University of Fort Hare
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HEALTH RESEARCH ETHICS COMMITTEE

STANDARD OPERATING PROCEDURE FOR MONITORING AND AMENDMENT OF APPROVED RESEARCH STUDIES

1. DOCUMENT HISTORY

Date	Version No	Reason for revision
17 October 2022	1	Newly developed

2. PURPOSE OF THE SOP

This SOP aims to provide researchers, the UFH HREC, and the UREC with a report on health research monitoring.

3. SCOPE

3.1 Monitoring

The UFH HREC monitors all research they approve to ensure the research integrity and conduct of research. The UFH HREC may recommend and adopt other alternative measures for monitoring, which may include:

- random (announced and unannounced) inspection of research sites;
- monitoring of data and signed informed consent documentation;
- monitoring of recorded individual interviews/focus groups; and
- inspection to verify that researchers adhere to the methodological procedures stipulated in their research proposals.

The frequency and type of monitoring should reflect the *degree* and the *extent* of risk or harm to participants. Researchers should provide comprehensive and appropriate information to the HREC to facilitate the monitoring process. The informed consent should stipulate that such monitoring may occur during the research process.

3.2 Amendments

Researchers should inform and obtain approval of HRECs for *any* amendment to a proposal, informed consent documentation, or other documentation before implementation.

4. ABBREVIATIONS AND DEFINITIONS

Abbreviation/Definition	Description
REC	Research Ethics Committee
HREC	Health Research Ethics Committee
NHC	National Health Research Ethics Council
UREC	University Research Ethics Committee
Monitoring	Ensuring research conduct adheres to the REC-approved proposal by submitting and reviewing monitoring reports, in addition to permitting researchers to continue with their research for a *further year*.

Passive monitoring	The submission of a monitoring report to the HREC as set out as terms during the review process. *For HREC:* • Minimal risk studies – annual report. • Medium risk studies – six-monthly reports. • High-risks studies – three-monthly reports. **Or for children and adult's incapable of giving consent:** No more than minimal risk of harm – annual report. • Greater than minimal risk but provides the prospect of direct benefit/high probability of delivering significant generalisable knowledge – six-monthly report. • At the end of a study.
Active monitoring	Any additional appropriate mechanism for monitoring during the research conduct that the HREC deems necessary: • random inspection of research sites; • monitoring of data and signed informed consent documentation; • monitoring of recorded individual interviews/focus groups; • inspection to verify that researchers adhere to the methodological procedures stipulated in their research proposals.
Amendment	Any change to the proposal informed consent document or other documents while the research is in progress. HREC approval before the implementation of such changes is essential. Changes could be minor or extensive in nature: • Minor changes refer to, e.g., sample size, community entry, etc. • Extensive changes refer to a change in the comprehensive methodology, e.g., from individual interviews to focus groups.

5. RESPONSIBILITIES

5.1 HREC responsibilities

HRECs should request regular, *at least annual*, reports from researchers on matters including but not limited to:

- progress to date, or outcome in the case of completed research;
- current enrolment numbers;
- whether participant follow-up is still active or completed;
- information concerning maintenance and security of records;
- evidence of compliance with the approved proposal;
- evidence of compliance with any conditions of approval;
- list of adverse events in the past 12 months;
- list of amendments made in the past 12 months;
- list of sub-studies (if applicable).

HRECs should inform researchers *in writing* of concerns arising from such monitoring activities or request clarification if uncertainties arise.

HRECs should grant researchers *written permission* to continue their studies for a further year. The due date of the following monitoring report should be indicated clearly in the monitoring feedback letter.

5.2 Researcher's responsibilities

Researchers should provide HRECs with detailed monitoring reports (comprehensive and appropriate information) for all studies approved by the HREC on the dates indicated to researchers during the approval process.

Note: Monitoring reports should be provided for all HREC-approved studies of researchers and postgraduate students, which includes sub-studies.

Researchers should inform HRECs of any *incidents/adverse events* that occur during the research process.

Researchers should request *amendments* to the proposal, informed consent documentation or other documentation before changes are implemented.

6. PROCEDURE(S)

6.1 Monitoring

The Health Research Ethics Office should keep a database of all active research studies approved by HREC. Two months before a study's approval expires, the HREC administrator sends a reminder to the researcher and attaches a copy of a monitoring report (see attached) to be completed within *one week* of receiving the reminder. In the case where the researcher has already completed the study, a final monitoring report should be sent to the Ethics Office. The administrator forwards the monitoring report to the chairperson for their decision, upon which two HREC members will act as independent reviewers. The chairperson sends the reviewer names to the administrator.

The administrator sends the completed monitoring reports to the allocated HREC members for review. They then have five working days to review the information and return their comments to the administrator.

The administrator compiles an integrated report from the two reviews for the chairperson, who then reviews the feedback and notifies the administrator of the final decision.

The administrator sends a monitoring feedback letter to the researcher indicating that the study:

- needs clarification on certain aspects;
- is suspended until certain aspects are clarified or corrected;
- is terminated on request of the researcher or the REC;
- is completed;
- can continue for a further year (indicating the date of when the following monitoring report is due).

If *clarification, suspension,* or *termination* is the option chosen, this process is handled by the chairperson and the administrator:

- Clarification - the administrator sends a monitoring feedback letter to the researcher indicating which aspects need clarification. The researcher has to provide the administrator with the requested clarification for the chairperson's perusal. Once resolved, the study can continue.
- Suspension (temporary stoppage) – the chairperson notifies the researcher that the research is temporarily suspended. An urgent meeting is called with the chairperson, vice-chairperson, research administrator, and researcher to discuss the HREC's concerns and find immediate solutions. The REC can make recommendations or impose specific conditions. Once resolved, the study can continue.

- Termination (permanent stoppage) - if the researcher requests the termination of the study, the monitoring feedback letter will confirm this. On the other hand, if REC terminates the study, due process should be followed.

The decisions are ratified during the next REC meeting.

6.2 Suspension or termination of studies

Where circumstances indicate that a project is non-compliant with the approved proposal and the interest of the participants are at risk of harm, the HREC may withdraw approval after due process has been followed. There should be interaction with the researcher and other interested parties to ensure a fair and transparent process. If a decision is to withdraw approval, the HREC should inform the researcher and other interested parties involved in the study accordingly. The HREC should also recommend *remedial actions* where appropriate. In the case of suspension, the researcher should comply with the recommendations and conditions imposed by the HREC.

6.3 Amendments

HREC requires that researchers immediately report anything that might warrant *reconsideration of ethical approval* of the proposal, informed consent documentation, or other documentation, including but not limited to:

- severe or unexpected adverse effects on participants;
- proposed changes to the proposal;
- proposed changes to the informed consent documentation; and
- unforeseen events that might affect the continued ethical acceptability of the project.

Researchers must seek approval for the amendment. As soon as the HREC receives a request for an amendment, the administrator sends the request to the chairperson. The chairperson handles it through the *expedited review process (unless amendments are significant and require full committee approval)* by allocating it to two reviewers with three working days to give their review feedback. The administrator sends the amendment request to the reviewers and, on receipt, sends their reviews to the chairperson, who makes the final decision to approve the request. The decision is ratified during the following HREC meeting.

7. REFERENCE DOCUMENTS

- Standard Operating Procedures for monitoring and amendment of approved research studies, 2.2.4_SOP_Ethics_1.6. North-West University, 2021.
- The Rules for the Management of Research Ethics at the North-West University, 2016.
- Ethics in Health Research: Principles, Processes, and Structures (Department of Health, 2015).
- The Rules for the Management of research ethics at the University of Fort Hare
- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015).