HUMAN RESEARCH ETHICS COMMITTEE (HREC)
PASSIVE MONITORING FORM/ ANNUAL REPORT FORM

1. Passive monitoring reports are required by the HREC for low and medium risk studies (refer to the HREC Standard Operating Procedures).
2. Please note that the HREC mandates annual progress reports for low and medium risk projects. For high-risk projects, a progress report is required every six months.
3. No research may continue after the ethics approval expiry date indicated on the formal Human Research Ethics Committee approval letter.
4. The completed progress report should contain sufficient information to allow the HREC to conduct a substantive and meaningful review of the progress of the project, including any ethics-related challenges or problems encountered.
5. The content of this report will be treated under the HREC's usual confidentiality regulations.
6. The Final report should be submitted to HREC after completion of data collection.

HREC reference number

SECTION A: RESEARCHER(S) 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: REPORT INFORMATION

1. Research report.	
Date of Approval	
Commencement date	
Expected date of completion	
Date(s) of approval of amendment(s) since the original approved proposal (if applicable)	

2. Provide a short summary of each amendment(s) (if applicable).

3. Number of participants **Fill in the number of participants or indicate N/A, do not leave any box blank.**	
To be investigated as per protocol/proposal	
Already entered into the research project	
Already completed participation	
Withdrawn from study before study completion	

4. Provide reasons for participants withdrawing (if applicable).

5. Describe your project findings to date.

6. Serious Adverse Events (SAEs). **Please complete with a value (amount) if any serious adverse event has occurred that were related to the study, not-related to the study, possibly related to the study, or indicate not applicable (N/A) if no serious adverse event took place. Please provide a listing of all SAE's (if any) encountered during the course of the study. Do not leave any box blank.**	
Related	
Not-related	
Possibly-related	

7. Details of SAEs encountered.

8. Provide any of the following: An article/abstract or a summary of findings if the study is completed.

SECTION C: CHECKLIST FOR RISK ASSESSMENT

	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 by law reserved 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/we, _____ (full names and surnames) confirm that the information provided in this report is complete and accurate. I/we understand that I/we have responsibility for the protection of the rights and welfare of the research participants and the ethical conduct of this research in accordance with international research ethics principles. I/we confirm that I/we have complied with applicable TUT policies and procedures, as well as with applicable national legislation. I/we confirm that the research was/is conducted by qualified personnel as indicated in the approved research proposal. No changes were made to the consent process without prior approval by the TUT Human Research Ethics Committee. Legally effective informed consent/assent was obtained from all the research participants. Unanticipated harms or serious adverse events to research participants were reported to the TUT Human Research Ethics Committee in a timely manner.

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. Proof of Registration	*All Students*	☐	☐	☐
2. Approved research proposal	*All Applicants*	☐	☐	☐
3. Informed consent form used in obtaining informed consent from participants (if applicable)	*All Applicants*	☐	☐	☐
4. Gatekeeper permission letters (if applicable)	*All Applicants*	☐	☐	☐
5. Turnitin/Similarity Report	*All Applicants*	☐	☐	☐

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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