







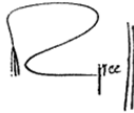



**Faculty of Health Sciences**









<b>ETHICS OFFICE</b>		<b>Standard Operating Procedure</b>	
<b>Title</b>	SOP for incident and serious adverse event reporting and management		
<b>SOP no</b>	2.2.4_SOP_Ethics_1.3	<b>Version no</b>	3
<b>Date of approval</b>	1 November 2023	<b>Revision date</b>	November 2026
<b>Web address</b>	<a href="http://health-sciences.nwu.ac.za/healthethics">http://health-sciences.nwu.ac.za/healthethics</a>	<b>Page no</b>	Page 1 to 4

**1 COMPILATION AND AUTHORISATION**

<b>Action</b>	<b>Designated person</b>	<b>Signature</b>	<b>Date</b>
Compiled by:	Prof M Greeff		25 August 2016
			4 April 2018
Updated by:	Prof GW Towers		27 July 2023
Checked by:	NWU-HREC		8 Sept 2016
			27 July 2023
	NWU-AnimCareREC		8 Sept 2016
			27 July 2023
	Ethics Office		8 Sept 2016
			27 July 2023
Faculty Management Committee		9 Nov 2016	
			27 July 2023

Authorised by:	Prof Minrie Greeff as Head of the Ethics Office		9 Nov 2016 4 April 2018
	Prof Wayne Towers as Head of the Ethics Office		27 July 2023

## 2 DISTRIBUTION

Department/Unit	Name	Signature	Date
Ethics Office	Prof M Greeff		10 Nov 2016 4 April 2018
	Prof GW Towers		27 July 2023
Chairperson on behalf of NWU-HREC	Dr GW Towers		10 Nov 2016 4 April 2018
	Prof P Bester		27 July 2023
Chairperson on behalf of NWU-AnimCareREC	Prof CB Brink		10 Nov 2016 4 April 2018 27 July 2023
Executive Dean of the Faculty of Health Sciences	Prof A Kotzé		10 Nov 2016 4 April 2018 2 August 2023
Faculty of Health Sciences	Ms L van Ronge		10 Nov 2016 4 April 2018
	Ms L Sengati		27 July 2023

## 3 DOCUMENT HISTORY

Date	Version no	Reason for revision
9 Nov 2016	1	Procedure formulated as a SOP
4 April 2018	2	Change in university structure
1 November 2023	3	Revision of SOP

## 4 PURPOSE OF THE SOP

The purpose of this document is:

- a. To provide a clear description of the steps to follow when reporting an incident or adverse/serious adverse event in a prompt and confidential manner.
- b. To give guidance to the REC to manage it with insight and sensitivity.

## 5 SCOPE

This document covers the process to be followed from the occurrence of the incident or adverse event to the successful management thereof.

## 6 ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/definition	Description
AE	Adverse event
SAE	Serious adverse event
NWU	North-West University
NWU-AnimCareREC	North-West University Animal Care, Health and Safety in Research Ethics Committee
NWU-HREC	North-West University Health Research Ethics Committee
Incident (Human)	An unanticipated occurrence that arises with participants or researchers during research that has no direct link to the research. It could have unexpected and often negative consequences for the health, privacy and safety of the participants involved in the research, the researchers involved, the NWU and/or the larger community.
Adverse event (Human)	A problem/situation/reaction that arises during research that has a direct link to the research. It could have unexpected and often negative short term consequences for the health and safety of the participants involved in the research.
Serious adverse event (Human)	A serious problem/situation/reaction that arises during research that has a direct link to the research. It could have unexpected and often negative long term and lasting consequences for the health and safety of the participants involved in the research.
Adverse event (Animal)	Any and all animal-related events (untoward occurrence related to the project procedure) that threatens or affects animal wellbeing, human safety (i.e. of the researcher, student or NWU-Vivarium staff), and/or the integrity or safety of the environment (e.g. animal holding facility or university premises)
Incident (Animal)	An animal-related incident pertaining to something unrelated to experimentation that threatens or negatively affects the wellbeing of the animal, the safety/health of the researcher, and/or the integrity of the environment (for example infrastructural failure or error in the animal holding facility (or other University facility)) or any emergency, negligence or challenge that impacts on animal wellbeing, within the jurisdiction of NWU-AnimCareREC, particularly at the University and any of its facilities).

## 7 RESPONSIBILITIES

All researchers conducting research that encounter incidents or adverse/serious adverse events should report it to the applicable REC within 24 hours.

The Executive and Serious Adverse Event (SAE) committee, as a sub-committee of the REC, has to effectively manage the reported incident/adverse event within a 24-hour period.

## 8 PROCEDURE(S)

- 8.1 When an incident or adverse event happens, the researcher must stop the study immediately and take all reasonable and appropriate steps to avoid further occurrences.
- 8.2 The researcher must within a reasonable time, but as soon as possible (within 24 hours) complete the form(s) prescribed for this process (see addenda 1 and 2 (NWU-HREC) and 3 (NWU-AnimCareREC)). Care should be taken to describe how the incident/adverse event was contained and how the matter will be resolved.
- 8.3 The researcher then electronically reports the incident/adverse event and how it will be resolved, as well as the steps to be taken to prevent further incidents/adverse events of this nature to the Executive and Serious Adverse Event (SAE) committee, as a sub-committee of the applicable REC using the prescribed form within the first 24 hours of occurrence.
- 8.4 This electronic notification should also be followed up telephonically by phoning the applicable chairperson (NWU-HREC: 018 299 2095 or NWU-AnimCareREC: 018 299 2234) indicating that an incident or adverse event has occurred.
- 8.5 The form should be sent via email to:
  - a. Ethics-HRECIncident-SAE@nwu.ac.za (for research with human participants)
  - b. Ethics-AnimCareIncident-SAE@nwu.ac.za (for research with animals)
- 8.6 The email is automatically sent to the members of the Executive and Serious Adverse Event (SAE) Committee of the applicable REC, which includes the Chairperson and the Vice-chairperson/s of the REC, the Head of the Ethics Office and at least two other REC members.
- 8.7 The first person responding to the email sends it to the specific sub-committee members identified on the email, excluding the abovementioned emails, to prevent it from being sent out again as a new report.
- 8.8 The matter is handled as confidential within 24 hours.
- 8.9 Support staff (of the Ethics Office) and the researcher are not included during this process to ensure that the privacy of all involved is maintained while the incident is being handled.
- 8.10 Based on the decision made by the Executive and Serious Adverse Event (SAE), the chairperson of the REC will contact the involved researcher and will indicate to them, the way forward. If it is determined that there is evidence that the Incident/SAE is not sufficiently contained and requires further intervention, then the Chairperson will indicate to the researcher that the study should be suspended, until a full review of the situation can be instituted.
- 8.11 A meeting is scheduled as soon as possible between the Executive and Serious Adverse Event (SAE) Committee and the researcher to decide how the incident/adverse event will be handled.
- 8.12 If additional assistance is required in the incident management strategy, other members could be co-opted.
- 8.13 Any further reports from the researcher, following the initial notification, are to be sent directly to the chairperson (for NWU-HREC to [Petra.Bester@nwu.ac.za](mailto:Petra.Bester@nwu.ac.za) and for NWU-AnimCareREC to [Tiaan.Brink@nwu.ac.za](mailto:Tiaan.Brink@nwu.ac.za)). The chairperson then sends these to the Executive and Serious Adverse Event (SAE) Committee, which includes the Head of the Ethics Office.
- 8.14 Once the incident/adverse event has been satisfactorily dealt with (according to the mutual agreement of the committee members and other parties involved) and all outstanding documentation has been received, then the incident/adverse event report can be finalised and signed by the Head of the Ethics

Office, the chairperson and the other members of the Executive and Serious Adverse Event (SAE) Committee.

- 8.15 If the Executive and Serious Adverse Event (SAE) Committee deem it necessary to include the Deputy Dean: Research and Innovation and/or the Executive Dean, then a meeting will be scheduled as soon as possible, where the matter will be reported.
- 8.16 Following completion of this process, the applicable senior administrative assistant will be informed of the incident/adverse event by receiving a hard and/or electronic copy of all the required documentation related to the reporting and management of the incident/adverse event.
- 8.17 The senior administrative assistant will place the incident/adverse event on the agenda of the next REC meeting, during which the chairperson will give a very brief description of the incident/adverse event and the manner in which it was handled.
- 8.18 Should any NWU personnel or infrastructure be threatened/hurt/damaged within the boundaries of the RSA, then the following number should be immediately contacted 018 299 2211 for facilitation of this emergency situation. Researchers should adhere to all guidelines as indicated in the Occupational Health and Safety policies of the universities, during this process.

## 9 REFERENCE DOCUMENTS

None

## 10 ADDENDA

No	Document name
1	Incident report form when conducting research with human participants
2	Adverse/serious adverse event report when conducting research with human participants
3	Instructions for adverse event containment and reporting (AnimCare)

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