

 (Logo of the Institute/ EC)	SOP Template for Single Ethics Review and Decision-Making Process <i>(Name of the Institutional EC)</i> Version No: _____ Date: _____
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(SOP may be adapted for institutional requirements and ethical requirements)

1. **Purpose:** This Standard Operating Procedure (SOP) establishes the workflow for undertaking single ethics review of multicentre research by a Single EC at the study coordinating institution, henceforth referred to as 'Single EC'.
2. **Scope:** This SOP applies to the Single EC Secretariat as well as all members of the Single EC, undertaking single ethics review of multicentre research.

3. **Responsibility:**

- 3.1 The Single EC will review, approve and monitor the multicentre research studies to be undertaken as per Guidelines/ Regulations across multiple sites in India.
- 3.2 The Single EC Secretariat will receive the study documents, check them for completeness, manage communications, ensure pre-meeting review and maintain documentation.
- 3.3 Member Secretary of the Single EC will categorize the risk level of submissions, identify primary/ secondary reviewers/ need for external consultants / subject experts/ others, prepare meeting agendas followed by meeting for timely Single EC review.
- 3.4 The Member Secretary/ Secretariat will ensure that the Single EC meets regularly, adopts best practices, try to keep their turnaround time of approximately one month.
- 3.5 The Single EC members will conduct a comprehensive review of the common protocol while considering site-specific requirements and socio-cultural contexts, provide comments on assessment forms, and participate in decision-making.

4. **Detailed Instructions**

4.1 **Pre-meeting Procedures**

- 4.1.1 The Single EC Secretariat/ Member Secretary will screen the submission to check if a complete set of documents have been submitted, including - initial review form, multicentre research protocol, informed consent documents (PIS & ICF), investigators' CVs, training certificates, and COI declarations, community engagement and dissemination plans, etc.
- 4.1.2 The Single EC Secretariat/ Member Secretary will confirm that the multicentre protocol has undergone a scientific review by an independent scientific committee/peer review group (at the coordinating/ participating site), and comments/ approval is included in the submission.
- 4.1.3 The Single EC Secretariat/ Member Secretary will categorize the study (based on risk), into the relevant type of review (exemption from review/ expedited review/ full committee review) and plan ethics review.
- 4.1.4 The Single EC/ Secretariat shall determine the need to involve subject experts/ independent consultants or invite community or patient representatives for pre-meeting or during meeting review.
- 4.1.5 The Member Secretary of the Single EC will determine if a multicentre proposal qualifies for exemption from review based on the justification provided by the PI of the coordinating site (c-PI). If a multicentre proposal qualifies for an expedited review, it will be conducted by Chairperson, Member Secretary and one or two designated members of the Single EC.

- 4.1.6 For full committee review, the Secretariat/ Member Secretary in consultation with the Single EC Chairperson will assign primary and secondary reviewers, and assess the need to invite subject experts/ independent consultants/ participant representatives/ others.
- 4.1.7 The Secretariat/ Member Secretary will provide all relevant documents to EC members at least 7 calendar days prior to the Single EC meeting.
- 4.1.8 The EC members should conduct the initial review of the study protocol and study related documents as per the pre-defined study assessment form, and share comments with the EC Secretariat/ Member Secretary prior to the meeting.
- 4.1.9 The Single EC Secretariat/ Member Secretary will seek clarifications (if any) from the c-PI prior to the meeting, and include the multicentre research proposal in the meeting agenda.

4.2 Meeting and Decision-Making

- 4.2.1 The Single EC members will meet to evaluate the multicentre protocol for social value, scientific design, and methodological rigor (including study type, objectives, duration, sample size including control groups, withdrawal criteria, etc.), expertise, budgets and site preparedness across all participating sites.
- 4.2.2 The Single EC members will conduct a benefit-risk assessment, recruitment and advocacy materials, site-specific ethical concerns, safeguards for vulnerable groups, privacy and confidentiality measures, any payment for participation, medical management and compensation for research-related injury, any community engagement plans (overall and site-specific), potential Conflicts of Interest (COI), and strategies for research translation and dissemination.
- 4.2.3 The complete informed consent document in English will be reviewed in detail and approved by the Single EC. The Single EC will scrutinize the Informed Consent Process for simplicity and clarity, ensuring all required elements are present in the Informed Consent Form (ICF) and Participant Information Sheet (PIS), along with contact details of the Site PI and the Single EC.
- 4.2.4 The Single EC shall review the scientific approvals and comments of the Scientific Committee, specifically with respect to site related observations (if any).
- 4.2.5 In case of need they may involve/invite or/ seek opinion of subject experts or local experts to understand the scientific as well as ethical concerns or those related to the informed consent process or review of ICF translations or any other related matters.
- 4.2.6 They may involve or consult the Member Secretary at any of the participating sites for site-specific issues or invite EC members from participating sites to join the meeting, if the proposal involves sensitive matters and local inputs are required.
- 4.2.7 The Single EC will accord one of the following decisions: approved, approved with suggestion, ask for revision, or disapprove with reason. If needed, the Single EC may provide suggestions (on protocol or ICD) specific to other sites.
- 4.2.8 The Single EC will determine the frequency and nature of monitoring (e.g., review of progress reports or site visits) based on the risk profile of the research.

4.3 Post-Meeting Procedures

- 4.3.1 The Single EC will issue a single approval letter listing names of all investigators and participating sites. The letter will clearly state names of sites along with any site-specific implementation conditions.

- 4.3.2 The Single EC Secretariat will verify that the translated versions of ICD are appropriate and match the Single EC approved English version of the document, by engaging with relevant language professionals, or other experts or independent consultants or member secretaries of the local EC to ascertain the quality of translations. Alternatively, back-translated versions in English may be sought for review, specifically where research is sensitive/ involves higher risk/ vulnerable persons or groups.
- 4.3.3 The Single EC letter will be sent to participating site PIs who will submit them to the institutional authorities for information and record.
- 4.3.4 If a site disagrees with the Single EC's decision, the site may be withdrawn from the study.

References

1. National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, New Delhi: Indian Council of Medical Research; 2017. Available from: https://ethics.ncdirindia.org//asset/pdf/ICMR_National_Ethical_Guidelines.pdf (Accessed on 1 April 2026).
2. ICMR Common Forms for Ethics Committee Review. Indian Council of Medical Research. Available from: https://ethics.ncdirindia.org/Common_forms_for_Ethics_Committee.aspx (Accessed on 1 April 2026).

Prepared by:

Approved by:

Effective Date:

Review Date: