health
MPUMALANGA PROVINCE
REPUBLIC OF SOUTH AFRICA

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

REF: SOP/01/ 07/2023: AM-MPHREC

MPUMALANGA
THE PLACE OF THE RISING SUN

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Abbreviations

- **MPHREC:** **Mpumalanga Provincial Health Research and Ethics Committee**
- **NHREC:** **National Health Research and Ethics Committee**
- **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. The committee will sample research projects that need to be monitored and assign such sampled projects to the sub-committee to undertake monitoring of ethically approved research projects.

2. PURPOSE OF THE SOP

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.

3. GUIDING PRINCIPLES

3.1 Monitoring

3.1.1 MPHREC has the right to monitor the research they approve;

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.

3.2 Amendments

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

4. RESPONSIBILITIES

4.1 MPHREC

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

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

4.2 Researchers

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

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

4.4.3 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 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 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 are ratified during the next MPHREC meeting.

5.2 Termination of Research Studies

5.2.1 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, after due process has been followed;

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

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

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

5.2.5 It should also recommend remedial actions where appropriate;

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

5.3 Request for amendments

5.3.1 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:

5.3.1.1 serious or unexpected adverse effects on participants;

5.3.1.2 proposed changes to the proposal;

5.3.1.3 proposed changes to the informed consent documentation;

5.3.1.4 proposed changes to the monitoring sheets of human wellbeing;

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

5.3.2 Researchers must seek approval for the amendment before the change can be implemented and the study continues;

5.3.3 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.

5.3.4 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.

5.3.5 The decision is ratified during the following REC meeting.

6. TEMPLATE FOR ACTIVE MONITORING

Research Project Title`	Stage / Phase	Activities Involved	Start Date of the Project	Estimated Completion Date of the Project	Progress (Deliverables)	Recorded Serious Adverse Events	Serious Adverse Events Mitigations	Challenges/ Comments

7. ACTIVE MONITORING SOP APPROVAL

APPROVED/ NOT APPROVED

DR LK NDHLOVU

HEAD: HEALTH

6/7/2023

DATE

Effective date 10/07/2023