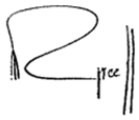
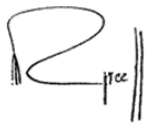
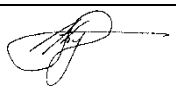
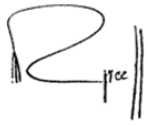
Faculty of Health Sciences

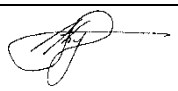
ETHICS OFFICE	Standard Operating Procedure		
Title	SOP for incident and serious adverse event reporting and management		
SOP no	2.2.4_SOP_Ethics_1.3	**Version no**	2
Date of approval	4 April 2018	**Revision date**	April 2021
Web address	http://health-sciences.nwu.ac.za/healthethics	**Page no**	Page 1 to 4

1 COMPILATION AND AUTHORISATION

Action	Designated person	Signature	Date
Compiled by:	Prof Minrie Greeff		25 August 2016 4 April 2018
Checked by:	HREC		8 Sept 2016
	AnimCare		8 Sept 2016
	Ethics Office		8 Sept 2016
	Faculty Board		9 Nov 2016
Authorised by:	Prof Minrie Greeff as Head of the Ethics Office		9 Nov 2016 4 April 2018

2 DISTRIBUTION

Department/Unit	Name	Signature	Date
Ethics Office	Prof Minrie Greeff		10 Nov 2016 4 April 2018

Chairperson on behalf of HREC	Dr Wayne Towers		10 Nov 2016 4 April 2018
Chairperson on behalf of AnimCare	Prof Tiaan Brink		10 Nov 2016 4 April 2018
Executive Dean of the Faculty of Health Sciences	Prof Awie Kotzé		10 Nov 2016 4 April 2018
Faculty of Health Sciences	Ms Leanie van Ronge		10 Nov 2016 4 April 2018

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

4 PURPOSE OF THE SOP

The purpose of this document is:

- 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.
- 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
HREC	Health Research Ethics Committee
NWU	North-West University
AnimCare	The Ethics Committee on Animal Care, Health and Safety in Research
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 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 human safety (i.e. of the researcher, student or NWU Vivarium staff), animal wellbeing, and/or the integrity or safety of the environment (e.g. animal holding facility or university premises)
Incident (Animal)	An animal-related incident pertains to something unrelated to experimentation that threatens or negatively affects the safety/health of the researcher, the wellbeing of the animal 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 AnimCare, 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 incident and adverse event 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)

- 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.
- 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 (HREC) and 3 (AnimCare)). Care should be taken to describe how the incident/adverse event was contained and how the matter will be resolved.
- 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 Incident and Adverse Event Committee as a sub-committee of the applicable REC using the prescribed form within the first 24 hours of occurrence.
- It should also be followed up telephonically by phoning the applicable chairperson (HREC 018 285 2291 or AnimCare 018 299 2234) indicating that an incident or adverse event has occurred.
- The form should be sent via email to:
  - Ethics-HRECIncident-SAE@nwu.ac.za (for research with human participants)
  - Ethics-AnimCareIncident-SAE@nwu.ac.za (for research with animals)
- The email is automatically sent to the members of the Incident and Adverse Event Committee of the applicable REC which includes the Chairperson of the REC, the Head of the Ethics Office and at least two other REC members.
- 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.
- The matter is handled as confidential within 24 hours.
- 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.
- The chairperson of the REC contacts the involved researcher and indicates to him/her that the study should be suspended until a full review of the situation can be instituted.
- A meeting is scheduled as soon as possible with the Incident and Adverse Event Committee to decide how the incident/adverse event will be handled.
- If additional assistance is required in the incident management strategy, other members could be co-opted.

- Any further reports from the researcher are sent directly to the chairperson (for HREC to wayne.towers@nwu.ac.za and for AnimCare to tiaan.brink@nwu.ac.za). The chairperson then sends these to the Incident and Adverse Event Committee which includes the Head of the Ethics Office.
- Once the incident/adverse event has been satisfactorily dealt with (according to the mutual agreement of the committee members and other parties) and all outstanding documentation has been received, the incident/adverse event report is finalised and signed by the Head of the Ethics Office, the chairperson and other members of the Incident and Adverse Event Committee.
- If the Incident and Adverse Event Committee deem it necessary to include the dean, a meeting is scheduled and the matter is reported to him.
- Following completion of this process, the applicable administrator 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.
- The administrator 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 dealt with.
- Should any NWU personnel or infrastructure be threatened/hurt/damaged within the boundaries of the RSA they should immediately contact 018 299 2211 for facilitation of this emergency situation.

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)

Original details: (23239522) G:\My Drive\2.2.4_SOPs_HSEthics\2.2.4_SOP_Ethics_1.3_SOP_for_Incidents_and_SAE.docm
25 June 2018

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