



**Tshwane University
of Technology**

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**TSHWANE UNIVERSITY OF TECHNOLOGY
HUMAN RESEARCH ETHICS COMMITTEE
STANDARD OPERATING PROCEDURES**

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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 experiments¹ 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 Convention on Civil and Political Rights – 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 not limited 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 the 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 ⁴should 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 disadvantage⁵.

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.

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 incapacity⁶.
- 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,

⁶ SAMRC REC Standard Operating Procedures, 29 January 2023

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 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.
- Traumatized 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.

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 amendment¹⁴.

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	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> - 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
		<ul style="list-style-type: none"> - 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.
<p>Medium risk</p>	<p>A potential risk of harm or discomfort, but appropriate steps can be taken to mitigate the overall risk</p> <p>Context:</p> <p>Research in which remedial interventions can be undertaken should harm occur, and the risk may not lead to substantial harm</p>	<ul style="list-style-type: none"> - 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
		<p>identifiers collection and information can be linked back to a participant.</p> <ul style="list-style-type: none"> - 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.
<p>High risk</p>	<p>A real and foreseeable risk of harm and discomfort may lead to a serious adverse event if not properly managed.</p> <p>Context:</p> <p>Research in which the foreseeable risk may lead to substantial harm.</p>	<ul style="list-style-type: none"> - 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 believes 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 participants¹⁶.
- 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** maximum¹⁷.

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, for 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 automatically¹⁸. 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.

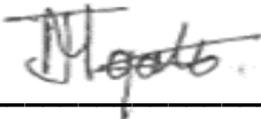
These Standard Operating Procedures should be considered in conjunction with:

- 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



Prof J Agumba
HREC Chairperson

13/11/2024

Date

Confirmation of Approval



Prof Tinyiko Maluleke
Vice-Chancellor

2024-12-05

Date

Addendum A

Table 1. Postgraduate Student Application (Masters or Doctoral)

APPLICATION STEPS	CATEGORY 1	CATEGORY 2	CATEGORY 3	CATEGORY 4
	Research involving Human Participants and the Environment	Research <i>NOT</i> involving Human Participants, the Environment or Animals	Research involving <i>BOTH</i> Human Participants or the Environment and Animals	Research involving Animals
(Start here)	APPLICANT/S	APPLICANT/S	APPLICANT/S	APPLICANT/S
1. APPLICANT/S CREATE and SUBMIT PROPOSAL to ASSIGNED SUPERVISOR/S.	↓	↓	↓	↓
2. SCREEN and REVIEW PROPOSAL WITH APPLICANT/S/S INPUT WHEN NECESSARY.	↑	↑	↑	↑
3. SUPERVISOR/S SUBMIT PROPOSAL to DEPARTMENT.	↓	↓	↓	↓
Committee #1 (Department)	DEPARTMENT	DEPARTMENT	DEPARTMENT	DEPARTMENT
1. (DCPS) SCREEN and REVIEW PROPOSAL WITH SUPERVISOR/S INPUT WHEN NECESSARY.	↓	↓	↓	↓
2. SUPERVISOR/S SUBMIT PROPOSAL to FACULTY	↑	↑	↑	↑
Committee #2 (Faculty)	FACULTY	FACULTY	FACULTY	FACULTY
1. (FCPS) - SCREEN and REVIEW PROPOSAL WITH SUPERVISOR/S INPUT WHEN NECESSARY.	↓	↓	↓	↓
2. (FCRE) - QUALITY CHECK and RECORD KEEPING.	↑	↑	↑	↑
3. (FCRE) - FACULTY SUBMIT PROPOSAL to HREC and/or AREC.	↓	↓	↓	↓
Committee #3 (HREC)	HREC	HREC	HREC	AREC
1. SCREEN and REVIEW PROPOSAL WITH SUPERVISOR/S INPUT WHEN NECESSARY.	↓	↓	↓	↓
2. HREC INFORM SUPERVISOR/S OF FINAL DECISION WITHIN 21 WORKING DAYS.	↑	↑	↑	↑
3. SUPERVISOR/S INFORM APPLICANT/S OF FINAL DECISION.	↓	↓	↓	↓
(End here)	APPLICANT/S	APPLICANT/S	APPLICANT/S	

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

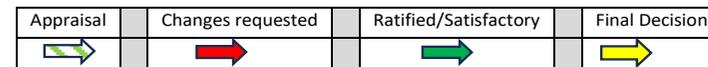
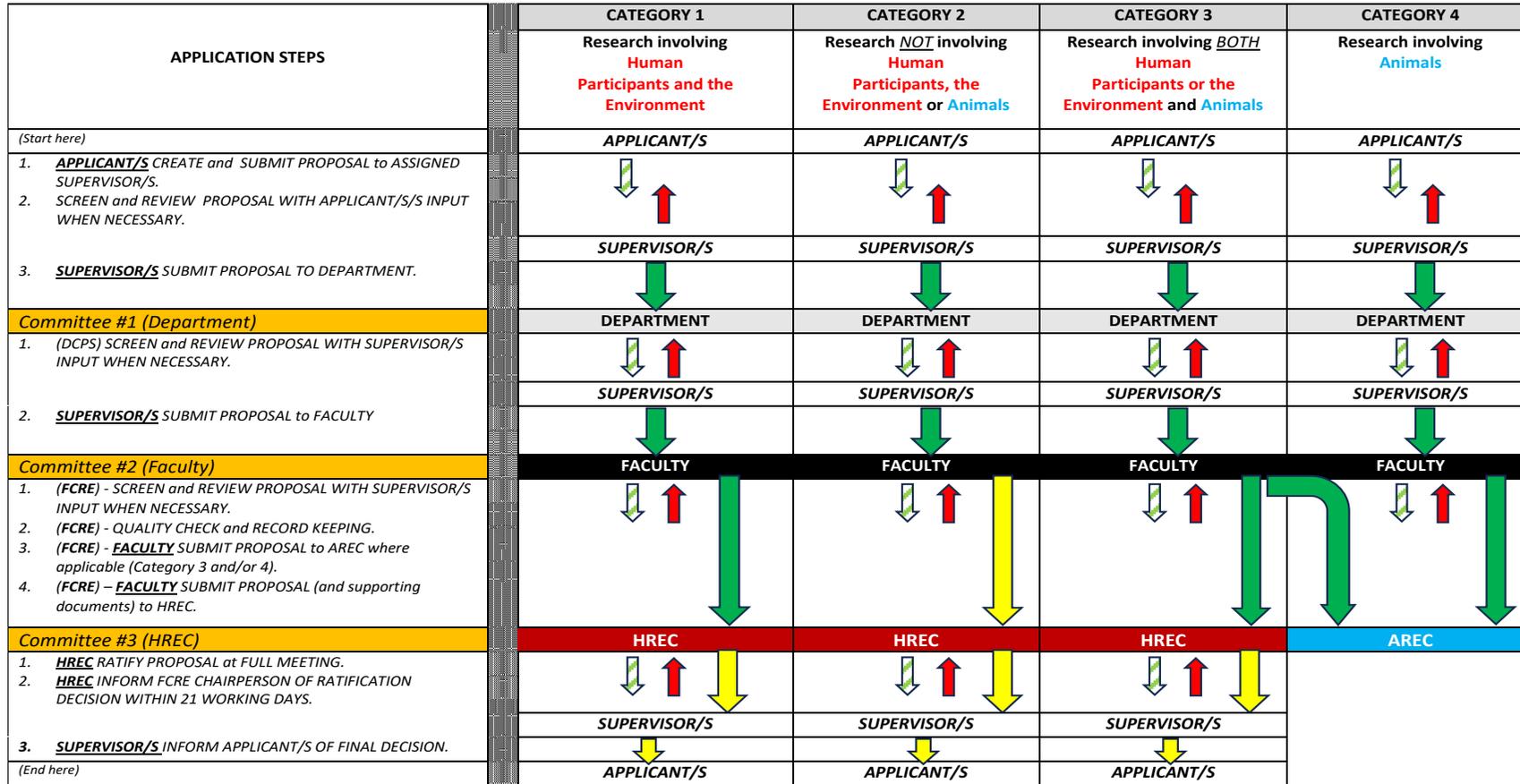


Table 2. Undergraduate Student Application (Bachelors, Diploma or Postgraduate Diploma)



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

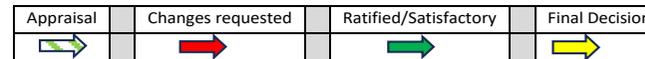
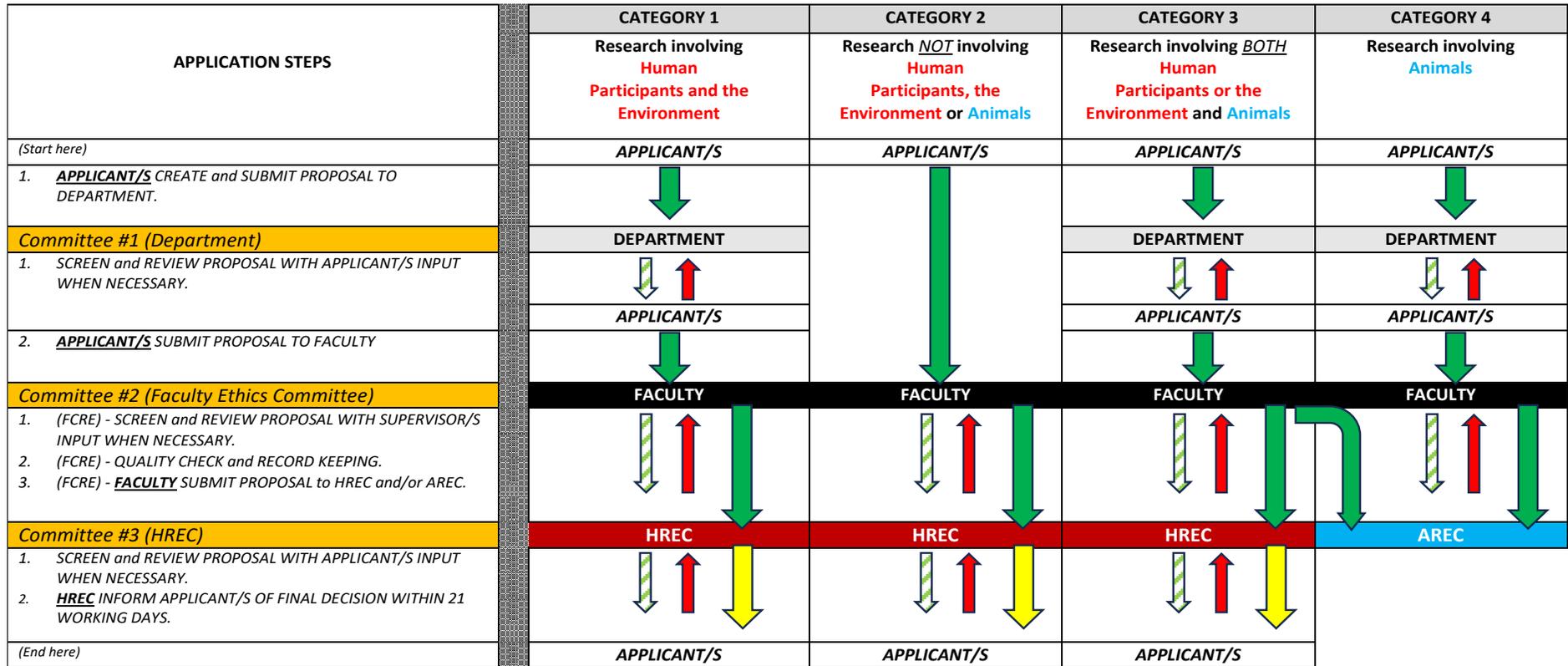


Table 3. Academic Staff Application (Non-Degree - with affiliation to an Academic Department)



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

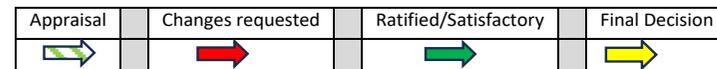


Table 4. Non-Academic Staff Application (Non-Degree - without affiliation to an Academic Department)

APPLICATION STEPS	CATEGORY 1	CATEGORY 2	CATEGORY 3	CATEGORY 4
	Research involving Human Participants and the Environment	Research <i>NOT</i> involving Human Participants, the Environment or Animals	Research involving <i>BOTH</i> Human Participants or the Environment and Animals	Research involving Animals
(Start here)	APPLICANT/S	APPLICANT/S	APPLICANT/S	APPLICANT/S
1. APPLICANT/S CREATE PROPOSAL and SUBMIT to HREC and/or AREC.				
Committee #1 (HREC)	HREC	HREC	HREC	AREC
1. SCREEN and REVIEW PROPOSAL WITH APPLICANT/S INPUT WHEN NECESSARY. 2. HREC INFORM APPLICANT/S OF FINAL DECISION WITHIN 21 WORKING DAYS.	 	 	 	
(End here)	APPLICANT/S	APPLICANT/S	APPLICANT/S	

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

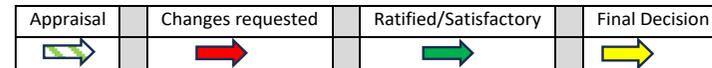
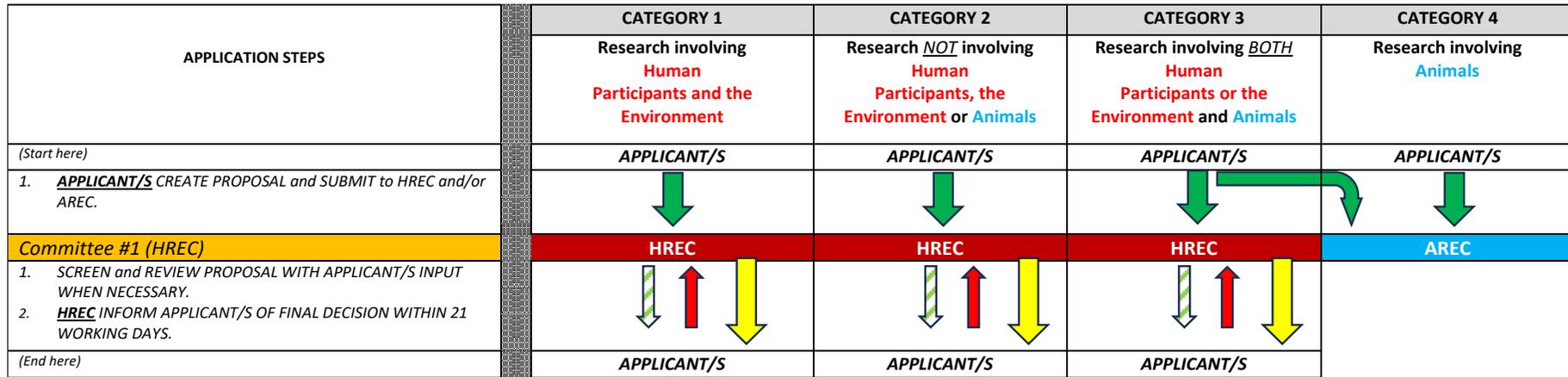


Table 5. External Application (National and International (including collaborations))



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

