the HREC for formal ethics review and approval after referral from the FCRE that received and screened the research project.

4.5.5.7. All decisions and minutes of the FCRE are ratified at the next HREC full committee meeting.

4.5.5.8. Suspension or Discontinuation of Projects

The HREC reserves the right to suspend any FCRE's approval and request changes or clarifications from undergraduate applicants. If there are minor comments, the HREC may request additional information or changes without suspending FCRE's approval. If the comments are deemed more significant, the FCRE's approval will be suspended, and the applicant will be notified that the research project will need to be reviewed at the next full HREC meeting. The FCRE chairperson or administrator will notify the supervisor, and, if applicable, the applicant, of the suspension of ethical approval within one day of receiving the notice of suspension from the HREC.

4.5.5.9 Reciprocal recognition of reviews

The NDoH's South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, section 5.5.1.4 allows for reciprocal recognition of review decisions:

a. The South African ethics legal framework requires that research leaders must obtain approval from their institutional REC. In principle, this means that RECs have the authority to review and approve research protocols only for research sites or geographic areas within their own South African jurisdiction. Thus, when there is

a proposal for a research study or project that collects data from multiple sites or geographic areas within South Africa, more than one REC may be involved in the review and approval processes.

b. RECs may, at their discretion, recognise the review and approval of a research protocol granted by another registered South African REC.

c. Reciprocal recognition means that two or more registered RECs decide to recognise each other's review.

d. The HREC will decide to use reciprocity recognition on a case-by-case basis.

e. The documents to be submitted/filed for reciprocal review, at a minimum, will include copies of the approval letter from the other REC, the proposal, and the ethics review application, as well as the notes of the local REC member whose review led to the REC decision to use reciprocal recognition. Furthermore, the decision must be tabled for minuting at the next HREC meeting.

f. The HREC may reverse their decision for reciprocal review if justifying circumstances arise. The reasoning supporting a reversal of recognition should be documented.

g. The roles and responsibilities of each REC involved in the reciprocal review process will be clearly described and agreed in writing by the participating RECs. The possibility of reciprocal recognition of reviews should occur in a collaborative, and harmonious manner, bearing in mind that each REC retains the responsibility of protecting the safety, rights and interests of participants enrolled in the studies it has approved.

h. The following three aspects will be included in the agreement between the RECs: how RECs are participating in the particular reciprocal recognition arrangement, how protocol amendments will be managed, and how adverse events or unanticipated problems will be managed.

i. The researcher should submit to the HREC a cover letter outlining the request and any relevant arrangements, the full proposal with all

associated documents, and formal ethics approval from the other REC. In case of studies undertaken at multiple sites, the local REC, in conducting reciprocal reviews, reviews the protocol in terms of ethical, local values and methodological aspects related to implementation at the local site.

j. The Chairperson of the HREC will consider the application outlined in (i) above and the relevant reciprocal review documentation and decide on the most appropriate way forward. Depending on the nature of the application, this may include:
    (i) A fully-constituted HREC full committee review,
    (ii) An expedited HREC review, or
    (iii) Deferral of an expedited review to a full committee review.

k. The outcome of the review will be communicated to the researcher as soon as possible, in writing, with a view to facilitating any amendments that may be required. The final approval will be issued after the HREC ratifies it.

l. The Chairperson of HREC will report the process and outcome of the reciprocal review for ratification to the full HREC meeting.

4.5.5.10 Complaints

FCREs/RECs are expected to provide adequate opportunity for any interested person, including but unlimited to research participants, research assistants, researchers and members of the wider community, to express a concern or to lodge a complaint or grievance that may arise during the research process.

Complaints about REC-related business should be directed to the relevant FCRE. If the matter remains unresolved at FCRE level, the complaint should be escalated to the HREC. If the matter remains unresolved at HREC level, it will be resolved via the institutional complaints process, such as . research integrity office or Senate.

Complaints in the context of this document refer to (NHREC Guidelines - Guideline to Manage Complaints, Compliments and Suggestions, 2024):

a) Adjudicate complaints about the functioning of the Research Ethics Committee.

b) A complaint from a researcher who believes that the Research Ethics Committee has discriminated unfairly against them.

c) Refer matters involving allegations of violation of ethical or professional rules or standards by a healthcare provider to the relevant statutory health professional council or body.

d) Institute remedial measures and disciplinary action, where warranted, to facilitate compliance with legal, ethical and professional norms and standards, as required for responsible conduct of research.

If the complaint is related to research misconduct or research integrity issues, it should be referred to the Research Integrity Office (section 4.5.5.12).

4.5.5.11 Appeals

I. 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 review report from this Committee/Council will be ratified by the HREC and will be binding on all the concerned parties.

II. 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 within three weeks of the decision being communicated to the research participant. 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

III. 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.

4.5.5.12 Research Misconduct

All researchers have a moral obligation and professional responsibility to report research misconduct in their work environments. All whistleblowers are protected in terms of the Policy on Prevention of Fraud, Corruption and Theft (Policy#: VCPOL010).

Research misconduct refers to any of the following:

i. Fabrication and/or falsification of data and research results.
ii. Authorship disputes in publications.
iii. Plagiarism in proposing, performing, reviewing or reporting research.
iv. Deviation from or failure to adhere to the approved research proposal without prior approval from the HREC.
v. Researcher misrepresentation and/or falsification of credentials.
vi. Deception in the carrying out of research.
vii. Piracy of research materials.
viii. Failure to obtain the required informed consent.
ix. Breaches of confidentiality, or
x. Any other issues relating to research integrity or misconduct will also be considered.

The following procedures and/or principles are applicable to reporting research misconduct:

I. Staff shall be guided by the Policy on Prevention of Fraud, Corruption and Theft (Policy#: VCPOL010).

II. Staff shall report research misconduct to any member of Management, the Chairperson or Deputy-chairperson of the Faculty Committee for Research Ethics (FCRE), the Chairperson of the HREC, or the Deputy Chairperson of the HREC.

III. The HREC Chairperson or Deputy Chairperson will refer the incident of alleged misconduct to the Research Integrity Office to screen and

evaluate the allegation, and if warranted, a subsequent investigation shall be initiated.

IV. Incidents of research misconduct will be managed in accordance with the University's disciplinary procedures contained in the TUT Staff Code of Conduct.

5 Participant Information and Informed Consent Requirements

5.1 Separate participant information and informed consent documents must be submitted for the following studies –

- Main study
- Pharmacogenomic research
- Genomic research
- Consent and/or assent for minors (children under the age of 18 years).

5.2 Vulnerability and Incapacity

5.2.1 According to the National Department of Health's South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, "South Africa is home to a number of vulnerable communities. Where factors usually associated with vulnerability are integral to the research, the proposal should demonstrate how vulnerability would be managed."[3]

5.2.2 Researchers must take particular caution before undertaking research involving participants in such communities, and RECs should ensure that:

- Persons in these communities are not being involved in research merely because they are expediently accessible, while the research could be carried out in a less vulnerable community;
- The research is relevant to the health needs and priorities of the community in which it is to be carried out;
- Research participants know they will take part in research and the research will be carried out only with their consent;

[3] National Department of Health: South African Ethics in Health Research: Principles, Processes and Structures, 2024

- Particular attention [4]should be given to the content, language(s) and procedures used to obtain informed consent. A participant is free at any time to withdraw consent for further involvement in the research, and the participant must be reassured that s/he will not face any unfair negative consequence or disadvantage[5].

5.3 Before a participant is able to give informed consent, the following essential elements must be understood and appreciated.

- Purpose of the research.
- Population and sampling that show the relevance of sampling, sample size and sampling procedure.
- That consent is being given to participate in research.
- Expected duration of the participant's involvement.
- Description of the procedures to which the participant will be subjected, including any experimental procedures that are innovative and have not been used in the health care environment.
- The benefits of participation in the study while all potential negative consequences of participation are known are explained.
- Remuneration, if any, and if not.

5.4 The informed consent document should be at the literacy level of the target population.

5.5 Future participants should be helped to arrive at an informed decision by, for example, the use of appropriate language, the selection of a non-threatening environment for interaction, and the availability of peer counselling.

Information on the following areas below may be found useful by participants –

i. Qualifications of the investigator.
ii. Explanation of participants' responsibilities.
iii. Description of potential risks or discomforts.
iv. Information regarding the benefits to the participants or to others will be shared, both during and after the research.

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[5] *Ibid*

v. Explanation of the extent to which confidentiality will be maintained and sustained.
vi. Statement that sponsors (if any) of the study may be able to inspect research records.
vii. Statement that the research has been approved by an accredited research ethics committee.
viii. Sharing of contact details of the research ethics committee representatives.
ix. Explanation regarding compensation for research-related injuries.
x. Explanation regarding consequences of injury, including medical treatments.
xi. Explanation of who to contact in the event of research-related injury.
xii. Statement that participants' data may be added to a big database of journals/funders/researchers/sponsors (participants have a right to decline consent to data sharing).

5.6 From the outset, participants must be assured that their participation is voluntary. They must be informed that refusal to participate or a decision to discontinue participating will not involve any form of penalty. Participants must be made aware of their right to be informed of relevant new findings from the research, and the consequences of their withdrawal from a research study. Equally, they should be informed if the investigator might terminate their participation. Educational materials should be developed where necessary.

NOTE: The above points are viewed as essential elements of informed consent, and all should be incorporated into an informed consent form

5.7 Informed consent is a vital requirement in the ethical conduct of research. Informed consent can be regarded as valid only when it is given freely without deceit or coercion as well as misrepresentation.

5.8 HREC requirements for informed consent process for new application

5.8.1 A comprehensive description of the process for obtaining informed consent, including the process for ensuring the understanding and acknowledgement of the information provided.

5.8.2 Clear justification for the intention to include individuals in a research project who cannot consent and a full account of the arrangements for obtaining informed consent for such individuals.

5.8.3 The adequacy, completeness, and clarity of written and spoken information to be given to the research participants and, when applicable, to the r participants having these conditions, such as unconscious participants, participants with dementia or any other condition where it may be relevant, their legally acceptable representatives.

5.8.4 Guarantee that research participants will receive information that becomes available during research applicable to their participation.

5.8.5 The provisions made for receiving and responding to queries and complaints from research participants or representatives during research.

5.8.6 In all instances, ***verbal*** and ***written*** informed consent, and assent in the case of minor participants, should be obtained, unless there are good reasons to the contrary, such as a situation of coma, emergency, or mental incapacity[6].

5.8.7 Verbal consent, ***where a participant is illiterate,*** should be obtained in the presence of and countersigned by a literate, ***independent witness confirming that all the relevant information was provided to the research participant in a manner that is easily comprehensible.***[7] The right thumbprint can also be used for consent purposes.

5.8.8 For ***minor participants under the age of 18 years,*** consent should be sought from the ***parent or legal guardian.***

5.8.9 In addition to the parent or legal guardian, consent must also be obtained from the minor participant if the minor is capable of understanding. Maturity,

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6[6] SAMRC REC Standard Operating Procedures, 29 January 2023
7[7] Ibid

psychological state of mind and age should be considered. Special care should be taken to create an informed consent document that will be understandable to minors. Where a minor is incompetent to consent, assent from the minor may be obtained. However, in all cases, the proposal must provide sufficient information outlining the steps that will be taken to obtain the child's assent and how it will be documented. [8]

5.8.10 Following approval of the original English versions, all translations with authenticity certificates (or other methods used to confirm accuracy) must be submitted to the Committee for information and filing.

5.8.11 Information regarding the insurance for the study should be included (if any).

5.8.12 Readability scores and tests of understanding should be included.

For more useful information, refer to The South African Ethics in Health Research Guidelines: Principles, Processes and Structures. Third Edition, Department of Health, Republic of South Africa, 2024.

6 Vulnerable Participants

6.1 The NDoH guidelines on health research present the following as *"vulnerable groups"*[9] –

- Minors (children and adolescents).
- Women.
- Adults with incapacity to provide informed consent.
- People in dependent relationships (prisoners, psychiatric patients).
- Persons highly dependent on medical care.
- Persons with physical disabilities.
- Collectivises.
- Subordinates.

6.2 The Committee must pay special attention to protecting the welfare of certain classes of participants –

8[8]. HREC Terms of Reference and Standard Operating Procedures, Stellenbosch University, Approved by Senate Ethics Committee, 9 June 2023.

[9] South African Ethics in Health Research: Principles, Processes and Structures, Department of Health, 2024

- Minors (children and adolescents).
- Persons with intellectual or mental impairment.
- Disabled persons.
- People in dependent relationships (prisoners, patients with mental problems and students).
- Persons participating in research as groups (referred to as collectives).
- Pregnant women.
- People whose first language is not English.
- Traumatised and comatose patients.
- Terminally ill patients.
- Minorities.
- Students.
- Employees.

6.3 The HREC may impose additional measures to protect the welfare of participants, especially with regards to informed consent.

6.4 The HREC may consider it obligatory to conduct post-research investigations.

6.5 Types of research that need additional attention include reviewing whether there was compliance with the additional measures imposed. Should compliance be defective, the Committee may withdraw approval for the research study concerned.

- Research involving indigenous medical systems.
- Emergency care research.
- Innovative therapy or interventions.
- Research necessitating ambiguity of information for participants.
- LGBTQ.

7 Ethics Review Process: Review of Applications and Approval Process

7.1 Two separate steps are engaged in reviewing and approval of an application

(i) Scientific review, which is done prior to the meeting by DCPS and FCPS, and;

(ii) Ethical screening and review by the FCRE (refer to Addendum A); and

(iii) Ethics review by the HREC (refer to Addendum A).

7.2 **Scientific Review:** This review is to ensure the scientific validity of the study. Each application is sent to at least two independent reviewers who are experts in the field. The researcher must make any changes requested or recommended by the DCPS and FCPS before the application is submitted for ethical screening by the FCRE and subsequent submission to HREC for ethics review (Addendum A). The reviews are conducted according to a set review form. Applicants do not suggest or choose their reviewers. The scientific review conducted by the DCPS and FCPS is important in terms of relevance within local circumstances, irrespective of reviews for funding. Proposals will not be considered for ethics review, should they have not passed the scientific review process as described here.

7.3 **Ethics Review:** The Committee will consider all aspects of the proposal and must be satisfied that the research meets the following criteria: respect for the autonomy of participants and study communities, informed consent, scientific validity, fair selection of study population, favourable risk-benefit ratio, collaborative research, and research translation, to mention a few. There must be justice, fairness, as well as beneficence for research participants.

7.4 The HREC Chairperson will allocate one proposal for a comprehensive review to at least two members of the HREC with requisite skill and experience. These members will present their findings to the HREC during a fully constituted meeting. All members will be expected to familiarise themselves with the summary of the findings and the consent forms for all proposals.

7.5 HREC members will participate on an equal basis in a transparent and fair deliberation process regarding the science and ethical aspects of the proposal as presented, including the risks and benefits, the value of the research, fairness in the selection of participants, informed consent process and procedure, and including any other ethics-related issues.

7.6 After considering inputs from the reviewers of a submission/application, the HREC will make one of the following four decisions by consensus – *approved, approved with stipulations, provisional approval, require major amendments, meaning referred back, or rejected.*

7.7 Proposals requiring minor amendments may be approved outside the meeting by a sub-committee comprising the Chairperson or Deputy-Chairperson, with additional members where necessary and noted/ratified at the next meeting.

7.8 Proposals requiring major amendments will need to be resubmitted to a full Committee meeting.

7.9 Rejected submissions may be resubmitted as a revised proposal for a new review by the full Committee.

7.10 Decisions are recorded in writing and will include the reasons for the rejection.

7.11 The applicant will be informed about the approval, approval with stipulations, provisional approval, referred back, or rejection [10] within **21 working** days (excluding recess) after the meeting. The feedback will be written and not verbal.

- **Approval** – the proposed research is approved in its current form, with no changes required. The date of approval is considered the date that all conditions were considered to be met.
- **Approved with stipulations** – the proposed research is approved, and minor alterations are required.
- **Provisional approval** – The proposed research has no major ethics/ethical concerns, but a number of clarifications and/or methodological changes are required. The research applicant must

[10]. HREC Terms of Reference and Standard Operating Procedures, Stellenbosch University, Approved by Senate Ethics Committee, 9 June 2023.

resubmit the revised application. The review can be finalised by an ***expedited review process,*** meaning without having to serve before the full Committee again.

- **Referred back:** the proposed research has major methodological and/or ethical concerns and requires considerable revision. The research applicant must resubmit the revised research application. The revised research application will be reconsidered at a convened full Committee meeting.
- **Rejected:** The proposed research may not be resubmitted.

7.12 No recruitment, screening or enrolment on a study may take place before the HREC issues a written approval. This includes written approval for amendments and renewals.

7.13 There will be no retrospective approval for completed research by the HREC or for research submitted to another REC in the absence of prior arrangements.

7.14 Studies not conducted in accordance with the approved proposal will be suspended by the HREC.

7.15 Should the applicant not address the comments raised by the HREC within *six months* after the latest feedback, such an application may lapse at the discretion of the HREC. Once the application has thus expired, a fresh application should be submitted to the HREC.

8 Expedited Review Procedures

8.1 In extraordinary circumstances, the Chairperson, Deputy-Chairperson or an *ad hoc* committee will evaluate a request for expedited review. In this circumstance, the applicant is required to give a well-motivated request for an expedited review. The timeframe for this review will be at the HREC's discretion; however, such a review should occur within 10 working days of the receipt of the expedited review request.

8.2 Groups of the research that may qualify for an expedited review include –

- Research that requires urgent review with the appropriate motivation from internal TUT environments and/or external environments;
- Research that ***poses no more than minimal risk*** to the participants;
- Research that needs ***minor changes*** to the proposal; and
- Research that requires ***urgent amendments.***

8.3 A new application may be considered to be suitable for expedited review if the risk of the proposed research meets the criteria as defined herewith –

- ***Minimal risk research***[11] - the probability and magnitude of harm or discomfort anticipated in the research is not greater, in and of itself, than that ordinarily encountered in daily life during the performance of routine physical or psychological examinations or tests.

8.4 **Minor amendments**[12] do not change the risk-benefit profile of the study in any way. Minor amendments include, but are unlimited to:

8.4.1 Additional investigators or study sites

8.4.2 Small changes in the consent process

8.4.3 Change in background information or literature review update

8.4.4 Period (life cycle) of the study

8.4.5 Other changes that do not affect the study design and will not impact on the study outcomes or results.

8.4.6 Administrative changes

8.4.7 More strict inclusion or exclusion criteria.

8.5 **Major amendments**[13] require a change(s) to the study methodology or procedure that may result in an alteration of the risk-benefit profile of the study, such as:

8.5.1 Change in study aims, objectives or design.

8.5.2 Resulting changes to consent documents.

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[11] HREC Terms of Reference and Standard Operating Procedures, Stellenbosch University, Approved by Senate Ethics Committee, 9 June 2023
[12] *Ibid*
[13] *Ibid*

8.5.3 Additional study procedures.

8.5.4 Easing of inclusion or exclusion criteria.

8.6 The expedited review may be carried out by the Chairperson of the Committee or by an *ad hoc* committee convened by the Chairperson. The full Committee will ratify the decisions during the next meeting. Administrative changes that will have no effect on the study may be approved by the Secretariat.

8.7 Generally, research with the potential to cause physical or psychological harm will not be considered for expedited review.

This includes –

- Research involving experimental medicine or surgical interventions
- Research involving invasive procedures and
- Those involving sensitive personal or cultural issues.

9 Proposal Amendment

9.1 Proposal amendment is a change that is administrative or has an impact on the integrity or safety of participants, alters the scientific value of the research or interpretation of the results, affects data validity, study design, planned statistical analyses or significantly changes other aspects of the research. The nature and examples of ***minor*** and ***major*** amendments are discussed in sections **8.4** and **8.5,** respectively.

9.2 The proposed amendments that have been lodged will be tabled as part of the agenda at the next Committee meeting and will be reviewed by the full Committee. Administrative amendments will be approved by the HREC Administrative Office.

9.3 The following documents should be submitted to the HREC Ethics Office 14 working days before the next meeting –

a. Cover letter explaining the nature and reason for the amendment.
b. Application form that includes an explanation for each amendment.
c. Revised proposal with track changes.

d. Revised informed consent form with track changes.

e. Any other relevant material that was revised with the amendment[14].

10 Continued Review/Annual Renewal

10.1 Continued review of research study will be conducted at appropriate intervals. This process is done once a year. Continued review can also be done more frequently if the Committee requests it.

10.2 Research studies receive a one-year approval letter from HREC with the opportunity of an additional one-year renewal of approval, which will be monitored until graduation and/or completion of the study, with the requirements for annual renewals as per 10.3 below.

10.3 An application for annual renewal (in the form of an annual report) of a research study must be submitted to the Committee **once a year** (annually) after the study was approved for the first time for low and medium-risk studies and **six months** (bi-annually) after the study was approved for the first time for high-risk studies.

10.4 The renewal request must be lodged with the Committee at least **two months** before the first approval expires. It is the researcher's/PI's responsibility to ensure that the renewal is given before the life cycle of the approved study expires.

10.5 Annual renewals will be given for the study to continue only after receiving a satisfactory annual progress report.

10.6 To carry out a continuing review, all members will receive the proposal summary as well as the status report on the progress of the research proposal.

10.7 The following documents should be submitted to the HREC Office **14 working days** before the following meeting –

i. Application form.

ii. Cover letter.

iii. Proposal summary.

[14] SAMRC Standard Operating Procedures, January 2023

iv. Status report of the study.

10.8 The status report must be completed, dated, and signed by the Researcher/PI. The report should include the following –

i. Number of participants for the study.
ii. Any information deemed relevant.
iii. Community engagement outcomes.
iv. Summary of *serious adverse events* (SAEs), if any, including the outcome of the SAE/s (*see Template for Active Monitoring of research proposals).*

11 Serious Adverse Events

- Serious Adverse Events are defined as any event temporally associated with the individual's participation in research that meets any of the following criteria: results in death, is life-threatening (places the participant at immediate risk of death from the event as it occurred).
- Adverse events that occur in the research arena include but are not limited to medication side effects (in the case of clinical trials, injury, psychological) injury, psychological harm or trauma, or death, thereby negatively affecting the research participants and requiring an intervention.
- Should the researcher experience a serious adverse event, the researcher should complete the serious adverse events reporting form, which includes the summary of serious adverse events (SAEs) and any information deemed relevant. The report should include the outcome of the SAE/s and the mitigation process that was followed to address the situation.
- A TUT Human Research Ethics Committee meeting is scheduled as soon as possible to decide how a serious adverse event will be handled. Once the incident/adverse event has been reviewed (including all the required documentation related to the reporting and management of the serious adverse event) by the HREC, the researcher/study panel will be informed in writing of the outcome.

11.1 Applicable procedures for Serious Adverse Events for researchers:

- All serious adverse events occurring at a research site must be promptly reported to the HREC by the researcher by completing and submitting the serious adverse events reporting form to the office of the HREC within three to a maximum of 15 calendar days of the adverse event occurring.
- Following the submission of the initial SAE report, six-month progress reports should be submitted until the final progress/study report is submitted.
- Researchers have a moral obligation and a professional responsibility to report serious adverse events in their field of study.

11.2 Applicable procedures for Serious Adverse Events for the HREC:

- The HREC has the authority to suspend or terminate a study if it deems it necessary in case the occurrence of SAEs is repeated in a single study.
- The Committee has the authority to immediately suspend all research activities of a research project where the SAEs involve significant increases in the risk profile of the research participants or research team members. In such cases, the HREC Chairperson shall submit a report of his/her decision to a full HREC meeting for review and further discussions.
- A summary of all submitted SAE's reports will be included in the agenda of the following HREC meeting for review and discussion.
- SAEs that are uncommon to the type of research study or SAEs that are repeated will be investigated, and appropriate action will be taken if deemed necessary by the HREC.

12 Failure to present annual progress reports and/or application for renewal will lead to the deregistration of the study.

12.1 Resubmissions

Major discrepancies will usually result in a refusal to approve the proposal or amendment. A new submission will have to be made.

13 Documents acknowledged by HREC

13.1 Translated patient information sheets and informed consent forms (Certificate of Translation must be included),

- The HREC will evaluate the participant information leaflet and informed consent documents. The Committee may request changes in wording or content of the English version, if necessary.
- The Committee will **only officially approve the English version.**
- A certificate of translation or letter from the researcher declaring that the translation is an accurate reflection of the English version must be submitted to the Committee only when the English version of the informed consent document and/or the information leaflet has been provisionally approved by the Committee.
- The HREC reserves the right to check translations and delay approval of the study if the translations are deemed to be of poor quality.

13.2 Translated questionnaires and patient diary cards (certificate of translation must be included).

14 Recording and Archiving of Decisions

14.1 The Committee will maintain a record of all research proposals received and reviewed.

14.2 The Committee will retain on file a copy of each research proposal and application submitted for approval. The file will include information sheets, consent forms, and all relevant correspondence, all of which are in the form in which they were approved. A list of the Committee members who formed part

of the discussions of the application and when the Committee's final decision was reached will be kept.

14.3 One set of all submitted documents related to applications will be retained in the HREC Administrative Office for at least ***five years***, after the completion of the study. This will include electronic and hard copies of the documentation.

15 Monitoring

15.1 The HREC has an obligation to ensure that the conduct of all research approved is monitored. Monitoring is done yearly and ongoing reporting by researchers. An audit or review of a study may be carried out at the discretion of the Committee. This audit normally takes place when there may be a concern for participant safety or other factors that may put the integrity of the research outcomes at risk.

15.2 The Principal Investigator/s (PI/s) will report on the progress of the project annually. The PI/s must submit all monitoring reports, such as SAE reports, to the Committee.

15.3 For changes in the PI and high-risk studies, the HREC may request more frequent updates. This process will be expedited so that it does not hold up the study.

15.4 No changes to the study procedures or proposals should be initiated without prior written approval from the Committee. In the event of immediacy, an expedited review process can be followed as set out in ***section 8***.

15.5 The HREC will engage additional appropriate mechanisms for monitoring, including, but not limited to, random inspection of research sites, data, and signed consent forms, as well as records of focus group interviews where applicable.

15.6 Active monitoring (site visits) will be conducted by the HREC for high-risk studies, as required, and passive monitoring (reports) will be conducted for low and medium-risk studies.

15.7 It is a requirement that researchers report timeously anything that might warrant ethics review approval of the proposal, such as SAE, proposed changes in the proposal, or unforeseen events that might affect the continued ethical acceptability of the project.

15.8 The NHREC may ask to review site monitoring reports on an *ad hoc* basis as part of the monitoring process.

15.9 The HREC may also monitor high-risk studies on an ad hoc basis.

15.10 If the research project is discontinued before the expected date of completion, the researcher/s must inform the Committee and give reasons for the discontinuation.

16 Complaints and Suspension or Discontinuation of Research

16.1 The HREC understands and appreciates the fact that research participants, community stakeholders and researchers have the right to recourse. As a result thereof, the contact details of the Committee Chairperson and Secretariat must be available to the above-listed parties so that in the event that they wish to forward complaints, they can do so with ease.

16.2 Should the Committee be convinced that circumstances have arisen that a research project is not being conducted in accordance with the approved proposal and that the dignity, rights, as well as the participants' welfare, are being compromised, the Committee may withdraw approval following the guidelines as provided in the HREC Policy.

16.3 The Committee will inform the researcher of the action the HREC is taking and will recommend immediate discontinuation or suspension of the project. The researcher must then discontinue the research and comply with any special conditions required by the Committee. The PI should document the HREC withdrawal of the study approval and accordingly report this to relevant authorities, collaborators or sponsors.

17 Risk Management

17.1 As a way to monitor risks related to research, risk analysis should be conducted annually between the Risk Manager and the Chairperson of the HREC.

17.2 The analysis will focus on the following areas of research ethics at TUT as follows:

17.2.1 Strengths, weaknesses, opportunities and threats (SWOT analysis).

17.2.2 Enabling the HREC to identify and analyse internal strengths and weaknesses and external opportunities and threats shaping current and future operations of the Committee and assist in the development of the strategic direction of the HREC.

17.2.3 Enabling the Committee Chairperson together with the Risk Manager to develop risk mitigation strategies.

17.3 The risk level descriptors will always be clearly indicated in decision letters for researchers, meaning ranging from Minimal Risk to High Risk.

17.4 Table 1 offers a guide for minimal risk, low risk, medium risk, and high risk, respectively. To provide oversight, the HREC is required to provide final approval and/or ratification of research ethics decisions.

Table 1 Risk classifications of research studies

Risk Category	Definition	Examples
Minimal risk	"Where probability and magnitude of possible harms implied by participation are no greater than those posed by everyday life in a stable society or routine medical, dental, educational or	• Research involving the analysis of existing statistics • Literature review • Documents and information in the public domain, for example, in public libraries, public archives, websites, newspapers, or newsletters.

Risk Category	Definition	Examples
	psychological tests or examinations."	
Low-risk	Research in which the only foreseeable risk is one of inconvenience or discomfort.	- Market research surveys. - Collection of data anonymously through the use of questionnaires and surveys (no personal identifiers collected and information cannot be linked back to a participant). - Research in which the investigation of a largely uncontroversial topic is undertaken through interviews, surveys, and participant observation. - The research will collect information that would generally not be regarded as sensitive, such as opinions rather than personal information. - Research with the environment that does not involve hazardous chemicals or pathogens such as carcinogens. - Design-led research in architecture, interior architecture, landscape architecture, urban design, and industrial design.

Risk Category	Definition	Examples
		- Use of anonymised data from existing health systems or medical schemes database. - Focus groups with the potential loss of anonymity though not involving a sensitive subject. - Interviews with professionals, officials and practitioners in their official capacity. - Computer simulations.
Medium risk	A potential risk of harm or discomfort, but appropriate steps can be taken to mitigate the overall risk **Context:** Research in which remedial interventions can be undertaken should harm occur, and the risk may not lead to substantial harm	- The risk of harm is reasonable concerning the anticipated benefit/knowledge gained. - Information gathered is personal, rather than opinions or attitudes, or is a combination of them. - Research in which the investigation of a mostly controversial topic is undertaken through interviews, focus groups, surveys and participant observation. - Research on commercially available cell lines where cells are infected or undergo genetic modification. - Collection of data through the use of questionnaires and surveys, where data includes personal

Risk Category	Definition	Examples
		identifiers collection and information can be linked back to a participant. - Research on participants that may come from a vulnerable or marginalised group, such as children under the age of 18, pregnant women, people living with HIV, people diagnosed with chronic illnesses, people living in poor socio-economic conditions and mentally compromised individuals. - Use of patients' information in existing health systems and or medical schemes databases.
High risk	A real and foreseeable risk of harm and discomfort may lead to a serious adverse event if not properly managed. **Context:** Research in which the foreseeable risk may lead to substantial harm.	- Research investigating illegal activities, for example, involving participants who are illegal immigrants. - Revealing information that may put the participants/ the researchers in great danger. - Research involving the deception of the participants. - Bio-physical research involving the collection of biological material through invasive procedures.

Risk Category	Definition	Examples
		- Data collected that may uncover illegal activities, such as gang activities, human trafficking.

(*Adapted from: (1) Risk level descriptors for human participants for use at the North West University. (2) Pope, A. (2011). How to Tell Whether Your Planned Research must Undergo Ethics Review).*

18 International Research

18.1 For International/Cross-Boundary research collaborations conducted in South Africa, there must be a principal investigator in the country. Researchers will seek legal guidance regarding the agreements governing the research grant, which they must submit together with their application. Researchers must also consult the *Montreal Statement on Research Integrity in Cross Boundary Research, 2013,* in this regard.

18.2 In instances where the Committee belives that conditions have become apparent that a research project is not being conducted according to the approved proposal and that the dignity, rights as well as welfare of participants are being undermined, the Committee will withdraw the approval after following the process as provided for in the HREC Policy.

18.3 The HREC will review all applications based on the South African Constitution, Acts, Rules, and Regulations under which the Committee operates and is accountable thereto.

18.4 The HREC is obliged to review research proposals for research conducted outside South Africa only if a TUT researcher/PI is involved.

18.5 The monitoring, regulation, payment of participants, and requirements regarding informed consent for children or parental consent pose serious challenges and concerns with regards to the approval of research conducted in another country. If the country in which the research is conducted has an

ethics review system or research ethics committee, such a committee must also approve the research. The contact details on the informed consent form must be local numbers that are accessible to the participants. An email address of the PI in South Africa must also be included.

18.6 Ethical clearance and/or decisions on these studies will be determined by the legislation, guidelines and circumstances and the context of the respective countries.

18.7 For all collaborative research (national and international), the researcher/s should ensure the proposal submitted for HREC review and approval has the relevant Intellectual Property agreements/Memorandums of Understanding between the host research institution and the collaborating institution(s) that detail all aspects of the research, including management of the research itself, research data management that includes the fate of the data and samples after completion of the study, financial arrangements, approach to research output publications, infrastructure development, allocation of intellectual property rights (ownership of data), dispute resolution mechanisms and dissemination and feedback of research findings to research participants.

19 Genetic Research

19.1 For human genetic research, the researcher/PI needs to add a sub-proposal or appendix to the main proposal, defining the objectives and procedures to be followed.

19.2 The Committee will only allow genetic research within the scope of the proposal, for example, *medication toxicity, specific disease entity studied within the proposal*, meaning pharmacogenetic research. *No open-ended genetic research will be approved*[15]. HREC will consider the following for Genetic Research –

- Social and cultural significance of the study.
- The balance between the contribution of knowledge and the potential harm to individuals or collectives.

[15] *Ibid*

- The confidentiality and privacy of stored genetic information or research results relating to identified or potentially identified participants[16].

19.3 The samples should be stored in the Republic of South Africa. Information regarding the place and length of storage of the samples should be included and must be clear.

19.4 Where the researchers deem it necessary to store samples outside South Africa, a separate motivation thereof is required, explaining the reasons why it is necessary to store samples outside the Republic of South Africa.

19.5 In cases where the samples are to be exported from South Africa, an Export Permit must be obtained through the National Department of Health (NDoH).

19.6 For the specific collection of a blood sample for pharmacogenetic or pharmacogenomic research, a separate informed consent must be submitted to the HREC. The informed consent must contain at least the information as follows –

- The genetic research will be limited to the medication (specify name) and disease and/or condition (specify name) under investigation.
- No unspecified open-ended research will be conducted without prior consent from the participant and/or approval from the Committee.
- Information on privacy and confidentiality.
- Information regarding compensation in the event of a study-related injury.
- In cases where samples are to be exported to a central laboratory outside South Africa, the physical address of the laboratory must be specified.
- It has to be emphasised that in the consent form, participants must consent for their blood samples to be shipped to a dependable laboratory outside the Republic of South Africa.
- The samples will be stored for a period of ***15 years*** maximum[17].

[16] SAMRC Standard Operating Procedures, January 2023
[17] *Ibid*

- The NDoH, through the South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, obligates researchers to include in the informed consent as applicable the following:
    i. **Narrow (restrictive) consent:** the donor permits the use of the biological specimen for single use only; no storage of leftover specimen, and no sharing of data or specimens. This form necessitates new consent if further use is desirable.
    ii. **Tiered consent:** the donor provides consent for the primary study and chooses whether to permit storage for future use, sample and data sharing.
    iii. **Broad consent:** the donor permits the use of the specimen for current research, storage and possible future research though the precise nature of future research, which may be unclear at present. The nature of the future usage should be described as fully as possible and should stipulate that further prior ethics review of the new study is mandatory. Permission may be sought to reconnect with the individual if intended future use is outside the scope of the current and/or original consent.

19.7 It is expected that participants will receive results from the genetic study, they should be counselled about possible effects that the genetic outcome information might have on them. The counselling session must be included in the consent form.

19.8 The counselling sessions can be held at any of the following times –

- During the time of obtaining consent for the genetic research, and
- In the future, prior to giving the study feedback,

20 Non-Therapeutic Research with Minors

20.1 Section 71(3)(a)(ii) of the National Health Act (Act No. 61 of 2003), (hereafter, NHA), requires the Minister of Health to consent to "non-therapeutic health

research with minors", only after considering whether the following four criteria are met:

i. in such manner and on such conditions as may be prescribed;
ii. with the consent of the Minister;
iii. with the consent of the parent or guardian of the minor and
iv. if the minor is capable of understanding and obtaining consent from the minor.

20.2 Section 92 (a) of the NHA states that the Minister may delegate authority to any person in the employ of the State, a Council, Board or Committee established in terms of the NHA to give consent.

20.3 The Minister has delegated authority to provide Ministerial Consent for "non-therapeutic" research with minors to the HREC, which has been found to be compliant with the National Health Research Ethics Council (NHREC) audit and achieved full registration with the NHREC. Correspondence in this regard was sent to the HREC on 7 October 2014.

20.4 Regulations for research with human participants, published on September 2014 (R719), contain **'Form A'** that sets out the four criteria to be met for the additional review of "non-therapeutic" health research with minors. Acceptable use of Form A should provide enough evidence that all RECs perform these reviews appropriately.

21 Benefit Sharing

21.1 If the proposed research results in downstreaming commercialisation/commercial exploitation, ffor example, biomarker research could form the basis of/result in the creation of diagnostic products, the proposal should have reference to an equitable and collective benefit-sharing plan for the study participants, host community, or country/region. In particular, the proposal or accompanying documents, such as a Material Transfer Agreement, Commercialisation Plan, or Benefit-Sharing Plan, should ensure that any/all of the above parties receive an equitable share of the benefits that arise from intellectual property or subsequent use/commercialisation of the samples or products, or the rights in

those samples or products by the researcher, sponsor, third party, for example, a collaborator who may be granted access to those samples and any subsequent parties.

Such benefits can take the form of monetary compensation, the product for the participant and host country, or a royalty-free licence for the country/region to use the invention/product. In some instances, where research is publicly funded (for example, HSRC, SAMRC and CSIR), such benefits may accrue automatically[18]. Funders such as the Gates Foundation may also impose a Global Access Plan as a condition of funding, which allows for global benefit sharing.

22.2 If participants are asked to waive their rights to any potential future commercialisation benefits, the waiver request should be justified in the proposal. In addition, the host country should be assured of royalty-free access to any downstream invention. The waiver should be covered/mitigated by a funder-imposed Global Access Plan or equivalent (e.g. publicly-funded research may be governed by statutes/regulations, which obliged public benefit accrual) *This is also in the spirit of the Singapore Statement on Research Integrity of 2010, which emphasise that the value and benefits of research are vitally dependent on the integrity of research.*

* Adapted from the South African Medical Research Council (SAMRC), Standard Operating Procedures of January 2023.

23 Publication of Research Results

23.1 Researchers have an obligation to disseminate research results in a timely and competent manner. Researchers should share data and findings openly and promptly as soon as they have had an opportunity to establish priority and ownership claims. The whole publication process should be done in an ethical and professional manner. Researchers should limit professional comments to their recognised expertise when engaged in public discussions about the application and importance of research findings and they should clearly

[18] *ibid*

distinguish professional comments from opinions based on personal views. It is important that researchers ensure that false expectations are not raised in vulnerable populations. Results should be disseminated to the participants and community members, using appropriate communication channels and formats including language that is accessible to participants and community members in which the study was conducted.

23.2 Study results remain the investigator's intellectual property irrespective of source of funding, and all results that have scientific merit should be published. In cross-boundary collaborative research, local investigators must have access to data as part of the collaboration agreement, as stated in the research proposal, detailed in section 19, Benefit Sharing, above.

23.3 Requests to withhold findings, to change or tone down the content of research results is unethical and unacceptable. Sponsors and stakeholders, however, should be afforded an opportunity to comment on research findings before publication, without any entitlement to dismiss the facts, change the conclusions or unreasonably delay dissemination of the results. In collaborative research with pharmaceutical or other funding organisations, the conditions of publication should be spelt out in the proposal. The Committee should be content that there is no apparent interference with the researchers' rights to publish research findings. Researchers should take responsibility for the trustworthiness of their research results. Before any public release of research outcomes, participants should be accorded an opportunity to hear about the results.

24 Press Release of Research Outcomes

24.1 Scientists have an obligation to convey research results during press releases in an ethically acceptable manner. Researchers should communicate with the HREC in collaboration with the TUT Public Relations Office in order to ensure that they adhere to all relevant policies relating to communication within and outside the University.

25 Compliance with Legislations, Declarations, Treaties and National Guidelines

25.1 It is in the spirit of the documents below that the HREC accomplishes its mandate and obligation to review and approve research proposals at TUT:

The Constitution of the Republic of South Africa, 1996 (Act No. 108 of 1996).

- The National Health Act, 2003 (Act No. 61 of 2003).
- Department of Health*: South African Ethics in Health Research: Principles, Processes and Structures, 3rd Edition*, 2024.
- The World Medical Association Declaration of Helsinki, 2013
- The Belmont Report, 1979.
- Council for International Organisations of Medical Sciences (CIOMS): International Ethical Guidelines for Health-related Research Involving Humans, 2016.
- Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa, 2006.
- ICH GCP Guidelines E6(R2) 2016.
- The Association of British Pharmaceutical Industry (ABPI) Compensation Guidelines.
- FDA Code of Federal Regulations, Parts 50, 56 & 312.
- The Singapore Statement on Research Integrity, 2010.
- The Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations, 2013.

26 Replacement of previous HREC Standard Operating Procedures

26.1 This HREC Standard Operating Procedure document replaces all previous HREC Standard Operating Procedures that were developed and approved.

27 Review and approval of HREC Standard Operating Procedures

27.1 This HREC Standard Operating Procedure document may be reviewed and approved by the HREC.

These Standard Operating Procedures should be considered in conjunction with:

- Addendum A – Flowcharts.
- Research Policy.
- Policy on Postgraduate Studies.
- Policy on Prevention of Fraud, Corruption and Theft.
- HREC Terms of Reference.

Approved by HREC:

Date of approval: 13 November 2024

Confirmation of Approval

13/11/2024

Prof J Agumba **Date**

HREC Chairperson

Confirmation of Approval

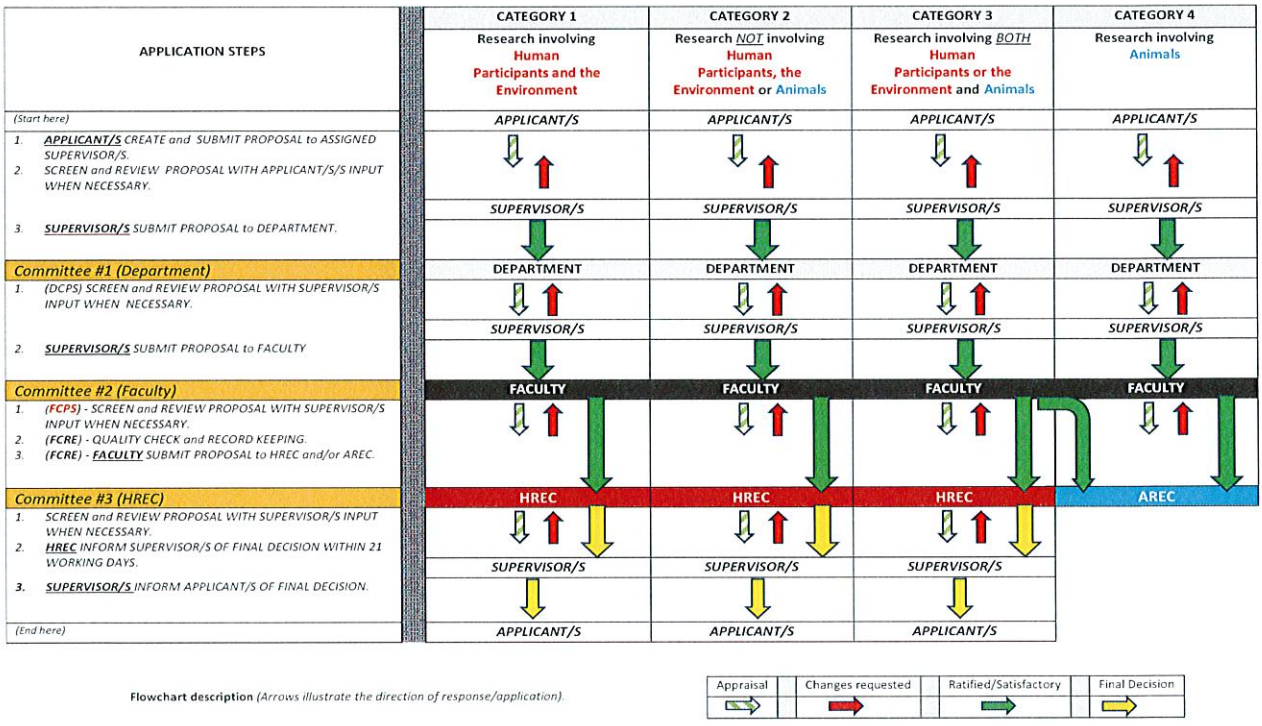
2024-12-05

Prof Tinyiko Maluleke **Date**

Vice-Chancellor

Addendum A

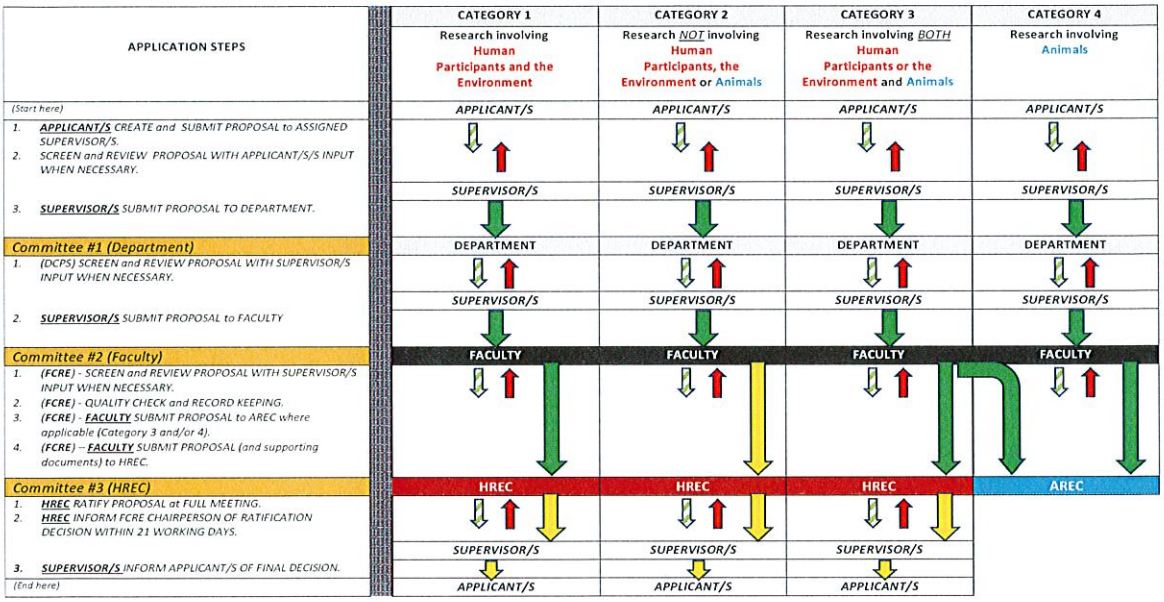
Table 1. Postgraduate Student Application (Masters or Doctoral)



Flowchart description *(Arrows illustrate the direction of response/application).*

Appraisal	Changes requested	Ratified/Satisfactory	Final Decision

Table 2. Undergraduate Student Application (Bachelors, Diploma or Postgraduate Diploma)



Flowchart description *(Arrows illustrate the direction of response/application).*

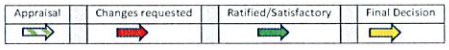


Table 3. Academic Staff Application (Non-Degree - with affiliation to an Academic Department)

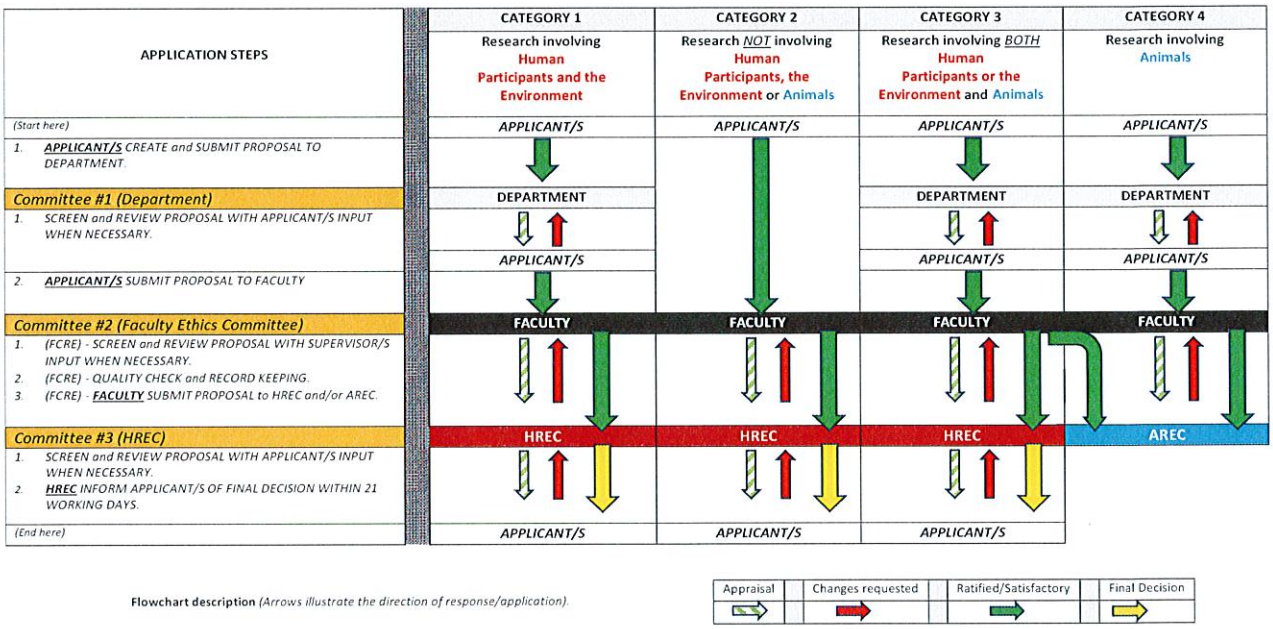


Table 4. Non-Academic Staff Application (Non-Degree - without affiliation to an Academic Department)

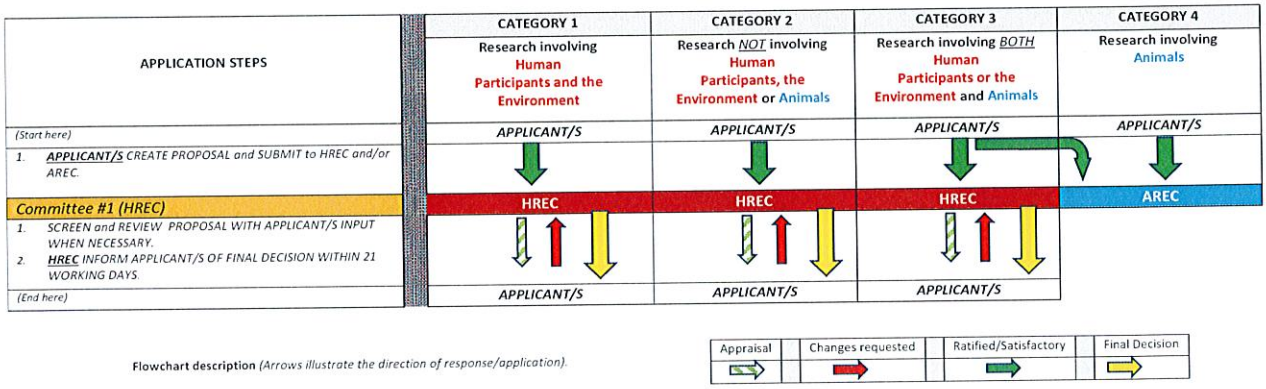
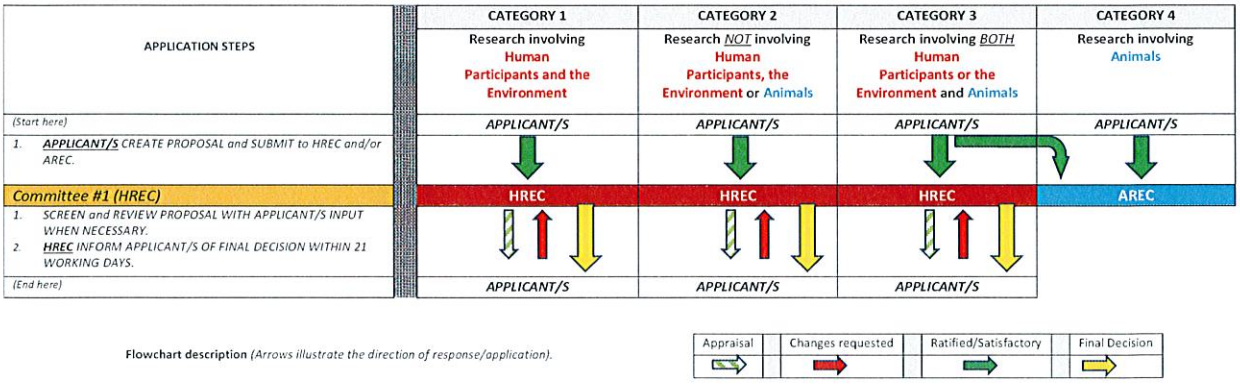


Table 5. External Application (National and International (including collaborations))



Flowchart description *(Arrows illustrate the direction of response/application).*