

FACULTY OF HUMANITIES




Standard Operating Procedure: SOP_HSSREC_2.3

SOP for incident and serious adverse event reporting and management


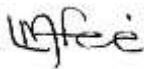
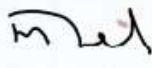
Faculty of Humanities

Standard Operating Procedure			
Title	SOP for incident and serious adverse event reporting and management		
SOP No	SOP_HSSREC_2.3	Version No	2
Date of approval		Next Revision date	April 2023
Web address		Page No	

1 COMPILATION AND AUTHORISATION

Action	Designated person	Signature	Date
Revised by:	Prof. C. van Eeden		7 April 2021
Checked by:	Prof. J. Rothmann		22 April 2021
Authorised by:	Prof. M. Nel		28 Sep. 21

2 DISTRIBUTION

Department/Unit	Name	Signature	Date
HSSREC	Prof. M. Heyns		27/4/21
Faculty of Humanities: Faculty Board	Prof. LM Fourie		29 Sept 2021
Committee for Research, Innovation and Higher Degrees	Prof. M. Nel		28 Sep. 21

3 DOCUMENT HISTORY

Date	Version No	Reason for revision
8 March 2018	1	Revision of 2015 SOP in line with NHREC audit of 30 November 2017. Based on the SOP of the NWU: HREC.
27 April 2021	2	Revision of 2018 SOP in line with NHREC requirements. Based on the SOP of the NWU: HSSREC: 2018.
29 October 2021	3	Final approval of HSSREC SOP documentation by Faculty Board and Deputy Dean Research and Innovation, Faculty of Humanities.

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 HSSREC to manage such events 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
HSSREC	Human Social Sciences Research Ethics Committee
SCRE	Senate Committee for Research Ethics
Incident	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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 HSSREC within 24 hours.

An Incident and adverse event committee, as a sub-committee of the HSSREC, 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 Addendum 1 HSSREC Incident Report Form When Conducting Research with Human Participants). 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 HSSREC using the prescribed form within the first 24 hours of occurrence. The form should be sent via email to the HSSREC chairperson (Prof Jacques Rothmann, 21081719@nwu.ac.za) It should also be followed up telephonically by phoning the applicable chairperson (Prof Jacques Rothmann at 018 299 1595)

indicating that an incident or adverse event has occurred.

The email is sent by the chairperson to the members of the *Incident and Adverse Event Committee* of the HSSREC and if necessary, to the Deputy Dean Research and Innovation of the Faculty of Humanities and the Head of the SCRE.

The matter is handled as confidential within 24 hours.

Secretarial staff, e.g. the Administrator, is 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 HSSREC 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 (comprising the HSSREC chairperson; deputy chairperson and two HSSREC committee members)*, designated by the chairperson 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 HSSREC to 21081719@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 relevant parties involved in the research) and all outstanding documentation has been received, the incident/adverse event report is finalised and signed by the chairperson and other members of the *Incident and Adverse Event Committee*. The Deputy Dean of Faculty and the SCRE are informed of the process and outcome.

If the *Incident and Adverse Event Committee* deem it necessary to include the Deputy Dean Research and Innovation of the Faculty of Humanities, a meeting is scheduled and the matter is reported to them.

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 HSSREC 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.

9 REFERENCE DOCUMENTS

None.

10 ADDENDA

No	Document name
Addendum 1	Incident report form when conducting research with human participants.



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 the approved research procedures and/or interventions.

Please complete the form according to the following guidelines:

- Researchers need to complete Sections A to C.
- The Chairperson of the Human Social Sciences Research Ethics Committee (HSSREC) 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):
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Please describe the incident that is being reported in detail (please ensure that you respond to the 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	N/A
<p>Will this incident require that the proposal will have to be changed?</p> <p><i>If yes, please ensure that an amendment request is submitted to the HSSREC as soon as possible.</i></p>			

SECTION C: SIGNATURE

By signing this document, I certify that the information provided is accurate and complete.

Signature by the primary investigator		Date	
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SECTION D (for office use only):

14. HSSREC report	Yes	No	N/A
Has the incident been satisfactorily reported?			
Has the incident been satisfactorily addressed?			
<p>If yes, please explain the manner in which the incident was managed with the project leader/principle investigator/study leader and participant/s:</p>			

HSSREC Chairperson	Signature	Date