

HUMAN RESEARCH ETHICS COMMITTEE (HREC) SERIOUS ADVERSE EVENTS REPORTING FORM ACTIVE MONITORING

Serious adverse events and the reporting process is described in the TUT Human Research Ethics Committee Standard Operating Procedures, Section 11.

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use E2D Guideline defines an adverse event as “any untoward medical occurrence in a patient administered a medicinal product and which does not necessarily have to have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (for example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to this medicinal product.”

Serious Adverse Events (SAE) can also occur in non-pharmaceutical research. According to the DoH Ethics in Health Research Guidelines, a SAE is defined as an event relating to an unforeseen harmful event related to the study (e.g. injury/death due to an experimental intervention), thereby negatively affecting the research participants and requiring an intervention.

Any and all serious adverse events, whether significant or unexpected, relating to undesirable consequences for the research participants or research team should be reported to the TUT Human Research Ethics Committee by completing this document within 3 calendar days to a maximum of 15 calendar days of the adverse event occurring as per the Safety Reporting During Clinical Trials in South Africa guidelines (South African Health Products Regulatory Authority). Following the submission of the initial SAE report, 6-monthly progress report's should be submitted until the submission of the final progress/study report.

The serious adverse events reporting form should be submitted to the office of the HREC within the timelines provided at: ItsueniMM@tut.ac.za and MofokengPP@tut.ac.za.

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

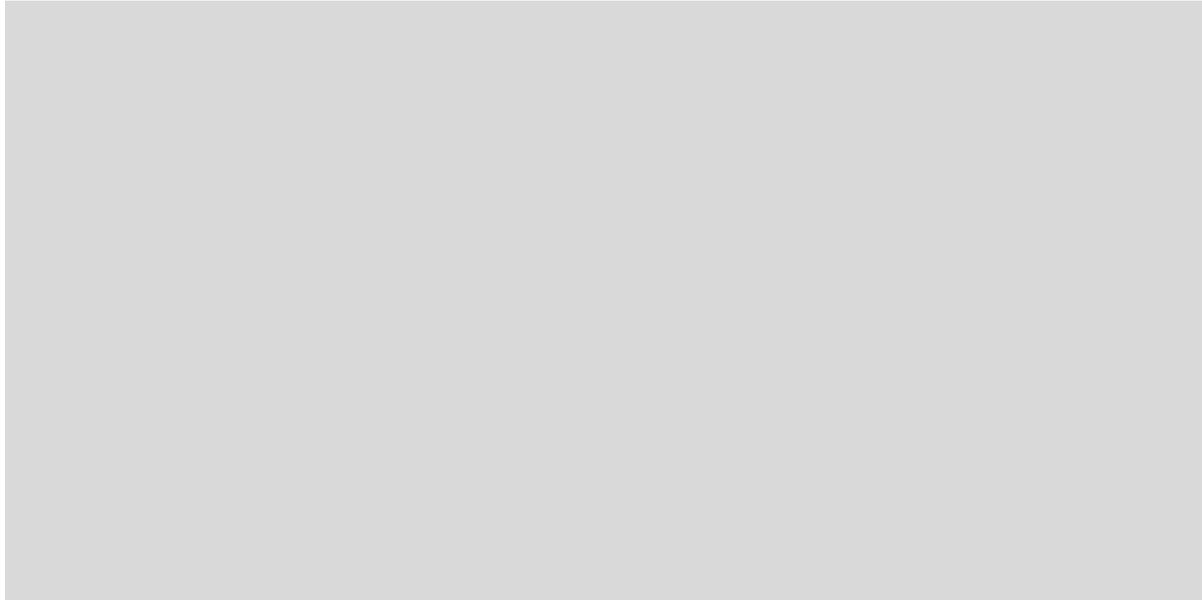
Email address

Department

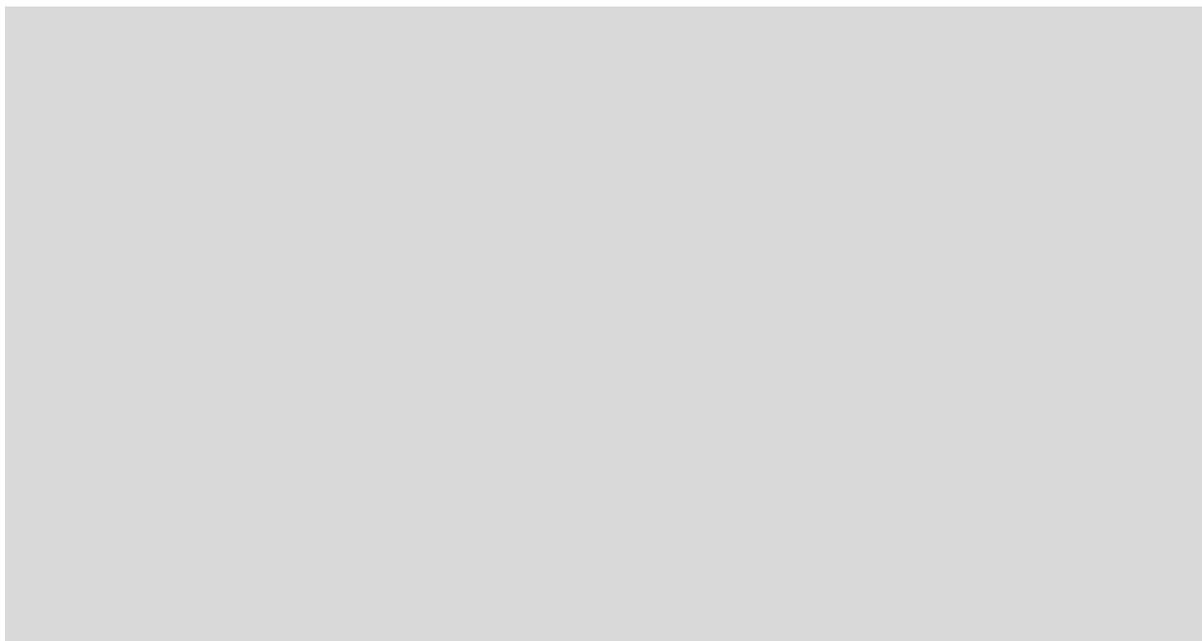
Faculty

SECTION B: SERIOUS ADVERSE EVENT (SAE) INFORMATION

- 1. Describe the nature of the serious adverse event that took place in your study including when, how, where, and to whom:**



- 2. Describe the impact of the adverse event on the research participants or any other stakeholder:**



3. What actions did the researcher take to address the adverse event?

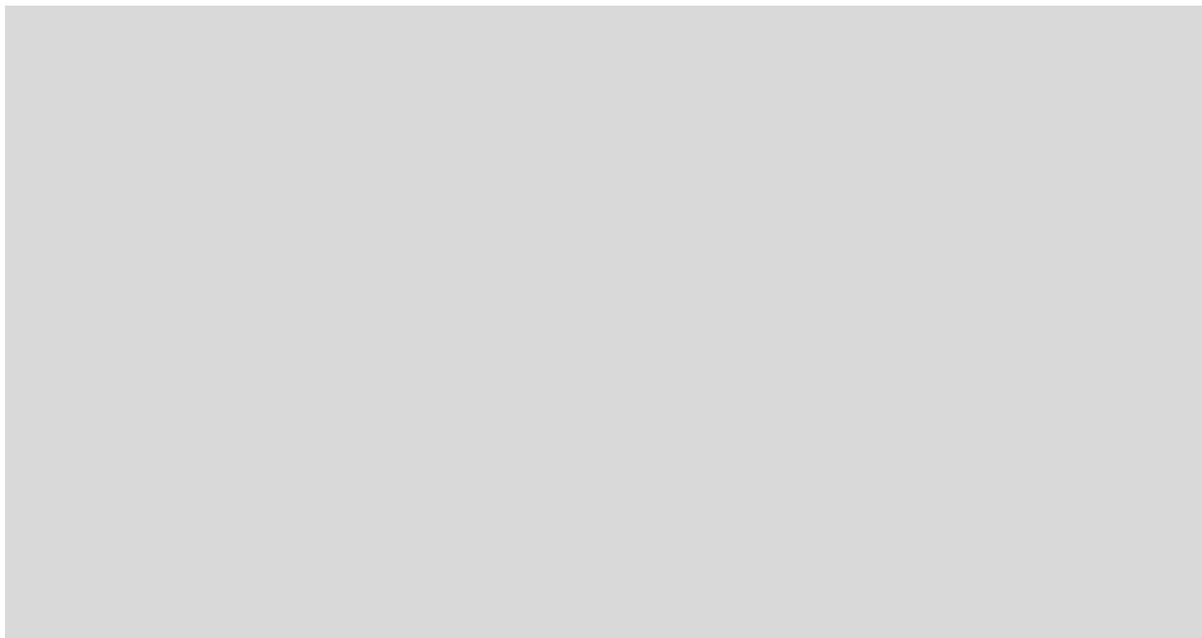
4. Was the study discontinued due to the occurrence of the adverse event?

5. Please indicate the intervention that was implemented following the adverse event, which the researcher is proposing as an amendment to the originally approved proposal to address the adverse event that was experienced?

- 6. How does the proposed amendment affect the method that was adopted to investigate the study (e.g., research design, sampling, data collection, procedure, and data analysis):**



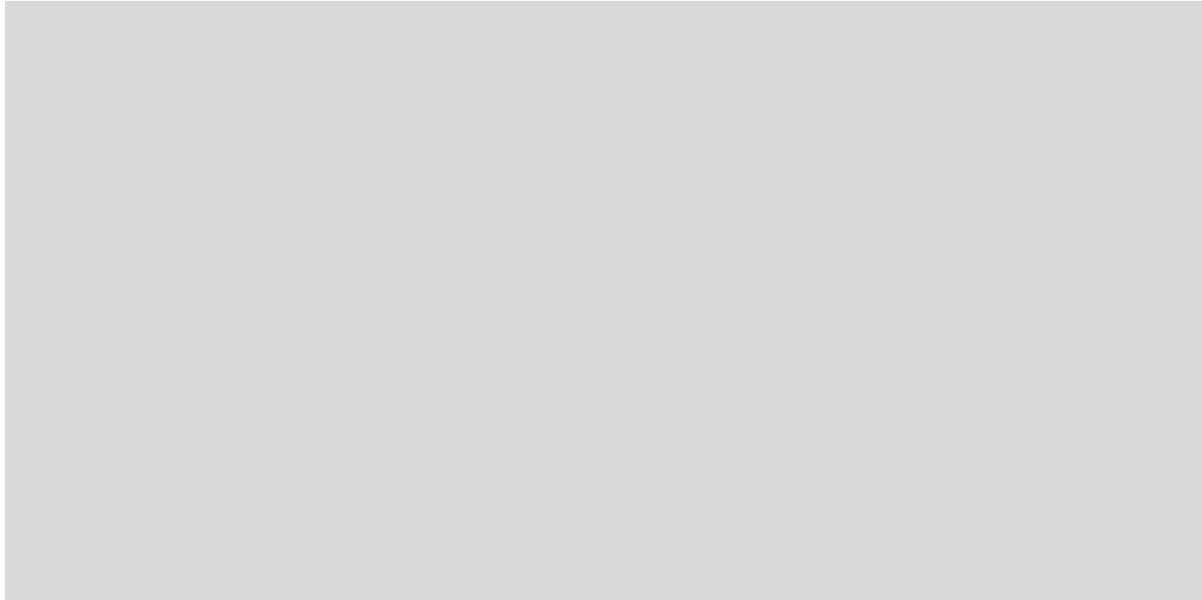
- 7. What is the impact of the proposed amendment on the ethical risks that are posed by the study following the adverse event (see the TUT Ethics Checklist and the Risk Categories included in HREC Standard Operating Procedures Section 17.4 in this regard):**



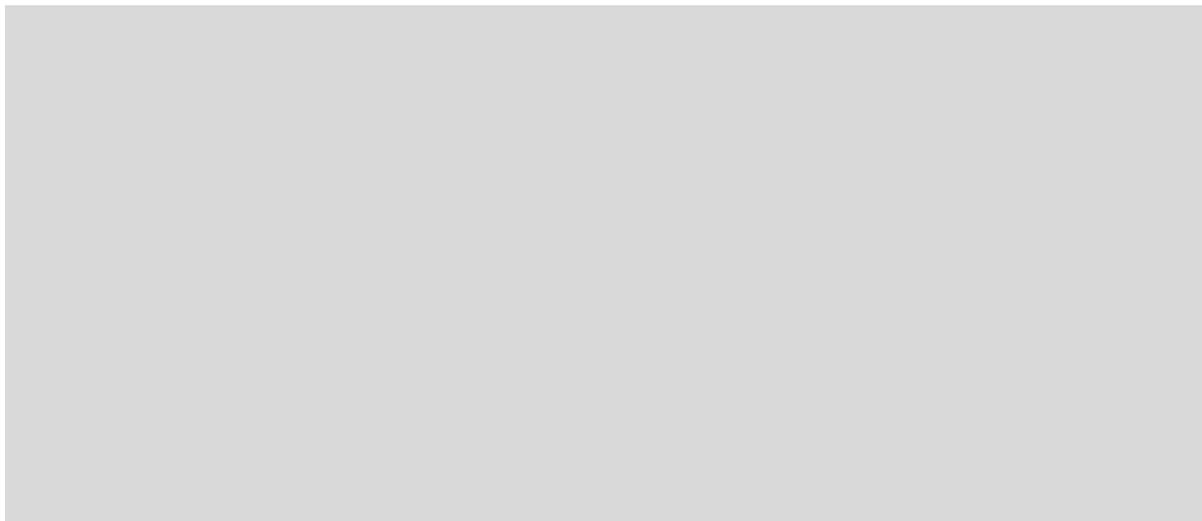
- 8. Describe how the ethical risks following the adverse event were identified in the research design, sampling, data collection, procedure and data analysis were adjusted:**

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- 9. If the study is registered with another academic or non-academic institution, clarify the relevant amendment(s) to the study to be reported to the Tshwane University of Technology Research Ethics Committee:**



- 10. If data was collected from institutions other than TUT, such as academic and non-academic institutions i.e. (hospitals, clinics, schools etc.), the researcher should submit the amendment to all institutions. Identify such institutions below and indicate how the researcher will contact these. A copy of the amended ethical clearance certificate from all institutions should also be submitted to the TUT HREC:**



SECTION C: 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	<i>All Students</i>			
2. Approved research proposal	<i>All Applicants</i>			
3. Informed consent form used in obtaining informed consent from participants (if applicable)	<i>All Applicants</i>			
4. Gatekeeper permission letters (if applicable)	<i>All Applicants</i>			
5. Turnitin/Similarity Report	<i>All Applicants</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.

Data Privacy Notice Compliance Office: Tel. (012) 382-5665, muthelonm@tut.ac.za, www.tut.ac.za,
Private Bag X680, Pretoria 0001