health
MPUMALANGA PROVINCE
REPUBLIC OF SOUTH AFRICA

MPUMALANGA PROVINCIAL HEALTH RESEARCH ETHICS COMMITTEE (MPHREC) STANDARD OPERATING PROCEDURE (SOP) FOR RAPID AND EXPEDITED REVIEW PROCESS

Ref SOP/01/06/2024: Research

MPUMALANGA
THE PLACE OF THE RISING SUN

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ABBREVIATIONS AND DEFINITIONS

• MPHREC:	Mpumalanga Provincial Health Research Ethics Committee
• NHREC:	National Health Research Ethics Council
• RECs:	Research Ethics Committees
• SOP:	Standard Operating Procedure
• Expedited review	An expedited review process consists of a faster review (two weeks) of a research-related request through the process of the chairperson of the MPHREC allocating two MPHREC members for this fast-track review. The request is approved and only ratified during the next MPHREC meeting.
• Full review	A full review process consists of a more extensive, time-consuming review done before the MPHREC meeting, by a minimum of two MPHREC members allocated to this task by the chairperson of the MPHREC but deliberated on in a face-to-face manner during a full sitting of the MPHREC meeting. MPHREC members are encouraged to be independent, objective and informed during their assessment and to act without fear of favour in their scientific and ethical reviews. An engaging decision-making processes about the application ensures that the decisions move from aggregate, debate to consensus. A review of this nature ensures: o Protection of participants from harm. o Protection of the researcher. o Holding researchers accountable. o Promotion of important social and ethical values.
• Minimal risk	Where the probability and magnitude of possible harm implied by participation are no greater than those posted by daily life in a stable society.
• Major incident	Refers to major incidents where resources are so constrained that responding urgently and appropriately is difficult, e.g., natural, or man-made. – such as floods, tornados, earthquakes, outbreak of deadly disease, deadly contamination of water resources, political violence, and armed conflict with resultant injuries to humans. The planning of the research and ethics clearance processes must usually occur rapidly and in time for deliberation curtailed.
• Rapid Review	Refres to a speedy processing of ethics review applications in about 36-48 hours.

1. PURPOSE

1.1 The purpose of the SOP is to provide researchers, the Mpumalanga Provincial Health Research Ethics Committee (MPHREC) with guidelines for the management of rapid and expedited reviews, as well as for the decision-making processes during these types of reviews.

2. SCOPE

2.1 The SOP applies to MPHREC, researchers / and other stakeholders involved in research projects involving human participants and are in need of rapid or expedited review process.

2.2 The NHREC guidelines (NDoH 2024) permits RECs to establish procedures for Rapid and Expedited Reviews.

3. RAPID REVIEWS

3.1 Rapid review process permits speedy processing of ethics review applications in circumstances that require accelerated preparation for a research project. The usual example of such circumstances is a major incident. However, accelerated preparation for research could be justifiable in a localised emergency context too, e.g., an outbreak of cholera in one geographical area.

3.2 Rapidity of review processes refers to the speed at which administrative processes are carried out, rather than implying the review process becomes cursory and lacking in thoroughness.

3.3 The MPHREC should carefully assess the nature of the research to determine the appropriate review process, bearing in mind that not all research during a major incident is necessarily urgent.

3.4 Careful ethical reflection is essential, notwithstanding any perceived urgency. All the usual ethical norms and standards must be considered.

3.5 The possibility of reciprocal recognition of reviews should occur in a collaborative, harmonious manner, bearing in mind that each REC bears the responsibility of protecting the safety, rights and interests of participants enrolled in the studies it has approved.

3.6 The Rapid Review Process

3.6.1 In a public health emergency, preparations for research must occur rapidly. Speedy processing of ethics review applications is desirable.

3.6.2 Responsibilities of the Researchers:

3.6.2.1 Decide what it is that you want to request to be rapid.

3.6.2.2 Develop the necessary documentation as required by the request.

3.6.2.3 Complete an appropriate application form guiding the MPHREC (Annexure 1).

3.6.2.4 Clearly indicate:

3.6.2.4.1 The title of the research,

3.6.2.4.2 The researcher(s),

3.6.2.4.3 What it is that is being requested,

3.6.2.4.4 If changes were made the nature thereof and where it was made, which documents are attached to the application, and

3.6.2.4.5 Add any explanation to clarify your application

3.6.2.5 Submit the application to the MPHREC secretariat through the NHRD portal (nhrd.health.gov.za), selecting MPHREC from the list of RECs when sending the application.

3.6.3 Responsibilities of the MPHREC:

3.6.3.1 The chairperson allocates the review to a minimum of three reviewers and notifies the secretariat.

3.6.3.2 The application is sent by secretariat (within a day) to three to five independent reviewers who have 36-48 hours for review.

3.6.3.3 As soon as the reviewer reports are received, the chairperson of the MPHREC makes a consolidated response and forwards it to the secretariat.

3.6.3.4 A formal letter of decision of the MPHREC with feedback is sent to the applicant as soon as possible after the decision.

3.6.3.5 If corrections are needed, they are done by the applicant and sent back to the MPHREC secretariat. A rebuttal letter should be included indicating what, how and where in the documentation the corrections were addressed (Corrections should be highlighted in the various documents as well). The total set of new documentation should be included as this will then be the set used for monitoring purposes as required by the NHREC.

3.6.3.6 The updated application is re-sent to the same independent reviewers for the review of the corrections (24 hours).

3.6.3.7 Corrections are either approved by reviewers or further corrections are requested. If additional corrections are requested, they should be corrected (as previously indicated) and resubmitted by the applicants to the MPHREC secretariat.

3.6.3.8 If approved, a letter of approval is sent to the researcher(s) by the MPHREC secretariat.

3.6.3.9 Research can start or continue according to the approved application.

3.6.3.10 The decision is ratified during the next MPHREC meeting.

4. EXPEDITED REVIEW

4.1 The NHREC permits RECs to establish procedures for expedited reviews under two conditions:

4.1.1 Only in certain research studies where research activities pose no more than minimal risk to human participants.

4.1.2 During major incidents where planning of the research and ethics clearance processes must usually occur rapidly.

4.2 The nature of these reviews refers to:

4.2.1 Amendment requests of limited extent.

4.2.2 Aspects of the study that can only be approved as the research progresses, e.g. questionnaires, interview schedules, etc. and that were set out as conditions during the approval.

4.2.3 Transfer of data for analysis.

4.2.4 Systematic, rapid or critical reviews should these require ethics approval.

4.2.5 Major incidents where resources are constrained, i.e. necessitating rapid, yet appropriate planning and ethics clearance of said study with the time for deliberation curtailed.

4.2.6 Collection and use of new/additional data.

4.3 Other types of studies that normally do not need ethical clearance but where the researcher wants an ethics number for publication purposes:

4.3.1 Research that relies exclusively on publicly available information or that is accessible through legislation or regulation. This does not mean that ethical considerations are irrelevant to the research.

4.3.2 Research involving observation of people in public spaces and natural environments, provided:

4.3.2.1 the researcher does not interact directly with individual groups.

4.3.2.2 the researcher does not stage any intervention.

4.3.2.3 the individuals or groups do not have a reasonable expectation of privacy.

4.3.2.4 dissemination of research findings does not identify any individual or groups.

4.3.3 Research that relies exclusively on secondary use of anonymous (non-identifiable) data.

4.3.4 Quality assurance and quality improvement studies, programme evaluation activities and performance reviews not intended for publication. Should publication be envisaged, ethics approval should be obtained before the activity as MPHREC cannot grant retrospective ethics approval.

4.4 The Expedited Review Process

4.4.1 Expedited processes for minimal risk studies

4.4.1.1 Responsibilities of the Researcher:

4.4.1.1.1 Decide what it is that you want to request to be expedited.

4.4.1.1.2 Develop the necessary documentation as required by the request.

4.4.1.1.3 Complete an appropriate application form guiding the MPHREC (Annexure 1).

4.4.1.1.4 Clearly indicate:

4.4.1.1.4.1 The title of the research,

4.4.1.1.4.2 The researcher(s),

4.4.1.1.4.3 What it is that is being requested,

4.4.1.1.4.4 If changes were made the nature thereof and where it was made, which documents are attached to the application, and

4.4.1.1.4.5 Add any explanation to clarify your application

4.4.1.1.5 Submit the application to the MPHREC secretariat through the NHRD portal (nhrd.health.gov.za), selecting MPHREC from the list of RECs when sending the application.

4.4.1.1.6 Upload all required documents on the NHRD portal.

4.4.1.2 Responsibilities of the MPHREC secretariat and MPHREC Chairperson:

4.4.1.2.1 The chairperson allocates the review to a minimum of three reviewers and notifies the secretariat.

4.4.1.2.2 The application is sent by secretariat (within two days) to three to five independent reviewers who have a week for review.

4.4.1.2.3 As soon as the reviewer reports are received, the chairperson of the MPHREC makes a consolidated response and forwards it to the secretariat.

4.4.1.2.4 A formal letter of decision of the MPHREC with feedback is sent to the applicant as soon as possible (approximately three working days) after the decision.

4.4.1.2.5 If corrections are needed, they are done by the applicant and sent back to the MPHREC secretariat. A rebuttal letter should be included indicating what, how and where in the documentation the corrections were addressed (Corrections should be highlighted in the various documents as well). The total set of new documentation should be included as this will then be the set used for monitoring purposes as required by the NHREC.

4.4.1.2.6 The updated application is re-sent to the same independent reviewers for the review of the corrections (three working days).

4.4.1.2.7 Corrections are either approved by reviewers or further corrections are requested. If additional corrections are requested, they should be corrected (as previously indicated) and resubmitted by the applicants to the MPHREC secretariat.

4.4.1.2.8 If approved, a letter of approval is sent to the researcher(s) by the MPHREC secretariat.

4.4.1.2.9 Research can start or continue according to the approved application.

4.4.1.2.10 The decision is ratified during the next MPHREC meeting.

4.4.2 Expedited process for major incidents

4.4.2.1 In order to carry out research in this context, planning of the research and ethics clearance processes must usually occur rapidly and expedited approval sought.

4.4.2.2 When the research is actually dependent on the context of a major incident, the proposal should be approached cautiously. Major incident research should take place with regard to matters that are unlikely to occur in "ordinary" contexts.

4.4.2.3 The MPHREC should consider carefully whether sufficient justification is presented for expedited processing.

4.4.2.4 Informed consent usually has to be obtained rapidly and, in a time, when vulnerability of participants is likely to be extreme. Participants may be incapacitated, which points to difficulties with the usual approach to informed consent. The MPHREC may need to consider alternative approaches such as proxy consent or delayed consent in particular circumstances.

4.4.2.5 Note: All actions and documentation as explained in Clause 4.1 must be followed.

4.4.2.6 However, the process of review will be shortened as discussed in 4.1 of this SOP.

5. SOP REVIEW

The SOP shall be reviewed every five year period or when a need arises.

6. APPROVAL OF THE SOP

APPROVED/ NOT APPROVED

DR LK NDHLOVU
HEAD: HEALTH

12/6/2024
DATE

Effective date 12 06 2024

Annexure 1
Application Form for Rapid or Expedited Review

.....

(Name of the Institution)

NHRD Ref. No:

SECTION 1: STUDY PURPOSE

Not for Degree Purposes/Quality Improvement: **Yes** ☐ **No** ☐

Postgraduate Degree/Diploma: **Yes** ☐ **No** ☐ (state which):

Undergraduate Degree/Diploma: **Yes** ☐ **No** ☐ (state which):

Rapid Review ☐ / Expedited Revied ☐ **(Please tick)**

SECTION 2: STUDY TITLE IN FULL (NO ABBREVIATIONS

Title of the study:

DETAILS OF THE PRIMARY INVESTIGATOR/RESEARCHER	
TITLE (Prof/Dr/Mr/Mrs/Miss/Ms/Other):	
FIRST NAME	
SURNAME	
TELEPHONE/CELL NO	
E-MAIL	
PERSAL NUMBER (EMPLOYEES)	
PROFESSIONAL STATUS, OR STUDENT YEAR OF STUDY AND DEGREE	
DEPARTMENT/DIVISION/RESEARCH ENTITY:	
SITES(S) WHERE THE RESEARCH WILL BE CARRIED OUT (Please furnish hospital/institution and department)	
MAIN SUPERVISOR DETAILS, IF ANY	
TITLE (Prof/Dr/Mr/Mrs/Miss/Ms/Other):	
FIRST NAME	
SURNAME	
TELEPHONE/CELL NO	
E-MAIL	
DEPARTMENT/DIVISION/RESEARCH ENTITY:	
NAME AND DATE OF ETHICS TRAINING	
FUNDING DETAILS	

FUNDER (SPECIFY):	
TOTAL ESTIMATED BUDGET:	

SECTION 3: RATIONALE FOR CONDUCTING THE RESEARCH

1. Choose reasons why expedited review from MPHREC is requested?	
a) Involves non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples.	☐
b) Involves clinical documentation materials that are non-identifiable (data, documents, records).	☐
c) Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s))	☐
d) Revised proposal previously approved through expedited review, full review or continuing review of approved proposal.	☐
e) Minor deviation from originally approved research causing no risk or minimal risk.	☐
f) Progress/annual report where there is no additional risk, for example activity limited to data analysis.	☐
g) For multicentre research where a designated EC has approved the proposal, a participating EC may review participating centre specific information and modifications in the study proposal through full committee meeting/expedited review depending on the importance of local consent related issues involved specific to the centre.	☐
h) Research during emergencies and disasters	☐
Any other (please specify):	
2. Is waiver of consent being requested?	Yes ☐ No ☐
3. Does the research involve vulnerable persons? If Yes give details:	Yes ☐ No ☐

Signature of PI:	
Date:	
Comments of MPHREC Secretariat:	
Signature of Member Secretary:	
Date:	