

HUMAN RESEARCH ETHICS COMMITTEE (HREC)

APPLICATION FOR ETHICAL CLEARANCE

SECTION A: APPLICANT DETAILS

Applicant/ Student details

Title Full names

Initials Surname

Student/ staff number Contact number

Email address

Qualification
registered for in full

Department

Faculty

Supervisor details (if applicable)/ Co-researcher

Title Full names

Initials Surname

Staff number Contact number

Email address

Department

Faculty

Co-supervisor details (if applicable)/ Co-researcher

Title Full names

Initials Surname

Staff number Contact number

Email address

Department

Faculty

SECTION B: DETAILS OF THE RESEARCH PROJECT

1. Research project title.

2. Short summary indicating the rationale, research question(s), proposed methodology, and potential ethical concerns (300-400 words).

3. Research project aim.

4. Research method (e.g., research design, population and size, inclusion and exclusion criteria, sampling method and total sample size, data collection, procedure, and data analysis).

- 5. Clarify the ethical risks that are posed by the study and provide the risk category (see the TUT Ethics and the Risk Categories included in the TUT Human Research Ethics Standard Operating Procedure Section 17.4).**

- 6. How will the ethical risks identified in the above question, be addressed in the research project?**

7. What steps will be taken in the case of adverse events or harm to participants?

8. Provide a detailed data storage plan, indicating where the data will be stored, period of data storage and how will the data be protected and destroyed.

9. If data will be collected from institutions other than TUT, (e.g., universities, hospitals, clinics etc.) what steps have been taken concerning ethical approval? Has ethical approval from the other Institution/s been obtained?

10. Does the research project involve minors? If so, how many minors will be involved? Will ministerial consent be required? If applicable, access required ministerial consent document to be included in submission at:
www.health.gov.za/ministerial-consent-operational-guidelines

11. Are there any conflicts of interest that you need to disclose? If so, explain how these conflicts will be dealt with ethically?

12. Has gatekeeper permission/ permission to conduct the study been obtained, if applicable (please elaborate)?

SECTION C: CHECKLIST FOR RISK ASSESSMENT

The following checklist provides a quick way to establish whether your research project involves potential ethical issues.

	YES	NO
Does the project involve a clinical trial, i.e. the testing of any novel medical or pharmaceutical interventions?		
Is physiological/physical stress, pain, or more than mild discomfort likely to result from participation in the study?		
Are drugs, placebos or other substances (e.g. food substances, vitamins) to be administered to the research participants?		
Is emotional/psychological stress, anxiety, or more than mild discomfort likely to result from participation in the study?		
Could any research participant or his/her family/community be at risk or be adversely affected by their participation in the research project? It includes any form of cultural, social or financial risk/harm.		
Are the research participants asked potentially sensitive, incriminating, confidential or personal questions about themselves (e.g. sexual activity, drug use) or their organisation (e.g. work satisfaction)?		
Does the project require the collection of any body tissues (e.g. muscle biopsy) or fluids (e.g. blood, urine) from the research participants?		
Does the project involve the use of human/animal specimens and/or samples that were originally collected for purposes other than this research?		
Will the study involve the recruitment of TUT staff and/or students as research participants?		
Are any of the research participants limited in their ability to give informed and voluntary consent, i.e. a member of a vulnerable population? This includes clinic patients, TUT staff members, TUT students, children, elderly, terminally ill patients, mentally disabled, institutionalised and prison groupings.		
Do you have a known/special relationship with any of the research participants (e.g. lecturer-student, practitioner-patient and friend/family relationships)?		
Will it be necessary for participants to take part in the study without their knowledge and consent at the time (e.g. covert observation of people in non-public places)?		
Will any kind of incentive (including compensation for time and transport) be offered to research participants?		
Does the project involve specialised procedures that are reserved by law for registered professionals, e.g. physicians, biokineticists, and nurses?		
Does the project involve the genetic manipulation/modification of any organism/ plant?		
Will the research project have a direct impact on the natural environment/ ecosystem (e.g. collection of soil samples or plant materials, the implementation of a rehabilitation programme and the disposal of chemical waste)?		
Has any organization provided financial or in-kind support for this project? This refers to potential conflict-of-interest issues that may affect the unrestricted publication of the research results. It includes direct material benefit that the researcher may receive from the sponsoring organization for a contract research project. However, it excludes bona fide research funding agencies, such as the NRF and MRC.		

SECTION D: DECLARATION

I, _____ (Full name and surname of applicant/student), declare that I have read and understood the relevant Guidelines for Ethics as prescribed by the TUT HREC. I have prepared this proposal with full cognisance of its content and will adhere to the ethical principles outlined therein when conducting my research project.

Indicate which of the following guidelines have been read:

MRC Guidelines on Ethics for Medical Research	<i>Indicate with 'X'</i>
Guidelines on Ethics for Medical Research - General Principles.	
Guidelines on Ethics for Medical Research - Reproductive Biology and Genetic Research.	
Guidelines on Ethics for Medical Research - Use of Biohazards and Radiation.	
Guidelines on Ethics for Medical Research - HIV Vaccine Trials.	
Human Sciences Research Council: Research Code.	
Department of Health: Guidelines for good practice in the conduct of clinical trials in human participants in SA.	
The National Department of Health Guidelines: South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024 (NDoH, 2024).	

Furthermore, I confirm that I will comply with the TUT Policy on Research Ethics and the TUT Policy on Plagiarism and that the details provided in this application form accurately and truthfully reflect my proposed research project. I undertake to conduct the study strictly per the approved research proposal attached to this application. Any amendments to the research proposal will be promptly communicated to the TUT HREC.

Additionally, I commit to informing my supervisors (if applicable) and the TUT HREC of any adverse events that may arise during the study or if any participants or other moral entities are harmed in the research process. I acknowledge the TUT Policy on Plagiarism and, as required, I hereby attach the similarity index report. I confirm that my submission includes the following documents which apply to the type of research project I am undertaking:

Document Checklist		Yes	No	N/A
1. FCRE confirmation letter with Memorandum of Changes (if applicable)	<i>All Students</i>			
2. FCPS report with Memorandum of Changes (if applicable)	<i>All Students</i>			
3. DCPS/DCRI report with Memorandum of Changes (if applicable)	<i>All Students</i>			
4. Proposal	<i>All Applicants</i>			
5. Turnitin/Similarity Report	<i>All Applicants</i>			
6. Information Leaflet/ Informed consent (if applicable)	<i>All Applicants</i>			
7. Data Collection Instrument (if applicable)	<i>All Applicants</i>			
8. CV(s) of Supervision Panel OR CV(s) of Applicant(s)	<i>All Students</i> <i>All Academic staff</i>			
9. Proof of Registration	<i>All Students</i>			
10. SAQA document/Certificate of equivalence	<i>All Foreign/International students</i>			

Applicant signature_____ Date_____

Supervisor signature_____ Date_____

Co-supervisor signature_____ Date_____

DATA PRIVACY NOTICE

Tshwane University of Technology (TUT) is committed to safeguarding personal information in line with the requirements of the Protection of Personal Information Act No.4 of 2013 (POPIA).

TUT confirms that any personal information collected in terms of this document shall be processed lawfully in compliance with POPIA. The University may, if necessary disclose your personal information to approved third parties or related agents to carry out its function(s) in accordance with the purpose for which the information is requested.

Such disclosure shall always be subject to a written agreement concluded between the University and such a third party ("the recipient") obligating the recipient to comply with strict confidentiality and all the information security conditions and provisions as contained in the POPIA.

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