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**ICMR Bioethics Unit**

Guidelines for ICMR Network of Institutions

# Joint Ethics Review of Multicentre Research

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**Edited by**

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New Delhi

| S. N | Abbreviations and Acronyms | |
|---|---|---|
| 1. | EC | Ethics committee |
| 2. | PI | Principal investigator |
| 3. | C-PI | Coordinating Principal Investigator |
| 4. | S-PI | Site Principal Investigator |
| 5. | SC | Scientific Committee |
| 6. | DEC | Designated Ethics Committees |
| 7. | PEC | Participating Ethics Committee |
| 8. | IPRs | intellectual property rights (IPRs) |
| 9. | COI | Conflict of Interest |
| 10. | CDSCO | Central Drugs Standard Control Organization |
| 11. | ICMR | Indian Council of Medical Research |
| 12. | SAE | Serious adverse events |
| 13. | DHR | Department of Health Research |
| 14. | NABH | National Accreditation Board for Hospitals and Healthcare Providers |
| 15. | SOP | Standard operating procedure |
| 16. | MoU | Memorandum of understanding |
| 17. | MTA | Material transfer agreement |
| 18. | ICD | Informed Consent Document |
| 19. | CRF | Case Record Forms |
| 20. | CTRI | Clinical Trial Registry-India |
| 21. | PIS | Participant Information Sheet |
| 22. | ICF | Informed Consent Form |
| 23. | GCP | Good Clinical Practice |

# Definitions:

**Multicentre Research:** Research that is conducted in more than one place/ centre usually following a common protocol and with multiple investigators. Each centre can further have multiple sites from which participants can be recruited. In certain studies, PIs from centres may be involved in different roles such as coordination, quality control and data management etc for the same common protocol.

**Study proposal/ Master Protocol:** The common protocol with uniform core objectives, methods, and measurement tools approved by Advisory Committee. The Master protocol may remain consistent across the sites in multicentre research however the consent form can be modified/ translated as per local requirements.

**Scientific Committee (SC):** May also be referred to as Central Scientific Advisory Committee (C-SAC)/ National Task Force (NTF) / Technical (Scientific) Advisory Committee (SAC)/ Steering Committee (SC)/ Project Review Committee (PRC). This committee includes a group of independent subject experts apart from investigators involved in the study/ or members of funding agencies/sponsors or its representatives. This committee could be an existing committee or appointed specifically for the study. Undertakes detailed scientific review and its approval. For multicentre studies, it may suggest (if required) waiver for review by other site specific scientific committees in view of time constraints or to avoid duplication.

**Monitoring Committee (optional):** This committee may be suggested or appointed by the joint ethics committee or sponsors to undertake closer oversight or monitoring. This committee may include experts from funding agencies/sponsors/partners/ EC members or other independent experts or members from EC as per requirement.

**Coordinating Principal Investigator (C-PI):** Coordinating PI is one who takes the overall responsibility of conducting multicentre research in collaboration with PIs from all the participating centres and is also responsible for ongoing communication between ethics committees and PIs at other participating centres.

**Site Principal Investigator (S-PI):** The S-PI is the person who takes the responsibility of conducting research at her/his participating centre in the multicentre research. Each centre can have additional co-investigator(s), who may conduct the study within the centre in association with and/or in the absence of the Site PI.

**Central Ethics Committee on Human Research (CECHR):** A committee appointed by the DG ICMR to act at the national level to guide ICMR regarding complex ethical issues or review research led by ICMR Headquarters Office or referred to it by ICMR institutions, other government Ministries and Departments.

**Designated Ethics Committee (DEC):** The Ethics Committee usually from the Coordinating Site (or any of the Participating sites), which assumes the responsibility of undertaking a common initial and continuing review of the multicentre research proposal with mutual agreement of all the participating centres. Responsible for conducting an in-depth Joint review and providing suggestions/ recommendations to PEC.

**Participating Centre Ethics Committee (PEC):** The Participating Centre ECs are located at the various participating centers in multicenter research (including DEC). PECs are responsible for a review of research according to the local requirements and for providing decision to the participating local sites. They may undertake an expedited reviews and accept the recommendations (if acceptable) of DEC or decide as per local requirements. They are responsible for monitoring research at local level.

**Joint Ethics Committee Review Meeting:** is a meeting coordinated by Designated Ethics Committee (DEC) where the Participating Ethics Committees (PECs) meet for joint discussion amongst the ethics committees of all participating sites in order to undertake a detailed ethics review and to give recommendations followed by final decision making by individual site ECs (PECs).

1. **Introduction:**

Collaborations in research provide a unique opportunity to present meaningful outcomes in research. The ability to quickly recruit a large number of people, document population and subpopulation variety, statistical power, generalizability, improved relevance and increased likelihood of practice and/or policy translation are all primary benefits of multicentre research. These collaborations can be inter-departmental/inter-institutional or international and also multicentre involving public and/or private research centres and agencies. During the COVID-19 pandemic, the significance of international/national cooperation and collaboration has been clearly demonstrated. The need for quick and informed ethics review as the situation demands becomes the need of the hour, especially in pandemics, emergencies and disasters. In this regard, a step-by-step ethics review and governance framework for multicentre research is an important research tool that can facilitate fast-tracking decision-making while ensuring the protection of human research participants.

Currently in India, for multicentre research, all centres seek approval from their respective ECs, which would consider the local needs and requirements of the population and safeguard the dignity, rights, safety and well-being of the participants. However, there are reported delays and barriers due to the requirement for multiple ethical approvals, the inability to use technology, managing Conflict of Interest (COI), ambiguity in ownership of materials and data, intellectual property rights (IPRs), joint publications etc. The ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, has discussed the process for common ethics review for multicentre research. This guideline provides more detailed step-by-step guidance for undertaking a joint ethics review for multicentre research specifically for the ICMR network of institutions.

2. **Purpose:**

This guidance attempts to illustrate the roles; responsibilities of the stakeholders involved in the Joint ethics review of multicentre research for ICMR Institutions. It also elaborates on the steps to be adopted to streamline the ethics review process of multicentre research being undertaken by ICMR so that research can proceed expeditiously, however, without compromising any ethical values or principles in order to protect the research participants.

3. **Scope:**

This guidance applies to ECs, investigators/ and other stakeholders involved in multicentre biomedical and health research involving human participants undertaken and led by ICMR or its network of institutions. This guidance does not extend to the clinical trials that require approval from Central Drugs Standard Control Organization (CDSCO) under the Drugs and Cosmetics Act and Rules as amended from time to time. These guidelines are complementary to the main ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, the reference document.

4. **Ethical principles for multicentric research**

The core 12 ethical principles of biomedical and health research should be followed as elaborated in ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017. While multicentric research facilitates increased productivity and validity, larger and more meaningful outcomes and interpersonal and varied ethical issues

may arise. A few additional principles are enunciated here to be applied before, during and after the completion of multicentric research.

- Principle of Collegiality: Treating all members of a research team or lab with respect and dignity
- Principle of Trust: Researchers must trust that their collaborators will provide accurate information regarding the approved research protocol, keep accurate records, and sharing information openly and honestly with all collaborators.
- Principle of Fairness: All contributing parties should be treated with fairness regarding intellectual property rights, authorship or acknowledgement on the publication of the research and their contributions acknowledged appropriately.
- Principle of Accountability: All stakeholders involved in research must be able to justify the work that has been done and be accountable for its outcome.
- Principle of Cooperation: Researchers must share information and resources and coordinate efforts to attain a mutual goal. Cooperation requires collegial and trusting relationships and can be formalized through communication.

## 5. Responsibilities:

**5.1. Coordinating PI (C-PI):** Coordinating PI is the one who takes overall responsibility for the conduct of the multicentre research along with site (S-PIs) from all the participating centres. He/ she is involved in ongoing communication between the designated Ethics Committee (DEC) and S-PIs of other participating centres. In most cases, the EC of her/his centre would serve as the Designated Ethics Committee.

- To ensure scientific review and approval is obtained from the Scientific Committee before submission for ethics review.
- To fill out the Common Review Application form - Part 1 and to ensure completeness of documentation using the checklist provided in the form (Annexure 15) https://ethics.ncdirindia.org/Common_forms_for_Ethics_Committee.aspx
- To function as a link between DEC and S-PIs and to communicate the recommendations of DEC to S-PIs and the PECs.
- To submit information regarding any amendments/ Serious adverse events /other significant events and to submit a collated annual report to DEC and Scientific Committee.
- To communicate the concerns received from one centre to other centres/PEC/DEC (if required) depending on the significance of the concern that may impact other centres as well.

**5.2. Site Principal Investigator (S-PI):** The S-PI is the person who takes overall responsibility for the conduct of multicentre research at her/ his participating centre. Each centre can have additional co-investigator(s), who may conduct the study within the centre.

- To modify the study proposal and Informed consent form according to the local context before the submission to the Participating Centre's Ethics Committee for review.
- To prepare required recruitment material or advocacy material, audio-visual aids/ other tools/ brochures/ etc as per requirement and to get them translated into local languages in consultation with participating sites for local relevance.
- To fill out the Common Review Application form - Part 2 and to ensure completeness of documentation using the checklist provided in the form (Annexure 15). https://ethics.ncdirindia.org/Common_forms_for_Ethics_Committee.aspx

- To devise strategies for community engagement with the participating populations/ communities involved (as per need and requirements of the study).
- To function as a link between PEC and Coordinating PI to communicate the recommendations.
- To initiate the study in their centre as and when approval from the PEC is obtained.
- To ensure back translation of the informed consent document in English along with the certificate and to submit the same to the coordinating PI for documentation.
- To submit information regarding any amendments, deviations, violations, and non-compliances and prepare the annual report (from sites) and submit it to PEC and the coordinating PI.
- To report serious adverse events related to the study, unanticipated problems involving risks to participants or others, significant to PEC.

**5.3. Designated Ethics Committee (DEC):** The EC at the coordinating site assumes the responsibility to coordinate/undertake a common review of the research proposal with mutual agreement of all the ECs of participating centres. The EC is required to fulfil the following criteria to be identified as the DEC.

**Essential criteria:**

- Should be the EC of one of the participating centres, located in India and willing to conduct a common ethics review of specific multicentre research.
- Have minimum 3 years of experience in reviewing research protocols.
- Registered with regulatory authorities such as CDSCO and/or DHR (as per New Drugs and Clinical Trials Rules, 2019).

**Desirable criteria:**

- Accredited by NABH or has undergone any other national/ international recognition/ quality assurance programs.

**Role:** The National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 describe the roles and responsibilities of the EC under section 4.7. In addition, the following are the responsibilities of DEC.

- To ensure completeness of documentation/ prior scientific approval for the submission made by Coordinating PI.
- DEC should have the infrastructure to host virtual meetings with the EC members/researchers/and other stakeholders if needed.
- To identify lead discussants/ primary and secondary reviewers/ scientific reviewers who will lead discussions during the joint EC meeting.
- To plan Joint ethics committee review on a mutually convenient date and time and to ensure that all PECs members are invited to join this Joint EC review online
- To conduct a detailed initial and continuing review of the study for all centres involved in multicentre research.
- The DEC must ensure that the participating centres are comparable in their equipment, staff, timetables and recruitment.
- As per requirement, decide about the need to invite Community representatives/ patient representatives/ to the meeting or to recommend the need for setting up of Community Advisory Board or other requirements for Community engagement depending upon the design of the study (if required).
- To provide recommendations to the participating centres after the review as DEC.

- To issue a decision letter for its own centre (as PEC).
- To review annual and progress reports, adverse events, protocol deviation/ violation and any other documents deemed significant.
- To review submissions (if any) from PEC regarding any specific local issue(s) faced by PEC and plan further action. For significant matters pass on information to the coordinating PI to share with all participating sites
- To maintain and update a repository of copies of study-specific documents, which include the submissions made by the site PIs to their PECs, the centre-specific consent forms and decision letters issued by the PECs.
- To network with all PECs of the study and communicate on regular basis.

**5.4. Ethics Committees of the participating centres (PEC):** EC which assumes the responsibility to undertake the review of the research proposal at the participating centre in multicentre research shall be called the PEC (DEC is also PEC for its own centre). PEC should ensure respect of participants and communities; recommends changes to informed consent documents (if locally relevant and necessary), translations into the local language, review informed consent and monitor conduct of research as per local requirements at their respective centres/ participating sites.

**Essential Criteria of PEC**:

- PEC located in India must be registered with DHR/CDSCO depending on the review they undertake.
- Participating Ethics Committee must agree to be a part of joint ethics review and to facilitate review at the local level (such as conduct expedited review/ accept recommendations of joint meeting) and issue decision letter.

**Role:** The National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 describes the roles and responsibilities of the EC under section 4.7. In addition, the following are the requirements:

- PEC to ensure the suitability of S-PI, Site and participants / Site specific protocol (feasibility of conducting the research in the communities, taking into account factors such as the availability of necessary infrastructure and qualification and training of S-PI.
- May identify lead discussants/ primary and secondary reviewers/ scientific reviewers (if needed) who will lead discussions when the PEC splits to deliberate the proposal in local context during the Joint review.
- To review participating centre-specific information and related modifications needed in the study proposal through full committee meeting/expedited review in a routine or fast-track manner depending on the type of research and ethical issues associated with it and to safeguard the rights, safety and well-being of research participants.
- The type of review required is decided by the member secretary in consultation with the chairperson above.
- To attend the Joint EC meeting virtually conducted by the DEC on a mutually convenient date and time.
- The PEC can accept/reject/ modify a multicentric research proposal depending on the ethical issues associated with the research specifically pertaining to the local context.
- To issue the final decision letter for the study at the centre to S-PI.
- To review the progress reports/ annual reports/ amendments/ deviations or any other locally relevant issues etc at the participating site.

- To review serious adverse events related to the study, causality assessment, protocol deviations at the centre, unanticipated problems involving risks to participants or others, and significant complaints/any potential non-compliance. Significant SAEs or other modifiable events must be reported to other PECs / DEC/other relevant regulatory authorities as per requirement.
- To ensure prompt communications to DEC if there are specific concerns that may impact other centres as well.
- PEC can suspend/ withdraw/ amend any approval granted at the participating sites on the grounds of non-compliance / unforeseen risks to the participants.

## 6. JOINT Ethics Review:

### 6.1. Process

- The meeting is to be organized ONLINE on a mutually convenient date and time and all EC members are to be informed in advance.
- The Meeting link is to be generated by Designated EC at the Coordinating Site and is to be shared with member secretaries of all participating sites.
- The Joint EC meeting is to be attended by all Participating Ethics Committee members (preferably) or at least the minimum quorum requirements are fulfilled by the PEC members in the breakout rooms to facilitate decision-making.
- During the meeting the Coordinating PI (and other S-PIs) may make a presentation followed by a discussion on scientific merit and ethical aspects of the research protocol.
- Lead Discussants or Primary/ Secondary reviewers/ identified from the Designated Ethics Committee may lead these discussions. Likewise, PEC may also identify lead discussants or primary/ secondary reviewers for their local review in the breakout session.
- Following the Joint meeting with members of DEC and all PECs the Site Ethics committees may spilt into separate Meeting rooms (online) to discuss local concerns and issues and review the informed consent translations.
- The time for PECs to deliberate local issues may be decided mutually before they break into individual rooms. They are required to come back to the main meeting after due deliberations.
- The ethics committees of all participating centres (excluding the DEC) are responsible for review at the local level to safeguard research participants and ensure appropriate community engagement, informed consent forms and processes are in place for monitoring and oversight at the local level.
- The PECs on rejoining the joint meeting may inform and discuss their concerns with the full group and seek solutions before the joint group comes to a consensus in the joint review process and DEC can provide recommendations.
- The recommendations that emerge in the deliberations are to be duly noted and minuted and shared by the DEC with the coordinating PI to be further shared with S-PIs and Site PECs. Need for Community Advisory Board (CAB), if any, can be considered during the joint review.
- Participating site ECs can still maintain their autonomy to accept the recommendations, as such, or to modify them by issuing an approval letter.
- PECs must focus on socio-cultural context, local ethical concerns, implementation of research, informed consent translations, periodic review, local site monitoring and oversight of research.

- There is a need to ensure good communication and coordination between the researchers and EC Secretariats of participating sites.
- Common protocol should be adopted across all the participating sites. Site-specific modification can be done with agreement from EC to address the site-specific unique features without changing the protocol significantly and must be reported to DEC.
- Decision letter is issued by PECs to S-PIs of respective participating centres after the review. The decision letter (approval/ modification) is forwarded to Coordinating PI and the coordinating PI should keep the DEC informed about the same.

**6.2. Benefit-risk assessment**

- During the Joint ethics meeting an assessment of benefits and risks with respect to the research proposal submitted must be undertaken.
- The Local PECs should assess the probability of any altered risks at a particular site due to local reasons.
- The comments should be shared with other ethics committees during the joint EC meeting.

**6.3. Informed consent document**

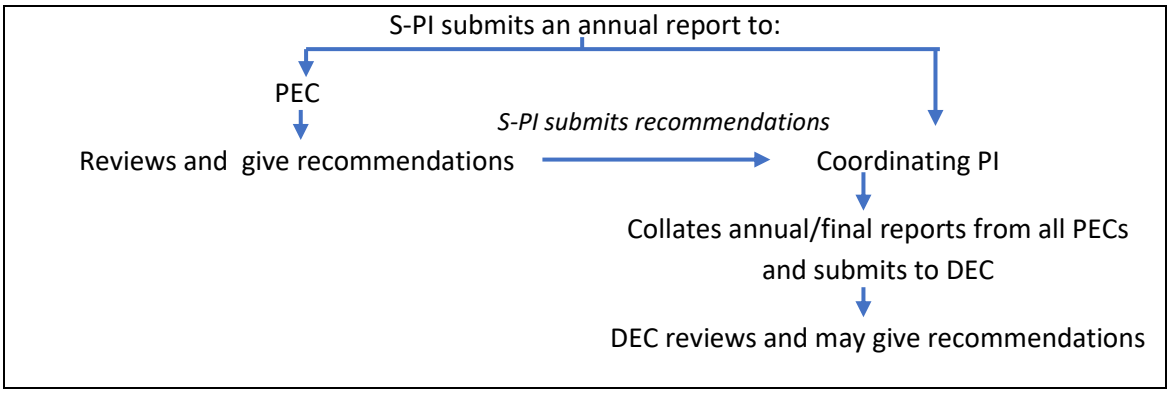
- The informed consent document should explicitly mention that the study is a part of the multicentre study and is prepared in a simplified manner. It may include audio/visual/other advocacy materials to improve the understanding of participants.
- The informed consent for every participating centre should incorporate modifications which are site-specific and as per the local needs.
- The S-PI should ensure local translation and thereafter back translation of the informed consent document in English along with the certificate. A copy of the same must be submitted to the coordinating PI for documentation.
- PEC must ensure that the overall content of the Informed Consent Document is uniform in terms of information related to the type of data collected, methods of data collection, plans for analysis, data sharing, data storage and secondary use of data.
- The identity of the research team and contact persons with addresses and phone numbers of the S-PI and coordinating PI for queries related to the research and Chairperson/Member Secretary of the PEC, DEC or helpline for appeal against violations of ethical principles and human rights should be mentioned in the document.

**6.4. Privacy and confidentiality**

- Joint Ethics Meeting should review the provisions in place for protecting the privacy and confidentiality of the research participant across all PECs.
- The need to have an MoU/ MTA between the participating centres and Coordinating Centre may be assessed and suggested if required (optional).
- The data sharing, custodianship of data and its maintenance/storage etc. should be clearly described in the protocol.
- In an event of a breach of privacy/confidentiality, the S-PI should inform the PEC and Coordinating PI. The decision of the PEC may be conveyed to the Coordinating PI and DEC.
- Any additional data to be collected from a particular PEC should be justified and must be informed to the DEC

### 6.5. Annual and Final Report

- The S-PI should submit /present the annual and/or final report at the PEC for review and recommendations and forward the report along with PEC recommendations to the coordinating PI.
- The coordinating PI must collate, summarize and document all the annual reports and final reports.
- The coordinating PI / S-PIs should submit the summarized final report to the DEC and may present the report if a final Joint ethics meeting is conducted.

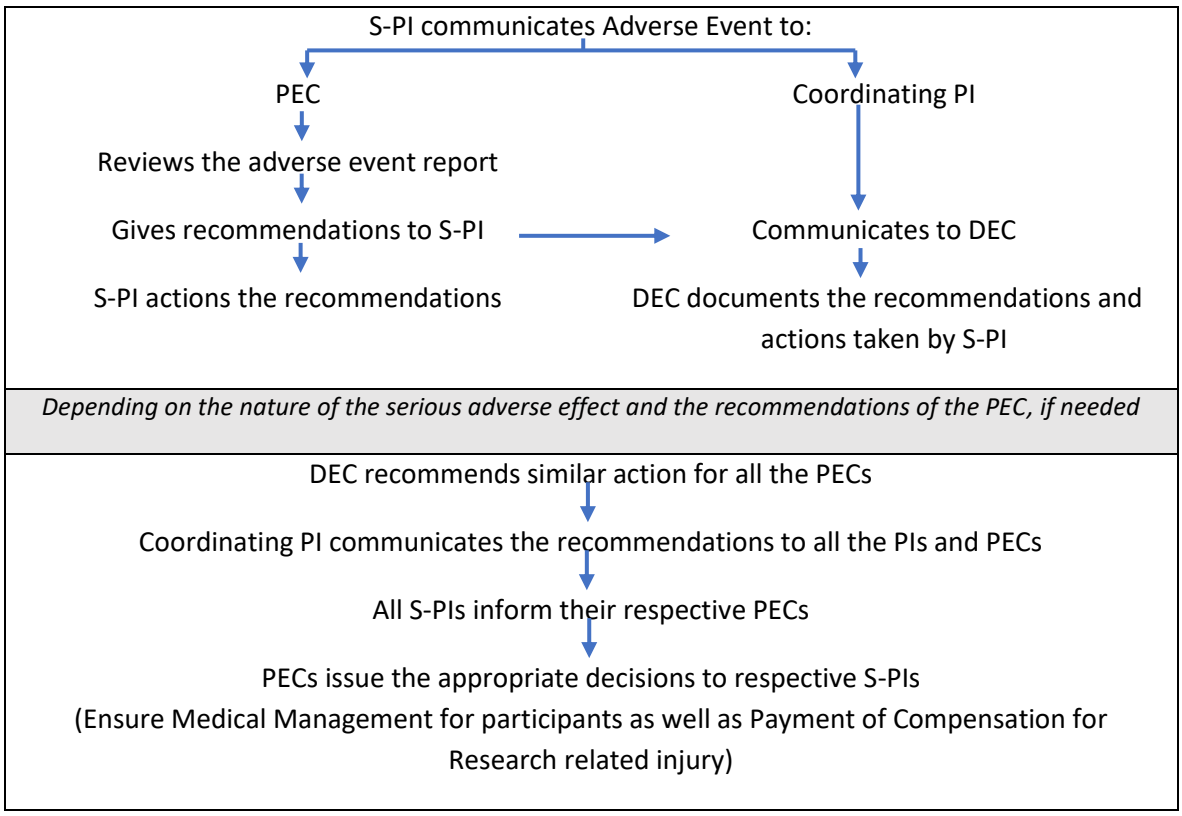



### 6.6. Protocol Amendment: Submission and Review Process:

- Major/ minor amendments in the protocol are to be submitted by Coordinating PI to DEC for review, the recommendation of which shall be communicated to all S-PIs and PECs.
- All amendments/ deviations/ violations made should be communicated to the DEC for information by Coordinating PIs at the earliest.
- ICMR Common Form (Annexure 4; Available at: https://ethics.ncdirindia.org/CECHR_PDF/New/5CECHRApplicationFormForAmendments.pdf) to be used for submission for joint ethics review.

### 6.7. Serious Adverse Events, Adverse Events, Deviations and Other Types of Reportable Events, Suspension and Termination of studies:

- Reporting of Serious Adverse Events, Adverse Events, Deviations and other types of reportable events for each centre should be done within 24 hours of knowledge by site PI to PEC and to Co-PI. ICMR common form (Annexure 6; Available at: https://ethics.ncdirindia.org/CECHR_PDF/New/7CECHRSAEReportingFormat.pdf)
- The PEC can suspend or terminate the approval of studies in accordance with any local concerns violations/policies and procedures. The same is to be communicated with the coordinating PI and DEC.
- The PEC can convey their concerns and decision, if any, to DEC for consideration. The DEC may advise the other centres regarding the same.
- For any research involving higher risk provisions in the budget or through Insurance Policy/ Corpus funding / Institutional grants should be in place for covering costs required for medical management and for Payment of compensation for research-related injury (if required for any participant).
- If the research as a whole is suspended or terminated by the DEC, the coordinating PI will promptly notify all S-PIs and PEC.




### 6.8. Record keeping and archiving

- Access to all the records and their control will be maintained by PECs and DEC for a minimum period of 3 years following the completion or termination of the study. PEC will archive only Centre Specific Records and information as shared by the DEC
- The S-PIs and PECs should refer to their institutional SOPs or sponsor requirements for record-keeping and archiving beyond 3 years.

### 6.9. Post-research access and benefit sharing

- The Joint Ethics Meeting should ensure that methods of benefit sharing are included in the master protocol and must follow any prior agreements between the researchers and sponsors regarding the same.
- Efforts are to be made by S-PI to communicate back the findings of the study which may be relevant to participants or share back any benefits that are applicable.
- Post-research benefits and care should be uniform to all the participants across all the centres.

### 6.10. Publication Policy

- Plans for manuscript publication and a common final report with contributors from the participating sites should be decided before the initiation of the study.
- ECs of all participating sites may plan a joint LOA (Letter of Agreement) between all participating sites for clarity in the roles and responsibilities regarding their collaboration and publication at the very beginning itself.
- The publication rights, authorship sequence and other details need to be carefully worked out well before data collection. The primary author should be the person who has done most of the research work related to the manuscript being submitted for

publication. the same is to be communicated with the EC before the initiation of the study.

- The research plan and outcomes emanating from the research can be brought into the public domain through public registries, report health department websites or other data repositories and scientific and other publications while safeguarding the right to privacy of the participants.
- The study should be registered on the CTRI portal prior to initiation.

***Note:*** *Please refer to section 3.5 on Responsible authorship and publication and Section 10.8 for Publication aspects of ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017 for detailed information.*

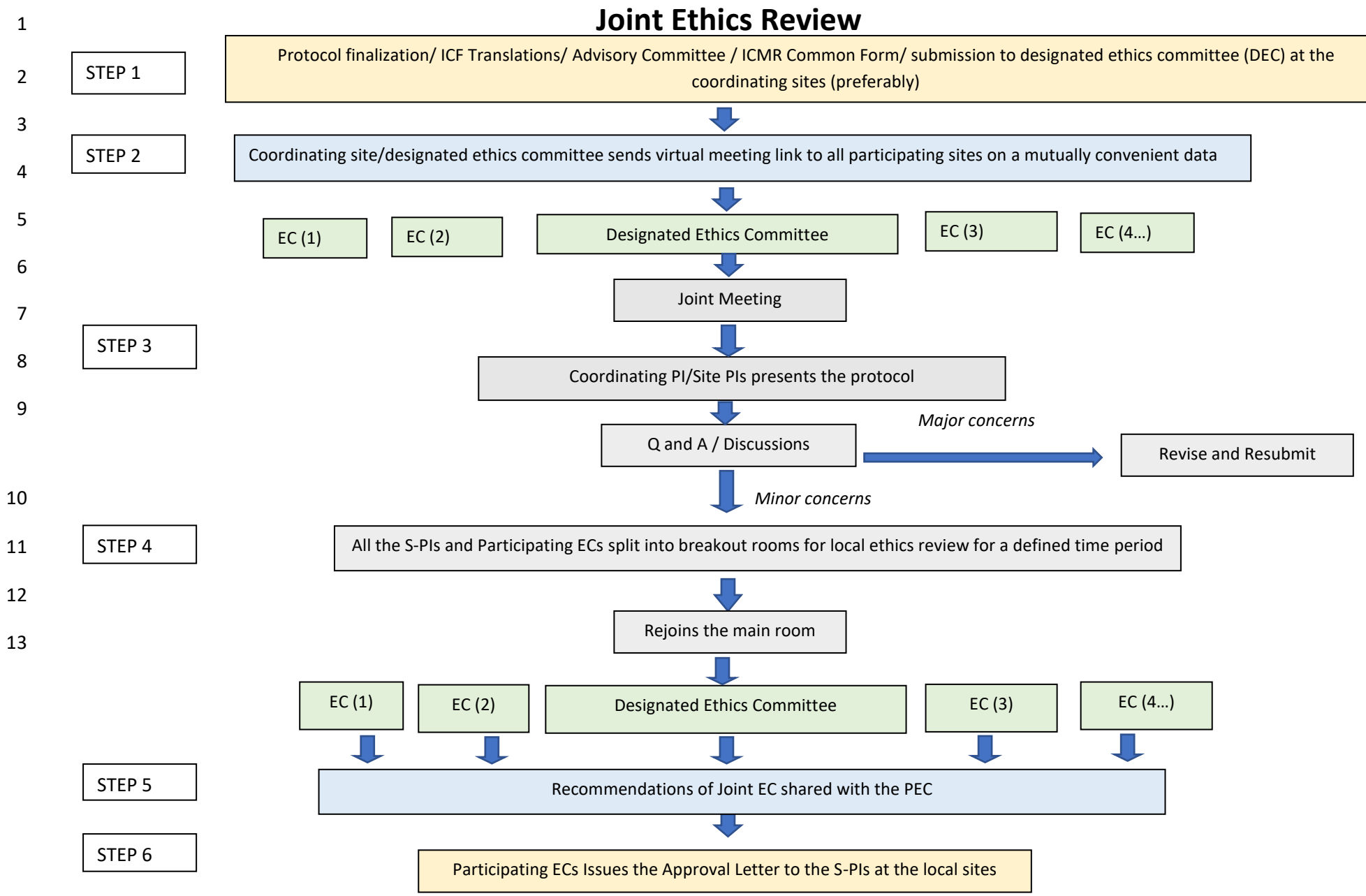
**7. Research Governance**

- Scientific Committee assume the responsibility to undertake a prior scientific review and to deal with the technical and scientific issues arising during the conduct of the study.
- Other sub-committees may be constituted as per need such as Quality Assurance Committee, Publication Committee, Project management committee, SAE and Causality assessment committee etc, and DSMB as per requirement.
- Subject matter experts having no conflict of interest, who are not the investigators, members of funding agencies, sponsors, or their representatives for the study to preferably make up the Scientific Committee.
- The Monitoring Committee (if any) may be comprised of independent experts or representatives from funding agencies/sponsors/partners/ ECs to deal with issues arising during the study.
- Confidentiality agreements and Conflict of Interest declarations are to be signed by experts who are invited for review/ monitoring.
- All annual/ final / progress reports from the local participating centre may be collated and presented by coordinating PI to DEC and scientific committee to oversee the ethical and scientific conduct and monitor any oversight. (Annexure -3- Common forms for Annual Report) (https://ethics.ncdirindia.org/CECHR_PDF/New/4CECHRContinuingreportorAnnualReportForm.pdf).
- Depending on the design of the study, the risk to the participant, noncompliance, SAE, complaint, protocol deviation, and site visits may also be undertaken by the DEC or PEC as deemed necessary.
- The following table illustrates the suggested governance mechanism for multicentre research

| Role | Before Study | During Study | After study |
|---|---|---|---|
| Scientific Committee | Checks for technical and scientific soundness of the proposal and gives recommendations | In case of event ( could be deviation, amendment/ serious adverse affect), reviews the proposal and provides guidance/ action. | Reviews the final report and gives insight |
| Coordinating PI | Ensures all scientific guards and ethical principles are incorporated in the proposal. Submits to the DEC and ensures compliance | Responsible for the overall scientific and ethical conduct of the study. Communicates with the DEC in case of adverse event Communicates recommendations from the committees to S-PIs if need be | Submits final report to the scientific committee and DEC |
| Site PI | Ensures all scientific guards and ethical principles in the local context are incorporated . Prepares the translated ICF and submits to PEC | Responsible for the centre specific scientific and ethical conduct of the study. Communicates with the coordinating PI Ensures compliance | Submits final report to the coordinating PI and PEC |
| DEC | Checks for scientific and ethical soundness of the proposal and gives recommendations for PECs and approval for own site as PEC | In case of adverse event, reviews the proposal and provides guidance / action Maintains communication with PECs | Reviews final report and gives insights |
| PEC | Checks for scientific and ethical soundness of the proposal and informed consent process in the local context and gives approval/ decision to conduct study at site | In case of adverse event, reviews the proposal and provides guidance /action | Reviews final report and gives insights |
| Monitoring Committee | Appointed by Funding agency or by DEC as per the requirement of the study | Reviews reports and ensures compliance May undertake site visit, if need be | Submits report to DEC for review |

***"This document does not replace any preexisting national guidance materials, nor does it supersede any administrative or legislative obligations that may be mandated by a particular jurisdiction"***

**Annexure 1: Flowchart for Joint Ethics Review**



**References:**


1. ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017.

   https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf

2. ICMR National Guidelines for Ethics Committees reviewing Research During the COVID-19 Pandemic, April, 2020.
   https://www.icmr.gov.in/pdf/covid/techdoc/EC_Guidance_COVID19_06052020.pdf

3. ICMR common forms for EC review" and fill in the application form and submission (Common Forms for Ethics Committee Review- Available at: https://ethics.ncdirindia.org/Common_forms_for_Ethics_Committee.aspx).

4. National Registry for Ethics Committees Reviewing Biomedical and health Research (DHR NAITIK PORTAL) https://naitik.gov.in/DHR/Homepage

5. ICMR Research Integrity and Publication Ethics Policy. Available at: https://main.icmr.nic.in/sites/default/files/upload_documents/ICMR_policy_ripe.pdf

6. Multicentre initial review form available at:
   https://ethics.ncdirindia.org/Common_forms_for_Ethics_Committee.aspx

ICMR Bioethics Unit

# (Annexure 15)
# Initial Review Form for Multicentric Research

**EC Ref. No. (***for office use):*

## PART 1 (To be filled by coordinating PI)

General Instructions: a) Tick one or more as applicable. Mark NA if not applicable. Attach additional sheets if required
b) For submission to Designated Ethics Committee and to be shared with PIs at Participating Centres

## SECTION A - BASIC INFORMATION

### 1. ADMINISTRATIVE DETAILS

(a) Name of Institute under which Designated Ethics Committee is constituted:

(b) Name of the Ethics Committee:

(c) Name of Coordinating Principal Investigator:

(d) Designation and Qualification:

(e) Department/Division: (e) Date of Submission: Click here to enter a date.

(f) Address for communication *(include email and mobile no.)*

(f) Type of review requested[1]**:**

Exemption from Review ☐ Expedited Review ☐ Full Committee Review ☐

(g) Title of the study:

Acronym/ Short title, (If any):

(h) Protocol number (If any): Version number: Date: Click here to enter a date.

(i) Number of studies where applicant is a:

i) Principal Investigator at time of submission: ii) Co-Investigator at time of submission:

(j) Duration of the study:

### 2. FUNDING DETAILS AND BUDGET

(a) Total estimated budget for study:

At site In India Globally

(b) Self-funding ☐ Institutional funding ☐ Funding agency ☐ **S**

*(Specify)*

[1] *Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017on Page 36 Table 4.2. for the types of review*

## SECTION B -RESEARCH -RELATED INFORMATION

### 3. OVERVIEW OF RESEARCH

(a) Lay Summary of study[2] (within 300 words)

(b) Type of study:

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

### 4. METHODOLOGY

(a) Sample size/ No. of Participants (*as applicable)*

| At site | In India | Globally |
|---|---|---|
| Control group | Study Group | |

Justification for the sample size chosen (*100 words*); In case of qualitative study, mention the criteria used for selection

(b) Is there an external laboratory/ outsourcing involved for investigations?[3] Yes ☐ No ☐ NA ☐

(c) How was the scientific quality of the study assessed?

| | | | | | |
|---|---|---|---|---|---|
| Independent external review | ☐ | Review by Sponsor/Funder | ☐ | Review within PI's institution | ☐ |
| Review within multi-centre research group | ☐ | No Review | ☐ | | |

Date of review: Click here to enter a date.

Comments of Scientific Committee, if any (100 words)

[2] *Summarize in the simplest possible way such that a person with no prior knowledge of the subject can easily understand it.*

[3] *If participant samples are sent outside for investigations, provide details of the same and attach relevant documentation such as an MTA/ MoU etc.*

## SECTION C - PARTICIPANT RELATED INFORMATION

### 5. RECRUITMENT AND RESEARCH PARTICIPANTS

(a) Type of participants in the study:

Healthy volunteer ☐ Patient ☐ Vulnerable person/ Special groups ☐ Others *(Specify)* ☐

Who will do the recruitment?

Participant recruitment methods used:

Posters/ leaflets/Letters ☐ TV/Radio ads/social media/Institution website ☐ Patients / Family/Friends visiting hospitals ☐ Telephone ☐

Others *(Specify)* ☐

(b) i. Will there be vulnerable person/special groups involved? Yes ☑ No ☐ NA ☐

ii. If yes, type of vulnerable person /special groups

Children under 18 yrs. ☐ Pregnant or lactating women ☐

Differently abled (Mental/Physical) ☐ Employees/Students/Nurses/ Staff ☐

Elderly ☐ Institutionalized ☐

Economically and socially disadvantaged ☐ Refugees/Migrants/Homeless ☐

Terminally Ill (stigmatized or rare diseases) ☐

Any other *(Specify)*: ☐

iii. Provide justification for inclusion/exclusion

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

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

If yes, Monetary ☐ Non-monetary ☐ Provide details

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

If yes, Monetary ☐ Non-monetary ☐ Provide details

(e) Are there any participant recruitment fees/ incentives for the study provided to the PI/ Institution?

If yes, Monetary ☐ Non-monetary ☐ Provide details Yes ☐ No ☐

## 6. BENEFITS AND RISKS

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

Yes ☐ No ☐

If yes, categorize the level of risk[4]:

| | | | |
|---|---|---|---|
| Less than Minimal risk | ☐ | Minimal risk | ☐ |
| Minor increase over minimal risk or Low Risk | ☐ | More than Minimal Risk or High Risk | ☐ |

ii. Describe the risk management strategy:

(b) What are the potential benefits from the study?

| | Yes | No | If yes, Direct | Indirect |
|---|---|---|---|---|
| For the participant | ☐ | ☐ | ☐ | ☐ |
| For the society/community | ☐ | ☐ | ☐ | ☐ |
| For improvement in science | ☐ | ☐ | ☐ | ☐ |

Please describe how the benefits justify the risks

(c) Are Adverse Events expected in the study[5]? Yes ☐ No ☐ NA ☐

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

If Yes, Specify

## 7. INFORMED CONSENT

(a) Are you seeking waiver of consent? If yes, please specify reasons and skip to question 8. Yes ☐ No ☐

(b) Version number and date of Participant Information Sheet (PIS):

Version number and date of Informed Consent Form (ICF):

(c) Type of consent planned for:

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Signed consent | ☐ | Verbal/ oral consent | ☐ | Witnessed consent | ☐ | Audio-Video (A/V) consent | ☐ |
| Consent from LAR (If so, specify from whom) | ☐ | For children<7 yrs parental/LAR consent | ☐ | Verbal assent from minor (7-12 yrs) along with parental consent | ☐ | Written Assent from Minor (13-18 yrs) along with parental consent | ☐ |

Other *(specify)* ☐

(d) Who will obtain the informed consent?

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| PI/Co-I | ☐ | Nurse/Counselor | ☐ | Research Staff | ☐ | Other *(Specify)* | ☐ |

Any tools to be used

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

[5] *The term adverse events in this regard encompass both serious and non-serious adverse events.*

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

English ☐ Local language ☐ other ☐ (*specify*)

List the languages in which translations were done

If translation has not been done, please justify

(f) Provide details of Consent requirement for previously stored samples if used in the study[6]

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

| | | | | | |
|---|---|---|---|---|---|
| Simple language | ☐ | Data/ Sample sharing | ☐ | Compensation for study related injury | ☐ |
| Risks and discomforts | ☐ | Need to recontact | | Statement that consent is voluntary | |
| Alternatives to participation | ☐ | Confidentiality | ☐ | Commercialization/benefit sharing | ☐ |
| Right to withdraw | ☐ | Storage of samples | ☐ | Statement that study involves research | ☐ |
| Benefits | ☐ | return of research results | ☐ | Use of photographs/ identifying data | ☐ |
| Purpose and procedure | ☐ | Payment for participation | ☐ | Contact information of PI and Member Secretary of EC | ☐ |
| Others*(Specify)* ☐ | | | | | |

## 8. PAYMENT/COMPENSATION

(a) Who will bear the costs related to participation and procedures[7]?

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

(b) Is there a provision for free treatment of research related injuries? Yes ☐ No ☐ NA ☐

If yes, then who will provide the treatment?

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

Sponsor ☐ Institution/ Corpus funds ☐ Project grants ☐ Insurance ☐

(d) Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? If yes, specify. Yes ☐ No ☐ NA ☐

(e) Is there a provision for ancillary care for unrelated illness during the study period? If yes, please specify. Yes ☐ No ☐ NA ☐

[6] *Information on re-consent requirements can be found at National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 54 in Section 5.8*

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

## 9. STORAGE AND CONFIDENTIALITY

(a) Identifying Information: Study Involves samples/data. If Yes, Specify Yes ☐ No ☐ NA ☐

Anonymous/unidentified ☐ Anonymized: Irreversibly Identifiable ☐
reversibly coded ☐ coded ☐

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

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

(c) Where will the data be analyzed[7] and by whom?

(d) For how long will the data be stored?

(e) Do you propose to use stored samples/data in future studies? Yes ☐ No ☐ Maybe ☐
If yes, explain how you might use stored material/data in the future?

# SECTION D: OTHER ISSUES

## 10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

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

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

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

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

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

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

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

## SECTION E: CHECKLIST FOR COORDINATING PI

**11. CHECKLIST**

| S.No | Items | Yes | No | NA | Enclosure No. | EC Remarks |
|---|---|---|---|---|---|---|
| **ADMINISTRATIVE REQUIREMENTS** | | | | | | |
| 1. | Cover letter | ☐ | ☐ | ☐ | | |
| 2. | Brief CV of all Investigators | ☐ | ☐ | ☐ | | |
| 3. | Good Clinical Practice (GCP) training of investigators in last 3 years | ☐ | ☐ | ☐ | | |
| 4. | Approval of Scientific Committee/ NTF/ Central Advisory Committee/ Any other | ☐ | ☐ | ☐ | | |
| 5. | Agreement/MTA / LOA between collaborating partners | ☐ | ☐ | ☐ | | |
| 6. | Insurance policy/certificate | ☐ | ☐ | ☐ | | |
| 7. | Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification | ☐ | ☐ | ☐ | | |
| 8. | Copy of contract or agreement signed with the sponsor or donor agency | ☐ | ☐ | ☐ | | |
| **PROPOSAL RELATED** | | | | | | |
| 9. | Copy of the detailed protocol | ☐ | ☐ | ☐ | | |
| 10. | Participant Information Sheet (PIS) and Informed Consent Form (ICF)(English and translated) | ☐ | ☐ | ☐ | | |
| 11. | Assent form for minors (12-18 years) (English and Translated) | ☐ | ☐ | ☐ | | |
| 12. | Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated) | ☐ | ☐ | ☐ | | |
| 13. | Advertisement/material to recruit participants (fliers, posters etc) | ☐ | ☐ | ☐ | | |

| **PERMISSION FROM GOVERNING AUTHORITIES** | | | | | | |
|---|---|---|---|---|---|---|
| | **Other Registration/ permissions** | **Required** | **Not required** | **Received** | **Applied dd/mm/yy** | **EC Remarks** |
| 14. | CTRI[8] | ☐ | ☐ | ☐ | Enter date | |
| 15. | HMSC[9] | ☐ | ☐ | ☐ | Enter date | |
| 16. | Tribal Board | ☐ | ☐ | ☐ | Enter date | |
| 17. | Any Other | ☐ | ☐ | ☐ | Enter date | |

| **ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY** | | | | | | |
|---|---|---|---|---|---|---|
| | **Item** | **YES** | **NO** | **NA** | **Enclosure no.** | **EC remarks** |
| 18. | | ☐ | ☐ | ☐ | | |

*[8]CTRI: Clinical Trial Registry- India, [9]HMSC: Health Ministry's Screening Committee*

## PART 2 (To be filled by S-PI at the Participating Centre)

General Instructions: a) Tick one or more as applicable. Mark NA if not applicable. Attach additional sheets if required
b) For submission to Participating Ethics Committee (PEC) and to be shared with coordinating PI

## SECTION A - BASIC INFORMATION

### 1. ADMINISTRATIVE DETAILS

a) Name of the institute under which PEC is constituted:

b) Name of the Ethics Committee:

c) Name of Site Principal Investigator:

d) Designation/ Qualification: e) Department/ Division:

f) Address for communication (include mobile no. and email address):

g) Expected duration of the study**:** Estimated budget at the participating site:

## SECTION B - RESEARCH INFORMATION

### 1. OVERVIEW OF RESEARCH

a) Briefly describe the role of the participating center in the study (*50-100 words*):

b) Briefly mention local changes made in protocol, if any:

c) Type of review requested**:**

Exemption from Review ☐ Expedited Review ☐ Full Committee Review ☐

## SECTION C – PARTICPANT RELATED INFORMATION

### 1. PATIENT RECRUITMENT AND RESEARCH PATIENTS

a) Number of participants to be recruited at site:

b) Site specific/ community concerns, if any

c) Briefly mention local changes in Recruitment/ Advocacy material:

d) Copy of the Local Recruitment/ Advocacy material: Yes ☐ No ☐

### 2. INFORMED CONSENT

a) Who will obtain the informed consent?

S-PI/Co-S-PI ☐ Nurse/Counselor ☐ Research Staff ☐ Other *(Specify)* ☐

Any tools to be used

b) Language/s ICD is translated in:

c) Version number and date of the Participant Informed Sheet (PIS) :

d) Version number and date of the Informed Consent form (ICF) :

e) Copy of the Local ICD translations enclosed: Yes ☐ No ☐

f) Back translation of the ICD in English with the translation certificate Yes ☐ No ☐

g) Changes made in informed consent form (ICF), if any:

h) Copy of the audio / visual transcript for consent enclosed, if any: Yes ☐ No ☐

**3. DATA AND STORAGE**

i) Brief details on data collection, storage, sharing, transfer, if any?

## SECTION D – OTHER ISSUES

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

## SECTION E – CHECKLIST FOR S-PI AT PARTICPATING CENTER

**1. CHECKLIST**

| Sr.No | Items | Yes | No | NA | EnclosureNo. | EC Remarks |
|---|---|---|---|---|---|---|
| **ADMINISTRATIVE REQUIREMENTS** | | | | | | |
| 1. | Cover letter | ☐ | ☐ | ☐ | | |
| 2. | Brief CV of Site Principal Investigator / other site Co-PI | ☐ | ☐ | ☐ | | |
| 3. | Good Clinical Practice (GCP) training of investigator in last 3 years | ☐ | ☐ | ☐ | | |
| 4. | Agreement between collaborating partners | ☐ | ☐ | ☐ | | |
| 5. | MTA between collaborating partners | ☐ | ☐ | ☐ | | |
| 6. | Insurance policy/certificate | ☐ | ☐ | ☐ | | |
| **PROPOSAL RELATED** | | | | | | |
| 7. | Copy of the modified protocol | ☐ | ☐ | ☐ | | |
| 8. | Participant Information Sheet (PIS) and Informed Consent Form (ICF) (English and translated) | ☐ | ☐ | ☐ | | |
| 9. | Assent form for minors (12-18 years) (English and Translated) | ☐ | ☐ | ☐ | | |
| 10. | Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated) | ☐ | ☐ | ☐ | | |
| 11. | Advertisement/material to recruit participants (fliers, posters etc) | ☐ | ☐ | ☐ | | |
| 12. | Any other relevant information/documents related to the study | ☐ | ☐ | ☐ | | |

# Frequently Asked Questions

## Joint Ethics Review for Multicentric Research

1. **What is a joint ethics committee meeting? What is its quorum?** A joint ethics committee meeting is a combined or joint meeting of all participating sites ethics committees. This meeting is coordinated by the Designated Ethics Committee (DEC) and attended by all members of the Participating Ethics Committee (PEC). The coordinating PI and PIs of participating centres can be invited to this meeting to present the protocol and to answer to the queries raised by members. The joint EC provides recommendations to the individual participating site ECs. There is no quorum requirement for the joint ethics committee as it is not a decision-making body but provides recommendations to PEC for decision making. Quorum is required for local PECs for decision-making as mentioned in ICMR National Ethical Guidelines, 2017.
2. **How do all the participating sites attend joint ethics review meeting for the multicentre research proposal?** The DEC sends the virtual meeting link to all the participating sites. The meeting could be digitally recorded (audio/video) with the permission of members and the secretariat is responsible to note the attendance/ participation in the online meeting. All the members of PEC (preferably) may join the meeting or the members needed to fulfil the quorum for decision making should attend.
3. **Who can attend the meeting for ethics review procedures?** The participating ethics committees of all participating can attend the meeting virtually to discuss the protocol as a group. In the meeting, the coordinating PI/Site PIs may present the protocol.
4. **If any of the PEC is unable to attend the joint ethics review meeting, how should the review proceed in this case?** If one of the PEC does not attend the joint ethics review meeting, the DEC would share the recommendations of the joint ethics committee meeting with the participating site PI who in turn would communicate this to the local PEC. The local PECs can conduct an expedited/full committee review of research as per local requirements and issue a decision letter.
5. **In the event that a member of the PEC is not able to attend the joint ethics review meeting, will there be any concerns?** Preferably, all members of PEC must attend the joint ethics review meeting or at least the members who would fulfil the minimum quorum requirements for decision-making at the level of the local PEC should attend the joint meeting.
6. **How do PECs and DECs maintain communication? Are there any specific roles assigned to members for coordinating communication?** The coordinating principal investigator is responsible for ongoing communication between designated Ethics Committee (DEC) and PIs at other

participating centres who in turn communicate with the PECs. The PIs of local participating centres communicate between PEC and coordinating PI.

7. **If one of the PEC refuses to grant approval for the study, how should the research be further conducted?** If any PEC does not grant approval for a study at a site, the reasons must be shared with others during the joint ethics committee meeting Protocol could be reframed to address the concerns or the reasons for not incorporating the changes may also be justified. However, if there is no scope to incorporate the changes and the PEC is not willing to approve the study in present form, that particular site may be dropped off from the study.
8. **Is there a need for site-specific changes in the common protocol, what is the procedure for the review?** PECs can suggest locally relevant site-specific protocol or informed consent changes which do not change the design of the study or have implications for other sites or data analysis plan.
9. **Should the approval date for a multicentre study be the same for all the participating sites?** During the joint ethics committee meeting, preferably a common date of the start of study may be decided. However, due to local requirements or study-related requirements, the date could also be different for different sites. The group may decide if the local centres can initiate the study as and when the approval from the PEC is obtained.
10. **What are the procedures for reporting amendments to a research proposal? How shall ECs review protocols with amendments?** In case of any amendments in the research study, it is primarily the responsibility of the coordinating PI to submit any amendments to DEC and once approved, to communicate with all S-PIs who must inform PECs about the same. Major amendments affecting participant safety to be reviewed by DEC and minor amendments to be informed and noted by DEC and PEC. In case the research proposal is revised with minor modifications/amendments, the Member Secretary can plan an expedited review for the same. Research proposals that have revisions with major modifications or resubmissions may be placed before the DEC full committee meeting for reconsideration for approval.
11. **When should the annual reports for all PECs be submitted?** ICMR National Ethical Guidelines,2017 states the EC should review the annual report (counted from the day of approval or date of actual start of the study) for continuation of study. The PIs of the participating sites should prepare the annual report (from sites) and submit to PEC and the coordinating PI. Furthermore, the coordinating PI prepares the collated annual reports and submits it to DEC at least a month before completion of the year in order to give time to DEC to review and grant extension before expiry of the year/term.
12. **In case of reporting any amendments, where should the amendment of a research proposal be submitted?** The PIs of the participating sites should collect information regarding any amendments, deviations, violations, non-compliances (from sites) and submit to PEC and the coordinating PI. Furthermore, the coordinating PI submits it to the DEC

13. **How can conflict of interest (COI) be managed in multicentre research?** Participating Centre Ethics Committee (PEC) should ensure disclosure of conflict of interest of EC members or of investigators at all levels. COI within the DECs/PECs should be declared and managed in accordance with the standard operating procedures (SOPs) and ICMR National Ethical Guidelines For Biomedical and Health Research involving Human Participants, 2017.
14. **Who owns the data in multicenter research?** Institutes hosting/implementing the research are the custodians of the data/ samples and data custodianship and transfer etc. should be discussed before a research project is initiated. C-PI or Site PIs have no claim for ownership. Researchers should ensure clarity about data ownership, publication rights and obligations following data collection. MoUs vetted by the institution and/or PEC should be in place.
15. **What are the protocols for data/ samples/ biological material transfer in multicenter research? Are there any regulatory approvals that need to be obtained?** If there is an exchange of biological material/data/ samples involved between local participating sites, the PECs may require appropriate MoU and/or material transfer agreements (MTA) to safeguard the interests of participants and ensure compliance while addressing issues related to confidentiality, sharing of data, joint publications, benefit sharing, post analysis handling of the leftover biological materials, safety norms, etc. The PIs of the local participating sites may sign a joint MTA with the purpose and quantity of the sample being collected.
16. **In multicenter studies, who can be the lead authors in the publication?** ICMR National Ethical Guidelines, 2017 states that the primary author should be the person who has done most of the research work related to the research to be conducted before publication. The same to be clarified right from inception and roles and responsibilities for coordinating PI, as well as participating PIs, be clearly known. Coordinating PI should discuss and deliberate among other stakeholders and decide upon the authorship and intellectual property rights and the same should be communicated to joint EC at the time of submission.

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**This guidance document provides a step-by-step procedure to undertake joint ethics review for multicentre research being undertaken by ICMR and its network of Institutions**

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