Indian Council of Medical Research

OPERATIONAL GUIDELINES FOR SINGLE ETHICS REVIEW OF MULTICENTRE RESEARCH IN INDIA

2026

INDIAN COUNCIL OF MEDICAL RESEARCH
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OPERATIONAL GUIDELINES FOR SINGLE ETHICS REVIEW OF MULTICENTRE RESEARCH IN INDIA

INDIAN COUNCIL OF MEDICAL RESEARCH
NEW DELHI
2026

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प्रतापराव जाधव
PRATAPRAO JADHAV

सत्यमेव जयते

आज़ादी का अमृत काल

राज्य मंत्री (स्वतंत्र प्रभार)
आयुष मंत्रालय
व
राज्य मंत्री
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
भारत सरकार

MINISTER OF STATE
(INDEPENDENT CHARGE) OF
MINISTRY OF AYUSH AND
MINISTER OF STATE OF
MINISTRY OF HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA

Message

I am pleased to note that Indian Council of Medical Research is bringing out the Operational Guidelines for Single Ethics Review of Multicentre Research in India, 2026, a significant step towards improving the efficiency and ethical conduct of biomedical and health research in the country and thereby improving research participant protection.

ICMR, as one of the oldest and the apex bodies for the promotion and governance of biomedical research in India, continues to play a pivotal role in advancing ethical research practices. These guidelines address critical challenges in multicentre research and are expected to streamline review processes, improve coordination, and reinforce ethical standards.

Government of India under the visionary leadership of Hon'ble Prime Minister Shri Narendra Modi ji and able guidance of Hon'ble Union Minister of Health and Family Welfare, Shri Jagat Prakash Nadda ji, is committed to ensure the safety and well-being of citizens in India.

By enabling a more efficient ethical review system, these guidelines will enable timely, high- quality multicentre research that strengthens public health outcomes in India. They promote inclusion of diverse populations, including those in remote and underserved areas, thereby enhancing equity and better representation. Through improved harmonisation, stronger collaboration, and consistent standards, the guidelines will generate robust evidence to inform policy, support responsive healthcare delivery, and contribute to equitable health outcomes in line with the vision of Viksit Bharat.

सर्वे भवन्तु सुखिनः। सर्वे सन्तु निरामयाः।

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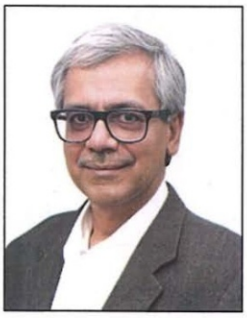

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सचिव, भारत सरकार
स्वास्थ्य अनुसंधान विभाग
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Secretary, Government of India
Department of Health Research
Ministry of Health & Family Welfare &
Director-General
Indian Council of Medical Research

FOREWORD

Indian Council of Medical Research has continuously worked to strengthen ethical governance in biomedical and health research. The evolution from common ethics review to joint ethics review, and now to a Single Ethics Review model, reflects a thoughtful and incremental reform based on experience. Each step has aimed to reduce duplication, improve harmonisation, and eliminate multiple layers of approval that did not proportionately enhance participant protection.

The Single Ethics Review model represents a decisive advancement replacing repetitive reviews with structured reliance on one competent Ethics Committee, with robust responsibilities for oversight, monitoring, and contextual adaptation. This approach strengthens, rather than dilutes, participant protection by ensuring consistency, quality, and accountability across all participating sites.

As India advances toward the vision of Viksit Bharat, strengthening the research ecosystem remains essential. Timely, high-quality multicentre research generates evidence that informs policy, improves healthcare delivery, and responds to diverse population needs. Public health outcomes depend not only on scientific innovation but also on ethical systems that enable research to be conducted efficiently and responsibly.

Through these Operational Guidelines for Single Ethics Review, India affirms its commitment to delivering research that is scientifically robust, ethically sound, and responsive to national priorities. By streamlining processes, this initiative positions India to deliver what is required for its people evidence-based solutions that improve health, strengthen public trust, and contribute meaningfully to national development.

Rajiv Bahl

(Rajiv Bahl)

New Delhi
April 2026

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MESSAGE

I am glad to note that the ICMR is bringing out the Operational Guidelines for Single Ethics Review of Multicentre Research. ICMR has consistently been at the forefront of developing and strengthening ethical standards for human research in the country, and its guidelines are widely recognized both nationally and internationally.

In recent years, biomedical and health research in India has evolved rapidly. In a country as diverse as ours, it is essential to remain responsive to emerging scientific advancements while ensuring robust protection of research participants. The present guidelines have been developed to address this need by streamlining the ethical review process and promoting greater consistency across institutions. The Single Ethics Review process minimizes duplication, strengthens coordination, and enables more efficient conduct of studies across multiple sites. It is expected to facilitate the timely generation of high-quality evidence and support its effective translation into policy and practice to address national health priorities.

Further, by enabling the inclusion of diverse and geographically dispersed populations, including those in underserved regions, these guidelines strengthen equity and representation in research. Enhanced collaboration, harmonisation of processes, and adherence to consistent ethical standards will contribute to more reliable evidence and improved public health outcomes. I am confident that this document will be widely referred to and effectively implemented, thereby advancing the conduct of high-quality, ethical research in the country.

Dr. Renu Swarup
Chairperson,
ICMR-Central Ethics Committee on Human Research (ICMR-CECHR)
Former Secretary to the Govt of India, DBT, Ministry of Science and Technology

PREFACE

“ICMR Operational Guidelines for Single Ethics Review of Multicentre Research, 2026”, developed under the leadership of Dr. Rajiv Bahl, DG, ICMR and Secretary, DHR, represents a significant advancement in the governance of multicentre biomedical and health research in India. By designating one competent Ethics Committee to undertake a comprehensive ethics review which would be applicable across participating sites, the model seeks to minimise unnecessary duplication while preserving institutional responsibilities for local implementation, monitoring, and contextual safeguards. This approach shifts the focus from procedural repetition to structured reliance, promoting consistency in ethical decision-making and strengthening participant protection through coordinated oversight rather than multiple parallel approvals.

The success of this framework rests fundamentally on trust in institutional competence, mutual cooperation among participating investigators and ethics committees, and transparent, continuous communication throughout the research lifecycle. By fostering shared accountability and harmonised standards, the Single Ethics Review approach supports the efficient conduct of high-quality multicentre studies while remaining responsive to diverse local contexts. In doing so, it advances a collaborative culture of ethics governance that enables research to address national health priorities responsibly and effectively.

These guidelines have been developed through the collective expertise of the Expert Advisory Committee, providing clear operational procedures, accountability mechanisms, and quality assurance processes designed to benefit researchers, institutions, and, ultimately, the participants in these studies. Special recognition is due to Dr. Abha Saxena (Former WHO Ethics Unit, Geneva), whose role as an external advisor

and extensive global experience were instrumental in shaping these guidelines to align with international benchmarks.

Sincere appreciation is also extended to the peer reviewers, commentators, and participants in meetings and, whose valuable insights greatly enriched this document. The dedicated efforts of the scientific and support staff of the ICMR Bioethics Unit in preparing these guidelines are likewise gratefully acknowledged. A special mention to Dr. Elna Paul Chalisserry, Consultant, ICMR Bioethics Unit for her coordination and valuable assistance in the preparation of this guideline.

This guideline is intended to serve as a reference for researchers and ethics committees not only in India but also to be widely consulted internationally, providing an implementable system that minimises delays and redundancies while upholding the highest standards of participant protection.

Dr. Gitanjali Batmanabane
Chairperson,
ICMR Expert Advisory Committee

Dr. Roli Mathur
Scientist G and Head,
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1. INTRODUCTION

Multicentre research involves conducting a study across multiple institutions or sites using a common protocol to address shared research questions. Participating sites may either undertake the same set of protocol activities or distinct components of the same study, such as participant recruitment, interventions, data analysis or data management. Good collaboration strategically pools expertise, resources, and infrastructure to enable the recruitment of larger and diverse participant cohorts, more inclusive research with enhanced statistical power, scientific validity and generalizability, to generate scalable evidence for quality research outcomes, public health action or policy formulation.

Multicentre research spans a wide range of biomedical and health research domains, including basic or applied research; genetic and genomic research; epidemiological and population-based studies; implementation and health systems research; public health surveillance and survey-based research; studies involving the secondary use of data and biological samples; multicentric clinical trials of drugs, biologics, vaccines, and medical devices; and investigator-initiated clinical studies; among others. Multicentre research is also increasingly conducted through national/ regional/ international networks, often involving institutions with varying capacities and diverse socio-cultural contexts.

Effective collaboration in multicentre research relies on mutual trust among collaborators, which must be established upfront and reinforced through mutual respect, and transparent & continuous communication at every stage of the study. The primary role of the Ethics Committee (EC) is to protect the rights, safety, and well-being of research participants. The EC must uphold this by ensuring that the research is high-quality and employs robust tools and methods for safeguarding research participants. Creating a supportive research environment in the country will go a long way in improving health research outcomes for the population.

These guidelines have been developed to facilitate the ethics review of all types of multicentre biomedical and health research in India, including clinical trials. The applicability of these guidelines to regulatory clinical trials is subject to the requirements outlined in the Drugs and Cosmetics Act, 1940 & New Drugs and Clinical Trial (NDCT) Rules, 2019 & other applicable regulations.

The Operational Guidelines for Single Ethics Review for Multicentre Research in India are an addendum to the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017.

1.1 Current Challenges in Ethics Review of Multicentre Research in India

In India, multicentre biomedical and health research is being conducted after seeking ethics approval from the Ethics Committee (EC) at each participating site involved in research, a process that has often resulted in delays without clear evidence regarding the value addition towards the protection of research participants. The ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 had introduced a common ethics review approach, wherein it was suggested that a designated EC conducts the common ethics review and provides recommendations that are shared with local ECs. The local ECs then conduct an expedited review focusing only on site-specific issues before issuing approvals at individual sites. Subsequently, the ICMR Joint Ethics Review Guidelines, 2023, proposed a joint ethics review approach, in which a Designated Ethics Committee and Participating ECs convene in a single virtual meeting to reach a harmonised decision where individual ECs have an opportunity to utilise breakout rooms for discussions around site-specific issues. However, significant operational and logistical constraints have made the widespread adoption of either of these models elusive. Additionally, there are several other challenges related to the conduct of ethics review and implementation of multicentre research (Table 1).

Table 1: Key Challenges in Ethics Review and Implementation of Multicentre Research

	Challenge(s)
1.	Multiple separate reviews of the same protocol have led to duplicative submissions, delayed approvals and wastage of resources.
2.	Differences in risk categorisation, informed consent and protocol requirements, etc., result in poor harmonisation and non-uniform implementation of study procedures.
3.	Ethics Committees remain less focused on ethical considerations and more on coordination of multicenter research and thus may not add incremental value to participant protection.
4.	Large multicentre studies implemented through field units, including remote or underserved areas, face additional barriers, due to lack of institutional affiliation or as local ECs are not available.

To overcome these systemic challenges and streamline the ethics review process, a **Single Ethics Committee Review** mechanism for multicentre biomedical and health research, supported by clear, operational guidelines, is warranted. With the release of these guidelines, single ethics review will replace earlier common and joint ethics review mechanisms, and should be adopted for undertaking ethics review of all multicentre research conducted in India. This is expected to bring about a transformational change, boosting the research ecosystem in India and putting India as a leader on the global map.

2. ETHICAL PRINCIPLES FOR MULTICENTRE RESEARCH

Building on the ethical principles outlined in the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017), the following collaborative principles operationalise these standards within the multi-institutional context of multicentre research. These principles guide ethical conduct, coordination, and accountability and shall be applied across all stages of the research lifecycle.

2.1 Key Collaborative Principles

2.1.1 Trust and Collegiality: All stakeholders must maintain professional respect, treat all members with dignity, and recognise each other's competence through mutual learning and cooperation.

2.1.2 Shared Responsibility: All stakeholders have defined roles and responsibilities and share collective responsibility for ethical conduct and oversight while being individually accountable for their contributions.

2.1.3 Communication: All stakeholders should collaborate through established communication mechanisms and share resources to achieve common research objectives while upholding ethical standards.

2.1.4 Fairness and Transparency: Research contributions should be fairly recognised and acknowledged appropriately with clear documentation of intellectual property and authorship across all sites.

2.1.5 Flexibility: While streamlining processes to avoid duplication, the system must remain adaptable to local contexts and requirements to ensure thorough ethical oversight while accommodating site-specific needs.

3. SINGLE ETHICS REVIEW

The single ethics review process simplifies the ethics review of multicentre research by delegating the responsibility to undertake ethics review to a Single Ethics Committee (Single EC) located at one mutually agreed upon study coordinating site from amongst all the participating sites. This requires cooperation and understanding of all participating study sites. Single ethics review must be anchored in trust, competence, independence, and impartiality, amongst participating study sites, recognising, accepting and implementing the Single EC's decisions. Settings without formal institutional structures, usually underrepresented in research, such as field sites, community-based locations, or outreach centres, stand to gain with the new possibility of inclusion under a uniform and robust ethical oversight framework that complies with applicable ethical and regulatory requirements.

3.1 Process Overview

3.1.1 The Single EC undertakes a comprehensive ethics review of the multicentre research protocol, including all site-specific documents submitted by the Coordinating PI (c-PI).

3.1.2 The review by the Single EC must consider national, regional and local contexts, as per the study sites involved in research.

3.1.3 It must ensure scientific robustness while focusing on strengthening the ethical and participant-protection aspects of the study across all participating sites.

3.1.4 Upon review, the Single EC would grant an ethics approval, which would apply to all participating sites of multicentre research.

3.1.5 If revision is required, the Single EC would provide consolidated comments to the c-PI, who would address these comments (in communication with participating sites), revise the protocol and related documents, and resubmit them to the Single EC for review.

3.1.6 The Ethics review of the multicentre research would be the overall responsibility of the Single EC at the coordinating study site. For most studies, the site EC would have no role in ethics review, research oversight or monitoring.

3.1.7 The ethics committee to be appointed as the Single EC must meet the eligibility criteria as specified in Table 2.

3.2 Limitations of Single Ethics Review

While the single ethics review model offers significant benefits, its effective implementation requires the following considerations:

3.2.1 The Single EC may experience increased administrative and technical burden in conducting ethics review for all participating sites, ensuring effective ethics review, continuing review, safety monitoring, and oversight across multiple sites due to the volume, complexity, and scale of multicentre research, particularly in geographically dispersed settings.

3.2.2 Inclusion of additional or new sites, removal, or substitution of previously approved sites can cause additional burden to the Single EC.

3.2.3 The Single EC may have limited familiarity with the local socio-cultural, institutional, and operational contexts of all participating sites.

3.2.4 Other participating institutions and the site ECs may perceive less importance or reduced involvement in decision-making, ethics review, oversight and monitoring of research activities at their sites.

Table 2: Eligibility Criteria for Single Ethics Committee

Essential Criteria
1. EC has a meeting calendar and meets regularly (preferably once a month).
2. It has valid registration with the Department of Health Research (DHR) and/ or the Central Drugs Standard Control Organisation (CDSCO), as applicable, through Naitik or Sugam portal.
3. EC members are well-trained and updated in ICMR National Ethical Guidelines, EC SOPs, GCP Guidelines, NDCT Rules and other relevant guidelines and regulations, as applicable.
4. EC demonstrates capacity for undertaking an efficient and timely ethics review, which is independent as well as competent.
5. It possesses a dedicated EC office and a secretariat with staff, having defined roles and responsibilities for communication and administrative actions.
Desirable Criteria
6. The Single EC is accredited through the National or International Accreditation program.
7. Institution hosting the Single EC must be an active research study site involved in the recruitment of research participants.
8. Availability of a robust and independent Scientific Review Committee/ or an established peer review mechanism for undertaking scientific review at the Single EC's institution.
9. The Single EC has prior experience in conducting an ethics review of multicentre research/ studies.
10. Availability of technological infrastructure and resources, such as an electronic EC platform, video conferencing, secure communication channels, document archival system, etc.

3.2.5 Differences in infrastructure, funding, participant populations, and administrative capacity across institutions may impact the uniform applicability of Single EC decisions.

3.2.6 There is a possibility of selecting the Single EC based on convenience alone, without considering the competence and efficiency of the Single EC.

3.2.7 Communication and coordination between stakeholders involved in the multicentre studies may be less than optimal, impacting EC functioning.

3.2.8 Review of informed consent form, especially translated versions and review of site-specific considerations, may be challenging.

3.3 Addressing the Limitations

These limitations must get addressed through strengthened coordination by the c-PI with site-PIs, active incorporation of site-specific inputs in the protocol and prior detailed planning. There should be robust communication across participating sites. The Single EC must be duly prepared to handle the ethics review and its members should be adequately trained. The multicentre study protocol must have a dedicated section to discuss the local relevance as well as the ethical safeguards to be implemented at each of the participating sites. This should be reviewed carefully by the Single EC, which could further suggest risk-based monitoring, centralised documentation, clear conditions and site-specific safeguards in approval letters, to ensure consistency, accountability, and context-sensitive ethical oversight. Defined limits for additions/ changes in approved sites, as well as limits on the number of multisite studies that a Single EC may handle at a given time, can be set to ease the Single EC's workload while ensuring quality and promoting equity across institutions. The c-PI must set up a mechanism and dedicated time for effective coordination amongst sites and to ensure that suggestions made by the Single EC are effectively followed at all the participating study sites. The informed consent form review may require engagement with language experts or subject experts or independent consultants to review translations.

Overall, a well-thought-out and planned coordination plan can be very helpful in facilitating a single ethics review and the conduct of multicentre research in India.

4. IMPLEMENTATION

This section describes the implementation steps for conducting a single ethics review in multicentre research studies.

4.1 Multicentre Research Coordination

4.1.1 The multicentre research study must have a Coordinating PI (c-PI) to lead the study, decided with mutual agreement amongst participating site PIs.

4.1.2 In sponsored multicentre research, usually the sponsor coordinates with the study sites. However, for the implementation of the Single EC model, a c-PI must be identified by the investigator themselves or the sponsor for overall study coordination. The responsibility for overall coordination of ethics review lies with the c-PI.

4.1.3 The final version of the multicentre protocol should outline clear plans for coordination and communication among participating sites to address contextual, cultural, and operational variations.

4.1.4 The protocol must include a list of all participating institutions and investigators, along with their names and contact information.

4.1.5 The study protocol must provide the framework for governance, operations and coordination across sites.

4.1.6 If required, the multicentre study protocol must pre-emptively plan and include additional budgets related to scientific review, Single EC review, additional manpower or support, for review, communication and networking among sites.

4.1.7 Communications between participating sites must be efficient and timely. Digital platforms such as email, video conferencing, and online portals may be utilised to facilitate hassle-free communication and harmonisation of efforts.

4.1.8 This protocol must be reviewed, finalised and mutually accepted by all participating site PIs. In case of any disputes/ issues, they should be resolved amicably through a defined mechanism, such as periodic (e.g., monthly) meetings and appropriate communication channels between investigators.

4.2 Scientific Review

4.2.1 Multicentre research studies must be scientifically robust and require a prior review by a scientific expert group at the coordinating site. In case this is not feasible, a scientific review may be undertaken by another scientific committee at any other participating site.

4.2.2 The c-PI must submit the multicentre protocol (with version number and date) to an expert group/ committee, which could be an institutional scientific committee or an independent expert group. Alternatively, a peer-review process may be involved for undertaking a comprehensive and independent scientific review.

4.2.3 Multiple scientific reviews at all study participating sites are not required. However, this scientific review is in addition to the review undertaken by funding agency or sponsor and must be undertaken by an expert group/ independent peer group at the participating institution to ensure that the multicentre research is scientifically sound and relevant to the context and would address local concerns, ensuring meaningful outcomes and eventual translation.

4.2.4 The scientific review must also look at the proposed coordination plans for governance of the multicentre research.

4.2.5 At this time, it would also be appropriate to identify the c-PI and the Single EC that would review the research study.

4.2.6 The comments of the scientific committee/ experts, along with the approval letter, must be submitted as part of the submission being made to the Single EC for ethics review.

4.3 Identification of the Single Ethics Committee

4.3.1 It is important to note that the designation of a Single EC is a functional arrangement intended to facilitate efficient, consistent, and harmonised ethics review for multicentre research and does not confer any superior status or authority beyond the scope of its assigned review responsibilities. Similarly, the designation of c-PI is a functional arrangement to facilitate a single ethics review.

4.3.2 The EC at the c-PI's site (provided it meets the eligibility criteria specified in Table 2) must serve as the Single EC.

4.3.3 The c-PI must communicate with the member Secretary of the Single EC in advance to receive confirmation about eligibility and timelines.

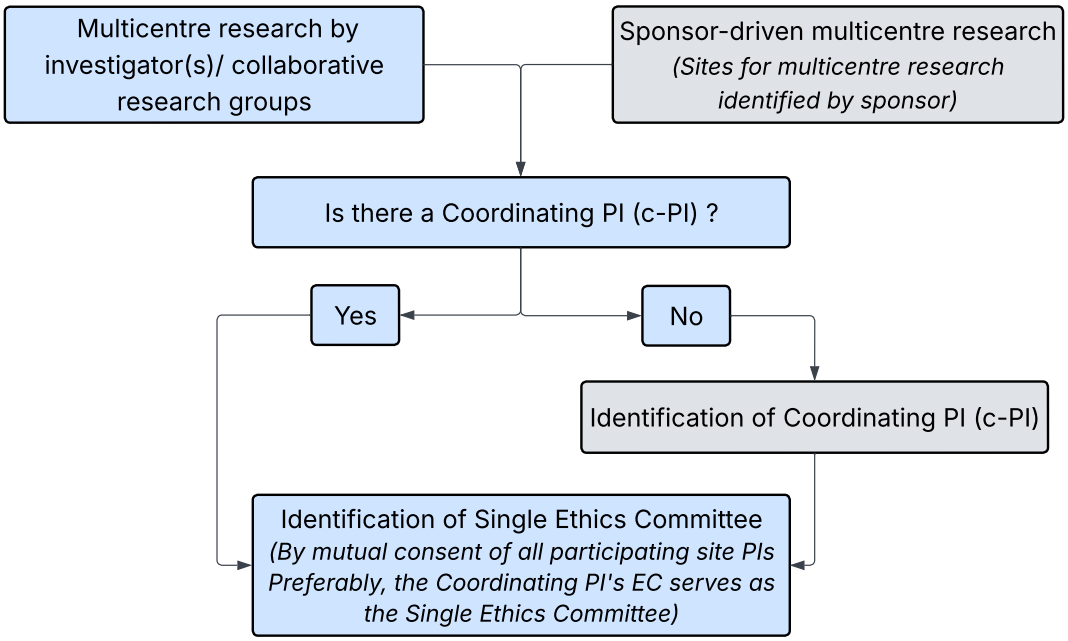
4.3.4 Initially, it is expected that there may be hesitation amongst the ECs in taking up this responsibility. Efforts should therefore be directed to strengthen the research protocol with a section discussing the ethical safeguards for adequate protection of research participants, for improving the understanding of the Single EC undertaking ethics review.

4.3.5 In case the EC at the study coordinating site does not meet the eligibility criteria, or it is unable to take up this role, another eligible and willing participating site EC may be identified by investigators to undertake the single ethics review, and accordingly, a change in c-PI would facilitate overall study coordination amongst sites and with the Single EC (Refer Figure 1).

4.3.6 If there is no coordinating site and more than one EC meets the eligibility criteria to serve as the Single EC, the site PIs shall arrive at a mutual agreement to designate the Single EC from amongst all the suitable/ eligible ECs, and the participating site would become the coordinating site, and the PI shall be designated as c-PI.

4.3.7 Ethics approval is often a prerequisite for the release of research grants. Since funding may be received much later, the proposed Single EC at the coordinating site must have adequate resources/ provisions to support the single ethics review process.

Figure 1: Identification of Single Ethics Committee



4.3.8 To be eligible to serve as a Single EC, an independent EC (an EC without an institutional affiliation) must fulfil the essential eligibility requirements and demonstrate capacity to undertake a robust and independent scientific review process before ethics review.

4.4 Single Ethics Review Process

4.4.1 The c-PI shall serve as the single point of contact between Single EC and site Principal Investigators (site PIs).

4.4.2 The c-PI shall harmonise inputs from all participating site PIs into a common multicentre research protocol that can be implemented across all sites. The protocol must include a section detailing ethical considerations at all participating sites.

4.4.3 The c-PI shall submit the proposal on behalf of all the sites to the Single EC at the coordinating site for ethics review. For details, refer to Table 3.

Table 3: List of Documents to be submitted by the c-PI to the Single Ethics Committee

Document(s)
1. Initial Review Form for single ethics review (with site information, roles and contact details).
2. Multicentre research protocol (with version No. & Date) including names, affiliation and contact details of all participating sites.
3. Informed consent documents including Master ICF, PIS, and site-specific / translated/ back-translated versions as well as recruitment process and advocacy material.
4. Community engagement plans at participating sites (if any).
5. CV and relevant training certificates of all PIs and Co-PIs.
6. Data management, communication, networking, budget, MoU/ MTA etc.
7. Ethical considerations highlighting local and site-specific issues and additional safeguards.
8. Peer review/ Scientific Committee approval with comments.
9. Conflict of interest declarations from all investigators (if applicable).
10. Authorship, publication, dissemination plan, access and data sharing.
11. Checklist of applicable regulatory/ administrative requirements.

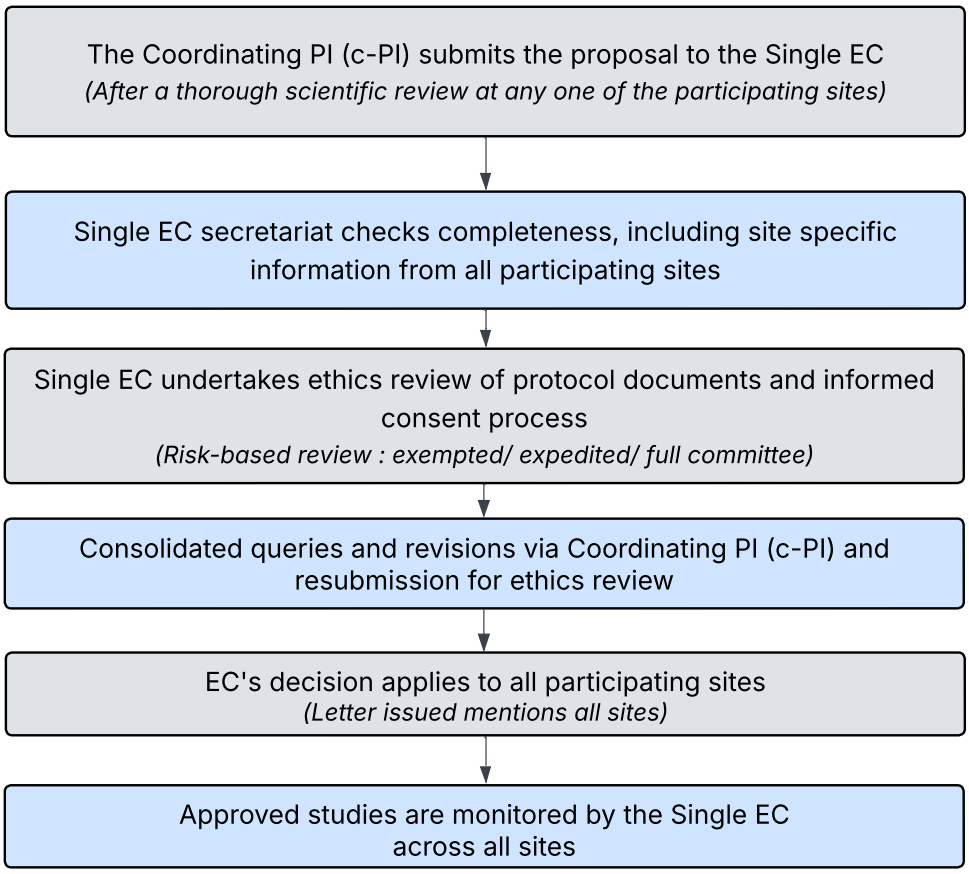
4.4.4 The Single EC's Secretariat shall verify that all required documents, including site-specific information for all the participating sites have been submitted.

4.4.5 Single EC shall undertake an ethics review of the multicentre research protocol on behalf of all participating study sites.

4.4.6 Depending on the risk involved, the Member Secretary/ Single EC Secretariat shall categorise the study into any of the three types, as applicable, namely; exemption from review, expedited review, and full committee review and plan next steps accordingly.

4.4.7 The Single EC shall undertake an ethics review of all submitted study protocol documents. It must ensure that site-specific ethical considerations are adequately addressed. Refer to Figure 2 for workflow of single ethics review.

Figure 2: Workflow of Single Ethics Review



4.4.8 The Single EC shall maintain a secure centralised repository of all study-related documents, communications, decisions, and amendments.

4.4.9 The Single EC must develop a Standard Operating Procedure (SOP) for undertaking the ethics review for multicentre research studies.

4.4.10 The Single EC must undertake a detailed review of informed consent form and process to ensure voluntariness in recruitment across sites.

4.4.11 The Single EC must be efficient in undertaking ethics review and ensure timely communication to improve ethics review. Table 4 enlists some ethical considerations for a single ethics review.

Table 4: Ethical Considerations for Review by the Single Ethics Committee

Ethical consideration(s)	Role of the Single Ethics Committee
1. Social Value & Scientific Design	• Assesses whether the multicentre design is scientifically and socially justified and adds value beyond a single-site study in terms of generalisability, diversity of populations, selection of suitable sites, and external validity. • Ensures consistency of objectives, endpoints, and methodology across all sites while permitting justified contextual adaptations. • Reviews whether the study addresses a relevant public health or clinical need applicable across participating regions. • Ensures that prior scientific review has been undertaken and suggestions incorporated. • Check if the implementation plan for governance, coordination & networking between sites is included. • Check that a section on ethical considerations is provided with respect to site-specific requirements.
2. Benefit- Risk Assessment	• Evaluates the overall benefit-risk to research participants in the multicentre research as a whole. • Evaluates additional site-wise risk, if any, due to variations in population group, local/ social sensitivities, infrastructure, healthcare access and emergency care availability. • Ensures that risk-mitigation strategies are adequate, feasible, and uniformly implemented across all participating sites. • Ensure harmonised SAE reporting, conduct monitoring to ensure adherence to complex procedures and safety checklists across sites. • Implement risk-based monitoring with frequent on-site or remote reviews and provide targeted support to strengthen site operations and compliance.
3. Participant Selection & Recruitment	• Reviews inclusion and exclusion criteria to ensure equitable recruitment across diverse sites. • Examines site-specific recruitment strategies to avoid undue inducement, coercion, or exclusion of vulnerable populations. • Ensures consistency in eligibility assessment while allowing justified local recruitment approaches. • Review plans for recruitment, advocacy and engagement.

4. Research involving vulnerable persons	• The Single EC must carefully review the requirement for additional safeguards if the research study involves vulnerable persons or groups such as minors, communities located in geographically remote areas, socially or economically disadvantaged populations, persons with limited literacy, etc. • The EC may suggest additional safeguards and close monitoring to ensure their well-being.
5. Informed Consent	• Ensures that the informed consent document uniformly discloses that the study is a multicentre study and includes the contact details of the site investigator/s, the c-PI and the Single EC, which has reviewed the study and the contact information about the investigator/s at the local study site. • Ensures that all translated versions are accurate and fully consistent with the ethics committee-approved English informed consent form. • Seeks inputs from relevant experts/ independent consultants, etc., if required to address local scientific, ethical, or cultural concerns.
6. Privacy and Data/ sample sharing	• Reviews plans for collection, storage, secondary research and sharing of biological samples and/ or data, including identifiable information, to ensure consistency with participant consent and ethical approvals. • Evaluates plans for access control and accountability for shared samples/ data in compliance with applicable data protection and regulatory requirements. • For research involving sensitive personal data or a high risk of breach of confidentiality/ misuse of data, to ensure secure handling and anonymisation.
7. Budget, Payments & Compensation	• Reviews adequacy and proportionality of site-wise budget allocations to ensure all sites can implement protocol requirements without compromising participant safety or data quality. • Ensures that participant payments and compensation for research-related injury are equitable, considering local requirements, preventing differential standards of care or undue operational pressure at any site. • Ensures budgetary provisions and/ or insurance mechanisms are in place for research involving high risk.

	• Reviews transparency of arrangements, accountability among sponsor, coordinating centre, and participating sites, and timelines for payments/ reimbursements and provisions for research-related injury.
8. Community Engagement	• Reviews site-specific community engagement plans to manage inter-site variability in local norms and community power dynamics. • Ensures that engagement strategies respect regional sociocultural norms while maintaining uniform ethical standards across all sites.
9. Investigator Qualifications & Site Capability	• Assesses adequacy and comparability of investigator qualifications, trained manpower and expertise. • Ensures that all sites are well equipped with infrastructure to implement the protocol uniformly and safely.
10. Conflicts of Interest (COI)	• Reviews and manages COI disclosures across all participating sites to identify site-specific, institutional, or sponsor-related. • Monitors changes in COI during the multicentre study and requires timely revision of COI management plans if new financial, professional, or institutional relationships arise.
11. Dissemination and post-trial access	• Reviews plans for dissemination of study results, ensuring equitable post-trial access to interventions or benefits for participants, communities, and relevant stakeholders across all participating sites, and ensures that appropriate provisions are in place for follow-up of participants after trial completion. • Ensures dissemination strategies and feasibility of post-trial commitments are culturally appropriate and accessible to diverse populations irrespective of geographic location.

4.5 Review of Informed Consent Process

4.5.1 The informed consent form must contain all the basic elements as described in the National Ethical Guidelines.

4.5.2 The informed consent process must be reviewed keeping in mind the following additional requirements as applicable: a) the process used for obtaining informed consent, including the identification of those responsible for obtaining consent and the procedures adopted for vulnerable populations, if any; b) adequacy, completeness and understandability of the information to be given to the research participants, and when appropriate, their LARs; c) contents of the Participant Information Sheet (PIS) including the local language translations;

d) provision for audio-visual recording of consent process, if applicable, as per relevant regulations; e) if consent waiver or verbal/ oral consent request has been asked for, this should be reviewed by assessing whether the protocol meets the criteria.

4.5.3 The protocol documents must include the core informed consent document in English (Participant information sheet and Informed consent form) along with its site-specific versions in English, and their translations into the local language(s). The site-specific versions must include the names of the c-PI, site PI, the local study site, and the name of the person to be contacted when required.

4.5.4 Any participant advocacy, community engagement or recruitment material (if applicable) must also be submitted for ethics review.

4.5.5 The complete informed consent document in English must be reviewed in detail and approved by the Single EC.

4.5.6 In case the Single EC has members who understand other languages, the translated versions may be reviewed, however, primarily this would be the responsibility of Single EC Secretariat to verify that the translated versions of ICD are appropriate and match the Single EC approved English version of the document. Therefore, the Single EC secretariat shall be required to engage with relevant language professionals, or other experts or independent consultants or the member secretary of the local EC to ascertain the quality of translations. They may alternatively seek back-translated versions in English for review, specifically where research is sensitive/ involves higher risk/ vulnerable persons or groups.

4.6 Site-Specific Considerations

4.6.1 Ethical considerations may or may not be similar across all participating sites. Therefore, the Single EC shall remain vigilant and ensure that contextual, cultural, and community-specific considerations are adequately incorporated into its review and decision-making.

4.6.2 The multicentre research protocol should explicitly address site-specific ethical considerations from all participating sites, including participant protection measures, language adaptations in the consent process, and community engagement strategies. In addition, all relevant site-specific details must be provided in the initial review form (Refer Annexure 2), which will be duly reviewed by the Single EC before granting approval.

4.6.3 It is very important for the Single EC to invest in extra efforts and time to ascertain that the study is relevant to the local population. Whenever necessary, the Single

EC may decide to seek inputs through community representative(s)/ subject matter experts/ or consult the Member Secretary of the site EC to understand site-specific scientific, technical, or ethical issues that fall beyond the core expertise of the reviewing committee, particularly for studies involving remote or underserved sites/ diverse population groups.

4.6.4 For studies with high-risk/ sensitive matters where local EC involvement is warranted, the Single EC may seek written comments or invite the Member Secretary of the local site EC/ and one-two site EC members (if required) to join the Single EC meeting online to provide their comments. This would however require additional efforts on the part of the Member Secretary of the Single EC to coordinate with Member Secretary of site EC and receive site specific inputs which may be relevant to certain types of research studies.

4.7 Single EC Decision

4.7.1 After the initial review, the Single EC may grant approval and communicate its decision to c-PI. However, in case they need more information, the Single EC shall communicate its queries or comments to the c-PI for response.

4.7.2 The c-PI shall address the Single EC's comments, incorporate required changes into the core protocol and revise the study protocol after discussing internally with the respective site PIs and/ or sponsors (if applicable). The c-PI shall then resubmit the revised protocol, along with all site-specific revisions as applicable, to the Single EC for further review.

4.7.3 The single ethics review and approval should be timely and efficient (preferably with a turn-around time of one month) to avoid any unnecessary delays arising from administrative or procedural requirements that do not have a direct bearing on the safety, rights, and well-being of research participants.

4.7.4 Upon satisfactory review of the responses to its comments, the Single EC shall issue an approval letter that would apply to all participating study sites.

4.7.5 The approval letter must specify the list of all approved participating sites (with names of PI/ co-PI), including the names of sub-sites/ field units involved; the approved protocol (with version number and date); list of all other approved documents such as informed consent document or other study tools (stating version number and date); and the validity of the approval, conditions and suggestions, frequency of continuing review report, annual report submission requirements among others.

4.7.6 Wherever necessary, the approval letter must provide site-specific suggestions on matters such as participant recruitment, informed consent process, additional safeguards for vulnerable persons, or other site-specific considerations (as applicable).

4.7.7 The approval letter must mention the ethics monitoring and oversight plan, either uniform across all sites or tailored to individual sites, detailing the frequency, scope, and reporting requirements for site-level oversight.

4.7.8 The Single EC shall communicate the final approval to the c-PI, who in turn would communicate with the site PIs, and plan study initiation in compliance with the Single EC approval and keep the Single EC informed of the date of start.

4.7.9 The Site PI shall also keep the institutional authorities informed, such as the Head of Institution/ Research, by sharing a copy of the Single EC approval letter. The site EC may also be informed if it was involved in the ethics review.

4.8 Addition of New Sites Post Ethics Approval

4.8.1 In general, all study sites of multicentre research should preferably be identified a priori and included in the study protocol before submission of the study for scientific review as well as single ethics review. This helps improve study coordination and conduct, and avoids re-reviews later due to the addition of sites after review is completed. Therefore, further onboarding of sites at a later time after study initiation should be avoided, except for specific reasons warranting inclusion for successful conduct of multicentre research.

4.8.2 For certain types of multicentre research, the addition of new sites after study initiation (in a second phase) may be necessary in view of the nature of the research; however, the plan for the addition of new sites and criteria should be given in the research protocol in advance. This possibility of inclusion of additional sites at a later stage would be reviewed by the Single EC at the time of initial review.

4.8.3 In some cases, the addition of new sites may become important after study initiation, due to reasons such as dropping of earlier sites or amendments in protocol or other reasons that were not known before. In such cases, the request for the addition of new sites with reasons and details may be submitted by c-PI to the Single EC for review with appropriate justification to the Single EC, for consideration.

4.8.4 The Member Secretary/ secretariat of the Single EC must remain vigilant when a new site is proposed for inclusion, particularly noting if any local factors or conditions at proposed new sites may pose additional risks.

4.8.5 The Single EC Secretariat may review the requirements/ eligibility for the addition of new sites, along with timelines and decide if the addition of sites later would require a full or an expedited ethics review.

4.8.6 No newly added site shall initiate study activities until approval for site inclusion has been granted by the Single EC and all applicable institutional permissions have been obtained.

4.9 Monitoring and Oversight

4.9.1 Single EC would be responsible for monitoring and oversight across all participating sites and shall determine an appropriate frequency for receiving the continuing review reports based on the level of risk (every quarter, biannually, or at least annually). This should be clearly stated in the approval letter for compliance by study investigators.

4.9.2 In determining the nature and intensity of monitoring across all participating sites, the Single EC shall consider all relevant risk categories, including physical risks arising from study procedures or interventions, as well as psychosocial risks such as stigma, emotional distress, breaches of confidentiality, or other potential social harms.

4.9.3 Risk may differ at different sites and must be accordingly considered by the Single EC and therefore, risk determination at participating study sites must be carried out carefully.

4.9.4 Based on the study design, risk profile, site characteristics, sponsor requirements, and participant safety considerations, the Single EC may determine the need for a Data and Safety Monitoring Board (DSMB) and indicate this in the decision letter. The DSMB may accordingly be set up by the sponsor(s)/ institution and its report be shared with Single EC through c-PI from time to time.

4.9.5 The c-PI must collate continuing review information, prepare a consolidated report covering work done at all participating sites and submit the progress report to the Single EC before expiry of the term of approval.

4.9.6 Single EC must evaluate progress of ongoing research studies, review SAE Reports from all sites along with protocol deviations/ violations and non-compliance, any new information pertaining to research and assess final reports of all research studies.

4.9.7 Single EC must suggest corrective action for deviations/ violations/ complaints and seek reports of monitoring done by sponsors and review the DSMB reports.

4.9.8 The Single EC may plan an actual site monitoring (for-cause or routine) for a research study involving a high degree of risk to participants or if there are heightened societal concerns, vulnerable persons or media reports or any other concern and in such cases, the Single EC may coordinate with the site EC Member Secretary to plan and designate local EC members to undertake the site visit.

4.9.9 In addition, research institutions also have an oversight responsibility to ensure compliance of the research conduct as per the approved version of the research protocol. Research Integrity Office in institutions must oversee and ensure adherence to ethical standards, data integrity, address research misconduct, and facilitate consistent implementation of approved protocol. The research institutions must set up systems to ensure quality in the conduct of research and close oversight.

4.10 Serious Adverse Event (SAE) reporting

4.10.1 All Serious Adverse Events (SAEs) must be reported as per applicable timelines and reviewed by the Single EC in multicentre research. The site PI shall inform c-PI, who shall notify the Single EC and sponsor (if applicable) within 24 hours of becoming aware of the event.

4.10.2 The Single EC shall promptly review the SAE to assess causality, participant safety, adequacy of site response, corrective and preventive actions, need for protocol amendments, and determine compensation for research participants for research-related injuries as per applicable requirements for biomedical and health research/ clinical trials.

4.10.3 Single EC must examine measures taken for medical management of SAEs and ensure that the participants do not have to bear the cost of study-related injuries.

4.10.4 The Single EC may constitute a SAE sub-committee for causality assessment. Reporting requirements must be followed as applicable for biomedical and health research/ clinical trials.

4.10.5 The single ethics review model enables the Single EC to issue consistent SAE recommendations and harmonised safety decisions applied uniformly across all participating sites, thereby strengthening participant protection. Further, it allows early identification of patterns or safety signals that may be missed when SAEs are reviewed in isolation by multiple participating ECs.

4.11 Protocol Deviations & Non-Compliance

4.11.1 The site PI shall report protocol deviations, violations, non-compliance and adverse events to the c-PI in a timely manner, who would communicate with Single EC for review and recommendations.

4.11.2 In such cases, the Single EC shall review as per applicable procedures through expedited/ full committee reviews and decide needful action.

4.12 Study Completion, Dissemination and Post Research Access

4.12.1 Upon study completion, sponsors and investigators should strive to continue to provide beneficial interventions, wherever feasible.

4.12.2 The multicentre research protocol shall include provisions for post-research access and benefit-sharing, along with site-specific implementation plans.

4.12.3 When relevant, the protocol should also include plans for translation of research outcomes to public health policy or public health measures.

4.12.4 Site PIs shall disseminate study results to local participants and communities through appropriate mechanisms (e.g., community meetings, participant letters, local media), as described in the protocol, as well as plan for translation of research outcomes to public health measures.

4.12.5 Research that is completed, irrespective of positive or negative results, must be published. The protocol shall include a clear timeline for publication as well as plans for fair, transparent, and timely dissemination of study findings on completion of the study.

4.13 Documentation & Archival

4.13.1 Single EC must enable transparency through documentation of all communications, check registration of research with relevant databases such as Clinical Trial Registry of India (as applicable), standardized tracking & archival/ retrieval mechanisms, and Single EC's SOPs (Refer Annexure 1).

4.13.2 All documentation and communications should be appropriately dated, labelled and filed by the Single EC for at least 3 years after completion of study or more as per applicable regulatory requirements. Records may be archived for a longer period, if required by the sponsors/ regulatory bodies or in view of type of study.

4.13.3 ECs may develop dashboards for accessing information and plan electronic storage of records wherever feasible.

4.14 International Collaborations

4.14.1 Any multicentre studies involving international collaborations, approved elsewhere in any other country will still require an EC review in India.

4.14.2 Indian participating centres should function as partners with the collaborator(s) and sponsor(s) in terms of ownership of samples and data, analysis, dissemination, publication and IPR related to research in India, as may be considered appropriate.

4.14.3 There should be good communication between international participating centres and in case of any conflict, the decision of the EC of the Indian participating centre(s), based on relevant facts/ guidelines/ law of the land, shall prevail.

4.14.4 The institution should protect against imposition of moral or ethical standards of the sponsoring country which may not be in agreement with India's ethical and regulatory requirements. Ethics Dumping or export of unethical research practices from higher to lower income setting should not be allowed.

4.14.5 The institution/ EC should not accept international proposals which cannot be conducted in the country of origin.

4.15 Training

4.15.1 All investigators involved in multicentre research must receive specialised training on operational aspects of single ethics review.

4.15.2 The c-PI must plan internal methods for coordinating and keeping the team trained and updated.

4.15.3 The research PIs/ Co-PIs must be well versed and trained in ethics in order to ensure effective implementation of research and protection of research participants.

4.15.4 Members of Single ECs reviewing multicentre research must undergo training in the single ethics review process and in reviewing site-specific information. Further EC members must remain updated with ethical guidelines and regulatory requirements, and specifically with respect to single ethics review.

4.15.5 The Single EC members must receive training to handle site-specific protocol and informed consent reviews, so that they are relevant and able to discharge their functions, monitor and protect research participants even at remote locations.

5. LIST OF REFERENCES

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2. Central Drug Standards and Control Organization (CDSCO) SUGAM online portal. Available from: https://www.cdscoonline.gov.in/CDSCO/homepage (Accessed on 16 Apr 2026).
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6. ANNEXURES

Annexure 1: Sample SOP Templates

The following sample SOP templates 1 and 2 are provided for reference for the members and secretariat of Single EC at the study coordinating institution and may be adapted as per institutional policies and ethical requirements.

SOP Template 1

Title: Single Ethics Review and Decision-Making Process

Version No:

Date:

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).
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Prepared by: **Approved by:**

Effective Date: **Review Date:**

SOP Template 2

Title: Management of Continuing Review, Study Monitoring and SAE Reports
Version No:
Date:

1. **Purpose**: The purpose of this Standard Operating Procedure (SOP) is to establish the framework for the Single EC to carry out continuing review, monitoring and management of Serious Adverse Event (SAE) reports in multicentre research, to maintain continuous vigilance over participant rights and welfare.
2. **Scope**: This SOP applies to the Single EC Secretariat as well as all members of the Single EC for conducting continuing review of approved multicentre research and review of SAEs and unexpected events.
3. **Responsibility:**

3.1 The Single EC has primary role for ensuring participant welfare throughout the multicentre study through continuous evaluation of the progress of ongoing proposals. The Single EC will monitor study progress, review unexpected events, participant recruitment, protocol deviations/ violations and non-compliance, as well as management of SAE reports and where required, administrative checks at sites. It will also examine any new information pertaining to the study and assess final reports of all research activities.

3.2 It is the responsibility of the Single EC Secretariat to remind the Coordinating PI (c-PI) regarding timely submission of continuing review reports, as per timeline determined by Single EC during initial review.

4. **Detailed Instructions**

4.1 ***Continuing Review***

4.1.1 The Single EC will conduct continuing review of the multicentre study at appropriate periodic intervals proportionate to the degree of risk, at least once a year.

4.1.2 The Single EC will determine the date(s) of continuing review and clearly specify the date(s) at the time of initial review, and indicate this in the approval letter/ communication letter to the c-PI.

4.1.3 The Single EC Secretariat will notify the c-PI a month in advance of the date(s) determined by the Single EC for submission of continuing review reports. This will ensure timely continuing review.

4.1.3 The Single EC Secretariat will notify the c-PI a month in advance of the date(s) determined by the Single EC for submission of continuing review reports. This will ensure timely continuing review.

4.1.4 The Single EC Secretariat will check completeness of the continuing review reports submitted, and share with primary and/ or secondary reviewers at least one week prior to next the scheduled Single EC meeting.

4.2 *Study Monitoring*

4.2.1 Depending on the degree of risk to the participants, the nature of research, vulnerability of study participants, and duration of study, the Single EC can choose to review the study more frequently or conduct on-site monitoring visits.

4.2.2 Where necessary, the Single EC will seek report(s) from the Data Safety and Monitoring Board (DSMB)/ or monitoring/ audit reports by the sponsors.

4.2.3 During monitoring, the Single EC will verify adherence to the approved version of the common protocol and informed consent process, recruitment of participants, concerns or complaints (if any), and compliance with requirements for medical management as well as compensation for research - related injury/ SAEs (if any).

4.2.4 Site Monitoring can also be done and it can be routine or "for cause" and will be decided at a full committee meeting of the Single EC. "For cause" monitoring at specific sites may be required in situations where there are high number of protocol violations/ deviations and/or SAE reports, adverse information/ complaints received from participants, media reports or any other source, non-compliance with Single EC directions; misconduct by the researcher(s), and any other cause as decided by the Single EC.

4.2.5 Any findings from monitoring that impact participant safety will be shared by the Single EC with all participating Site PIs and their respective institutional authorities immediately upon knowledge.

4.3 *Managing SAE Reports*

4.3.1 The Single EC is responsible for the review of SAEs at the site, and when required, subject experts, pharmacologist members, primary and secondary reviewers may be involved in the review and causality assessment. The single EC may constitute a SAE sub-committee (optional).

4.3.2 The Single EC requires the site PI to inform the c-PI, who shall notify the single EC and sponsor (if applicable) within 24 hours of becoming aware of the SAE. The follow-up detailed report with PI's opinion on relatedness of SAE to the study shall

examine the measures taken for the medical management of SAEs. Participants should not have to bear costs for the management of study-related injury.

4.3.4 The Single EC/ SAE sub-committee will determine compensation for research participants for research-related injuries as per applicable timelines/ regulatory requirements.

4.4 *Protocol Deviations*

4.4.1 The Single EC will examine protocol deviations/ violations at any site(s) reported by the c-PI and suggest corrective actions. If the violations are serious, the Single EC may halt the study temporarily or permanently at all/ specific site(s).

4.4.2 The EC may report to the relevant institutional head(s)/ government authorities where there is continuing non-compliance to ethical standards.

4.5 *Addition of New Study Site(s)*

4.5.1 The Single EC Secretariat shall examine the need for the addition of new sites or justification provided by c-PI.

4.5.2 Upon receipt of a request for the addition of new site(s) from the c-PI, the Single EC will review site-specific details (investigator CVs, infrastructure, local ICD translations etc.) for the new site before approving the site(s) addition.

4.5.3 It will determine if there is an additional risk to research participants in view of local requirements or determine the need for full ethics review or otherwise, if there are no additional risks, plan an expedited review primarily to verify suitability of site investigator qualifications and to check site preparedness for inclusion in the study.

4.6 *Study Completion and Archival*

4.6.1 The Single EC will verify the plans for data analysis and reporting of results, plan for benefit sharing and translation of results and sample archival, and ensure the c-PI maintains records for the duration required by relevant guidelines/ regulations.

4.6.2 Upon study conclusion, the Single EC Secretariat will seek a Study Completion Report, publications (if any) and a summary of results for the Single EC's perusal.

Prepared by: **Approved by:**

Effective Date: **Review Date:**

Annexure 2: Initial Review Form (for submission to Single EC)

APPLICATION FORM FOR INITIAL REVIEW BY THE SINGLE ETHICS COMMITTEE

General Instructions:

- *Tick one or more as applicable in the checkboxes provided.*
- *Fill in details in the blanks provided & Attach additional sheets wherever required*

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

SECTION A–CORE STUDY INFORMATION

(to be filled by Coordinating PI)

1. ADMINISTRATIVE DETAILS

a) Name of Coordinating Institution:
(With the Single EC)

b) Name of the Single EC:

c) Name of Coordinating PI (c-PI):
Designation: Qualification:
Department/ Division:

d) Type of review requested:
☐ Exemption from Review ☐ Expedited Review ☐ Full Committee Review

e) Title of the multicentre study:

Acronym/ Short title, (If any):

f) Protocol Version number: Date:

2. FUNDING DETAILS AND BUDGET (For all sites)

a) Total budget: Study Duration:

b) Type of funding: ☐ Self-funding ☐ Institutional funding ☐ Sponsor/ Funding agency ☐ Any Other
Specify:

c) Name of Sponsor/ Funding agency (if any):

d) Participant recruitment fees/ incentives paid to the c-PI/ Site-PI/ Institution?
☐ None ☐ Non-Monetary ☐ Monetary
Provide details:

3. OVERVIEW OF RESEARCH

a) Lay Summary of study (within 300 words):

b) Type of study:

☐ Basic Sciences	☐ Clinical	☐ Cross Sectional
☐ Retrospective	☐ Epidemiology/ Public Health	☐ Case Control
☐ Prospective	☐ Socio-behavioural	☐ Cohort
☐ Qualitative	☐ Biological samples/ Data	☐ Systematic Review
☐ Quantitative	☐ Mixed Method	☐ Any other:

4. METHODOLOGY

a) No. of study sites: Total sample size for all sites:

b) Justification for the sample size chosen (*100 words*).

c) Multicentre Study Coordination plan/ Governance plan included in submission:
☐ NA ☐ No ☐ Yes, provide details:

d) Is there a need for adding new sites at a later stage?
☐ NA ☐ No ☐ Yes, provide details:

e) Is there an external lab/ outsourcing involved for investigations?
☐ NA ☐ No ☐ Yes, provide details:

5. RECRUITMENT AND RESEARCH PARTICIPANTS

a) Who will do the recruitment at sites?

b) Recruitment methods used:
☐ Posters/ leaflets/ Letters ☐ TV/ Radio ads
☐Telephone ☐Social media/ Institution website
☐Patients / Family/ Friends visiting hospitals
☐Any other, please state:

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

☐ Children under 18 years	☐ 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, please state:

d) Provide justification for inclusion:

e) Provide justification for exclusion:

f) Additional safeguards to protect participants:

6. BENEFITS AND RISKS

a) Potential benefits: ☐ Direct ☐ Indirect ☐ Other:

b) Anticipated risks/ discomforts:

- ☐ None
- ☐ Minimal risk
- ☐ Minor increase over minimal or Low Risk
- ☐ <Minimal risk
- ☐ >Minimal or High Risk

c) Risk management strategy:

d) How benefits justify the risks:

e) Are Adverse Events addressed in the protocol? ☐ NA ☐ No ☐ Yes, give details:

7. INFORMED CONSENT

a) Are you seeking waiver of consent?

☐ NA ☐ No ☐ Yes, specify reasons:

b) Core Informed Consent Document (PIS+ICF) Version No: Date:

c) Type of consent:

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

If Other (specify):

d) Who will obtain informed consent? ☐ Site PI/ Co-Site-PI ☐ Nurse/ Counsellor ☐ Research Staff ☐ If Other *(specify):*

e) Advocacy/ engagement tools: ☐ NA ☐ No ☐ Yes, provide details:

f) Audio-visual recording for consent: ☐ NA ☐ No ☐ Yes, provide details:

g) ICD translations: ☐ NA ☐ No ☐ Yes, specify languages:

h) Does the study involve use of previously stored samples/ clinical data.
☐ NA ☐ No ☐ Yes, details of original consent:

i) Elements of Informed Consent Process:

☐ Simple language	☐ Right to withdraw
☐ Purpose and procedures	☐ Alternatives to participation
☐ Benefits	☐ Data/ sample sharing
☐ Risks and discomforts	☐ Storage of samples
☐ Confidentiality	☐ Return of results
☐ Payment for participation	☐ Commercialization/ benefit sharing
☐ Need to recontact	☐ Use of photographs/ identifying data
☐ Statement that consent is voluntary	☐ Compensation for study-related injury
☐ Statement that study involves research	☐ Contact info of PI/ Member Secretary of Single EC

Additional elements (if required):

8. SCIENTIFIC REVIEW

a) How was the scientific robustness assessed?

☐ Scientific committee at c-PI's institution ☐ Peer Review Process
☐ Scientific committee at site-PI's institution ☐ Independent scientific committee
Please give details:

b) Date of Approval by Scientific Review Committee:

c) Comments of Scientific Committee, if any (200 words):

9. PAYMENT/ REIMBURSEMENTS/ COMPENSATION

a) Who will bear the costs related to participation and procedures?
☐ Not covered ☐ Study Budget ☐ Other Agencies
Provide details:

b) Is the budget planned for:
☐ Reimbursement/ Payments (in cash/ kind), provide details:
☐ Ancillary care for unrelated illness, provide details:

c) Provision for medical management for injury to the participants?
☐ NA ☐ No ☐ Yes, provide details

d) Is there a provision for compensation for research-related injuries?
☐ NA ☐ No ☐ Yes, provide details:
☐ Sponsor ☐ Institution/ Corpus funds ☐ Insurance ☐ Project grants
Provide budgetary details :

10. STORAGE AND CONFIDENTIALITY

a) Identifying Information (samples/ data): ☐ NA ☐ No ☐ Yes, provide details:

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

b) Provisions to Limit access/ safeguard data ☐ NA ☐ No ☐ Yes, provide details:
Place of storage: Duration of storage:

c) Storage of data/ samples for future studies? ☐ NA ☐ No ☐ Yes, provide details:

11. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

a) Will results be reported/disseminated? ☐ NA ☐ No ☐ Yes, provide details:

b) Will results be informed to participants? ☐ NA ☐ No ☐ Yes, provide details:

c) Any plan for post research benefit sharing? ☐ NA ☐ No ☐ Yes, provide details:

d) Any commercial value/Patent/IPR filing? ☐ NA ☐ No ☐ Yes, provide details:

e) Any additional information, not included in the form? If yes, provide the details:

SECTION B - SITE REVIEW FORM *Please make copies of Section B. To be filled in by the c-PI and Site PI at each participating site/ separately/ signed copies from all sites to be submitted to Single EC for Review*
1. BASIC INFORMATION
a) Name of Site Participating Institute:
b) Address for communication (include mobile/email):
c) Name of Site-PI: Designation: Qualification: Department/ Division:
d) No. of ongoing studies where Site-PI is a: ☐ PI ☐ Co-PI
e) Role of the participating site in the multicenter study (50-100 words):
f) Estimated budget at the participating site: Provision for ☐ Reimbursement ☐ Ancillary care ☐ Medical management ☐ Compensation for research related injury or harm
g) Other Site-specific requirements, if any: ☐ NA ☐ No ☐ Yes, provide details:
2. BENEFITS AND RISKS
a) Any specific additional risks/ community concerns unique to this site: ☐ NA ☐ No ☐ Yes, provide details of risks: b) Risk management strategy:
c) Any specific benefits/ safeguards for participants unique to the site: ☐ NA ☐ No ☐ Yes, provide details
3. INFORMED CONSENT
a) Site Specific Informed Consent Document: Version: Date:
b) Other material, if any: ☐ Recruitment ☐ Advocacy material ☐ Any other, provide details:
c) Translations of informed consent: ☐ NA ☐ No ☐ Yes, provide details:
d) Any other information relevant to site:

DECLARATION *To be filled in by the c-PI, Site PI along with their Participating site Co-PIs* *Each participating site to make a copy/ fill it separately/ submit a signed copy to Single EC*	
Name of the Participating Site:	
☐	I/ We certify that the information provided in this application/ Initial Review Form by c-PI or Site Review Form by Participating Site PIs is complete and correct.
☐	I/ We confirm that the study underwent a scientific review and includes a multicentre coordination/ governance plan for effective implementation of research.
☐	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 ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants and other applicable regulations and guidelines.
☐	I/ We confirm that this study will be conducted in accordance with the New Drugs & Clinical Trial Rules, 2019 under Drugs and Cosmetics Act 1940 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.
☐	I/ We will comply with all policies and guidelines of the institute and affiliated/ collaborating institutions where this study will be conducted.
☐	I/ We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the Single EC approved protocol.
☐	I/ We declare that expenditure in case of research related injury will be taken care of.
☐	I/ We confirm that an undertaking of use of leftover samples is provided, if applicable.
☐	I/ We confirm that we shall submit any protocol amendments, adverse events reports, significant deviations, progress reports/ final report, participate in any audit of the study if needed.
☐	I/ We confirm that we will maintain accurate/complete records of the study.
☐	I/ We will protect the privacy of participants and assure safety and confidentiality of study 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 (c-PI/ Co-PI/ Site PIs) which is being declared:
☐	I/ We declare/ confirm that all necessary government approvals will be obtained as per requirements wherever applicable.
Names: c-PI/ Site PI: Co-PI (1): Co-PI (2): Head of Institution:	**Signature:**

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The objective of the ICMR Operational Guidelines for Single Ethics Review of Multicentre Research is to streamline ethics oversight for multicentre studies while safeguarding participant rights and welfare. By enabling reliance on one competent Ethics Committee, the framework reduces duplication, promotes consistency, and supports timely initiation of high-quality research. Grounded in trust, mutual cooperation, and transparent communication, it strengthens coordinated accountability across institutions. Practical and forward-looking, these guidelines serve as a resource for researchers and ethics committees, supporting collaboration and strengthening India's research ecosystem to generate evidence that informs policy and benefits society.

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