health
MPUMALANGA PROVINCE
REPUBLIC OF SOUTH AFRICA

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

REF: SOP/01/06/2024: Research

MPUMALANGA
THE PLACE OF THE RISING SUN

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ABBREVIATIONS AND DEFINITIONS

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

1. PURPOSE

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

2. SCOPE

2.1 The SOP applies to MPHREC, researchers / and other stakeholders involved in multicentre research projects involving human participants.

2.2 The NHREC guidelines (NDoH 2024) permits RECs to establish procedures for reciprocal and joint reviews to:

3. GENERAL PRINCIPLES: RECIPROCAL RECOGNITION OF REVIEW DECISIONS

3.1 The South African ethico-legal framework requires that primary investigators (PI) or research leaders must obtain approval from their institutional REC. Further, RECs have authority to review and approve research protocols only for research sites or geographic areas within their own jurisdiction. Thus, when a PI or research leader proposes a research study or project that is to collect data from multiple sites or geographic areas, necessarily, more than one REC would be involved in the review and approval processes.

3.2 To prevent unnecessary duplication of work, RECs may, at their own discretion, recognise prior review and approval of a research protocol granted by another registered South African REC.

3.3 Reciprocal recognition means that two or more registered RECs decide to recognise each other's prior review.

3.4 This arrangement may involve formal agreements between the RECs explaining how the workload and responsibilities is shared and the basis on which recognition occurs. Alternatively, the committee may decide to use reciprocity recognition on a case-by-case basis.

3.5 RECs that recognise prior review in this manner must determine the nature of the documents to be filed at each office. The expectation is that, at minimum, copies of the approval letter from the other REC, the protocol, and the ethics review application as well as the notes of the local REC member whose review led to the REC decision to use reciprocal recognition must be on file. Further, the decision must be tabled for minuting at the next REC meeting.

3.6 RECs that recognise prior review in this manner may revise their decision to do so if justifying circumstances arise. The reasoning supporting a reversal of recognition should be documented.

3.7 The roles and responsibilities of each REC involved in the reciprocal review process should be clearly described and agreed in writing by the participating RECs. These guidelines deliberately do not impose use of reciprocal recognition of reviews on any REC; nor is there a prescribed method for agreeing to reciprocal recognition. The expectation is that RECs should communicate with each other, through their chairpersons, and agree on a way forward regarding review of a multi-site protocol when it is desirable to avoid duplication of effort. The possibility of reciprocal recognition of reviews should occur in a collaborative, harmonious manner, bearing in mind that each REC bears the responsibility of protecting the safety, rights and interests of participants enrolled in the studies it has approved.

3.8 Matters to be considered include which RECs are participating in the particular reciprocal recognition arrangement, how protocol amendments will be managed e.g., a site-specific logistical amendment may not lead to amendments at all sites, but only noting by the others, how adverse events or unanticipated problems will be managed e.g., it might be decided to report AEs in the usual way only to own REC and SAHPRA but with Serious Adverse Events (SAEs) to notify the other participating RECs.

3.9 It is important too that SA GCP 2020 be followed consistently.

3.10 It is possible that some RECs already have SOPs in place for reciprocal recognition of reviews.

3.11 The agreement might be reached by sharing the SOPs to ensure that all participating HRECs understand and can participate on the basis of a shared SOP.

4. MPHREC'S ROLE ABOUT RECIPROCAL REVIEW

4.1 MPHREC does not have any formal agreement with any other South African Research Ethics Committee on reciprocal review.

4.2 MPHREC will use its own discretion to recognize ethics approval granted by an accredited South African REC on a case-by-case basis.

4.3 Research application requiring reciprocal review are submitted to MPHREC using an appropriate form (Annexure 1).

5. RECIPROCAL REVIEW GENERAL PROCEDURES

5.1 Role by Researcher

5.1.1 Decide and develop the necessary documentation as required. These include:

5.1.1.1 Complete the appropriate form (Annexure 1).

5.1.1.2 Clearly indicate:

5.1.1.2.1 The title of the research,

5.1.1.2.2 The researcher(s),

5.1.1.2.3 What it is that is being requested,

5.1.1.2.4 Add any explanation to clarify your application.

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

5.1.1.4 Upload all required documents on the NHRD website (http://nhrd.health.gov.za), including copies of the approval letter from the other REC, the protocol, and the ethics review application as well as the notes of the local REC member whose review led to the REC decision to use reciprocal recognition.

5.1.2 Process by the MPHREC secretariat and MPHREC Chairperson:

5.1.2.1 The chairperson allocates the review to a minimum of two reviewers and notifies the secretariat.

5.1.2.2 The application is sent by administration (within two days) to two independent reviewers who have three working days to verify documents and provide feedback.

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

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

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

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

5.1.2.7 Documents are filed by the secretariat, and the decision is ratified during the next MPHREC meeting.

6. GENERAL PRINCIPLES: JOINT REVIEWS DECISIONS

6.1 Joint reviews occur when two or more RECs review a multi-site research protocol together. This joint review process facilitates capacity building, development of trust. and avoids unnecessary repetition of administrative work.

6.2 Ethics review of multi-site research protocols, e.g., where an identical protocol serves several research sites in South Africa may benefit from the joint review process.

6.3 When deliberations are completed and a decision to approve has been reached, each REC uses its own approval SOPs and processes.

6.4 Joint review does not exempt any of the RECs involved from their responsibilities, including monitoring and looking after the interests of participants at their sites.

6.5 The Primary Investigators (PIs) concerned are responsible for informing their institutional REC of the fact of multi-site research, as well as the names of the other RECs with jurisdiction over other research sites.

6.6 This information enables the Chairs of the RECs to arrange a joint meeting of the RECs involved to review, deliberate on and to approve the protocol concerned simultaneously.

6.7 Sometimes research is conducted in various African countries. Joint reviews involving South African and other African RECs can be used in similar manner to facilitate the ethics review and approval processes.

6.8 An inter-institutional MoU between the RECs involved that outlines the process, the expectations and the responsibilities is desirable.

7. MPHREC'S ROLE ABOUT JOINT REVIEWS

7.1 MPHREC does not have any formal agreement with any other South African Research Ethics Committee on joint review but may establish inter-institutional MoU with any South African registered REC, when necessary, on a case-by-case basis.

7.2 Research application requiring joint review follow the MPHREC application process using an appropriate form (Annexure 2).

8. JOINT REVIEWS GENERAL PROCEDURES

8.1 All applications for ethical clearance are submitted to the MPHREC through a common electronic application form (Annexure 2 or see MPHREC SOP Clause 4). 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).

8.2 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.

8.3 In order to be placed on the joint reviews meeting agenda, a research proposal must be handed in as described in Clause 8.1 no later than the published closing date for a particular MPHREC meeting. No late applications will be considered.

8.4 Full joint reviews process will be arranged with the other REC (s) to deliberate on and to approve the protocol concerned simultaneously.

8.5 Researchers should ensure that they include the correct documentation and follow the correct processes as not to hold up the expedited process.

8.6 MPHREC will participates in the joint reviews process as in line with the MPHREC SOP Clause 7 and 8.

9. SOP REVIEW

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

10. SOP APPROVAL

APPROVED/ NOT APPROVED

DR LK NDHLOVU

HEAD: HEALTH

12/6/2024

DATE

Effective date 12/06/2024

Annexure 1 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 2 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