University of Fort Hare
Together in Excellence

HEALTH RESEARCH ETHICS COMMITTEE

STANDARD OPERATING PROCEDURE FOR INCIDENT AND SERIOUS ADVERSE EVENT REPORTING AND MANAGEMENT

1. DOCUMENT HISTORY

Date	Version No	Reason for revision
11 July 2018	1	Newly formulated
31 January 2022	2	Updated

2. PURPOSE

To provide a clear description of the steps in reporting an incident or adverse/serious adverse event promptly and confidentially and to give guidance to the UFH HREC to manage an incident or adverse/adverse severe event with insight and sensitivity.

3. SCOPE

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

4. ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/Definition	Description
AE	Adverse event
SAE	Serious adverse event
HREC	Health Research Ethics Committee
UFH	University of Fort Hare
Incident (Human)	An unanticipated occurrence that arises with participants or researchers during research that has no direct link to the research; and the researchers involved, the UFH, and the larger community could have unexpected and often negative consequences for the health, privacy, and safety of the participants involved in the research,
Adverse event (Human)	A problem/situation/reaction that arises during research has a direct link to the research and 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 arises during research that has a direct link to the research and could have unexpected and often negative long-term and lasting consequences for the health and safety of the participants involved in the research.

5. RESPONSIBILITIES

Incidents or adverse/serious adverse events encountered by researchers in the process of conducting research should be reported to the UFH HREC within 24 hours. The incident and adverse event committee, as a sub-committee of the UFH HREC, has to effectively manage the reported incident/adverse event within 24 hours of reporting.

6. 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 24 hours complete the form(s) prescribed for this process (see Forms for reporting incidents and adverse events). The researcher should describe how the incident/adverse event was contained and how the matter will be resolved.

The researcher 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 UFH HREC using the prescribed forms within the first 24 hours of occurrence; or alternatively

Telephonically, it should also be followed up by phoning the Chairperson (UFH HREC 043 704 7368) indicating that an incident or adverse event has occurred. The form should be sent via email to: Ethics-HRECAdverse@ufh.ac.za (The email is automatically sent to the members of the Incident and Adverse Event Committee of the REC which includes the Chairperson of the UFH HREC, the Head of the Ethics Office, and least two other UFH HREC 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.

The support staff 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 UFH HREC 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 UFH HREC to dgoon@ufh.ac.za). The Chairperson then sends the completed reports to the Incident and Adverse Event Committee including 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 consider it necessary to include the dean, a meeting is scheduled and the matter is reported to him.

Following completion of this process, the 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 UFH HREC meeting. The Chairperson will give a very brief description of the incident/ adverse event and the manner in which it was handled.

Should any UFH personnel or infrastructure be threatened/hurt/damaged within the boundaries of the RSA, they should immediately contact 043 704 7368 to facilitate this emergency.

6. ADDENDA

No	Document name
1	Incident report form when conducting research with human participants
2	Adverse/serious adverse event report form when conducting research with human participants

7. REFERENCE DOCUMENTS

The UFH HREC adopts as its guiding reference documents the following:

- The National Health Act, No. 61 of 2003.
- Regulations Relating to Research with Human Participants, 19 September 2014.
- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)
- The Declaration of Helsinki, 2013.
- The Belmont Report, 1979.
- The Singapore Statement on Research Integrity, 2010.
- The Code of Federal Regulations of the USA (Title 45 Part 46).

- The International Conference on Harmonisation – Good Clinical Practice (ICH-GCP), 1997.
- Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa (Department of Health, 2006).
- The Rules for the Management of Research Ethics at the North-West University, 2016.
- The Rules for the Management of Research Ethics at the University of South Africa, 2016.
- The Rules for the Management of Research Ethics at the University of Cape Town, 2015.