health
MPUMALANGA PROVINCE
REPUBLIC OF SOUTH AFRICA

MPUMALANGA PROVINCIAL HEALTH RESEARCH ETHICS COMMITTEE (MPHREC) STANDARD OPERATING PROCEDURE (SOP) FOR ACTIVE MONITORING

REF: SOP/01/05/2024: Research

MPUMALANGA
THE PLACE OF THE RISING SUN

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ABBREVIATIONS

- **MPHREC:** Mpumalanga Provincial Health Research Ethics Committee
- **MPHRECTC:** Mpumalanga Provincial Health Research Ethics Committee Technical Committee
- **NHREC:** National Health Research Ethics Council
- **SOP:** Standard Operating Procedure

1 INTRODUCTION

Mpumalanga Department of Health Research and Ethics Committee (MPHREC) is committed to a policy of fair dealing and integrity in conducting its research activities. The committee will form sub-committees which will be tasked to undertake active monitoring of research projects. Active Monitoring is a quality control function designed to ensure that the study is run to a high standard and that all study related activities are fulfilled. The committee will sample research projects that need to be monitored and assign such sampled projects to the sub-committee (named MPHRECTC) to undertake monitoring of ethically approved research projects.

2 PURPOSE OF THE SOP

2.1 The purpose of this SOP is to provide researchers, the Provincial Department of Health and MPHREC with guidelines on the monitoring of approved studies and amendments.

2.2 Implementation of the SOP will assist in ensuring that:

2.2.1 The rights and well-being of human subjects are protected.

2.2.2 The reported research project data are accurate, complete, and verifiable from source documents.

2.2.3 The conduct of the research follows the currently approved protocol/amendment(s).

3 GUIDING PRINCIPLES

3.1 Monitoring

3.1.1 MPHREC has the right to monitor the research they approve using an appropriate monitoring form (See Annexure 1, below).

3.1.2 MPHREC may recommend and adopt any additional appropriate mechanism for monitoring, including:

3.1.2.1 Random (announced and unannounced) inspection of research sites.

3.1.2.2 Monitoring of data and signed informed consent documentation.

3.1.2.3 Monitoring of recorded individual interviews/focus groups.

3.1.2.4 Inspection that researchers adhere to SOPs and other approved research procedures.

3.1.3 The frequency and type of monitoring would reflect to the degree and the extent of risk of harm to participants (adults and children).

3.1.4 Researchers should provide comprehensive and appropriate information to the MPHREC to facilitate the monitoring process.

3.1.5 Informed consent documentation should indicate to participants that such monitoring may take place during the research process.

4 RESPONSIBILITIES

4.1 The roles of MPHRECTC

4.1.1 Request progress reports from researchers at least once a year on the following:

4.1.1.1 progress to date, or outcome in the case of completed research.

4.1.1.2 current enrolment numbers.

4.1.1.3 whether participant follow-up is still active or completed.

4.1.1.4 information concerning maintenance and security of records.

4.1.1.5 evidence of compliance with the approved proposal.

4.1.1.6 evidence of compliance with any conditions of approval.

4.1.1.7 list of adverse events in the past 12 months.

4.1.1.8 list of amendments made in the past 12 months.

4.1.1.9 list of sub-studies (if applicable).

4.1.2 Analyze and prepare a monitoring report on the collected data to assess the quality, impact, and productivity of research.

4.1.3 Inform researchers in writing of concerns arising from such monitoring activities or request clarification if uncertainties arise.

4.1.4 Grant researchers written permission to extend their studies for a further year.

4.2 The roles of Researchers

4.2.1 Researchers who have been sampled for active monitoring will be required to provide the MPHREC with a detailed report for the approved study.

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

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

5 GENERAL PROCEDURES

5.1 Monitoring Procedure for Research Studies

5.1.1 Monitors will be identified and assigned by MPHRECTC chairperson and the secretariat office for a particular study.

5.1.2 Preparation for monitoring: Identified Monitors will:

5.1.2.1 Familiarize themselves with the study to be monitored, ensuring they have a full understanding of the protocol and all the study procedures and any relevant regulatory requirements.

5.1.2.2 Make themselves aware of the current versions of the study documents in use. For example, but not limited to, the protocol, participant information sheet, consent form, case report forms, eligibility checklists and pharmacy accountability logs. The monitor will also review:

5.1.2.3 Review previous monitoring activities and recent site correspondence to identify issues requiring follow-up or resolution during the monitoring visit.

5.1.2.4 Review the current recruitment status of the study

5.1.2.5 Where required, the monitor will identify any patient medical notes that need to be requested for monitoring. If patient notes need to be randomly sampled, the randomization process does not need to be formal however the patient selection must be made by the monitor, not the researcher.

5.1.3 Arranging a monitoring visit

5.1.3.1 During an onsite visit, the monitor will record their name, signature and date of the monitoring visit on the Active Monitoring Form (Annexure 1) and ensure that an appropriate member of the study team also signs the form.

5.1.3.2 The monitor will complete active monitoring form as appropriate to evaluate and record the conduct and delivery of the study to date

5.1.3.3 If non-compliance is identified, this will be recorded in the active monitoring form and subsequent monitoring report to be prepared by the secretariat.

5.1.3.4 The monitor will verify that outstanding issues from any previous visits are addressed, documented and followed to resolution.

5.1.3.5 At the end of the monitoring visit the monitor will discuss any findings and expected next steps.

5.1.4 Documenting the monitoring visit

5.1.4.1 All active monitoring visits should be documented as evidence of study oversight.

5.1.4.2 Monitoring activities will be documented in a manner appropriate to the nature of the monitoring visit.

5.1.4.3 Monitoring documents must make it clear the nature of the monitoring activity, the personnel present, what was monitored, any findings and any required corrective and preventative actions.

5.1.4.4 Monitoring documents should be signed and dated by the Monitor and where applicable the member of the study team.

5.1.4.5 The monitoring visit will be reported promptly to the study team. Where possible, this should be sent within 1 week of the visit taking place.

5.1.4.6 Monitoring findings will be categorised as minor/major non-compliance or serious breach.

5.1.4.7 All monitoring documentation must be filed in the master file for the approved study by the secretariat.

5.1.5 Monitoring Follow Up

5.1.5.1 The monitor and study team are both responsible for tracking the resolution of any monitoring findings and timeframes.

5.1.5.2 The study team must inform the monitor of steps taken to resolve any actions and when actions have reached a resolution.

5.1.5.3 The monitor may arrange a follow up monitoring visit, if deemed necessary, to confirm all actions have been resolved.

5.1.5.4 Non-compliance will result in the suspension/termination of the study.

5.1.6 Monitoring activities and a summary of any findings will be presented at an MPHREC meeting to ensure members are aware of all monitoring activity taking place.

6 ACTIVE MONITORING FEEDBACK

6.1 The monitor completes the monitoring template and send it to the secretariat, who will communicate with the chairperson for the need to review the study.

6.2 The secretariat compiles an integrated report about the review process and submits to the chairperson who will then notify the secretariat of the final outcome.

6.3 When necessary, the secretariat sends a monitoring feedback letter to the researcher indicating any one of the following:

6.3.1 The need for clarification on certain aspects.

6.3.2 The suspension of the study until certain aspects are clarified.

6.3.3 Termination on request of the researcher or the MPHREC.

6.4 Where circumstances indicate that a project is non-compliant with the approved proposal and interest of the participants are at risk of harm or impact on human wellbeing exceeds what has been approved or can be justified, the MPHREC may withdraw approval.

6.5 A clear process should be followed that permits swift but proper investigation and decision-making to ensure protection of participants.

6.5.1 This should include interaction with the researcher and other interested parties to ensure a fair and transparent process.

6.5.2 If a decision is to withdraw approval, the MPHREC should inform the researcher and other interested parties notified by the secretariat.

6.5.3 It should also recommend remedial actions where appropriate.

6.5.4 In the case of suspension, the researcher should comply with the recommendations and/or conditions imposed by the MPHREC.

6.6 The decision is ratified during the next MPHREC meeting.

7 DURATION OF ACTIVE MONITORING

7.1 Active monitoring will be conducted at least once per annum for sampled projects.

7.2 However, a research project that is considered greater than low (minimal) risk may be subject to more frequent and detailed monitoring proportional to the risk of harm to participants.

8 REQUEST FOR AMENDMENTS

8.1 The MPHREC 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:

8.1.1 serious or unexpected adverse effects on participants.

8.1.2 proposed changes to the proposal.

8.1.3 proposed changes to the informed consent documentation.

8.1.4 proposed changes to the monitoring sheets of human wellbeing.

8.1.5 Unforeseen events that might affect continued ethical acceptability of the project.

8.2 Researchers must seek approval for the amendment before the change can be implemented and the study continues.

8.3 As soon as the MPHREC receives a request for an amendment, the secretariat notifies the chairperson in order to deal with the request through the expedited review process (unless amendments are significant, requiring full committee approval) by allocating it to two reviewers who have three working days to give their feedback of the review.

8.4 The secretariat 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.

8.5 The decision is ratified during the following REC meeting.

9 ACTIVE MONITORING SOP APPROVAL

APPROVED/ NOT APPROVED

DR LK NDHLOVU
HEAD: HEALTH

4/6/2024
DATE

Effective date 4/06/2024

ANNEXURE 1: MPHREC ACTIVE MONITORING REPORT FORM

- The purpose of this form is for MPHRECTC members (as reviewers) to monitor the progress of selected research projects onsite and report to the MPHREC.
- Reviewers should submit completed active monitoring reports to the MPHREC secretariat for consolidation.

Researcher's Name			
Supervisor Name (If applicable)			
Department/Centre			
Research Proposal Title			
Original Ethics Clearance Number		First Clearance Date	
Last Renewal Date (if applicable)		Number of Renewals	

Instructions to MPHRECTC member carrying out the active monitoring:

- Please complete all sections 1-11 below and comment on your observations.

1. Stage of Ongoing Research			
1.1. Data Collection Ongoing	☐	1.2. Data Collection Complete	☐
1.3. Data Analysis Ongoing	☐	1.4. Data Analysis Complete	☐
1.5. Research Report/Dissertation/ Thesis Writing	☐	1.6. Research Report/ Dissertation/ Thesis Writing Complete	☐

2. Research progress observed and/or reported by the researcher: (Please provide an overall summary of the research progress as reported by the researcher from the last clearance approval or renewal.)

Please click here to comment

3. Evidence of informed consent of participants, parents or guardians and assent of minors where applicable

Have there been any challenges in obtaining consent of participants to provide data in the period covered by this report?

3.1. Yes ☐ 3.2. No ☐

If yes, please provide details below, and indicate how the consent/assent was documented:

Please click here to comment

4. Evidence of consistency or changes in research methods, data collection instruments, and storage methods

Has there been any changes in research methods, data collection instruments and/or storage in the period covered by this report?

4.1. Yes ☐ 4.2. No ☐

If yes, please provide details below, and indicate how they were dealt with:

Please click here to comment

5. Documentary evidence of Reportable Events/Deviations, etc.

Ascertain if any of the following occurred during the period covered by this report. **Please indicate all associated supporting Adverse Events Reporting forms provided by the researcher, where applicable.**

5.1 Serious Adverse Event(s) (SAEs)	☐	5.2 Non-serious Adverse Event(s)	☐
5.3 Related AE(s)	☐	5.4 Unrelated AE(s)	☐
5.5 Anticipated AE(s)	☐	5.6 Unanticipated AE(s)	☐
5.7 Proposal Deviation	☐	5.8 Proposal Non-compliance	☐

NB 1: Check whether the researcher reported any SAEs and related AEs within 48 hours of discovery during the research period. .....

NB 2: Check whether any non-serious AEs, related AEs, all deviations from the proposal and non-compliances were reported within 5 working days of discovery during the research period. .....

6. Evidence of voluntary withdrawal of participants where applicable?

Check whether there has been any withdrawal of participants in the period covered by this report.

6.1 Yes ☐ 6.2 No ☐

If yes, please explain details below, and indicate how they were handled:

Please click here to comment

7. Evidence of informed consent of participants, parents or guardians and assent of minors where applicable

Have there been any challenges in obtaining consent of participants and assent of minors (where applicable) to provide data in the period covered by this report?

6.3 Yes ☐ 6.4 No ☐

If yes, please provide details below, and indicate how the consent/assent was documented:

Please click here to comment

8. Evidence of consistency and/or changes in data collection and/or storage methods

Has there been any changes in research methods, data collection instruments and/or storage in the period covered by this report?

6.5 Yes ☐ 6.6 No ☐

If yes, please provide details below, and indicate how they were dealt with:

Please click here to comment

9. Documentary evidence of Reportable Events/Deviations, etc.

Ascertain if any of the following occurred during the period covered by this report. **Please indicate all associated supporting Adverse Events Reporting forms provided by the researcher, where applicable.**

9.1 Serious Adverse Event(s) (SAEs)	☐	9.2 Non-serious Adverse Event(s)	☐
9.3 Related AE(s)	☐	9.4 Unrelated AE(s)	☐
9.5 Anticipated AE(s)	☐	9.6 Unanticipated AE(s)	☐
9.7 Proposal Deviation	☐	9.8 Proposal Non-compliance	☐

NB 1: Indicate whether the researcher report SAEs and related AEs within 48 hours of discovery during the research period. .....
NB 2: Indicate whether any non-serious AEs, related AEs, all deviations from the proposal and non-compliances were reported within 5 working days of discovery during the research period. .....
11.1 Yes ☐ 11.2 No ☐ If yes, please explain the nature of conflict(s) below, and indicate how they were addressed by the researcher: *Please click here to comment*

MPHRECTC Member's Signature		Researcher's Signature	
Date (DD/MM/YYYY)		Date (DD/MM/YYYY)	