health
MPUMALANGA PROVINCE
REPUBLIC OF SOUTH AFRICA

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

REF: SOP/01/05/2024: Research & Epidemiology

MPUMALANGA
THE PLACE OF THE RISING SUN

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DEFINITIONS AND ABBREVIATIONS

Definitions

1. Conflict of Interest means a conflict that arises when a person in a position of trust makes a decision from which they themselves, or friends, relatives or associates, or another organisation that they represent stand to benefit in some way.
2. Consensus means a generally accepted opinion or decision among a group of people.
3. Research means a systematic process of collecting and analysing data in order to increase the understanding of a phenomenon with which the researcher(s) are concerned or interested.
4. Research participant means a person who has consented to participate in research.
5. Minor means a person under the age of full legal responsibility.
6. Observational Clinical Research means any non-experimental clinical research where there is no manipulation of variables by the researcher and excludes retrospective research designs.
7. Sensitive Questions means questions, asked either verbally in an interview or as part of a questionnaire, that enquire about a participant's racial or ethnic origin, political opinions, physical or mental health condition, sexual life or practices, religious beliefs, criminal activity or law-breaking behaviour.
8. Retrospective means looking back in time. In relation to research designs, retrospective research deals with data that already exists at the time the research is planned.
9. Secondary Data means data that has been collected by an individual other than the researcher, and generally for a purpose other than that identified in a specific research proposal which identifies a need to utilise the data.
10. Contract Research means research carried out with the involvement, usually financial support or donation, of a manufacturer or supplier of materials that will be used in the research.
11. Adverse Event means an event that occurs during the course of research that either causes physical or psychological harm, or increases the risk of physical or psychological harm, or results in a loss of privacy and/or confidentiality to a research participant or others (such as family members).
12. Serious Adverse Event means an adverse event that causes, or has the potential to cause, physical or psychological harm to a participant. For example, a participant in a qualitative research study experiences a panic attack when recalling a stressful incident from childhood during an interview, requiring counselling and referral to a psychologist. Seriousness of an adverse event may also relate to frequency or

magnitude that is out of character compared to what is known about a related adverse event. For example, an adverse event that happens much more frequently than is expected or causes more harm than expected (in terms of what is known about the adverse event).

13. Research Proposal Deviation and Non-compliance means any action that is taken during the research process that is not in accordance with a MPHREC-approved research proposal, MPHREC Standard Operating Procedures (as these relate to a specific research proposal), or failure to follow written instructions of the MPHREC.
14. Scientific Misconduct means any action which wilfully compromises the integrity of scientific research, such as plagiarism or the falsification or fabrication of data.
15. External applications refer to application for ethical clearance submitted by researchers/organizations who are affiliated with any Mpumalanga Provincial Departments/Municipalities or do not have an MoUs with any of the Mpumalanga Provincial Departments/Municipalities.

Abbreviations

1. MPDoH	Mpumalanga Provincial Department of Health
2. MEC:	Member of the Executive Council
3. MPHREC	Mpumalanga Provincial Health Research Ethics Committee
4. MPHRECTC:	Mpumalanga Provincial Health Research Ethics Committee's Technical Committee
5. NHREC	National Health Research Ethics Council
6. REC	Research Ethics Committee
7. SOP:	Standard Operating Procedures
8. ToR:	Terms of Reference

1. PURPOSE OF THE MPHREC SOP

1.1 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 Health Research Ethics Committee (MPHREC).

1.2 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. RESEARCH REQUIRING ETHICAL CLEARANCE

2.1 In general, all research involving humans, or research requiring access to private data belonging to an organisation, requires ethical clearance meaning that a research proposal (see Annexure 13) must be submitted to the MPHREC for review before it is conducted.

2.2 The above includes research for non-qualification purposes.

2.3 Routine teaching and learning or quality assurance activities not contemplated as being for the purposes of research are not included in Clause 2.1 above. However, if there is any possibility that such activities might lead to a publication, or that publication may at some future time be desired, then prospective ethical clearance must be sought in line with Clause 2.1. Retrospective ethical clearance will not be considered under any circumstances.

2.4 Research requiring secondary use of existing data requires prospective ethical clearance.

2.5 Any research project with a unique title contemplated by a researcher or group of researchers requires individual ethical clearance. In some cases, larger or longer-term studies may encompass smaller individual studies by different groups of researchers. In such cases, the smaller studies which are identified as individual projects with a unique title must each obtain ethical clearance before proceeding with data collection. This will necessitate the submission of a research proposal to the MPHREC for review. It is not the case that the ethical clearance of a larger, encompassing study can be used as a substitute for ethical clearance of each individual smaller study.

3. WAIVERS

3.1 The following types of research (and only the following types) are eligible for waiver applications:

3.1.1 Research relying solely on information in the public domain, legislation or regulations including systematic reviews with or without meta-analysis.

3.1.2 The proposed research is of a purely theoretical nature and does not at any point involve data derived from humans, public or private organisations.

3.1.3 Research involving description of a single or small number (≤ 3) of anatomical specimens that cannot be linked to the identity of a person.

3.2 In such cases, a waiver application may be made to the MPHREC using the Application Form for Exemption from Review (Annexure 3).

3.3 Waiver applications undergo expedited review and are placed on the agenda of an MPHREC meeting for noting once approved.

3.4 If, after review, a waiver application cannot be approved the researcher is notified in writing and advised to submit a research proposal for ethical clearance.

4. APPLICATION PROCEDURE: INTERNAL APPLICATIONS

4.1 All applications for ethical clearance are submitted to the MPHREC through a common electronic application form (Annexure 1). The form can be downloaded from the Department's Website: www.mpuhealth.gov.za. The MPHREC application form is submitted with all annexures as required through the https://nhrd.health.gov.za, or emailed to the MPHREC secretariat (jerrys@mpuhealth.gov.za).

4.2 The version must appear on the file name and cover of the research proposal/application form cover page and must be changed to revised version of the proposal where a resubmission is made.

4.3 Documents that do not have all of the required signatures and dates will be returned to the researcher, regardless of submission deadlines.

4.4 In order to be placed on the agenda of an MPHREC meeting for consideration, a research proposal (see Annexure 13) must be handed in as described in Clause 4.1 no later than the published closing date for a particular REC meeting. No late applications will be considered.

4.5 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. APPLICATION PROCEDURE: EXTERNAL APPLICATIONS

5.1 Each research ethics application requiring ethical review to the MPHREC of an external research proposal must identify a Principal Investigator who takes responsibility for the application process and to whom all correspondence regarding the application will be sent.

5.2 The following must be taken into consideration by external organisations/parties when wishing to submit research proposals for ethical approval to the MPHREC:

5.2.1 The MPHREC Chairperson will make the final decision regarding the number of external research proposals to be included in any MPHREC meeting agenda, with

due consideration to employees of Mpumalanga Department of Health and other Mpumalanga Provincial Departments/Municipalities staff also making use of the MPHREC for ethical review of research proposals.

5.2.2 Research proposals submitted before the deadline for a specific MPHREC meeting but not included on the agenda of that meeting will be held over and included on the agenda of the MPHREC meeting occurring immediately after this (MPHREC meetings are held every quarter).

5.2.3 The MPHREC will not consider research proposals for research involving animals.

5.2.4 A fee may be levied in future for such a service to researchers not affiliated with Mpumalanga Provincial Government, details will be made available on www.mpuhealth.gov.za.

6. RESEARCH PROPOSAL RISK LEVEL IDENTIFICATION

6.1 All research proposals accepted for ethical review are initially stratified as low risk or greater than low risk, as MPHREC reviews only research proposal classified as minimal, low or medium risk. This is carried out as follows:

6.1.1 ***Step 1***

6.1.1.1 Research involving temporarily incapacitated adults (i.e., patients not capable of giving informed consent due to the influence of alterations in consciousness brought about by their condition, or other factors such as medication that they have received).

6.1.1.2 Research involving adults with factual incapacity.

6.1.1.3 Research involving prisoners.

6.1.1.4 Research involving deception, concealment or covert data collection.

6.1.1.5 Any research involving any of the above factors should be considered to be greater than low risk, regardless of any other factors or characteristics of the research. In addition, any research that uses a clinical trial design or any clinical research that uses an observational design should also be considered to be greater than low risk regardless of any other considerations (see Section 1 for definitions of these terms).

6.1.2 ***Step 2***

6.1.2.1 Assuming that neither of the decision points in Step 1 apply (i.e., the research at this point is not identified as being greater than low risk), the process continues by considering whether or not the proposed research involves either a survey or interview.

6.1.2.2 If any participants are younger than 18, then the research should be provisionally classified as greater than low risk.

6.1.2.3 If a questionnaire contains sensitive questions, or if an interview (individual or group) may involve questioning in a sensitive area, then the research should be provisionally classified as greater than low risk. Sensitive questions are defined in Section 1.

6.1.2.4 NB: If any single decision point above leads to provisional classification of the research as greater than low risk, then the final classification of the research must be as greater than low risk.

6.1.3 ***Step 3***

6.1.3.1 If the research data source (i.e., database or similar) has been previously ethically approved by a registered MPHREC, or if the data in the database was clearly intended for research purposes, then the research should be provisionally classified as low risk. However, if the data source was not, at the time that the

research proposal is considered, intended for research purposes then the research should be provisionally classified as greater than low risk.

6.1.3.2 If the research data have been or will be de-identified by the data owner, then the research should be provisionally classified as low risk. Otherwise, the research should be provisionally classified as greater than low risk.

6.1.3.3 If consent has been prospectively obtained for use of the data for research purposes, then the research should be provisionally classified as low risk. Otherwise, the research should be provisionally classified as greater than low risk.

6.1.3.4 NB: If any single decision point above leads to provisional classification of the research as greater than low risk, then the final classification of the research must be as greater than low risk.

6.1.4 ***Step 4***

6.1.4.1 If the proposed research is laboratory research:

6.1.4.1.1 If the research involves bio-banked tissues, then the research should be provisionally classified as greater than low risk. Otherwise, the research should be provisionally classified as low risk.

6.1.4.1.2 If the research involves sampling tissue from participants, then the research should be provisionally classified as greater than low risk. Otherwise, the research should be provisionally classified as low risk.

6.1.4.2 If any single decision point above leads to provisional classification of the research as greater than low risk, then the final classification of the research must be as greater than low risk.

6.1.4.3 NB: If the proposed research is not laboratory research, and it cannot be considered under any of the preceding research types in Step 1 - 4, then the research should be finally classified as greater than low risk.

7. REVIEW PROCESS

7.1 Full Review (using Application Form for Full Review: Annexure 1)

7.1.1 All research proposals that are classified as being of greater than low risk undergo full review.

7.1.2 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.

7.1.3 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.

7.1.4 Each of these research proposals is placed on an agenda for the next available MPHREC meeting.

7.1.5 The secretariat distributes a copy of the research proposal (including all annexures) and a copy of the Ethical Review Form (Annexure 14) to identifies reviewers with the relevant identifying sections completed (i.e., title of the study, researcher name etc.) at least seven calendar days before the relevant MPHREC meeting.

7.1.6 Reviewers independently complete the review for each of the research proposals assigned to them prior to the MPHREC meeting at which the research proposals will be discussed. Reviewers are guided by the criteria in the Ethical Review Form and associated descriptions of ethical acceptability in each case.

7.1.7 At the relevant MPHREC meeting, each reviewer gives a summary of the key findings of their review, followed by the decision that they have assigned.

7.2 Expedited Review (using Application Form for Expedited Review: MPHREC SOP for Expedited and Rapid Review)

7.2.1 Research proposals that are classified as being low risk may undergo expedited review and are submitted using an appropriate form (Annexure 2).

7.2.2 There is no requirement to place expedited review research proposals on the agenda of an MPHREC meeting prior to the review process.

7.2.3 For each research proposal undergoing expedited review, a minimum of two reviewers with an appropriate level of academic qualification is assigned by the Chairperson.

7.2.4 The reviewers independently complete each of the research proposal reviews assigned to them within a week period. Reviewers are guided by the criteria in the Ethical Review Form (Annexure 14) and associated descriptions of ethical acceptability in each case.

7.2.5 The reviewer assigns a decision to each of the research proposals (also recorded on the Ethical Review Form).

7.2.6 If the reviewer's decision is approved or approved subject to minor revision/clarification, then the Ethical Review Forms are returned to the Secretariat and then sent back to the researcher, for revision if required.

7.2.7 Revisions are done by the researcher, who submits version 02 of the Revised Research Proposal to the Secretariat after which an ethical clearance letter is issued.

7.2.8 If the reviewer's decision is provisionally approved subject to major revision (s), then the Ethical Review Form is returned to the Secretariat and then sent back to the researcher.

7.2.8.1 Revisions are done by the researcher, who submits a Revised Research Proposal to the Secretariat, which is then sent back together with the revised research proposal to the reviewer.

7.2.8.2 The reviewer completes another Ethical Review Form recoding the decision.

7.2.9 If the reviewer's decision rejected, then the Ethical Review Form is returned to the Secretariat and then feedback communicated to the researcher.

7.3 Reciprocal Review Process (see MPHREC SOP for Reciprocal and Joint Review)

7.3.1 A local application with a REC Clearance.

7.3.1.1 In the case of multi-centre studies, the possibility of reciprocal review will be explored through an expedited review process.

7.3.1.2 MPHREC may, at their own discretion, recognise prior review and approval of a research proposal by another registered REC to avoid duplication of effort.

7.3.2 An International Application with a REC Clearance.

7.3.2.1 The normal review processes will apply as indicated in Clause 7.1.

7.3.2.2 This application must be accompanied by the full report of the original research ethics committee approval.

7.3.2.3 Different ethics committees may come to different conclusions on the same protocol based on local values, issues or policies.

7.4 *The 'Ethical Considerations' Sub-section of the Research Proposal*

7.4.1 Ethical considerations relevant to a specific research proposal should be comprehensively described in this sub-section of the proposal.

7.4.2 The existence of an information letter and consent form as appendices to the proposal does not preclude full explanation of how the relevant aspects of ethical procedure (which may be repeated in the appendices) will be dealt with.

7.4.3 Specifically, issues related to the following should be described in detail as a minimum:

7.4.3.1 Informed consent and how this will be obtained (including how participants will be enrolled and how informed consent will be recorded).

7.4.3.2 Withdrawal of informed consent.

7.4.3.3 Risks and benefits of participation and how these will be communicated to prospective participants.

7.4.3.4 How confidentiality of participant data will be addressed.

7.4.4 Other details may be required, depending on the nature of the research.

7.4.5 It is important to note that the statement or description of the principles of research ethics (autonomy, beneficence, non-maleficence, and justice) alone is not adequate in this sub-section of the research proposal. These principles may be used as structural sub-headings; however, the emphasis should be on explaining the researcher's proposed actions in order to guarantee compliance with ethical norms and standards as set out in the NHREC guidelines.

7.4.6 More detailed information of some of the important ethical considerations are given below.

7.5 Informed Consent

7.5.1 The National Health Act (Act 61 of 2003) requires that written informed consent be obtained as a condition of health research involving a living person (including where tissue is removed from a living person for the purposes of research).

7.5.2 There must always be a record of the participant's informed consent, regardless of the research design or methodology used (see Annexure 9).

7.5.3 Thus, every research proposal must clearly explain this process and contain appendices showing examples of information sheets and consent forms to be used. In most cases, these will be in the form of a hard copy information sheet (giving information about the study in writing) and consent form.

7.5.4 Informed consent must be recorded in writing by the participant (or a parent/guardian) signing the consent form, unless the research involves electronic data collection without direct participant contact.

7.5.5 **Consent for Online Surveys**

7.5.5.1 In some cases, such as when a survey questionnaire is administered online, it is not possible to provide hard copies of these documents to participants nor to record their signatures.

7.5.5.2 In such cases, the online survey must be designed in such a way that participants are presented with a statement similar to that appearing on a normal consent form.

7.5.5.3 In place of a signature, some form of electronic input (such as a checkbox) must be selected by the participant in order to indicate that they give their consent to participate in the research.

7.5.5.4 The participant's decision (e.g., the data associated with the checkbox) must be recorded and retained by the researcher along with other response data.

7.5.6 **Consent for Voice Recordings**

7.5.6.1 In the case of research making use of voice recordings, a separate consent form must be provided to document participant's consent to having a recording made of their verbal response.

7.5.6.2 Voice recording should be destroyed two years after publication or, if publication of results does not apply, six years after the research has been completed.

7.5.7 **Consent for Photographs and Video Material**

7.5.7.1 Two specific scenarios are relevant to the use of photographic or video material.

7.5.7.1.1 In the first, use is proposed of photographs or video material that is in the public domain (i.e., it is not subject to any access restrictions).

7.5.7.1.2 In such cases, the material may be used 'as is' however every attempt must be made to establish ownership (or copyright) of the material and, if this can be done, permission of the owner(s) must be obtained before such material can be used.

7.5.7.1.3 In the second scenario, photographic or video material created specifically for the purposes of proposed research presents a more significant ethical challenge.

7.5.7.1.4 Because the specific details will vary from case to case it is not possible to be prescriptive, but the following principles apply and must be considered carefully during review:

7.5.7.1.4.1 The use of photographic or video material must be essential to the research method. This must be clearly explained and justified in the research proposal.

7.5.7.1.4.2 Individuals appearing in still or video images of any kind must give written informed consent to do so, in the same way that a research participant would be expected to give informed consent. In the case of children, the same norms apply as would apply to child research participants.

7.5.7.1.4.3 Regardless of any other considerations above, if photographic or video material is to be used as part of the research method the identities of all persons appearing in the photographs or on video must be protected at all times by making use of suitable technology (e.g. imaging technology that obscures facial or other identifying features).

7.5.8 **Minors: Assent**

7.5.8.1 If the proposed participants are younger than 18 years of age and are five years of age or older with normal cognitive function for their age, an assent form must be included.

7.5.8.2 Care must be taken to ensure that information is presented in the assent form in an age-appropriate way that facilitates understanding (this could include diagrams to enhance understanding).

7.5.8.3 A template for compiling assent forms (Annexure 9) may be used as a starting point and modified as required.

7.5.9 **Minors: Non-therapeutic Research and Ministerial Consent.**

7.5.9.1 The National Health Act sets out conditions for non-therapeutic research involving minors in s71(3)(a), one of which is that consent must be obtained from the Minister of Health.

7.5.9.2 The Minister of Health has, however, delegated authority to grant Ministerial consent for non-therapeutic research involving minors to registered RECs.

7.5.9.3 The NHREC has published operational guidelines that RECs should use when considering research proposals of this nature.

7.5.10 **Consent for Use of Secondary Data**

7.5.10.1 Consent may have already been given for secondary data – for example data derived from visits to a health clinic where patients may have given consent for future research usage of data at their first visit. In such cases, no further consent need be obtained.

7.5.10.2 If this is not the case, and collection of the data for research purposes has not previously been contemplated or foreseen, then a waiver of informed consent related to the data may be applied for. The specific conditions under which such waivers may be granted are set out in the NHREC Guidelines.

7.5.10.3 If consent has not been previously obtained, and the data in question has been collected for research purposes, then consent must be obtained from all persons from whom the data has been previously obtained.

7.5.10.4 Where it is foreseen or planned that data stored in clinical databases will be used for research purposes, the database itself may be granted ethical clearance.

7.5.10.5 This clearance does not mean that ethical clearance for the use of this data is not required. Research using such data must be described in a research proposal which must be submitted for ethical clearance.

7.5.11 **Information Letter and Consent Form**

7.5.11.1 All research proposals that involve informed consent must contain, as an annexure, an information letter for prospective participants and a consent from which each participant must complete and sign.

7.5.11.2 The information letter and consent from must be presented to prospective participants as a single document, however the consent from must start at the top of a new page.

7.5.11.3 Prospective participants must initial each page of the information letter in the space provided, and sign and date the consent form.

7.5.11.4 Each participant must give back to the researcher the initialled information letter and signed consent form and must be given a copy of these documents.

7.5.11.5 Information letters must:

7.5.11.5.1 Identify and contain contact details of the researcher and MPHREC Chairperson.

7.5.11.5.2 Not begin with "Dear Participant" as the person reading it for the first time will not be a participant.

7.5.11.5.3 Be written in non-technical, jargon-free and understandable language written directly referring to "I" (the researcher) and "you" (the participant). Indirect terms such as "the participant" or "the researcher" should not be used. An informal and friendly tone is encouraged in information letters.

7.5.11.5.4 Not consist of paragraphs copied and pasted directly from the methodology section of the research proposal without amendment.

7.5.11.5.5 Explain all of the factors listed by the NHREC. If a factor is not applicable, it should be included and clarified with a statement saying it is not applicable (e.g. there should always be a sub-heading about research funding, which in some cases may simply indicate that no funding has been obtained). Particular attention should be paid to voluntariness of participation, withdrawal of informed consent, possible benefits and risks, expected duration of participation, confidentiality, responsibilities of the researcher and participant, that the research has been reviewed and approved by the REC and the channel of communication regarding queries or complaints.

7.5.11.5.6 Make it clear that the participant does not have to make an immediate decision, that they may take some time to decide whether to participate or not, and are free to consult with others before deciding if they wish to do so.

7.5.11.5.7 Contain, at the bottom corner of each page, a place for the participant to initial each page.

7.5.11.6 Consent forms must:

7.5.11.6.1 Contain the title of the research, the date shown on the information letter and must identify and contain contact details of the researcher.

7.5.11.6.2 Be dated.

7.5.11.6.3 Confirm that the participant (i) understands the information provided, (ii) has had an opportunity to ask questions (and if so, obtain satisfactory answers) and (iii) voluntarily consents to participate in the research.

7.5.11.6.4 Provide place for both the researcher and participant to sign.

7.5.11.6.5 Not be pre-signed or pre-dated by the researcher.

7.5.11.7 An information letter and consent form template (Annexure 9) is available and should be used.

7.5.11.8 The information letter and consent form template may be amended if required, however care must be taken to retain all required elements of informed consent.

7.5.12 **Withdrawal of Informed Consent**

7.5.12.1 Withdrawal of informed consent without consequence is in line with the basic ethical principle of autonomy. This must always be made clear to participants, especially the unconditional nature of withdrawal.

7.5.12.2 Anonymous research participation presents a particular problem with regard to withdrawal of informed consent, as any given participant's data will not be identifiable and thus cannot be withdrawn if the participant chooses this option.

7.5.12.3 Although it might be possible to link consent forms to other types of data (e.g. anonymous survey questionnaires) in order to facilitate the process of withdrawal, doing this removes anonymity as participant data can be linked to other identifying data (i.e. a consent form with a name on it).

7.5.12.4 In such cases, Clause 7.5.12.2 should be clearly explained to prospective participants in the information sheet as part of the informed consent process.

7.5.12.5 Provision must be made for withdrawal of consent in cases where young children may be subjected to painful procedures – e.g. venipuncture.

7.5.12.6 In such cases, non-verbal cues and physical withdrawal among other possible indications of withdrawal of consent (or assent), must be clearly explained and the researcher's responses to this and actions must be described.

7.6 Risks and Benefits

7.6.1 In analysing the risk: benefit ratio in proposed research, benefits should always outweigh risks.

7.6.2 However, this should be viewed in a such a way that risk of harm is considered relative to anticipated benefit (including future benefit to others) and importance of the research.

7.6.3 Research of narrow scope, such as that at undergraduate or partial fulfilment Master's level, may have limited benefits and the risk: benefit ratio associated with such studies should take this into consideration.

7.6.4 Wherever there is a risk of emotional distress or physical injury, access to support or medical services should be provided.

7.7 Privacy and Confidentiality

7.7.1 If a participant is not required to provide any identifying information as part of the research, at any time, then their participation is anonymous.

7.7.2 In such cases confidentiality is a non sequitur as no identifying information is available to the researcher to protect.

7.7.3 If a participant is required to provide identifying information to the researcher, then their participation cannot be anonymous as the researcher is aware of their identity.

7.7.4 . In such cases the researcher undertakes to maintain strict confidentiality to prevent unauthorised people from gaining access to the participant's identifying information and thus associate their identity with other (perhaps sensitive) research data.

7.7.5 The term "anonymise", which is often used to refer to the process of removing identifying data from other data is a misnomer, as it does not "make" the data set anonymous. This should rather be referred to as de-identification.

7.7.6 Care must be taken to distinguish between anonymity and confidentiality correctly (as above) in any information communicated to participants for the purposes of informed consent.

7.7.7 In the case of confidentiality, the researcher must clearly explain how personal data will be protected (adequate protection is also a requirement of the Protection of Personal Information Act). This includes how electronic (including voice recording) and hard copy data will be stored and secured and for how long.

7.7.8 It is not possible to guarantee confidentiality when explaining research procedures to prospective participants for informed consent purposes. Certain circumstances may compel a researcher to breach their duty of confidentiality, such as if the researcher is ordered to do so by a court or if there is a convincing case that it would be in the public interest to do so.

7.7.9 It is important that all prospective participants understand that confidentiality is not absolute, and that they are aware of and understand the circumstances under which confidentiality may reasonable be breached.

7.8 *Gatekeepers Permissions*

7.8.1 Gatekeepers Permission from the departments/municipalities or external organisations for research to be conducted on their premises or using their resources must be obtained only once a research proposal has been ethically approved because ethics approval is normally a condition of external permission being granted.

7.8.2 In addition, the issuing of formal letters of permission prior to ethics approval may be problematic as the research design and method on which the decision to grant permission has been based may change after ethics review.

7.8.3 In cases where the viability of a research project is dependent on access to data requiring permission to access, a provisional letter of permission should be obtained. Final permission to access data will be at the discretion of the data owner, pending ethical approval.

7.9 Risk of Injury and Insurance

7.9.1 Participation in research may predispose participants to accidental injury or physical harm.

7.9.2 It is important that the details of insurance cover for related medical expenses (or the fact that there is not cover) is conveyed to prospective participants as part of the informed consent process (i.e. in verbal and written information about the research) where risk of injury or physical harm exists.

7.10 Contract Research

7.10.1 In some cases, research may be carried out as part of an arrangement with a manufacturer or supplier of materials or instruments used in the research.

7.10.2 By their nature, such situations tend to represent a conflict of interests and require forethought to avoid ethical conflicts, using an appropriate form (Annexure 17).

7.10.3 Although the term "contract research" is often used to describe these situations, the presence of a contract or agreement may be instrumental in avoiding many of the ethical pitfalls. The absence of a clear agreement on the other hand is generally more problematic.

7.10.4 Generally, contract research should only occur when there is a written agreement between the manufacturer or distributor and the respective department.

7.10.5 Issues such as the publication of results, the use of trade names, use of the department's name and intellectual property rights (and how this is influenced by payment or donation of materials) must be clearly set out in the agreement.

7.10.6 The agreement must be approved by the Accounting Officer and follow the same procedures as any legal agreement with an external party.

7.10.7 This agreement must be approved before submission of the research proposal to the MPHREC for review.

7.10.8 Under any other circumstances there can be no expectations on the part of a manufacturer or supplier in relation to dissemination or publication of research results.

7.10.9 Manufacturers or suppliers may provide materials for the research at no cost without a written agreement if they choose to do so, but trade names of the materials should not appear in any research proposal, report, dissertation, thesis, manuscript or published article and the manufacturer or supplier may not use the Department's name in relation to the research for promotional purposes or have any claim to intellectual property related to the research.

7.10.10 Importantly, the existence of a written agreement does not in any way ensure compliance with ethical norms and standards.

7.10.11 REC review of these research proposals should give particular attention to the potential conflict between manufacturers and suppliers, rights of participants and the rights of the broader scientific community.

7.11 Research Involving Human Biological Materials

7.11.1 Research proposals for research involving biological materials transferred from a provider to a recipient must be accompanied by a completed Material Transfer Agreement from relevant bodies.

7.11.2 The Material Transfer Agreement must be signed by both the provider and the recipient at the time it is submitted to the MPHREC for consideration.

8. DECISION-MAKING

8.1 Decision Categories

The following decision categories are used to indicate decisions about ethical clearance reached by reviewers.

Decision	Decision Criteria
Approved	**Approved:** The ethics application can be accepted "as is" and no revision is required.
Approved subject to clarification/minor revision to REC Chairperson's satisfaction.	**Minor revision required.** Minor revision includes: • Minor amendments to any subsection of the ethics application as follows: o Minor amendments to information letters, consent forms or questionnaires etc. This typically is limited to improvement of language or grammar, layout or formatting, correction of typographical errors in proposal and/or related

	documents that will improve comprehension or readability by research participants. o Suggestions that an assessor feels may add value to the proposal from an ethical perspective, but the inclusion/exclusion of which is left to the discretion of the supervisor.
Provisionally approved subject to clarification/major revision(s) to the satisfaction of reviewers' or Chairperson(s).	In this context, "major" revision generally means revision: • That is required, not merely suggested and; • That must address problems, flaws or inconsistencies related to research ethics and that go beyond minor errors as described above. • Major revision includes: o Revision of the aims/objectives, research design, methods or ethical considerations and/or; o Significant revision of attachments such as information letters, consent forms, questionnaires, permission letters etc. and/or; o The above could include omissions, such as required annexures that are missing.
Rejected	Rejected means that the proposed research as a whole is not compatible with accepted ethical standards and cannot be salvaged with major revision. Research ethics applications that are rejected cannot be resubmitted for ethical review.

8.2 Decision-making Procedures

8.2.1 Decisions about ethical clearance of research ethics applications are made at an MPHREC meeting.

8.2.2 After MPHREC reviewers have presented a summary of their key findings and decision code as described in Clause 8.1, the Chairperson will enquire from the meeting whether there is consensus on the decision.

8.2.3 If there are two different decision categories equally split between reviewers then the meeting will be asked for consensus on the adoption of the stricter category, or alternatively whether the reviewer who gave the stricter category is willing to change it to a more lenient category after considering the reasoning of the reviewer who gave the more lenient category.

8.2.4 During discussions around achieving consensus, all members present at the MPHREC meeting may contribute and the supervisor (if present) may be asked for clarification of facts if required, although the supervisor may not contribute to the consensus decision. Supervisors who are not MPHREC members may be invited to MPHREC meetings in order to provide clarification about research under discussion, if necessary.

8.2.5 If, despite prolonged deliberation, consensus cannot be achieved on a decision category then the matter is put to a vote.

8.2.6 All MPHREC members who normally have voting rights may vote on such a decision, with the exception of the Chairperson who does not vote.

8.2.7 The decision achieving a simple majority will be recorded as the MPHREC's decision. In the event of a split decision, the Chairperson will cast the deciding vote.

8.2.8 If a decision is difficult to reach consensus on, and represents an ethically complex or challenging case, the Chairperson may suggest the establishment of an ad hoc subcommittee to further investigate the matter and report back to the MPHREC with a recommendation before it is put to a vote. There must be support from the Committee for this course of action, in the form of consensus or a simple majority if it is put to a vote.

9. COMMUNICATING A DECISION AND REVISION OF RESEARCH PROPOSALS

9.1 The Initial Decision

9.1.1 Final research ethics application review decisions, arrived at either by consensus or voting, are recorded in MPHREC meetings by both the Secretariat and the Chairperson.

9.1.2 After each MPHREC meeting, the Secretariat prepares decision letters for each research ethics application on the meeting agenda with a decision.

9.1.3 Each decision letter contains the following information:

9.1.3.1 The relevant identifying and contact details (e.g. researcher names, research proposal title etc.),

9.1.3.2 The decision taken (both the decision code and an explanation of what the code means),

9.1.3.3 An explanation of the next step(s) to be taken including documents that need to be completed and,

9.1.3.4 A reminder that the research may not be commenced until final ethical clearance has been obtained in writing with a clearance number.

9.1.4 If the decision is that the research ethics application is approved, then an ethical clearance letter is sent to the researcher.

9.1.5 Decision letters must be sent to the researcher by electronic mail within five working days of the MPHREC meeting at which the decisions were made.

9.2 Research Ethics applications Requiring Revision (Minor Revision)

9.2.1 Research ethics applications with a minor revision decision must be revised by the researcher in accordance with reviewer comments.

9.2.2 It is the responsibility of the researcher to check the revised version of the research ethics application and to ensure that all of the required revisions have been made.

9.2.3 When the researcher is satisfied that all of the required revisions have been made, the researcher must respond to each of the two reviewers' comments and explain what changes have been made to the original version of the research ethics application. If the researcher has elected to not implement a change suggested by a reviewer, then a concise reason for this should be provided.

9.2.4 The researcher must submit the response to reviewers and a copy of the revised research ethics application (with all required signatures on the cover page, and an updated version name indicated on the cover and revisions clearly highlighted) to the Secretariat.

9.2.5 The response to reviewers and revised ethics application is checked by the MPHREC Chairperson or a Vice Chairperson.

9.2.6 Once the MPHREC Chairperson or Vice Chairperson has approved the above, the Secretariat drafts an ethical clearance letter.

9.3 Research Ethics Applications Requiring Revision (Major Revision)

9.3.1 The researcher's responsibilities with regard to revision of the research ethics application, completion of required documentation and submission are the same as those described in Clauses 9.2.1-9.2.3.

9.3.2 Once the above have been received the Secretariat forwards the response to reviewers and revised research ethics application with an updated version name is indicated on the cover and revisions clearly highlighted to the reviewer(s).

9.3.3 If there is a need for further consensus decision-making, the revised ethics application is placed on a MPHREC meeting agenda and the procedure continues as per Clause 7.1 above.

9.3.4 If Clause 9.3.3 does not apply, the reviewer(s) must complete review of the revised research ethics application within 10 working days.

9.3.5 Review of the revised research ethics application should be limited to assessment of the researcher's compliance with the original revisions required by the reviewer

9.3.6 Based on the conclusion reached by the reviewer(s), a new decision is indicated by the reviewer(s).

9.3.7 The documents referred to in Clause 9.3.2 are forwarded to the Secretariat who in turn forwards the documents to the researcher.

9.3.8 If the decision after review of a revised research ethics application is a minor revision, the process continues as described in Clause 9.2.

9.3.9 If the decision after review of a revised research ethics application is again a major revision, the process continues as described in Clause 9.3.

9.3.10 If the decision code after review of a revised research ethics application is approved, the Secretariat drafts an ethical clearance letter.

10. FINAL ETHICAL CLEARANCE

10.1 When a completed response to reviewers and a copy of the revised research ethics application are received by the Secretariat following a minor revisions decision or the research review decision was approved, an ethical clearance letter may be drafted.

10.2 Every ethical clearance letter must contain the following:

10.2.1 The relevant identifying and contact details (e.g. researcher names, research proposal title etc.),

10.2.2 Confirmation that the research has final ethical clearance,

10.2.3 A unique clearance number,

10.2.4 Any applicable clearance conditions,

10.2.5 The date on which the clearance expires,

10.2.6 A short summary of the steps to be taken in the event that the research ethics application requires amendment, and

10.2.7 A short summary of the steps to be taken in order to renew ethical clearance.

10.3 Ethical clearance may be conditional.

10.3.1 The conditions of such clearance may vary from case to case but are generally related to intermediate steps in or deliverables of the research method that are not available for review at the time the research ethics application is submitted.

10.4 Research ethics applications that aim to generate and use questionnaires or measurement tools as part of the method should be conditionally approved, with a requirement that the newly generated questionnaire or measurement tool be ethically scrutinised in order to secure final unconditional ethical clearance.

10.5 Ethical clearance letters are delivered by electronic mail to the researcher.

11. APPEALS, REFERRALS AND COMPLAINTS

11.1 Appeals

11.1.1 Any researcher may appeal a decision of the MPHREC if they believe the decision to be unfair, using an appropriate form (Annexure 15)

11.1.2 Appeals must be submitted directly to the MPHREC Chairperson in writing, using an appropriate form, within 20 working days of the decision having been communicated.

11.1.3 On receiving an appeal, the Chairperson will convene and chair an ad hoc Appeal Committee within seven working days consisting of at least one Vice Chairperson and two other MPHREC members who were not the original reviewers of the research ethics application in question.

11.1.4 If the Chairperson is conflicted in the appeal, then a Vice Chairperson convenes and Chairs the Appeal Committee.

11.1.5 If necessary, MPHREC members or non-members with specialist expertise may be co-opted to the Appeal Committee.

11.1.6 The Appeal Committee will consider the appeal, and the original review documents and attempt to reach a decision on the matter by consensus which will be to either uphold the original decision or, if there are compelling reasons, to replace the original decision with a different decision.

11.1.7 If consensus is not possible then a voting procedure is followed, similar to that described in Clauses 8.2.5 - 8.2.8 above.

11.1.8 The decision reached by the Appeal Committee is final and communicated to the researcher in writing.

11.1.9 If, on the conclusion of the appeal process described above, a researcher still believes that the original decision or the appeal decision is unfair they may approach the NHREC and submit an appeal.

11.2 Complaints

11.2.1 Complaints related to any aspect of MPHREC functioning, or related to the conduct of MPHREC members, may be made by researchers, MPHREC members, research participants or members of the public.

11.2.2 Complaints should be directed in writing, using an appropriate form (Annexure 16), to the Chairperson of the MPHREC, after which the Chairperson will decide on the appropriate course of action depending on the complaint as per the MPHREC SOP for Complaints Management.

11.2.3 If a complainant does not wish to direct a complaint to the MPHREC Chairperson, then the complaint should be directed in writing to the department as outlined in the complaints management policy, obtainable from the MPDoH website (www.mpuhealth.gov.za).

11.2.4 If a complainant does not wish to direct a complaint to any of the above, they may do so anonymously to the department as per the department's whistle-blowing policy obtainable from MPDoH website (www.mpuhealth.gov.za).

12. WHISTLEBLOWING

12.1 Any person externally or internally to the MPDoH will be able to report any infringement or offence in relation to research by an MPHREC member, Chairperson, Co-Chairperson, Secretariat, administrator officer, researcher, research participant, any

MPDoH personal linked to research or any other person that may have committed such an offence.

12.2 Such reporting must be sent to the MPDoH ethics committee in writing, who will deal with the matter with confidentiality as per the MPDoH's internal Whistleblowers procedures as stipulated in the department's whistle-blowing policy obtainable from MPDoH website (www.mpuhealth.gov.za). The report will remain anonymous as far as possible in law.

13. RENEWAL OF ETHICAL CLEARANCE

13.1 Ethical clearance is valid until the date given on the relevant ethical clearance letter.

13.2 A short progress report must be submitted to the Secretariat by no later than two weeks after the ethical clearance renewal date (indicated on the ethical clearance letter, or last ethical clearance renewal letter).

13.3 Each MPHREC renewal application is reviewed by the Chairperson or one of the Vice Chairpersons and a recommendation is made to either renew the ethical clearance for an appropriate further clearance period (Annexure 4).

13.4 Possible grounds for not renewing existing ethical clearance include unapproved material deviations from research procedure, and previously unreported serious adverse events.

13.5 Researchers are notified about their ethical clearance renewal in writing by the Secretariat.

13.6 Renewal applications and their outcomes (i.e., successful, or unsuccessful) are placed on an agenda of the next available MPHREC meeting for noting.

13.7 If no application for renewal of ethical clearance is received by, at the most four weeks after the ethical clearance renewal date, the existing ethical clearance will have expired, and the position will be that any research activities conducted after this point will be done without ethical clearance.

14. AMENDMENTS TO RESEARCH PROPOSALS WITH CLEARANCE

14.1 General Procedures

14.1.1 Due to unforeseen circumstances, it may sometimes be necessary to amend a research ethics application with existing ethical clearance.

14.1.2 Researchers faced with the prospect of research ethics application amendments must apply to the MPHREC detailing the proposed amendments before they are implemented using an appropriate form (Annexure 5).

14.1.3 The research ethics proposal amendment application, with supporting documents where necessary, and a copy of the ethical clearance letter must be submitted to the Secretariat.

14.1.4 The MPHREC Chairperson and one Vice Chairperson review the submitted research ethics proposal amendment application and decide whether the proposed

amendments are material on the basis of, among other factors, whether the proposed amendments:

14.1.4.1 Affect the research method and the probability of delivering a meaningful and valid result.

14.1.4.2 Affect the informed consent process and whether this is viable or may necessitate a process of re-consenting.

14.1.4.3 Alter the risk to benefit ratio of the research in an unfavourable way or increase the possibility of harm to participants.

14.1.4.4 Whether the proposed amendments in any way infringe on the participants right to privacy.

14.1.5 If the two reviewers achieve consensus that the proposed research ethics application amendments are material, the student and supervisor or researcher are notified of the requirement for further review of the research ethics application.

14.1.6 Otherwise, the student and supervisor or researcher are notified that there is no need for further review of the research ethics application and that they may proceed with the implementation of the amended research ethics application.

14.1.7 If the proposed research ethics application amendments are material, the research ethics application, together with a copy of the original and amended research ethics application, is allocated to the two original research ethics application reviewers if possible.

14.1.8 The two original reviewers return their reviews of the proposed research ethics application amendments to the Secretariat within five working days and indicate their decision.

14.1.9 The Chairperson assesses the two reviewers' decisions. If the two decisions are the same, the Chairperson requests that Secretariat notify the student and supervisor or researcher of the decision. If the decisions are different, the Chairperson considers the two original reviewers' comments and makes a final decision which is communicated by the Secretariat to the student and supervisor or researcher.

14.1.10 If the decision referred to above in Clause 14.1.8 necessitates revision of the proposed amendments this is done to the satisfaction of the Chairperson, after which a final decision is communicated to the researcher.

14.1.11 A new ethical clearance letter is always issued after an application for amendments to a research ethics application with ethical clearance. The new ethical clearance letter clearly indicates that the application was made, what the outcome of the application was and any new conditions of ethical approval, or other details (such as monitoring etc.).

14.1.12 If Clause 14.1.7 applies, the original ethical clearance number is amended on the new ethical clearance letter by adding the following: 'Amendment 1'. The amendment version is incremented for any future approved amendments.

14.1.13 If Clause 14.1.7 does not apply, the original ethical clearance number is used on the new ethical clearance letter.

14.1.14 All amendment applications are placed on an agenda of the next available MPHREC meeting for notification or ratification.

14.2 Qualitative Research

14.2.1 Clause 14.1 above should be read with the understanding that approaches to the acceptability of research ethics application amendments differ among research approaches or paradigms (e.g. quantitative/positivist, qualitative/interpretivist/constructivist or mixed methods/pragmatic/post-positivist).

14.2.2 Whereas the emphasis in quantitative research is on the detailed description of a research method which is accepted to be final and should ideally not change, the approach to methodological adaptation in qualitative research is acknowledged to be far more fluid and evolving with progression of the research.

14.2.3 The threshold for judging materiality of amendments in quantitative research is thus accepted as being generally lower than in qualitative research.

14.2.4 However, amendments that can be argued to have ethical implications must be seen as material regardless of the research approach or paradigm.

15. MONITORING, REPORTING, SUSPENSION AND TERMINATION OF RESEARCH

15.1 Monitoring of Research

15.1.1 The MPHREC reserves the right to monitor any research that it has granted ethical clearance for, at any time and for any period of time until completion of the research using appropriate forms.

15.1.2 Requirements for monitoring of research are proportional to the risk of harm to participants.

15.1.3 Research that is considered greater than low (minimal) risk may be subject to more frequent and detailed monitoring.

15.1.3.1 Active monitoring

15.1.3.1.1 The MPHREC will form a sub-committee (MPHRECTC) which will be tasked to undertake active monitoring of research projects (see MPHREC SOP for Active Monitoring).

15.1.3.1.2 The MPHREC will sample research projects that need to be monitored and assign such sampled projects to the MPHRECTC to undertake monitoring of approved and ethically approved research projects using a standardised active monitoring tool (Annexure 10).

15.1.3.2 Passive monitoring

15.1.3.2.1 Through the office of the secretariat, MPHREC will request annually progress reports from researchers granted approval to conduct research using a standardised passive monitoring tool (Annexure 11).

15.1.3.2.2 Feedback will be collected once during the anniversary of the granting of ethical clearance (see MPHREC SOP for Passive Monitoring).

15.2 Reporting of Adverse Events

15.2.1 Adverse events occurring during any research cleared by the MPHREC must be reported to the Secretariat of the MPHREC using the appropriate form (Annexure 7).

15.2.2 Serious adverse and related events must be reported within 48 hours of the discovery of their occurrence, while non-serious related adverse events must be reported within five working days.

15.2.3 The Chairperson, together with one or both Vice-Chairpersons, may make immediate recommendations regarding the research methods and procedures in relation to the reporting of a serious adverse event, if this is believed to be necessary to protect the interests of participants.

15.2.4 Notwithstanding Clause 14.2.3 above, all serious related adverse events must be reviewed by the MPHREC at a meeting as close to the reporting of the adverse event as possible.

15.2.5 All adverse event reports must be submitted to the Secretariat within the time frames indicated above.

15.3 Suspension and Termination of Research

15.3.1 Using an appropriate form (Annexure 6 & 8), the MPHREC reserves the right to withdraw ethical clearance for any research with such clearance previously granted by the MPHREC if it is brought to the attention of the MPHREC, and there is reasonable prima facie evidence, that:

15.3.1.1 the research is non-compliant with the research ethics application that was granted ethical clearance, or the MPHREC SOPs, and

15.3.1.2 that the interests of research participants have been harmed or are at risk of harm.

15.3.2 The MPHREC reserves the right to intervene in any research that has not yet received ethical clearance if it is brought to the attention of the MPHREC, and there is reasonable prima facie evidence, that there has been interaction with human participants without prospective ethical clearance where this would have been required.

15.3.3 Research referred to in Clauses 15.3.1 and 15.3.2 above is considered suspended, pending an inquiry into the circumstances around the alleged non-compliance.

15.3.4 The Chairperson, in consultation with one or more Vice Chairpersons, may determine that research should be suspended, as per the definition in Clause 15.3.1.

15.3.5 Immediately following this determination, the Chairperson informs the relevant student and supervisor, or researcher, in writing of the suspension. This process must be completed within 24 hours.

15.3.6 Once the relevant student and supervisor, or researcher have been informed of the suspension, the relevant Head of Department and Vice-Dean: Research and Postgraduate Studies are notified.

15.3.7 The Chairperson convenes, within five working days, an inquiry into the suspension which includes representation from the research team, and the MPHREC.

15.3.8 Findings of the inquiry must be communicated to all parties as soon as they are finalised and may involve the following:

15.3.8.1 Lifting of the suspension and reinstatement of ethical clearance, or

15.3.8.2 Remedial action aimed at rectifying the non-compliance and reinstatement of ethical clearance (provided that the remedial action is complied with) or

15.3.8.3 Termination of the research.

15.3.9 In the case of Clause 15.3.8.1, the MPHREC may impose conditions on the reinstated ethical clearance, or specific monitoring and reporting requirements.

15.3.10 Researchers, have the right to appeal findings of an inquiry referred to in Clause 15.3.7.

16. CLOSURE OF RESEARCH PROJECTS

16.1 The MPHREC must be notified in writing of the closure of all research projects that have been granted ethical clearance, regardless of the reason.

16.2 Closure of the research has no implications for future publication arising from data collected and analysed as part of the research.

17. SCIENTIFIC MISCONDUCT AND UNPROFESSIONAL BEHAVIOUR

17.1 There is a moral obligation on all MPHREC members to be vigilant for, and report, any suspected scientific misconduct that they may become aware of at any stage of a research project.

17.2 Instances of suspected scientific misconduct should be reported to the Chairperson.

17.3 Once reported, instances of suspected scientific misconduct are dealt with according to the Department's policies.

17.4 There is a similar moral obligation and professional duty on all MPHREC members to be vigilant for, and report, any suspected unprofessional behaviour that they may become aware of at any stage of a research project.

17.5 Such suspected instances should be reported as described in Clauses 17.2 and 17.3 or through reporting mechanisms made available by the relevant statutory bodies (e.g. the Health Professions Council of South Africa).

17.6 Unprofessional conduct reported internally may also be reported to the relevant statutory body by the MPHREC.

18. REC FORMS

18.1 The table below gives an overview of the different REC forms accompanying this document, and when each should be used.

19. MPHREC SOP REVIEW

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

20. MPHREC SOP APPROVAL

APPROVED / NOT APPROVED

4/6/2024

DR LK NDHLOVU **DATE**

HEAD: HEALTH

Effective date 4/06/2024

ANNEXURES

Only Use/Retrieve the Relevant Annexure

Annexure 1	Application Form for Full Review
Annexure 2	Application Form for Rapid and Expedited Review
Annexure 3	Application Form for Exemption from Review
Annexure 4	Continuing Review / Annual report format/Passive Monitoring Form
Annexure 5	Application/Notification form for Amendments
Annexure 6	Protocol Violation/Deviation Reporting Form (Reporting by case)
Annexure 7	Serious Adverse Event Reporting Format
Annexure 8	Premature Termination/Suspension/ Discontinuation Report Format
Annexure 9	MPHREC Generic Information Sheet and Consent Form
Annexure 10	Active Monitoring Report Form
Annexure 11	Passive Monitoring Report Form
Annexure 12	Risks Levels
Annexure 13	Generic Proposal Template
Annexure 14	Ethics Review Form
Annexure 15	Appeals form
Annexure 16	Complaint form
Annexure 17	Conflict of interest declaration form

health
MPUMALANGA PROVINCE
REPUBLIC OF SOUTH AFRICA

MPUMALANGA
THE PLACE OF THE RISING SUN

(Annexure 1)

MPHREC Application Form for Full Review

.....

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

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):

SECTION 2: STUDY TITLE IN FULL (NO ABBREVIATIONS)

Title of the study:

SECTION 3: APPLICANT DETAILS

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 4: RESEARCH STUDY DETAILS

4.1 Objectives and end points of the research (plain language):

Primary (if applicable):

Secondary (if applicable):

Exploratory (if applicable):

Safety:

Other:

4.2 Brief study background (e.g., disease, procedures, medicines, etc.):

4.3 Brief summary of the research: (give a brief outline of the research plan such that reviewers can understand what is to be done. (*Do not say "see attached"*):

4.3.1 Design:

4.3.2 Duration of study:

Start Date: **(DD/MM/YYYY)**

Stop Date: **(DD/MM/YYYY)**

4.3.3 Study Participants:

a) Where and how the participants are selected (i.e. recruitment strategies):

b) Will vulnerable participants be recruited? **Yes** ☐ **No** ☐

If yes, justify the selection of vulnerable participants:

c) Age range of Participants:

d) Self-reported Gender: **Male** ☐ **Female** ☐ **Other** ☐

e) Number of participants to be recruited/studied:

f) Potential benefit to participants? **Yes** ☐ **No** ☐

If yes, explain in what way:

g) Potential risks to participants? **Yes** ☐ **No** ☐

If yes, explain in what way:

h) Are the participants being remunerated for participating in the study? **Yes** ☐ **No** ☐

If yes, please state what the remuneration is for and how much will be paid:

4.3.4 Please give a brief Summary of Inclusion and Exclusion Criteria (important ones only):

SECTION 5: RESEARCH STUDY TYPE

5.1 Select study type (check/tick all that applicable):

☐ Retrospective Record Review

What is the initial date for the records? **(DD/MM/YYYY)**

What is the final date for the records? **(DD/MM/YYYY)**

☐ Prospective Record review

What is the initial date for the patient records? **(DD/MM/YYYY)**

What is the final date for the patient records? **(DD/MM/YYYY)**

☐ Secondary Data Analysis of Previously Approved Study

☐ Qualitative

☐ Quantitative

☐ Cross-sectional

☐ Observational/Epidemiological

☐ Lab Based

☐ AI/Computer Based

☐ Health Economics

☐ Clinical Trial **(please give Phase, e.g. I, II, III or IV):**

☐ Other **(please give brief details)**:

5.2 Will this study involve the use of a Biobank? Yes ☐ No ☐

Please note: If this study collects human tissue as a component of the primary study, it is not considered

to be biobanking. Note: Biobank Ethics applications are dealt with by the Biobanks Ethics Committees and the application may not be considered by MPHREC.

SECTION 6: PARTICIPANT INFORMATION LEAFLET AND INFORMED CONSENT FORM

6.1 Has Participant Information Leaflet and Informed Consent Form (PIL/ICON) been attached?

Yes ☐ No ☐

If yes, please provide details of how have literacy and language diversity aspects been considered in the PIL/ICON:

6.2 In case of minors aged 7-17, has an Assent Form been attached?

Assent Form for 7–12-year-olds: Yes ☐ No ☐

Assent Form for 12 - 17-year-olds: Yes ☐ No ☐

Not Applicable ☐

6.3 Mark research procedure(s) that will be used:

☐ **Record review (patient file)**

☐ **Interview / Questionnaire form (must be attached)**

☐ **Clinical Examination (state below nature and frequency of examination)**

☐ **Medicine/medical devices/kits (state below names(s), dose(s), and frequency of administration (if applicable)**

- Please provide Professional Information or Package Insert (PI):

☐ **Blood sampling;** ☐**venous;** ☐**arterial**

- (state below amount to be taken and the frequency of blood sampling):

☐ **Biopsy(s)**

☐ **Any other invasive procedures (e.g. endoscopy)**

6.4 Will a questionnaire or interview be used in the research for data collection? It must be attached. (If not, this application cannot be considered).

Yes ☐ No ☐ Not applicable ☐

Is this attached? Yes ☐ No ☐ Not applicable ☐

Type of questionnaire (check/tick all that applicable):

☐ Self-Administered Questionnaire (SAQ)

☐ One-On-One Interview

☐ Focus Group Discussion (FDG)

☐ Delphi Study

☐ Quality of Life

☐ Other **(specify)**:

6.5 If a questionnaire or interview is to be used in this research, how have literacy and language diversity aspects been considered?

6.6 Who will carry out procedures: Outside vendor or PI/Sub-I/Co-I?

- Please specify roles and responsibilities:

6.7 Please include potential risks of the procedures:

6.8 Radiological Investigations or Treatments:

6.8.1 Will there be any form of radiation being used in the study for diagnostic / monitoring / or therapeutic purposes? Yes ☐ No ☐

If yes, please answer the following questions:

6.8.2 What form of radiation will this be?

☐ Radioisotopes

☐ Plain Xray's

☐ CT scanning

☐ PET/CT

☐ Other **(provide details of this)**:

6.8.3 Which radiological investigations are considered to be standard clinical care?

6.8.4 Which radiological investigations are considered to be for research purposes only?

Please justify.

SECTION 7: RISKS OF THE STUDY PROCEDURE(S)

7.1 Please consult the risk table at https://www.mpuhealth.gov.za/MPHREC documents/ **chose and indicate the level of risk to:**

Patients/Participants:

None/Minimal ☐ Low/Medium ☐ High/Very High ☐

Research team members:

None/Minimal ☐ Low/Medium ☐ High/Very High ☐

All other persons:

None/Minimal ☐ Low/Medium ☐ High/Very High ☐

7.2 Please indicate whether the patients/participants will be exposed to any levels of:

a) **Adverse effects** **Yes** ☐ **No** ☐ **N/A** ☐

If yes, please indicate which:

☐ Investigational Products (IP) used

☐ Standard of care

☐ Supportive care

b) **Physical discomfort/pain** **Yes** ☐ **No** ☐

If yes, please elucidate:

Is there a **distress protocol?** **Yes** ☐ **No** ☐

c) **Psychological stress** **Yes** ☐ **No** ☐

Is there a **distress protocol?** **Yes** ☐ **No** ☐

d) **Breach of confidentiality** **Yes** ☐ **No** ☐

e) **Potential stigmatization and or profiling** **Yes** ☐ **No** ☐

- If you have checked any of the above, **please provide details**:

SECTION 8: APPROVAL REQUIREMENTS

8.1 Please provide evidence of capacity building at the site(s) (if applicable)**:**

8.2 If this study involves health products, then SAHPRA approval is required.

Has this application been made? **Yes** ☐ **No** ☐

If yes, provide details:

8.3 Has permission of other relevant authority/ies been applied for? Yes ☐ **No** ☐ **N/A** ☐

☐ State name of authority/ies (If applicable):

☐ HoD permission:

☐ Hospital CEO (if applicable):

☐ District Manager (if applicable):

☐ Provincial:

☐ National:

☐ International (in case of studies outside South Africa)

☐ Other (provide details):

8.4 Has this study been submitted to other Ethics Committees/Institutional Review Board (IRBs),

inside or outside South Africa? Yes ☐ **No** ☐ **N/A** ☐

If yes, where has it been submitted, and what is the status of the application?

- Where:
- Status:

SECTION 9: ADDITIONAL INFORMATION

9.1 Confidentiality:

Will the patients/participants be exposed to any levels of Breach of confidentiality Yes ☐ No ☐

i. **In respect of the type of research methodology?**
(As an example, a focus group can offer no guarantee of confidentiality)
If yes, please describe how this will be managed or mitigated.

ii. **Has Mandatory Reporting requirements been considered and detailed as to the process if research involves minors, with due consideration of reporting timelines?**

9.2 Please explain how confidentiality will be maintained so that participants are not identifiable to persons not involved in the research:

For example:

i. Will the data collected be coded, anonymized, or pseudo-anonymised?

ii. Who will have access to identifiable data?

iii. Does your protocol/proposal make mention of how this process will be dealt with and details this in respect of POPIA's provisions?

iv. Has a POPIA statement been included in the Informed Consent Form?
As a minimum, the following statement should be included:

In accordance with the provisions of the ***Protection of Personal Information Act 4 of 2013*** *(as amended), I hereby consent:*

- *To my personal information (hereinafter 'data') being collected, processed, shared and stored in accordance with the research protocol/proposal as approved by the mphrec;*
- *To my anonymised data being shared, processed, and transferred by third parties and between third parties, and where relevant beyond the jurisdictional borders of South Africa;*
- *To all findings and results flowing from my anonymised data being broadly shared and published at the conclusion of the research.*

v. Does the sharing of data require the drafting and completion of a Data Transfer Agreement or a Cross Border Data Transfer Agreement? **Yes ☐ No ☐**

If so (Yes), this will be required to the submitted to the MPHREC for approval.

vi. Have you adequately dealt with this in your Information Sheet to participants? Do they have sufficient information or detail to understand what they are consenting to in terms

of the collection, processing, and storage of their data and what the risks are of a breach?

vii. Do you have a process in place to report a breach should this occur?

9.3 Any other information, which may be of value to the ethics committee should be provided here:

SECTION 10: DECLARATION AND CHECKLIST

10.1 Declaration

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 National Health Guidelines for Research (2024) and other applicable regulations and guidelines of research Human Participants.
☐	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 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/Researcher: .....

Signature: .....

Name of Co-PI: .....

Signature: .....

Name of Supervisor if any: .....

Signature: .....

10.2 CHECKLIST

s. No.	Items	Yes	No	NA	Enclosure No	MPHREC Remarks (If applicable)
ADMINISTRATIVE REQUIREMENTS						
1	Cover letter	☐	☐	☐		
2	Brief CV of the Primary Investigator	☐	☐	☐		
3	Approval of scientific committee	☐	☐	☐		
4	EC clearance of other centers	☐	☐	☐		
5	Agreement between collaborating partners	☐	☐	☐		
6	Insurance policy/certificate	☐	☐	☐		
7	Evidence of external laboratory credentials in case of an externally outsourced	☐	☐	☐		

	laboratory study certification					
8	Copy of contract or agreement signed with the sponsor or donor agency	☐	☐	☐		
PROPOSAL RELATED REQUIREMENTS						
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 (7-17 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

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(Annexure 2)

MPHREC 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:	

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(Annexure 3)

MPHREC Application Form for Exemption from 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):

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 WHY EXEMPTION FROM ETHICS REVIEW IS REQUESTED

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:	

(Annexure 4)

MPHREC Continuing Review / Annual report format/Passive Monitoring Form

.....

(Name of the Institution)

NHRD Ref. No:

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

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

a. Yes ☐ b. No ☐

5.1.1 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/ Researcher Signature		Secretariat Signature	

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

(Annexure 5)

MPHREC Application/Notification form for Amendments

.....

(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 ☐

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

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:		

(Annexure 6)

MPHREC Protocol Violation/Deviation Reporting Form (Reporting by case)

.....

(Name of the Institution)

NHRD Ref. No:

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:		

(Annexure 7)

MPHREC 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)

NHRD Ref. No:

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 [2]:	
Date of reporting SAE:	

.....

.....

.....

.....

1. Details of suspected intervention causing SAE [3]

.....

.....

.....

.....

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

.....

.....

.....

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

[3] *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)*

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 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:	

(Annexure 8)

MPHREC Premature Termination/Suspension/ Discontinuation Report Format

.....

(Name of the Institution)

NHRD Ref. No:

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

1. Date of MPHREC approval:	
2. Date of start of study:	
3. Date of last progress report submitted to MPHREC:	
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[a] (if any):	
7. Details of study participants:	Total participants to be recruited:
	Screened:
	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:	

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

Have any unexpected adverse events or outcomes observed in the study been reported to the MPHREC?	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:	

(Annexure 9)

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 emphasizing 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 emphasized 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 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).

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: _____

(Annexure 10)

MPHREC ACTIVE MONITORING REPORT FORM

.....

NHRD Ref. No:

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

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

Instructions to MPHRECTC member carrying out the active monitoring:

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

1. Stage of Ongoing Research			
1.7. Data Collection Ongoing	☐	1.8. Data Collection Complete	☐
1.9. Data Analysis Ongoing	☐	1.10. Data Analysis Complete	☐

1.11. Research Report/Dissertation/ Thesis Writing	☐	1.12. Research Report/ Dissertation/ Thesis Writing Complete	☐

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

Please click here to comment

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

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

6.1. Yes ☐ 6.2. No ☐

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

Please click here to comment

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

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

7.1. Yes ☐ 7.2. No ☐

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

Please click here to comment

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

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

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

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

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

6. Evidence of voluntary withdrawal of participants where applicable?

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

6.1 Yes ☐ 6.2 No ☐

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

Please click here to comment

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

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

6.3 Yes ☐ 6.4 No ☐

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

Please click here to comment

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

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

6.5 Yes ☐ 6.6 No ☐

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

Please click here to comment

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

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

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

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

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

(Annexure 11)

MPHREC PASSIVE MONITORING FORM

.....

NHRD Ref. No:

- 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*)			
1.13. Data Collection Ongoing	☐	1.14. Data Collection Complete	☐
1.15. Data Analysis Ongoing	☐	1.16. Data Analysis Complete	☐

1.17. Research Report/Dissertation/ Thesis Writing Ongoing		1.18. 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

8. 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?

8.1. Yes ☐ 8.2. No ☐

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

Please click here to comment

9. 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

10. 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

7. 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

8. 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/ Researcher Signature		Secretariat Signature	
Date completed (DD/MM/YYYY)		Date received (DD/MM/YYYY)	

(Annexure 12)

MPHREC RISK LEVELS

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.

(Annexure 13)

MPHREC GENERIC PROPOSAL TEMPLATE

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Section
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. Pilot study Explain in detail how you will pre-test your survey questionnaire or data collection instrument
16. Validity and reliability Discuss measures of Validity and Reliability or Trustworthiness
17. 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.
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.

(Annexure 14)

MPHREC ETHICS REVIEW FORM

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Application number:
Reviewer:

Criteria	N/A	Compliant	Needs clarification Incomplete	Unsatisfactory Missing
Follows procedures				
• Approved by HOD / Department	☐	☐	☐	☐
• Approval requested BEFORE research, NOT retrospective approval	☐	☐	☐	☐
Information and style of writing				
• Academic register – spelling, grammar, written for target group?	☐	☐	☐	☐
• Includes contact information - details of researchers and supervisors	☐	☐	☐	☐
• Written "invitingly"?	☐	☐	☐	☐
• Language ensures understanding & appreciation of processes	☐	☐	☐	☐
• Understandable – no excessive use of acronyms, abbreviations, jargon, technical terms	☐	☐	☐	☐
Scientific basis for conducting the study?	☐	☐	☐	☐
Social or educational value evident?	☐	☐	☐	☐
Research relevant to the needs of the participants and/or community?	☐	☐	☐	☐
Purpose of proposed research is clear and easily understandable	☐	☐	☐	☐
Supporting instruments provided where applicable (questionnaires, protocols, etc.)	☐	☐	☐	☐
Legal issues				
• Legal capacity to consent	☐	☐	☐	☐
• Physical/mental capacity to consent	☐	☐	☐	☐
• Consent from appropriate authority?	☐	☐	☐	☐
• Compliance with SA law	☐	☐	☐	☐
Expectation of participation clearly defined	☐	☐	☐	☐
Respect for autonomy & respect for participants				
• Consent/assent (voluntary, informed, written)	☐	☐	☐	☐
• Confirmation of confidentiality and privacy	☐	☐	☐	☐
• Full disclosure / no deception	☐	☐	☐	☐
• Strategies to provide participants access to results on completion of study	☐	☐	☐	☐
Non-maleficence (absence of harm). (Poor quality science is considered unethical. Harm could also be psychological, social, physical or economic).	☐	☐	☐	☐
• No coercion / No perverse or undue incentives to participate	☐	☐	☐	☐
• Suitable respect shown for participants	☐	☐	☐	☐
• No undue risk to researchers?	☐	☐	☐	☐
Beneficence (potential benefit) clearly defined?	☐	☐	☐	☐
Justice				
• Leave participants or community better, or no worse off? No exploitation?	☐	☐	☐	☐
• Selection, recruitment, exclusion and inclusion of participants is just and fair (procedural justice)	☐	☐	☐	☐

• Sample large enough / appropriate?	☐	☐	☐	☐
• Sample suitable for study? Not just convenience?	☐	☐	☐	☐
• Does not "take away" from essential services e.g. Duties of healthcare workers, teaching time, work obligations etc. (distributive justice)	☐	☐	☐	☐
Vulnerable participants/communities				
• Justification for their inclusion? (Can they be excluded and still answer the research question?)	☐	☐	☐	☐
• Added protection for vulnerable participants?	☐	☐	☐	☐
• No exploitation	☐	☐	☐	☐
Health & therapy related issues (e.g. Educational Psychology Students)				
• Research is distinct from therapy/services (highlighted as research)	☐	☐	☐	☐
• Ancillary care is arranged. Agreement with caregiver submitted for review (Lifeline and PsyCad NOT acceptable)	☐	☐	☐	☐

Reviewer, please indicate the risk factor below:

Risk Factor	*Please select one*	*Motivation (brief explanation of choice)*
Low Benefit - Low Risk	☐	Motivation
High Benefit - Low Risk	☐	Motivation
High Benefit - High Risk	☐	Motivation
Low Benefit - High Risk (Seldom approved)	☐	Motivation

Reviewer, please record your decision below:

Decision	Please select one
Approved	☐
Approved with minor revisions	☐
Major revision and resubmission required	☐
Not approved	☐

Please indicate comments and suggested changes to be made to the application document below:

(Annexure 15)

MPHREC APPEALS FORM

.....

NHRD Ref. No:

Please fill in the first table, providing as much detail as you can. Please send this completed form to MPHREC secretariat: Tel: 0137663766

Your contact details		
Name:	Email:	Phone number:
Research project you wish to make a complaint about		
Name of researcher (if known):	MPHREC (non-medical) Clearance number (if known):	
Title of research project (if known), or topic of the project:		
Reason for appeal		
Your signature:		Date:

Office use only
Description of action taken

health
MPUMALANGA PROVINCE
REPUBLIC OF SOUTH AFRICA

MPUMALANGA
THE PLACE OF THE RISING SUN

(Annexure 16)

MPHREC COMPLAINTS FORM

.....

NHRD Ref. No:

Please fill in the first table, providing as much detail as you can. Please send this completed form to MPHREC secretariat: Tel: 0137663766

Your contact details		
Name:	Email:	Phone number:
Research project you wish to make a complaint about		
Name of researcher (if known):	MPHREC (non-medical) Clearance number (if known) :	
Title of research project (if known), or topic of the project:		
Nature of complaint (please be as specific as you can)		
Your signature:		Date:

Office use only
Description of action taken

(Annexure 17)

MPHREC CONFLICT OF INTEREST DECLARATION FORM

.....

Name:	Email:	Phone number:
Research project you wish to make a DECLARATION about		
Name of researcher (if known):	MPHREC (non-medical) Clearance number (if known):	
Title of research project (if known), or topic of the project:		

Do you or your partner have any financial, academic, or other interest in the subject matter of the meeting, which may be considered as constituting a real, potential, or apparent conflict of interest?

Yes ☐ **No** ☐ **Name of the Member**_____

If yes, please provide the detail below:

Nature of interest:

_____

Name of the entity and or individuals:

_____

_____

_____

_____

If there is anything else, or the perception by others, that could affect your objectivity and independence in the meeting? If your answer is yes, please supply details of such.

_____

_____

_____

_____

I, _____ hereby declare that the disclosed information is correct, and no other situation of real potential or apparent conflict of interest is known to me. I undertake to inform the meeting of any status changes that may be brought to light because of any issue that may arise as the meeting progresses. I also undertake to timely inform the committee of any changes in these circumstances during the period when I am still serving as a committee member.

_____ Signature
Date: _____

_____ Witness
Date: _____