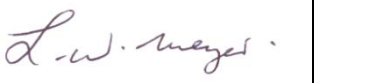
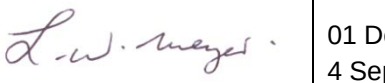
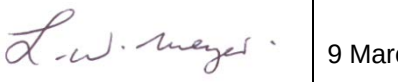
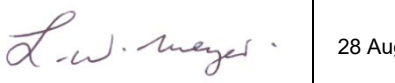
NWU-EMELTEN-REC

The Faculty of Health Sciences Ethics Office of the North-West University is acknowledged for the use of their document with minor adjustments made by the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC).

ETHICS OFFICE	**Standard Operating Procedure**		
Title	SOP for incident and serious adverse event reporting and management		
SOP no	SOP_Ethics_1.3	**Version no**	4
Date of approval	23/11/2017	**Revision date**	23/11/2021
Email address	Ethics-EMELTEN@nwu.ac.za	**Page no**	Page 1 to 9

1 COMPILATION AND AUTHORISATION

Action	**Designated person**	**Signature**	**Date**
Compiled by: Prof Minrie Greeff and amended by Prof Lukas Meyer	Prof Lukas Meyer		23/11/2017
Revised and Checked by:	NWU-EMELTEN Research Ethics Office: Prof Lukas Meyer		01 December 2018 4 September 2019
Approved by:	NWU-EMELTEN-REC Chair: Prof Lukas Meyer		9 March 2020
	Faculty Board: Faculty of Education Chair: Prof Lloyd Conley		15 April 2020
	SCRE Chair:		27 August 2020
Authorised by:	Chair of NWU-EMELTEN-REC: Prof Lukas Meyer		28 August 2020

2 DISTRIBUTION

Department/Unit	Name	Signature	Date
Chairperson on behalf of NWU-EMELTEN-REC	Prof Lukas Meyer		28 August 2020
Deputy Dean: Research and Innovation			
NWU-EMELTEN-REC Administrator	Mrs Villera le Roux		31 August 2020

3 DOCUMENT HISTORY

Date	Version no	Reason for revision
23/11/2017	1	Procedure formulated as a SOP
7 May 2018	2	Changing old NWU Logo to new NWU Logo
1 December 2018	3	Changing committee's name EMHS-REC to NWU-EMELTEN-
4 September 2019	4	Revision of document

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
NWU-EMELTEN-REC	North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee
NWU-EMELTEN-REO	North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Research Ethics Office
NWU	North-West University
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.

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 (NWU-EMELTEN-REC)). 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 (NWU-EMELTEN-REC 018 299 4778) indicating that an incident or adverse event has occurred.
- The form should be sent via email to:
  - Ethics-EMELTEN-Incident-SAE@nwu.ac.za (for research with human participants)
- 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 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 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 NWU-EMELTEN-REC to Lukas.Meyer@nwu.ac.za). The chairperson then sends these to the Incident and Adverse Event Committee.
- 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 chairperson of the REC 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

ADDENDUM 1

NWU-EMELTEN-REC

The Faculty of Health Sciences Ethics Office of the North-West University is acknowledged for the use of their document with minor adjustments made by the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC).

INCIDENT REPORT FORM WHEN CONDUCTING RESEARCH WITH HUMAN PARTICIPANTS

Note: An incident is seen as an unanticipated situation or issue that arises while conducting your research and that has no direct cause/effect due to an intervention.

Please complete the form according to the following guidelines:

- Researchers need to complete Sections A to C.
- The Chairperson of the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC) will complete Section D.

SECTION A: GENERAL INFORMATION

1. Project Leader/Principle Investigator/Study leader Details						
Surname			**Initials**		**Title**	
School/ Research unit						
E-mail						
Telephone	**Work**		**Cell**		**Fax**	
2. Student Details (if applicable)						
Surname			**Initials**		**Title**	
School/ Research unit						
E-mail						
Telephone	**Work**		**Cell**		**Fax**	
3. Details of approved research						

Title			
Ethics Approval Number			
Approval date		**Expiry date**	
Last submission of a monitoring report		**Date:**	

SECTION B: INCIDENT REPORT

Please describe the progress to date of the project (not more than 500 words):
Please describe the incident that is being reported in detail (please ensure that you respond to what, where, who, how, when of the incident):
Please describe the action that has been taken to date in detail in order to contain the incident:
Please indicate a possible strategy/action plan for correcting the incident:
Please indicate a possible strategy/action plan for ensuring that it will not occur again:

	Yes	**No**	**NA**
Will this incident require that the proposal will have to be changed? **If yes, please ensure that an amendment request is submitted to the Ethics Office as soon as possible.**			

SECTION C: SIGNATURE

By signing this document, I certify that the information provided is accurate and complete.			
Signature by the primary investigator		**Date**	

SECTION D (for office use only):

14. Ethics Office report	**Yes**	**No**	**NA**
Has the incident been satisfactorily reported?			
Has the incident been satisfactorily addressed?			
If yes, please explain the manner in which the incident was managed with the project leader/principle investigator/study leader and participant/s:			

NWU-EMELTEN-REC Chairperson	Signature	Date

ADDENDUM 2

NWU-EMELTEN-REC

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ADVERSE/SERIOUSADVERSE EVENT REPORT WHEN CONDUCTING RESEARCH WITH HUMAN PARTICIPANTS

Note: An adverse/serious adverse event is seen as a problem/situation/reaction that arises while conducting your research and that has a direct link to the research or the intervention.

Please complete the form according to the following guidelines:

- Researchers need to complete Sections A to C.
- The Chairperson of the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC) will complete Section D.

SECTION A: GENERAL INFORMATION

1. Investigator detail						
Surname:			**Initials:**		**Title:**	
School/Research unit:						
Address:						
E-mail:						
Telephone	**Work:**		**Cell:**		**Fax:**	
2. Details of approved research						
Title:						
Ethics Approval Number:						
Approval date:			**Expiry date:**			
Last submission of a monitoring report			**Date:**			

SECTION B: ADVERSE/SERIOUS ADVERSE EVENT REPORT

Site:	**Date of the event:**	**Date of the report:**
Participant code:	**Gender:** Male/Female	**Date of birth:** (dd/mm/yyyy)

Reason classified as adverse /serious adverse event:

___ Death (Date: _____)

___ Life-threatening

___ Significant disability

___ Required prolonged hospitalization

___ Medically significant or surgical intervention to preclude permanent impairment

___ Other: Specify

Severity of the event:

___ Mild

___ Moderate

___ Severe

___ Life-threatening

___ Fatal

Relationship to the investigative product/action:

___ Most probable

___ Probable

___ Unlikely related

___ Not related

Outcome at the time of the report:

___ Recovered

___ Recovered with sequelae

___ Ongoing

___ Fatal

___ Unknown: Specify

If fatal:

- **Date of death:**
- **Cause of death:**

How would future similar adverse/serious adverse events such as this be prevented:

SECTION C: SIGNATURE

By signing this document, I certify that the information provided is accurate and complete.			
Print Name:		**Title:**	
Signature by the primary investigator:		**Date:**	

SECTION D (for office use only):

14. Ethics Office report	**Yes**	**No**	**NA**
Has the AE/SAE been satisfactorily reported?			
Has the AE/SAE been satisfactorily addressed?			
If yes, please explain the manner in which the AE/SAE was managed with the principle investigator and participant/s:			

NWU-EMELTEN-REC Chairperson	**Signature**	**Date**