



RHODES UNIVERSITY

Where leaders learn

RHODES UNIVERSITY HUMAN RESEARCH ETHICS COMMITTEE

SOP 3.1 REPORTING OF UNANTICIPATED PROBLEMS / INCIDENTS / ADVERSE EVENTS

Approved by:	Name	Signature	Date
Human Research Ethics Committee	Dr Janet Hayward (Chair)		26/02/2024
Endorsed by:			
VC Legal Unit	Mr Ismail Amojee		08/03/2024
DVC: RISP	Dr Kwezi Mzilikazi		12/03/2024

COMPILED BY Dr Janet Hayward, Chair, Rhodes University Human Research Ethics Committee

DOCUMENT HISTORY

Version 1.01 (November 2014): Rhodes University Ethical Standards Handbook (comprising Institutional Policy, Terms of Reference and Standard Operation Procedures).

Version 2.0 (February 2024): Derived from division of previous version into separate documents and revised to align with RU Research Policy (2021) and DoH Guidelines (2015; 2024).

REPORTING OF UNANTICIPATED PROBLEMS / INCIDENTS / ADVERSE EVENTS

1. Purpose

The purpose of these guidelines is to outline procedures for reporting of unanticipated problems, incidents and/or adverse events during research with human participants.

2. Scope

Unanticipated problems, incidents and adverse events include but are not limited to:

- 1) negative consequences and/or outcomes of the research not covered in the ethics protocol or not remediated during the course of conducting the study,
- 2) researchers conducting the research outside the parameters laid out in the ethics clearance,
- 3) preventable injury to a study participant that has occurred as a result of reckless behaviour by a member of the research team carrying out a particular research study.

3. Reporting of Unanticipated Problems, Incidents and Adverse Events

3.1. Any researcher who experiences / witnesses / is culpable in an incident related to or because of their interaction with human participants must report this to the Chairperson of Rhodes University Human Research Ethics Committee (RU-HREC) as soon as possible, but within one month of the incident occurring.

3.2. Reports of unanticipated problems, incidents, and adverse events, submitted to the RU-HREC must include the following:

- 1) Appropriate identifying information for the research protocol, such as title, investigator's name, and RU-HREC number.
- 2) An explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem.
- 3) A description of any changes to the protocol or other corrective actions taken or proposed in response to the unanticipated problem.

3.3. Reports can also be submitted by other parties, whether internal or external, via the whistleblowing procedures outlined in SOP 3.3 PROCEDURES FOR REPORTING ALLEGATIONS OF MISCONDUCT / NONCOMPLIANCE / UNETHICAL RESEARCH PRACTICE.

3.4. A person reporting an adverse incident or event may request that they remain anonymous (with good reason) during the investigation, although their identity must be known to the Chairperson.

3.5. The report must contain the following particulars:

- 1) nature, time and date, location of the incident(s),
- 2) people involved and responses from relevant parties,
- 3) any remedial actions that have been taken.

4. Dealing with reports of unanticipated problems, incidents, and adverse events.

These procedures are outlined in SOP 3.3 CONSEQUENCES FOR NON-COMPLIANCE.

5. Effective date of this SOP

26th February 2024 with the next revision date being 26th February 2027, or as deemed necessary by a quorate meeting of RU-HREC.