health
MPUMALANGA PROVINCE
REPUBLIC OF SOUTH AFRICA

Standard operating procedures for the Mpumalanga Provincial Department of Health Research and Ethics Committee

REF: SOP/01/07/ 2023: Research & Epidemiology

MPUMALANGA
THE PLACE OF THE RISING SUN

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1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the standard procedures to be followed when obtaining and maintaining ethical approval for research proposals submitted to Mpumalanga Provincial Department of Health. Furthermore, the standard operating procedures is aimed at ensuring that the review of research studies maintain a balance between the benefit of research and its results (that may be translated into more and better health) and the respect for the participants.

2. INTRODUCTION

2.1 Mpumalanga Province provides a rich arena for health and health-related research because of its excellent health care infrastructure and geographic location as it shares borders with other African Countries (eSwatini and Mozambique). The rate of migration from the said bordering states is high for both economic opportunities and healthcare services. To ensure that residents of Mpumalanga Province are fairly and respectfully treated by researchers, the Provincial Department of Health in Mpumalanga has identified a need to establish the Mpumalanga Department of Health Research and Ethics Committee (MPHREC). This need emanated from: a substantial increase in a number of requests from clinicians and allied staff members to conduct research earmarked for service improvement and publication in scientific journals; staff members registering with academic institutions lacking ethics committees; a lack of an accredited research and ethics committee in the province; ethics committees in academic institutions only assisting registered students for ethical clearance despite having MoUs with the department; and to promote high ethical standards and a need to safeguard the rights, dignity and well-being of prospective participants.

2.2 The approval of an Independent Research Ethics Committee (REC) is a requirement for all clinical and public health research studies in human subjects, especially if research findings are to be shared with a broader audience through publication in an academic journal. A REC is responsible for safeguarding the rights, safety and well-being of all study subjects. Following approval, the investigator must advise RECs of any new information or changes to the study procedures that may affect the conduct of the study and/or increase the risks of study subjects. Consequently, the primary responsibility of each MPHREC member is to decide independently whether the proposed research protects the interests of participants adequately and keeps to exemplary standards in research activities. It is within this context that the Mpumalanga Provincial Department of Health has endorsed and approved the Provincial Health Research and Ethics Guidelines as a guiding document that will regulate research practices in the province.

3. SCOPE

This SOP applies to clinical and public health research studies involving human subjects, genetic modification of organisms or any research proposal that has an impact on people, particularly research studies to be conducted within Mpumalanga Province. The research proposals shall be reviewed in accordance with a standardised research proposal template/format provided for in the Provincial Research Guidelines **(See Annexure 1).**

3.1 Investigator or delegate
Compiles and submits the MPHREC application using tailored MPHREC application forms.

3.2 Secretariat of the MPHREC
Reviews the MPHREC application for compliance with ethical requirements, and an ethics clearance number is generated.

4. GENERAL PRINCIPLES

4.1 MPHREC shall not provide a retrospective review such as when a researcher conducts a study without getting ethical clearance and requires ethical clearance after conducting their study.

4.2 Research studies that may require an expedited review maybe afforded an expedited review only if they have satisfied all requirements in accordance with the research template and checklist. The process of approving major events such as outbreaks of deadly diseases, floods and other natural disasters shall be approved within 1 to 2 days, whereas the total process from submission to approval for major events such as protests and political violence shall take approximately 2 weeks.

4.3 MPHREC shall keep written records of all protocols received for review; this includes proposals, information sheets, informed consent forms, correspondences, approval and rejection letters, ethical clearance certificates, minutes and any other necessary record.

4.4 Decisions, which may be approval, revision of the protocol or rejection, shall be recorded in minutes. Specific suggestions for modifications and reasons for rejection shall be given. The outcomes of the review shall be communicated to the investigators by the Secretariat within 10 working days after MPHREC meetings.

4.5 Changes to the study (except for urgent safety changes) must not be implemented until MPHREC and any other required approvals have been received. In addition to protocol amendments, the MPHREC must be informed of any new information which is likely to affect the safety or well-being of the subjects, reports of new adverse reactions, addition of new investigator sites and suspension or early termination of the study. Annual safety reports must be provided to the MPHREC or more frequently if requested by the MPHREC.

4.6 The consent form and any information given to the participants must clearly provide full contact details of MPHREC secretariat who they can contact in the event of problems and complaints.

4.7 The MPHREC shall ensure that researchers accommodate participants that cannot understand and comprehend the language used in the information materials such as proposals and data collection tools by translating all necessary documents in a language that is easily understood by the participant. The enumerators must also be able to speak and understand the language used by participants.

4.8 In circumstances where in the approved project is non-compliant with the approved protocol and interest of participants are at risk of harm, MPHREC may withdraw approval after following due processes. The MPHREC shall inform the researcher and other interested parties in writing on the decision to suspend the projects and state reasons.

4.9 MPHREC shall submit report to NHREC on an annual basis or as and when required and make sure all the necessary records are available for inspections, assessments and audit.

4.10 Conclusion of the study: The MPHREC should be informed of the end of the study to close the application file.

5. APPLICATION PROCEDURE

5.1 All applications to MPHREC must be made on the common electronic application form. This can be downloaded from the Department's Website: www.mpuhealth.gov.za. The MPHREC application form and other required documents (Such as Questionnaire, Informed Consent Form, Information Sheet, a letter signed by the supervisor from an academic institution, or manager for non-academic research projects, time frames, disclose of conflict of interest, financial interest and/or any information that may result in perception of conflict of interest) are sent to the MPHREC Secretariat for finalising, locking and review of the application.

5.2 In the event MPHREC be unable to review proposals/protocols due to time constraints or any other reason beyond control, then the researchers may be advised to seek ethical clearance from other RECs. This option should only be explored when the secretariat and chairpersons have perused the proposals and satisfied themselves that the researcher has adhered to requirements of the MPHREC.

5.3 Subsequent to the attainment of the ethical clearance the researchers must provide a copy of the ethical clearance certificate (National Health Research EC registration number) to Mpumalanga Provincial Health Research Committee (PHRC) through the National Health Research Database (NHRD) prior to commencing with the project in the Mpumalanga Province. The PHRC will then advise the researcher about the permission process of using healthcare facilities / accessing villages within the province. Following this process, the research will be issued with a permission letter to access healthcare facilities/district in the province.

5.4 Approved research project's progress report must be submitted to MPHREC at least once a year, in writing on the appropriate form – in this context the term "oversee" means nothing more than the annual feedback; the MPHREC assumes no further responsibility for the research. Should a research leader fail to do this, the certificate of approval will be withdrawn, and in which case the project must be discontinued. The certificate of approval can be re- issued if a satisfactory report with reasons for the failure to report is provided.

5.5 Any changes to the original proposal must be brought up for consideration (in writing) to the Secretariat of the MPHREC for assessment and approval. The work covered by the changed applications may not start until a new letter of approval has been issued. A new MPHREC approval certificate will also be issued.

5.6 Any problems experienced during a research project must be reported to the secretariat of MPHREC, who will bring it to the notice of the chairperson to initiate relevant processes to resolve the problem.

5.7 The NHREC will monitor the work of the MPHREC through visits. The NHREC will deal with cases where there are disputes and could not be resolved by MPHREC, especially where a decision could not be made in relation to the approval of research applications by MPHREC.

6. REVIEW PROCESS

6.1 Once an application has been received for an ethical review, the secretariat shall pre-review the proposal and check if all necessary documentations are attached this shall be done using a standardised checklist to ensure that the application forms and proposals adhered to standards requirements of the committee. In the event that forms are not fully completed and proposals having deficiencies the secretariat shall advise researchers accordingly in writing.

6.2 Subsequently, only applications which have successfully passed the secretariat's pre-review stage will be further processed into being pre-reviewed by the committee prior to the sitting of the full committee meeting.

6.3 Should there be a proposal that requires specialised expertise and committee members do not possess such, this shall require specialised skills then a specialist/expert will be sought to be part of that particular review.

6.4 The chairperson shall lead the review process and should the chairperson be unavailable, the vice chairperson shall assume responsibilities of the chairperson. In the absence of both the chairperson and vice chairperson, members of the committee shall elect one MPHREC member to lead the review process. Whoever is leading the meeting shall be the person signing off minutes and decisions of the meeting together with the secretariat.

6.5 Should there be a need to have researchers presenting their proposals in order to clarify some of the queries that may arise during the pre-review and/or review stage then the researcher shall be invited to the meeting. After offering clarifications the researcher / supervisor shall be excused from the meeting to allow the committee to make decisions regarding the proposal.

6.6 Committee members should focus an extensive attention on study design and ethical issues, as these two elements can determine whether a protocol is scientifically sound or not. In an instance where MPHREC is unable to review a research proposal due to time constraints or any other reason beyond control, then the researchers may be advised to seek ethical clearance from other accredited RECs.

7. RECORD KEEPING AND COMMUNICATION OF DECISION

7.1 MPHREC shall keep written records of all protocols received for review; this includes proposals, information sheets, informed consent forms, correspondences, approval and rejection letters, ethical clearance certificates, minutes and any other necessary record.

7.2 Decisions, which may be approval, revision of the protocol or rejection, shall be recorded in minutes. Specific suggestions for modifications and reasons for rejection shall be given. The outcomes of the review shall be communicated to the investigators by the Secretariat within 10 working days after MPHREC meetings.

8. DISCLOSURE OF POTENTIAL CONFLICT OF INTEREST AND CONFIDENTIALITY

8.1 MPHREC members shall sign confidentiality forms on the first meeting of their term in office and will sign declaration forms each time the committee sits;

8.2 Should there be any conflicted member in any research application, the member shall recue him/herself from a meeting, until decisions are made on that particular research application;

8.3 These disclosures must cover the full range of potential interests;

8.3.1 Such as direct benefits like the provision of materials or facilities, and

8.3.2 Financial or in-kind support; for example, payment of travel, accommodation expenses to attend conferences.

8.4 Such disclosure should cover any situation in which the conflict of interest may, or may be perceived to, affect decisions regarding other people;

8.5 Researchers / supervisors have an obligation, at the time of reporting, proposing research, or seeking approval from MPHREC or other regulatory authorities to declare any conflict or interest which has a potential to influence the project and its conduct;

8.6 Members of MPHREC must recluse from the committee when discussion of projects in which they are personally involved takes place, and must not use their membership to gain a favourable advantage.

9. FREQUENCY OF MEETINGS, PREPARATION OF AGENDA, REGISTERS OF MEETINGS

9.1 The MPHREC shall sit at least once per quarter to review and approve research studies. Furthermore, the MPHREC will sit on an ad hoc basis as mandated by the need to develop/review urgent studies. Members of the MPHREC's working committee shall sit monthly in preparation of MPHREC meetings. The quorum of the meeting shall be 33% of the total number of committee members.

9.2 The secretariat shall do the following:

9.2.1 Issue invitations of the meetings;
9.2.2 Ensure that members of the committees notify the office if they are not able to attend the meeting;
9.2.3 Ensure that members of the committees receive research proposals/protocols to be reviewed within 15 working days of the scheduled meeting to ensure massive participation and effectiveness during the meeting;
9.2.4 Record minutes of the meetings and disseminate to members of the committees within 15 working days; and
9.2.5 The chairpersons of the committees may convene meetings on an ad hoc basis depending on the urgency of the matters.

10. HANDLING OF COMPLAINTS

10.1 Handling of minor complaints from researchers shall be done through the secretariat and the chairperson.

10.2 Complaints shall be received in writing and response of such complaints will be done in writing as well;

10.3 Major complaints shall be submitted in writing to the secretariat or chairperson and such complaints will be tabled for discussions in the committee meeting and the committee will respond to the complainant in writing;

10.4 The committee will make efforts to address complaints as presented to them should the complainant be unsatisfied with response; the Accounting Officer shall be approached for guidance.

11. REPORTING ON SERIOUS AND UNEXPECTED ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

11.1 Serious and Unexpected Adverse Events (SUAE), Serious Adverse Events (SAEs) and Adverse Events (AEs) must be reported to the MPHREC secretariat or the chairperson directly within 24 hours;

11.2 Such events may range from death through injury to emotional, social and dignitary harms arising from study participation;

11.3 These reports will be reviewed by MPHREC and a written feedback will be given to the researcher/investigator on each occurrence;

11.4 The MPHREC may, inter alia, require remedial actions, future preventative actions, amendment to the study or closure of the study.

12. PROTECTION OF ANONYMOUS WHISTLE BLOWING

12.1 The protection of anonymous whistle-blowers is crucial in research ethics to encourage individuals to come forward and report any misconduct, unethical practices, or violations without fear of retaliation.

12.2 Whistle-blowers play a vital role in ensuring the integrity and accountability of scientific research, and issues pertaining to whistle blowing will be handled in terms of the department's policy on the protection of whistle blowers.

12.3 Whistle-blowers will be informed about their rights and the protections available to them.

13. SAFETY MONITORING AND PROGRESS REPORT

In accordance with ethics legislations, MPHREC shall monitor adherence of the approved proposals/protocols to minimise risks and protect participants. The frequency and type of monitoring will be in accordance with the degree of anticipated risks to participants.

13.1 The MPHREC monitoring process will be done as follows:

13.1.1 Through quarterly reporting from departments and annual reporting from independent researchers. This will provide MPHREC with information on how the

approved research projects have/are progressing from the time of approval to the completion of those projects.

13.1.2 Departments will be required to submit these quarter progress reports to keep the committee abreast on the research protocols/proposals. Independent researchers will also be required to do the same.

13.1.3 Lines of communication between MPHREC and the applicant will be clearly specified in the communication of the review result of the applicant to outline how monitoring will be conducted

The following will be outlined on the clearance certificate:

- Ethically approved studies must apply for renewal annually
- Ethics approval will not be valid when an annual renewal is not granted by MPHREC
- Applications for annual renewal must be made a month before expiry date stipulated on the clearance certificate.

13.2 Active Monitoring

13.2.1 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 approved and ethically approved research projects. Below is the tool to be used when committee undertakes the active monitoring exercises.

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

13.2.2 The requirements laid down for follow-up reviews, the reviews, and communication procedure. This may vary from the requirements and procedure for the initial decision on an application.

13.2.3 The follow-up review intervals are determined by the nature and events expected in relation to particular research projects, though each research project should undergo a follow-up review at least once a year.

13.3 Events leading to indications for a follow-up review of a study

Indications that will make MPHREC decide to make a follow up or monitoring visits of a project includes:

13.3.1 Any protocol likely to affect the right, safety, and /or well-being of the research participants or the conduct of the study

13.3.2 Serious and unexpected adverse event related to the conduct of the study or study results, and the response taken by investigators, sponsors, and regulatory agencies, when applicable

13.3.3 Any event or new information that may affect the benefit/risk ratio of the study

13.3.4 A decision of a follow-up review will be issued and communicated to the applicant, indicating a modification, suspension, or termination of the MPHREC's original decision or confirmation that the decision is still valid

13.3.5 In the case of the premature suspension/ termination of a research project that was approved by MPHREC, the applicant should notify the MPHREC immediately of the suspension/ termination.

14. RESEARCH ETHICS QUALIFICATIONS OR EXPERIENCE

1.4.1 Members to be appointed must have adequate experience in research and ethics;

1.4.2 In case an appointed member has the relevant research experience and/or qualification, but does not have adequate experience in research ethics, it is the responsibility of the Accounting Officer to provide ethics training to the member.

15. ETHICAL APPROVAL AND CLEARANCE CERTIFICATE

15.1 Under the terms and conditions in the approval letters, it shall be stated that a researcher must immediately report anything that might warrant review of ethical approval of the proposal/protocol, including:

- Serious or unexpected adverse effects;
- Propose changes in protocol;
- Unforeseen events that might affect continued ethical acceptability of the project.

15.2 The ethical clearance certificate shall stipulate the following:

- In case of non-compliance, the researcher will be subjected to the certificate being withdrawn by the committee;
- The certificate will be valid for a period of 12 months;
- If the researcher hasn't collected data within that period, then the certificate will be considered as null and void and will have to be renewed through the ethics committee.

16. ANNEXURES/TEMPLATES TO BE USED

16.1 MPHREC Application Templates/checklist for Researchers

16.2 Risk Levels for Health and Health Related Research

16.3 Generic Consent Form (Adaptable)

16.4 MPHREC Research Proposal Evaluation Form

16.5 MPHREC clearance certificate

17. SOP REVIEW

These standard operation procedures shall be reviewed every five years or amended as and when necessary.

18. SOP APPROVAL

APPROVED / NOT APPROVED

DR LK NDHLOVU
HEAD: HEALTH

6/7/2023
DATE

Effective date 10/07/2023

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MPUMALANGA PROVINCE
REPUBLIC OF SOUTH AFRICA

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Litiko Letemphilo | Departement van Gesondheid | UmNyango WezeMaphilo

MPUMALANGA PROVINCIAL HEALTH RESEARCH AND ETHICS COMMITTEE APPLICATION FOR ETHICS APPROVAL [INITIAL REVIEW]

NB: RESEARCH MAY NOT COMMENCE WITHOUT ETHICS APPROVAL

SECTION A: ADMINISTRATIVE DETAILS

NAME: Principal Investigator (PI) - Prof/Dr/Mr/Mrs/Miss/Ms	
Gender:	
Race:	
Designation and Qualification:	
Professional status (if student, year of study):	
Hospital / Institution where employed	
Full Postal address:	
Contact telephone:	
Cell phone number:	
Email address:	
Full time/part time employment:	
NAME: Co-investigator- Prof/Dr/Mr/Mrs/Miss/Ms	
Designation and Qualification:	
Contact telephone:	
Cell phone number:	
Date of submission:	
Type of review requested:	Exemption from review ☐ Full committee review ☐
Title of the study:	
Protocol number/version (if any)	
WHERE WILL THE RESEARCH BE CARRIED OUT? (interaction with participants)	
Duration of the study:	
Purpose of research: For degree or non-degree:	
Funder (specify):	
Total estimated budget:	

SECTION B: RESEARCH RELATED INFORMATION

Aims and objectives: (please list):

Overview of Research (Lay summary (within 300 words):

Type of Study:

Basic Sciences ☐ Clinical ☐ Cross Sectional ☐ Retrospective ☐
Epidemiological/ Public Health ☐ Case Control ☐ Prospective ☐
Cohort ☐ Qualitative ☐ Socio-behavioural ☐Systematic Review ☐ Quantitative ☐
Biological samples/ Data ☐ Mixed Method ☐ Any others (Specify) ☐_____

Methodology (including justification of the sample size- 100 words):

Statistical Planning:
Has this project been discussed with:

- A professional statistician: Yes ☐ No ☐
- A person with a statistical background: Yes ☐ No ☐

If yes, provide the name of statistician: _____ contact: _____

SECTION C: PARTICIPANT RELATED INFORMATION

1. RECRUITMENT AND RESEARCH PARTICIPANTS

a) Type of participants in the study:

Healthy volunteers ☐ Employees ☐ Patients ☐ Vulnerable persons/ Special groups ☐

Others ☐ *(Specify)* .....

Who will do the recruitment? .....

Participant recruitment methods used:

Posters/ leaflets/Letters ☐ TV/Radio ads/ Social media/ Institution website ☐
Patients / Family/ Friends visiting hospitals ☐ Telephone ☐ Other, specify☐ _____

b) Will there be vulnerable persons / special groups involved? Yes ☐ No ☐ NA ☐

i. If yes, type of vulnerable persons / special groups

Children under 18 yrs ☐ Pregnant or lactating women ☐
Differently abled (Mental/Physical) ☐ Employees/Students/Nurses/Staff ☐
Elderly ☐ Institutionalized ☐ Refugees/Migrants/Homeless ☐
Economically and socially disadvantaged ☐ Terminally ill (stigmatized or rare diseases) ☐

Any other (Specify): .....

.....

.....

ii. Provide justification for inclusion/exclusion: .....

.....

.....

iii. Are there any additional safeguards to protect research participants?.....

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.....

c) Is there any reimbursement to the participants? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ ***Provide details***

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d) Are there any incentives to the participants? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ ***Provide details***

.....

.....

e) Are there any participant recruitment fees/ incentives for the study provided to the PI / Institution? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ ***Provide details***

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2. BENEFITS AND RISKS

(a) i. Are there any anticipated physical/social/psychological discomforts/ risk to participants?

Yes ☐ No ☐

If yes, categorize the level of risk[1] :
Less than Minimal risk ☐ Minimal risk ☐ Minor increase over minimal risk or low risk ☐
More than minimal risk or high risk ☐

ii. Describe the risk management strategy:

.....

[1] *For categories of risk refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 6 Table 2.1*

.....

(b) What are the potential benefits from the study?	Yes	No	If yes,	Direct	Indirect
- For the participant	☐	☐		☐	☐
- For the society/community	☐	☐		☐	☐
- For improvement in science	☐	☐		☐	☐

Please describe how the benefits justify the risks

.....

.....

(c) Are adverse events expected in the study? Yes ☐ No ☐ NA ☐

Are reporting procedures and management strategies described in the study? Yes ☐ No ☐

If Yes, Specify

.....

.....

3. INFORMED CONSENT

a) Are you seeking waiver of consent? If yes, please specify reasons Yes ☐ No ☐

If no, type of consent planned for :

Signed consent ☐ Verbal/Oral consent ☐ Witnessed consent ☐

For children<7 yrs ☐ Verbal assent from☐ Audio-Video (AV)☐

minor (13-18 yrs) along with parental consent☐

Other *(specify)* ☐

.....

.....

- Version number and date of Participant Information Sheet:.....
- Version number and date of Informed Consent Form: .....

b) Who will obtain the informed consent?

PI/Co-I ☐ Nurse/Counselor ☐ Research Staff ☐

Other *(specify)* ☐

.....

.....

c) Participant Information Sheet (PIS) and Informed Consent Form (ICF)

- English ☐ Local language ☐

Provide details ☐

.....

.....

d) Provide details of consent requirements for previously stored samples if used in the study

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.....

e) Elements contained in the Participant Information Sheet(PIS) and Informed Consent Form (ICF

Simple language	☐	Data/ Sample sharing	☐	Statement that consent is voluntary	☐
Risks and discomforts	☐	Need to recontact	☐	Commercialization/ Benefit sharing	☐
Alternatives to participation	☐	Confidentiality	☐	Statement that study involves research	☐
Right to withdraw	☐	Storage of samples	☐	Use of photographs/ Identifying data	☐
Benefits	☐	Return of research results	☐	Contact information of PI and Member	☐
Purpose and procedure	☐	Payment for participation	☐	Secretary of Ethics Committee	☐
				Compensation for study related injury	☐

Others(Specify) ☐

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.....

4. PAYMENT/COMPENSATION

(a) Who will bear the costs related to participation and procedures[2] ?

PI ☐ Institution ☐ Sponsor ☐ Other agencies ☐ *(specify)*

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.....

Is there a provision for free treatment of research related injuries? Yes ☐ No ☐ N/A ☐
If yes, then who will provide the treatment?

.....

.....

(a) Is there a provision for compensation of research related SAE? If yes, specify.
Yes ☐ No ☐ N/A ☐

Sponsor ☐ Institutional/Corpus fund ☐ Project grant ☐ Insurance ☐

(a) Is there any provision for medical treatment or management till the relatedness is determined for

[2] *Enclose undertaking from PI confirming the same*

injury to the participants during the study period? If yes, specify.

Yes ☐ No ☐ N/A ☐

.....

.....

(b) Is there a provision for ancillary care for unrelated illness during the study period? If yes, please specify.

Yes ☐ No ☐

5. STORAGE AND CONFIDENTIALITY

6. (a) Identifying Information: Study Involves samples/data. ***If Yes, specify***

Yes ☐ No ☐ NA ☐ Anonymous/Unidentified ☐ Anonymized:

Reversibly coded ☐ Irreversibly coded ☐ Identifiable ☐ If identifiers must be retained, what additional precautions will be taken to ensure that access is limited /data is safeguarded? (e.g. data stored in a cabinet, password protected computer etc.) .....

7.

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8.

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(b) Who will be maintaining the data pertaining to the study?

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(c) Where will the data be analyzed[3] and by whom?

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For how long will the data be stored?

.....

.....

(d) Do you propose to use stored samples/data in future studies? Yes ☐ No

[3] *For example, a data entry room, a protected computer etc.*

☐ Maybe ☐

If yes, explain how you might use stored material/data in the future?.....

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9. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

(a) Will the results of the study be reported and disseminated? If yes, specify. Yes ☐ No ☐ NA ☐

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.....

(a) Will you inform participants about the results of the study? Yes ☐ No ☐ NA ☐

) Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? If yes describe in brief (Max 50 words) Yes ☐ No ☐ NA ☐

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.....

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(a) Is there any plan for post research benefit sharing with participants? If yes, ***specify*** Yes ☐ No ☐ NA ☐

.....

(a) Is there any commercial value or a plan to patent/IPR issues? If yes, please provide details Yes ☐ No ☐ NA ☐

.....

(a) Do you have any additional information to add in support of the application, which is not included elsewhere in the form? If yes, provide details. Yes ☐ No ☐

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(b)

SECTION D: DECLARATION AND CHECKLIST

	1. **DECLARATION (Please tick as applicable)**
☐	I/We certify that the information provided in this application is complete and correct.
☐	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
☐	I/We confirm that this study will be conducted in accordance with the latest Guidelines for Research (Ethics in Health Research, 2015) and other applicable regulations and guidelines of research Human Participants.
☐	I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.
☐	I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted.
☐	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.
☐	I/We declare that the expenditure in case of injury related to the study will be taken care of.
☐	I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
☐	I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports and a final report and also participate in any audit of the study if needed.
☐	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
☐	I/We will protect the privacy of participants and assure confidentiality of data and biological samples.
☐	I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.
☐	I/We have the following conflict of interest (PI/Co-I):

	1. …… …… …… 2. …… …… ……
☐	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.

Name of PI: ……

Signature: ……

Name of Co-PI: ……

Signature: ……

Name of Supervisor: ……

Signature: ……

Name of HOD: ……

Signature: ……

2. CHECKLIST

s. No.	Items	Yes	No	NA	Enclosure No	EC Remarks (If applicable)
ADMINISTRATIVE REQUIREMENTS						
1	Cover letter	☐	☐	☐		
2	Brief CV of all Investigators	☐	☐	☐		
3	Good Clinical Practice (GCP) training of investigators in last 3 years	☐	☐	☐		
4	Approval of scientific committee	☐	☐	☐		
5	EC clearance of other centers	☐	☐	☐		
6	Agreement between collaborating partners	☐	☐	☐		
7	MTA between collaborating partners	☐	☐	☐		
8	Insurance policy/certificate	☐	☐	☐		
9	Evidence of external laboratory credentials in case of an externally outsourced laboratory study certification	☐	☐	☐		
10	Copy of contract or agreement signed with the sponsor or donor agency	☐	☐	☐		
11	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and	☐	☐	☐		

	modification(s) to protocol					
PROPOSAL RELATED						
1	Copy of the detailed protocol	☐	☐	☐		
2	Investigators Brochure (If applicable for drug/biologicals/device trials)	☐	☐	☐		
3	Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated)	☐	☐	☐		
4	Assent form for minors (12-18 years) (English and Translated)	☐	☐	☐		
5	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)	☐	☐	☐		
6	Advertisement/material to recruit participants (fliers, posters etc)	☐	☐	☐		
ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY						
1		☐	☐	☐		
2		☐	☐	☐		
3		☐	☐	☐		

For multicentre research.
MTA-Material transfer agreement; CTRI-Clinical Trial Registry-India; DCGI-Drug Controller General of India; HMSC- Health Ministry's Screening Committee; NAC-SCRT- National Apex Committee for Stem Cell Research and Therapy; IC-SCR-Institutional committee for Stem Cell Research; RCGM- Review Committee on Genetic Manipulation; GEAC- Genetic Engineering Approval Committee; BARC- Bhabha Atomic Research Centre

SECTION D: DECLARATION

Additional Annexures

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(Annexure 1)

Application Form for Expedited Review

.....

(Name of the Institution) MPHREC Ref. No.* ***(For office use):***

Title of study:

.....

.....

.....

Principal Investigator (Name, Designation and Affiliation):

.....

.....

.....

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?	Yes ☐ No ☐
If Yes give details:	
Signature of PI:	
Date:	
Comments of MPHREC Secretariat:	
Signature of Member Secretary:	
Date:	

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(Annexure 2)

Application Form for Exemption from Review

.....

(Name of the Institution) MPHREC Ref. No. *(For office use):*

Title of study: .... Principal Investigator (Name, Designation and Affiliation): ....

1. Choose reasons why exemption from ethics review is requested?	
a) Research on data in the public domain/ systematic reviews or meta-analyses.	☐
b) Observation of public behavior/ information recorded without linked identifiers and disclosure would not harm the interests of the observed person	☐
c) Quality control and quality assurance audits in the institution.	☐
d) Comparison among instructional techniques, curricula, or classroom management methods.	☐
e) Consumer acceptance studies related to taste and food quality.	☐
f) Public health programmes by government agencies.	☐
Any other (please specify in 100 words):	

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

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(Annexure 3)

Continuing Review / Annual report format

.....

(Name of the Institution) MPHREC Ref. No. *(For office use):*

Title of study: .... Principal Investigator (Name, Designation and Affiliation): ....

Date of MPHREC Approval:	
Validity of Approval:	to
Date of Start of study:	
Proposed date of Completion:	
Period of Continuing Report:	to
(a) Does the study involve recruitment of participants?	Yes ☐ No ☐
	If yes, Total number expected:
	Number Screened:
	Number Enrolled:
	Number Completed:
	Number on follow-up:
(b) Enrolment status –	Ongoing: ☐ Completed: ☐ Stopped: ☐

(c) Any other remark:	
(d) Have any participants withdrawn from this study since the last approval?	Yes ☐ No ☐ NA☐
If yes, total number withdrawn and reasons:	
(e) Is the study likely to extend beyond the stated period?	Yes ☐ No ☐
If yes, please provide reasons for the extension:	
(f) Have there been any amendments in the research protocol/Informed Consent Document (ICD) during the past approval period?	Yes ☐ No ☐
If yes, date of approval for protocol and ICD	
(g) In case of amendments in the research protocol/ICD, was re-consent sought from participants?	Yes ☐ No ☐
If yes, when / how:	
(h) Is any new information available that changes the benefit - risk analysis of human participants involved in this study?	Yes ☐ No ☐
If yes, discuss in detail:	
(i) Have any ethical concerns occurred during this period?	Yes ☐ No ☐
If yes, give details:	
(j) Have any adverse events been noted since the last review?	Yes ☐ No ☐
Describe in brief:	
(k) Have any SAE's occurred since last review?	Yes ☐ No ☐
If yes, number of SAE's :..... Type of SAE's:	

Is the SAE related to the study?	Yes ☐ No ☐
Have you reported the SAE to EC? If no, state reasons:	
(l) Has there been any protocol deviations/violations that occurred during this period?	Yes ☐ No ☐
If yes, number of deviations .... Have you reported the deviations to EC? If no, state reasons Yes ☐ No ☐	
(m) Are there any publications or presentations during this period? If yes give details?	Yes ☐ No ☐
Any other comments	
Signature of PI:	
Date:	

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(Annexure 4)

Application/Notification form for Amendments

.....

(Name of the Institution) MPHREC Ref. No. ***(For office use):***

Title of study: .... Principal Investigator (Name, Designation and Affiliation): ....

Date of MPHREC approval:				
Date of start of study:				
S.No	Existing Provision	Proposed Amendment	Reason	Location in the protocol/ICD [4]
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) ☐ 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:				

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

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(Annexure 5)

Protocol Violation/Deviation Reporting Form (Reporting by case)

.....

(Name of the Institution) MPHREC Ref. No. *(For office use):*

Title of study: .... Principal Investigator (Name, Designation and Affiliation): ....

Date of MPHREC approval:		
Date of start of study:		
Participant ID:		
Date of occurrence:		
(a) Total number of deviations /violations reported till date in the study:		
(b) Deviation/Violation identified by:	Principal Investigator/study team ☐	
	Sponsor/Monitor ☐	
	SAE Sub Committee/EC ☐	

(c) Is the deviation related to (Tick the appropriate box) :

Consenting	☐	Enrollment	☐	Laboratory assessment	☐
Investigational Product	☐	Safety Reporting	☐	Source documentation	☐
Staff	☐	Participant non-compliance	☐	Others *(specify)*	☐

.....
.....

(d) Provide details of Deviation/Violation:

…… …… …… ……
(e) Corrective action taken by PI/Co-I: …… …… …… ……

(f) Impact on (if any):	Study participant ☐
	Quality of data ☐
Are any changes to the study/protocol required?	Yes ☐ No ☐
If yes, give details: …… ……	
Signature of PI:	
Date:	

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(Annexure 6)

Serious Adverse Event Reporting Format

This form must be completed and returned to the MPHREC secretariat within 24 hours for serious adverse events and unexpected events. One form is to be completed per participant, even if several participants are involved in a similar adverse event.

.....

(Name of the Institution) MPHREC Ref. No. *(For office use):*

Title of study: .... Principal Investigator (Name, Designation and Affiliation): ....

PARTICIPANT INFORMATION	
Participant ID:	
Participant Age:	
Participant Gender:	
Weight:.....(Kgs)	
Height:.....(cms)	
SERIOUS ADVERSE EVENT (SAE)	
Suspected SAE diagnosis:	
SAE Report Type	Initial ☐ Follow-up ☐ Final ☐
If Follow-up report, state date of Initial report:	
Describe the event [5]:	
Date of reporting SAE:	
.....	

[5] *Duration, setting, site, signs, symptoms, severity, criteria for regarding the event serious*

.....
.....
.....

1. Details of suspected intervention causing SAE[6]

.....
.....
.....
.....

2. Have any similar SAE occurred previously in this study? If yes, please provide details.	Yes ☐ No ☐

.....
.....
.....

3. In case of a multi-centric study, have any of the other study sites reported similar SAEs?	Yes ☐ No ☐

(Please list number of cases with details if available):

.....
.....
.....

4. Tick whichever is applicable for the SAE: (Kindly note that this refers to the Intervention being evaluated and NOT disease process):

(a) Expected event ☐ Unexpected event ☐

(b) Hospitalization ☐ Increased Hospital Stay ☐ Death ☐

Congenital anomaly/birth defect ☐ Persistent or significant disability/incapacity ☐

Event requiring intervention (surgical or medical) to prevent SAE ☐

Event which poses threat to life ☐ Others (specify) ☐

.....
.....

In case of death, state probable cause of death

.....
.....

(c) No permanent/significant functional/cosmetic impairment ☐

(d) Permanent/significant functional/cosmetic impairment ☐

(e) Not Applicable ☐

5. Describe the medical management provided for adverse reaction (if any) to the research

[6] *Refers to research intervention including basic, applied and operational research or clinical research, except for investigational new drugs. If it is an academic clinical trial, mention name, indications, dosage, form and strength of the drug(s)*

participant. (Include information on who paid, how much was paid and to whom):

.....
.....
.....
.....

6. Provide details of compensation provided / to be provided to participants (Include information on who pays, how much, and to whom)

.....
.....
.....
.....

7. Outcome of SAE	Fatal	☐
	Continuing	☐
	Recovering	☐
	Recovered	☐
	Unknown	☐
	Other *(specify)*	☐ .....

8. Provide any other relevant information that can facilitate assessment of the case such as medical history:

.....
.....
.....
.....

9. Provide details about PI's final assessment of SAE relatedness to research:

.....
.....
.....
.....

Signature of PI:	
Date:	

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(Annexure 7)

Premature Termination/Suspension/ Discontinuation Report Format

.....

(Name of the Institution) MPHREC Ref. No. *(For office use):*

Title of study: .... Principal Investigator (Name, Designation and Affiliation): ....

1.	Date of EC approval:	
2.	Date of start of study:	
3.	Date of last progress report submitted to EC:	
4.	Date of termination/ suspension/ discontinuation:	
5.	Tick the appropriate	Premature Termination ☐
		Suspension ☐
		Discontinuation ☐
Reason for Termination/Suspension/Discontinuation:		
Action taken post Termination/ Suspension/Discontinuation (if any):		
6.	Plans for post study follow up/withdrawal (if any):	
7.	Details of study participants:	Total participants to be recruited:
		Screened:

[7] *Describe post-termination/suspension/ discontinuation follow up plans if any. Also describe any withdrawal plans for the study.*

	Screen failures:
	Enrolled:
	Consent Withdrawn Reason (Give details):
	…… …… ……
	Withdrawn by PI (Reasons (Give details)):
	…… …… ……
	Active on treatment:
	Completed treatment :
	Participants on follow-up:
	Participants lost to follow up:
	Any other:
	Number of drop outs (Reasons for each drop-out):
	…… …… ……
Total number of SAEs reported till date in the study:	

Have any unexpected adverse events or outcomes observed in the study been reported to the EC?	Yes ☐ No ☐
Have there been participant complaints or feedback about the study?	Yes ☐ No ☐
If yes, provide details: …… ……	
Have there been any suggestions from the SAE Sub Committee?	Yes ☐ No ☐
If yes, have you implemented that suggestion?	Yes ☐ No ☐
Do the procedures for withdrawal of enrolled participants take into account their rights and welfare?	Yes ☐ No ☐
(e.g., making arrangements for medical care of research participants): If Yes, provide details …… …… Summary of results (if any): …… …… ……	

Signature of PI:	
Date:	

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(Annexure 8)

MPHREC Generic Information Sheet and Consent Form

Introduction of the enumerator

Identify yourself and the institution you are representing.

Brief introduction and background of the study

Describe the problem that this research project is trying to solve and its intended purpose.

What will the study involve?

Will the participants be requested to provide a blood sample or provide any medical or private and personal information? In the informed consent document, it is important to not deviate too far from the topic of the study with examples to explain certain concepts. But on the other hand, you should seek to make sure all the necessary information is gathered.

Your voluntary participation and right to withdrawal

Request the potential respondent for permission to participate in the study and also indicate the estimated time of the interview.

Explain to the respondent that **participation is voluntary** and not being forced to take part in this study. The choice of whether to participate or not, is the respondent's decision alone. If they choose not to take part, they will not be affected in any way whatsoever. If they agree to participate, they may stop participating in the research at any time and there won't be any penalties or prejudice.

Confidentiality and Anonymity

Explain how confidentiality and anonymity will be upheld during and after the study, thus explain what will happen to the data collected.

Should the enumerator need to tape-record the interview, they should seek permission from the researcher first.

Study risks/discomforts

The enumerator must explain any risks and harm that maybe associated with participation in the study should there be any, these risks should be explained and discussed in the informed consent document. Inserting the section on potential risks may prevent the misunderstandings about the project. Some of the risks that may need to be mentioned include the risk to individual such as breach of confidentiality and other physical risks such as risks associated with drawing of blood or non-physical risks such as loss of privacy. There may be other unknown risks to participation that an investigator might want to share with participants. For example, research results could have the potential under certain circumstances be misconstrued and used to discriminate and/or stigmatize a population.

Study benefits associated with the study

Are there any immediate or indirect benefits from participating in the study? The consent form must clearly explain what the benefits will be. The researchers should be careful with emphasising more on immediate benefits such as nutritional supplements, food or compensation because this may lead to false inducement. However, the points that the researcher may need to mention on the informed consent are: benefits of the study to the society and likely lack of immediate benefit to participants.

How participants will be protected?

It should be emphasised in the consent form that the identity of the participants will be protected at all times, and that data will be kept secured in locked cabinets in a locked room or in password protected databases.

Who to contact if you have been harmed or have any concerns

This research has been approved by the Mpumalanga Provincial Health Research and Ethics Committee (MPHREC). If there are any complaints about ethical aspects of the research or any feeling that the respondent has been harmed in any way by participating in this study the MPHREC secretariat must be contacted on 0137663766 or chairperson on 0137663429.

CONSENT: (a consent should be documented with a signature on a separate sheet).

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I have been informed of the study purpose and of my rights as a study participant. The investigator has offered to answer my questions concerning this study. I hereby:

- consent to participate in the study: | Yes | No |
- allow the researcher to audio record the interview proceedings: | Yes | No |
- Consent for storage and future use of my information and blood sample: | Yes | No |

Participant's Name: _____ Name of Researcher/Witness_____

Signature: _____ Signature:_____

Date: _____ Date: _____

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(Annexure 9)

Active Monitoring Form

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

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(Annexure 10)

Ethics Applications: Determining the Level of Risk

1. **Minimal risk**
• Research involving the analysis of existing statistics, as well as literature, documents and information in the public domain, for example in public libraries, public archives, on websites, newspapers, or newsletters.
• The probability or magnitude of harm or discomfort anticipated in the research is not greater in itself than that ordinarily encountered in daily life (the concept of 'daily life' used as a benchmark should be that of daily life as experienced by the average person living in a safe, 'first-world' country).
• Not all research involving material in the public domain is 'minimal risk'. For example, some research studies involving social media, e.g. 'tweets' or 'Facebook' profiles, could be medium risk, depending on the research question under investigation.
2. **Low risk**
• Research in which the only foreseeable risk is one of discomfort or inconvenience.
• The potential risk that would be experienced by the participant by taking part in the research activity (by way of surveys, interview or activity) is not greater than what they would be exposed to in their daily lives, e.g. the questions asked during the interview will not require the participant to reflect on traumatic or negative experiences that would increase the risk of discomfort, emotional distress or harm OR ask them to divulge personal/sensitive information and experiences they would not normally share with a stranger.
• Research in which the investigation of largely uncontroversial topics is undertaken through interviews, surveys and observation.
• The participants are adults and not considered to be a vulnerable research population. Children are generally considered to be a vulnerable research population; however, this rule is not absolute and certain projects involving children may also be considered 'low risk'.
• The research will collect information that would generally be regarded as non-sensitive, such as opinion rather than personal information.
• The information can generally be collected anonymously. Please note the following: "A respondent may be considered anonymous when the researcher cannot identify a given

response with a given respondent. This means an interview-survey respondent can never be considered anonymous, since an interviewer collects the information from an identifiable respondent. An example of anonymity would be the mail survey in which no identification numbers are put on the questionnaires before their return to the research office". (Babbie & Mouton, 2001)
• A study of a social setting, a network, a set of activities, etc. that are not controversial and involve ethnographic methods (participant observation and interviews). A study of informal trade or of public life in a tourist destination could be examples. Much of the knowledge is of a public nature. (Sociology and Social Anthropology)
• Post-hoc analysis of large sample of student essays/exam papers where anonymity of students is assured; much standard socio-economic survey and interviewing work where standard protocols re informed consent, voluntary withdrawal and confidentiality are in place. (Sociology and Social Anthropology)
• Low risk research is research in which the investigation of largely uncontroversial topics is undertaken through interviews, surveys and participant observation. The participants in such research are typically adults or children who are unremarkable in terms of their social status, health status and/or development. As such, there is the little potential for discomfort or inconvenience on the part of participants; where such potential does exist, the predicted discomfort or inconvenience would be minor.
3. **Medium risk**
• Research in which there is a potential risk of harm or discomfort, but where appropriate steps can be taken to mitigate or reduce overall risk.
• It is highly probable that the participant would experience major discomfort, emotional distress, or a range of negative emotions while participating in the research activity. The participant would be asked to reflect on personal matters that they would not normally share with anyone outside of the research context or they would be asked to reflect on or respond to questions on a topic that is considered sensitive and/or controversial. The potential risk of participation could include emotional distress which could necessitate referral for counselling. The participants in the study would be groups that are considered vulnerable or stigmatised, but this could also include the case where non-vulnerable populations would be rendered vulnerable due to their participation in your research activities.
• A study of vulnerable social categories, e.g. relationships between children and adults as experienced by both these categories. A study of controversies about school discipline is an example. Some of the knowledge is private and is based on a relation of trust between researcher and participants. (Sociology and Social Anthropology).
• Dealing with potentially sensitive topics such as HIV, sexuality, rape, violence, but one cannot presume that sensitivity can be generalised across all cultural/social contexts. (Example: researchers in Uganda maintained that stigma re HIV not an issue there compared to SA, so very different context in which to make judgements re potential harm or discomfort.) (Sociology and Social Anthropology).
• Medium risk research is research in which there is an increased potential for emotional or psychological discomfort, due to either the topic investigated being controversial or connected to social stigma or the participants themselves being vulnerable. Such research could be harmful to the participant if not managed properly by the researcher.

• One or more of the following apply: ➢ The research topic is 'sensitive'. ➢ Information gathered is personal rather than opinion or attitudes, or a combination of both. ➢ The information needs to be collected with personal identifiers (name, student number, etc). ➢ The research participants may come from a vulnerable or marginalised group such as those with disabilities, people living with HIV or other chronic disease, the economically or educationally disadvantaged, etc.
4. **High risk**
• Research in which there is a real and foreseeable risk of harm and discomfort to participants and or the research team, and which may lead to serious adverse consequences if these risks are not managed in a responsible manner. High-risk research could also be described as research involving highly sensitive topics and/or the participation of very vulnerable and marginalised individuals/groups.
• Criminal activities that are linked to names, or ones in which victims of sexual abuse are asked questions about their abuse in ways that provoke flashbacks. (Sociology and Social Anthropology)
• A study involving vulnerable social categories where exploitation or severe personal loss is involved, e.g. research re sexual abuse, abortion, crime, drugs, witchcraft accusations, etc. The knowledge that is gained in this category of risk often involves intimate or secretive aspects. Information that is provided is often not meant to be published in detail. (Sociology and Social Anthropology)
• Research with/on political dissidents in a very repressive political environment; research on whistle-blowers. (Sociology and Social Anthropology)
• A study on bereavement. (Sociology and Social Anthropology)
• A study on children's access to pornography. (Sociology and Social Anthropology)
• High risk research is research in which there is a foreseeable risk of emotional or psychological discomfort or harm if not managed in a responsible manner. Such research involves intimate details of vulnerable participants, and highly sensitive topics. (Department of General Linguistics)
• A study on political refugees.
• A study on ex-criminals.
• Any study on prisoners.
• A study on cutting behaviour among adolescent girls, with a waiver of parental consent.
• A study of bereavement among adolescents in a high school setting.
• One or more of the following apply: ➢ Research involving highly sensitive topics and/or very vulnerable and marginalised individuals or communities. ➢ Research involving deception of research participants. ➢ Research investigating illegal activities; research involving participants who are illegal immigrants or engaged in illegal activities. ➢ Agreeing to participate in the research may well place participants at real risk of harm. ➢ Information revealed during the course of the research may place the researcher at risk

of breaking the law, e.g. research investigating gang activities and possession of illegal firearms.

- The research may reveal information that requires action on the part of the researcher that could place the participant or others at risk e.g. research involving child victims of physical or sexual abuse, victims of domestic violence, etc.

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Litiko Letemphilo | Departement van Gesondheid | UmNyango WezeMaphilo

MPUMALANGA PROVINCIAL HEALTH RESEARCH AND ETHICS COMMITTEE

NHREC REGISTRATION: REC----------

ETHICAL CLEARANCE CERTIFICATE

Name of Principal Investigator		**Ref Number/Version**	
Institution			
Supervisor			
Project title:			
Meeting Date		**Clearance Number**	

Approval of this project from MPHREC is valid from <<relevant date>> to <<relevant date>> subject to the following conditions being met:

1. The gatekeeper permission is obtained.
2. The Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
3. The Principal Investigator will notify the MPHREC of any event that requires a modification to the protocol or other project documents and submit any required amendments in accordance with the instructions provided by the MPHREC.
4. The Principal Investigator will submit any necessary reports related to the safety of research participants in accordance with MPHREC Standard Operating Procedures.
5. The Principal Investigator will report to the MPHREC annually in the specified format and notify the MPHREC when the project is completed at all sites.
6. The Principal Investigator will notify the MPHREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.
7. The Principal Investigator will notify the MPHREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation.
8. The Principal Investigator will notify the MPHREC of his or her inability to continue as Principal Investigator including the name of and contact information for a replacement.

The MPHREC wishes you every success in your research.

Yours sincerely,

(NAME)
MPHREC CHAIRPERSON
Tel:
Email:

Secretariat:

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RESEARCH PROPOSAL CHECKING TOOL

(Research studies)

Mpumalanga Provincial Health Research and Ethics Committee

RESEARCH PROPOSAL/TOPIC:

_____

_____

_____

NAME OF THE RESEARCHER: _____

INSTITUTION: _____

REQUEST FOR ACCESS:		
Sampled Population:		
Sampled Facilities:		
Sample Size:		
Ethics Certificate:	**Yes: Number:**_____	**No**
NHRD Number:		

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Section	Comments	Yes	No
1. Title Page: This should include the title of the project; name and student number, if student; your department or faculty; the name of the degree sought; the names of your supervisors, and the date of submission.			
2. Abstract (for some institutions) This should include the problem under investigation; the research methodology and theoretical orientation; and the expected outcomes and implications of the research.			
Introduction			
3. Background information Provide relevant background to the study, supported by evidence			
4. Research Aim/Purpose Provide the main aim of the study (A broader statement)			
5. Research Objectives List objectives of the study			
6. Research Questions/Research Hypothesis What are research questions to answer or what are some of the statements to test?			

7. Problem Statement Provide a concise statement about an area of concern, a condition to be improved, a difficulty to be eliminated, or a troubling question that exists in scholarly literature, in theory, or in practice that points to the need for meaningful understanding and deliberate investigation			
8. Significance of the Study The significance of the study should reflect on the extent of the contribution made by the study to improve our understanding, to change a concept or to promote a new hypothesis in a particular field of research			
9. Definition of Terminology Define main term used in the study, including operational definition of selected terms			
10. Literature Review The literature review provides the rationale for your research topic. It should give an overview of the current research on the topic area. It should identify a gap in the research. This is important because it shows why your topic is important. The literature review should also review relevant methodologies, which show how your research is to be done			
Research Methodology: this section will include a number of subsections. It should describe the type of study you propose to do as well as how you propose to do it. You need to describe your participants/subjects, your data collection procedure and method of data analysis, as well as the limitations of your project.			

11. Research Strategy Explain the qualitative and/or quantitative methods that you will use to gather data for your study in detail. These methods may include focus groups, depth interviews, observation, a survey questionnaire, an experimental study, etc.			
12. Target population Clearly define and delineate the target population and context of the proposed study.			
13. Sample strategy Discuss the method to be used for determining the target sample size of your study. Indicate the target sample size that you wish to achieve.			
14. Data collection instruments Explain the qualitative and/or quantitative methods that you will use to gather data for your study in detail. These methods may include focus groups, depth interviews, observation, a survey questionnaire, an experimental study, etc. Remember to comprehensively motivate your choice of data collection methods.			
15. Validity and reliability Discuss measures of Validity and Reliability or Trustworthiness			

16. Data analysis Briefly indicate how you would validate, edit, code and clean your data in preparation for statistical and / or qualitative analysis. Mention the software programmes that you will use to code and analyse your data.			
17. Pilot study Explain in detail how you will pre-test your survey questionnaire or data collection instrument			
18. Limitation of the research What are the potential limitation to this study			
19. Ethical considerations Discuss any potential ethical issues, benefits, confidentiality, privacy etc.			
20. Proposed time frame and Budget A brief timeline for the project Include a realistic project budget in this section in which you outline the major expenses you expect to incur during your research project.			
21. Bibliography A full list of all references cited in in the proposal. Any preferred referencing conventions.			

Please rate this proposal on a scale of 1 to 5, where 1 is the highest grade and 5 is the lowest:

Reviewer's Rating:

Interest and Importance	_____ (1=outstanding; 5 = poor)
Clarity of Goals and Design	_____ (1=outstanding; 5 = poor)
Scientific Methodology	_____ (1=outstanding; 5 = poor)
Feasibility of Project	_____ (1=outstanding; 5 = poor)
Relevance to IMACS	_____ (1=outstanding; 5 = poor)

OVERALL RECOMMENDATION: (*tick the relevant choice*)

Accept without revision---------- ☐
Accept after revisions requested in comments--------- ☐
Re-review after revision---------- ☐
Reject---------- ☐

Comments/Benefits:

_____

_____

_____

_____

Signature of reviewer: _____

Date: _____

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