health
MPUMALANGA PROVINCE
REPUBLIC OF SOUTH AFRICA

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

REF: SOP/01/05/2024 Research

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ABBREVIATIONS

MPHREC	Mpumalanga Provincial Health Research Ethics Committee
MPHRECTC:	Mpumalanga Provincial Health Research Ethics Committee Technical Committee
SOP	Standard Operating Procedure

1. INTRODUCTION

1.1 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.

1.2 While passive monitoring of research typically refers to the process of observing and tracking research activities and outcomes without directly interfering with or influencing the research itself.

1.3 This involves the collection of information and data related to research projects, publications, or research environments, often for purposes such as evaluation, assessment, and quality control.

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 for carrying out monitoring activities of approved research studies conducted in Mpumalanga Province.

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).

2.2.4 Researchers report to the MPHREC annually on the progress of their research.

3. SCOPE OF THE SOP

3.1 This SOP applies to all research passive monitoring activities conducted within the province and/or departments.

3.2 It includes data collection, analysis, and reporting related to research projects, publications, and research environments pertaining to an approved research project.

3.3 Passive monitoring is conducted once annually during the anniversary of an approved research project.

4. RESPONSIBILITIES

4.1 The roles of MPHREC/MPHRECTC

4.1.1 Request feedback on ongoing approved research projects in terms of:

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

4.1.1.2 current enrolment numbers or withdrawal of participants if any.

4.1.1.3 Any changes in data collection or storage.

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

4.1.3 Ensure that passive monitoring activities comply with privacy and data protection regulations.

4.1.4 Respect researchers' rights and privacy and use anonymized data wherever possible.

4.2 The roles of the Researchers

4.2.1 Researchers whose projects are about to be completed or due for renewal will be required to provide the MPHREC with a detailed report for the approved studies using an appropriate passive monitoring form (Annexure 1).

4.2.2 Researchers subject to passive monitoring should cooperate with the monitoring team by providing access to relevant data and information as required.

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

5. GENERAL PROCEDURES

5.1 Monitoring Procedure

5.1.1 The secretariat of the MPHREC keeps a database of all active research studies with ethical clearance (all studies to be granted a one-year approval clearance.

5.1.2 Two months before a study's approval expires, the secretariat of the MPHREC shall send a reminder to the researcher in case the researcher applies for an extension for the research permission.

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

5.1.4 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.

5.1.5 The secretariat sends a monitoring feedback letter to the researcher indicating any one of the following:

5.1.5.1 The need for clarification on certain aspects.

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

5.1.5.3 Termination on request of the researcher or the MPHREC; or

5.1.5.4 That the study can continue for a further year.

5.1.6 The decision is ratified during the next MPHREC meeting.

5.2 Documenting the monitoring visit

5.2.1 All passive monitoring forms should be documented as evidence of study oversight.

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

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

5.2.4 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.

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

6. AMENDMENTS AND TERMINATION OF RESEARCH STUDIES

6.1 Researchers should inform and obtain approval of MPHREC for any amendment to a proposal, informed consent documentation or other documentation before implementation thereof using an appropriate form (Annexure 2).

6.1.1 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.

6.1.2 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.

6.1.3 The decision is ratified during the following MPHREC meeting.

6.2 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.

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

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

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

6.3.3 It should also recommend remedial actions where appropriate.

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

7. PASSIVE MONITORING SOP APPROVAL

APPROVED/ NOT APPROVED

_____ 4/6/2024

DR LK NDHLOVU **DATE**

HEAD: HEALTH

Effective date 4 Oct 2024

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ANNEXURE 1: MPHREC ANNUAL PASSIVE MONITORING FORM

- The purpose of this form is for researchers to report to the MPHREC annually on the progress of their research
- The completed form to be submitted by the researcher to MPHREC secretariat on each anniversary of the granting of ethical clearance

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:

- Please complete all sections 1-5 below and provide explanations or clarifications where required.

1. Stage of Ongoing Research (*Mark with an X inside the box*)

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 Ongoing		1.6. Research Report/Dissertation/ Thesis Writing Complete	

2. Research Progress: (Please provide an overall summary of the research progress from the last clearance approval or renewal date to date whichever is applicable)

Please click here to comment

3. Informed consent of participants 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 explain details below, and indicate how they were handled:

Please click here to comment

4. Changes in data collection or storage methods

4.1 Has there been any changes in data collection methods or storage in the period covered by this report?

Yes ☐ No ☐

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

Please click here to comment

5. Ethical Issues and Adverse Events

5.1 Have any ethical concerns occurred during this period?

Yes ☐ | No ☐

If yes, give details:

Please click here to comment

5.2 Have any adverse events/ SAE's been noted since the last review?

Yes ☐ | No ☐

If yes, give details:

Please click here to comment

5. Withdrawal of participants

Has there been any withdrawal of participants in the period covered by this report?

a. Yes ☐ b. No ☐

If yes, please provide the total number withdrawn and reasons:

Please click here to comment

6. **Publication/Feedback**

6.1 Are there any publications or presentations during this period?

a. Yes ☐ b. No ☐

6.1.1 If yes, please provide details:

Please click here to comment

6.2 Have you provided feedback to the institution where the study is being conducted?

6.2.1 If yes, please provide details and the date when feedback was provided:

Please click here to comment

6.2.2 If no, please provide reasons and the date when feedback will be provided:

Please click here to comment

Primary Investigator/		Secretariat Signature	

Researcher Signature			
Date completed (DD/MM/YYYY)		Date received (DD/MM/YYYY)	

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(Annexure 2)

APPLICATION/NOTIFICATION FORM FOR AMENDMENTS

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(Name of the Institution)

NHRD Ref. No:

Title of study:

.....

.....

Principal Investigator (Name, Designation and Affiliation):

.....

.....

Date of MPHREC approval:				
MPHREC Number:				
Date of start of study:				
S.No	Existing Provision	Proposed Amendment	Reason	Location in the protocol/ICD [1]
a) Impact on benefit-risk analysis				Yes ☐ No ☐
If yes, describe in brief:				
b) Is any re-consent necessary?				Yes ☐ No ☐
If yes, have necessary changes been made in the informed consent?				Yes ☐ No ☐
c) Type of review requested for amendment:				Expedited review (No alteration in risk to participants) ☐

[1] *Location implies page number in the ICD/protocol where the amendment is proposed.*

		Full review by EC (There is an increased alteration in the risk to participants) ☐
d) Version number of amended Protocol/Investigator's brochure/ICD:		
Signature of PI:		