University of Fort Hare
Together in Excellence

HEALTH RESEARCH ETHICS COMMITTEE

STANDARD OPERATING PROCEDURE FOR NON-COMPLIANCE

1. DOCUMENT HISTORY

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

2. PURPOSE OF THE SOP

The purpose of this policy is to outline procedures for reporting and investigating non-compliance to the conditions and timelines specified on the ethical clearance granted by the UFH HREC. The UFH HREC will investigate and address all reports or allegations of non-compliance.

3. DEFINITIONS OF TERMS

Non-compliance: is any violation of any regulation governing human research or any deviation from the UFH HREC approved protocol. Non-compliance varies in nature, severity and frequency.

Minor Non-compliance: is a non-compliant incident that does not affect participants' safety, compromise data integrity, violate participants' rights or welfare or affect participants' willingness to participate in the research. Examples include a missed deadline for a continuing review, unintended errors due to an oversight.

Serious Non-compliance: is an activity that jeopardises participants' safety, rights or welfare, or the integrity of the data. Examples include:

Conducting health-related research without UFH HREC approval.

Research participants do not meet inclusion criteria but are still enrolled in a UFH HREC approval study potentially or actually increasing risk and adversely affecting their rights and welfare as research participants.

The current UFH HREC-approved consent form describing all potential risks and alternatives to participate is not used.

Activities that compromise participants' privacy and confidentiality.

Implementing substantive modifications to a Committee-approved protocol without prior HREC approval.

Enrolment of research participants when UFH HREC approval has lapsed.

Continuing Non-compliance: is a series of more than one non-compliant event that was addressed previously and an unaddressed non-compliant event that may compromise the integrity of the human research protection. The pattern may reflect a lack of knowledge or a lack of commitment on the part of the investigator and study team to abide by the UFH HREC, national and international research regulations, and procedures.

4. REPORTING NON-COMPLIANCE

Allegations, observations or evidence of non-compliance in health-related research approved by UFH HREC must be reported to the UFH HREC Chairperson by:

- Any member of the study team.
- UFH HREC members.
- Study monitors, auditors or sponsors.
- Research participants and others not directly involved with conducting or overseeing the research may also report incidents of non-compliance.

5. INVESTIGATORS' RESPONSIBILITIES

Report non-compliance on their studies.

May choose voluntarily to suspend or terminate a study until the potential issue is investigated and/or resolved.

Are expected to cooperate with any fact-finding and subsequent investigation and to keep all records related to the investigation.

Are expected to respond promptly in writing to all issues raised - this may include an explanation of the non-compliance and a plan of action to ensure that similar incidents will not occur in the future.

Must comply with all recommendations resulting from the investigation.

6. UFH HREC RESPONSIBILITIES

The UFH HREC subcommittee will review written materials, interview knowledgeable sources and collect relevant documentation. The subcommittee will compile a factual and objective written report of findings and evidence. In the opinion of the subcommittee or auditor(s), findings that are supported by a great number of evidences will be considered findings of non-compliance. The UFH HREC is responsible for making a final decision as to whether serious or continuing non-compliance has taken place. The UFH HREC Chairperson shall inform the principal investigator about the actions taken thus far and advice regarding further actions to be taken which include:

- Suspend or terminate the study if participants' safety and welfare are being jeopardised.
- Place the study on administrative hold pending the outcome of the investigation.
- Require periodic independent audits.
- Modify the research proposal.
- Modify continuing review timetable to include more frequent Committee reviews.
- Require the principal investigator and study team to receive additional education or training in research ethics and good clinical practice.
- Require oversight by a senior investigator.
- Limit the research of the investigator (by the number of active protocols or number of active participants).
- Refer to other institutional entities if the non-compliance rises to the level of scientific or professional misconduct.
- Require that participants currently or previously on the study be notified of the non-compliance when such information might affect their willingness to continue participating in the research.
- Require that participants be re-consented.
- Conclude that the investigation served as an educational tool and that, based on the principal investigator's response to the investigation (such as an audit), no further action is necessary.

The final report shall include the following information:

- Name of the institution conducting the research.
- Title of the research project and/or grant proposal in which the non-compliance occurred.
- Name of principal investigator on the protocol.
- UFH HREC reference number and reference numbers for any applicable federal funding.
- A detailed description of the non-compliance.
- Actions the institution is taking or plans to take to address the non-compliance.
- A copy of the final report may be sent to the:
- Principal investigator.
- Head of Department and/or Chairperson of the Departmental Research Committee.
- Grants and Funding Office at the University of Fort Hare, when research is funded.
- Any external sponsors, where applicable.

7. US FEDERAL REPORTING REQUIREMENTS

In keeping with Federal Wide Assurance requirements, the Human Research Ethics Committee Chairperson will promptly report the findings of serious or continuing non-compliance to the Office for Human Research Protections (OHRP), the FDA or both, where applicable. Administrative suspension or termination resulting from non-compliance (for

example, a missed deadline for continuing review) will not be reported to the OHRP or FDA unless considered serious or continuing non-compliance.

8. REFERENCE DOCUMENTS

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

- 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.