DRAFT OPERATIONAL GUIDELINES

SINGLE ETHICS REVIEW OF MULTICENTRE RESEARCH IN INDIA

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Table of Contents

1. Introduction

Multicentre research involves conducting studies across multiple 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, analysis or data management. This collaboration strategically pools expertise, resources, and infrastructure that enable the recruitment of larger and diverse participant cohorts. As a result, multicentre studies are more inclusive, enhance statistical power, scientific validity and generalizability, generating scalable evidence to robust research outcomes, public health action or policy formulation. Effective collaboration relies on mutual trust among collaborators, which must be established upfront and reinforced through transparent and continuous communication at every stage of the study.

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, and studies involving the secondary use of data and biological samples; multicentric clinical trials of drugs, biologics, vaccines, and medical devices; investigator-initiated clinical studies among others across institutions. Multicentre research is also increasingly conducted through national/ regional networks, often involving institutions with varying capacities and diverse socio-cultural contexts.

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, a process that has often resulted in delays. To streamline this, the ICMR National Ethical Guidelines (2017) introduced a common ethics review approach, wherein a Designated Ethics Committee conducts the common ethics review and provides recommendations which are shared with site ECs. The site 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 EC 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 both these models elusive.

Box 1: Examples of key challenges related to ethics review of Multicentre research.

- Multiple separate reviews of the same protocol have led to duplicative submissions, prolonged and unpredictable approval timelines, and inconsistent ethics decisions across sites. Differences in risk categorisation, informed consent requirements, and protocol conditions result in non-uniform implementation and lack of harmonisation in study procedures.
- Delays in ethics approvals undermine time-sensitive research, reduce policy relevance, waste public funds, contribute to loss of trained personnel, and in some cases lead to abandonment of studies or grants.
- Participating site ECs often conduct a full re-review of protocols rather than limiting assessment to site-specific ethical considerations. Such re-reviews often do not add incremental value to participant protection in research.
- Convening all participating site EC members in a single virtual meeting under the joint ethics review approach presents practical coordination challenges, especially in large multicentre studies involving multiple institutions, thereby limiting scalability and making implementation difficult or impracticable. Large multicentre studies implemented through field units, including those in remote or underserved areas where local ECs may be absent or inaccessible, face additional barriers, resulting in delayed initiation and/or exclusion of such sites from research participation.
- Limited communication between ECs, heterogeneity in EC expertise and workload, differing institutional capacities, and the absence of formal mechanisms for mutual reliance on another Ethics Committee's ethics review and decision impede coordinated multicentre ethics review.

To overcome these systemic barriers, a single ethics committee review mechanism for multicentre biomedical and health research, supported by clear and operational guidance, is warranted to streamline ethics review.

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.

Key Collaborative Principles:

2.1. Trust and Collegiality: Researchers and ethics committees must maintain professional respect, treat all members with dignity, and recognise each other's competence through mutual learning and cooperation.

2.2. Shared Responsibility: All stakeholders share collective responsibility for ethical oversight while being individually accountable for their contributions.

2.3. Communication: All investigators and members of ethics committees should collaborate through established communication mechanisms and share resources to achieve common research objectives while upholding ethical standards.

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

2.5. 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

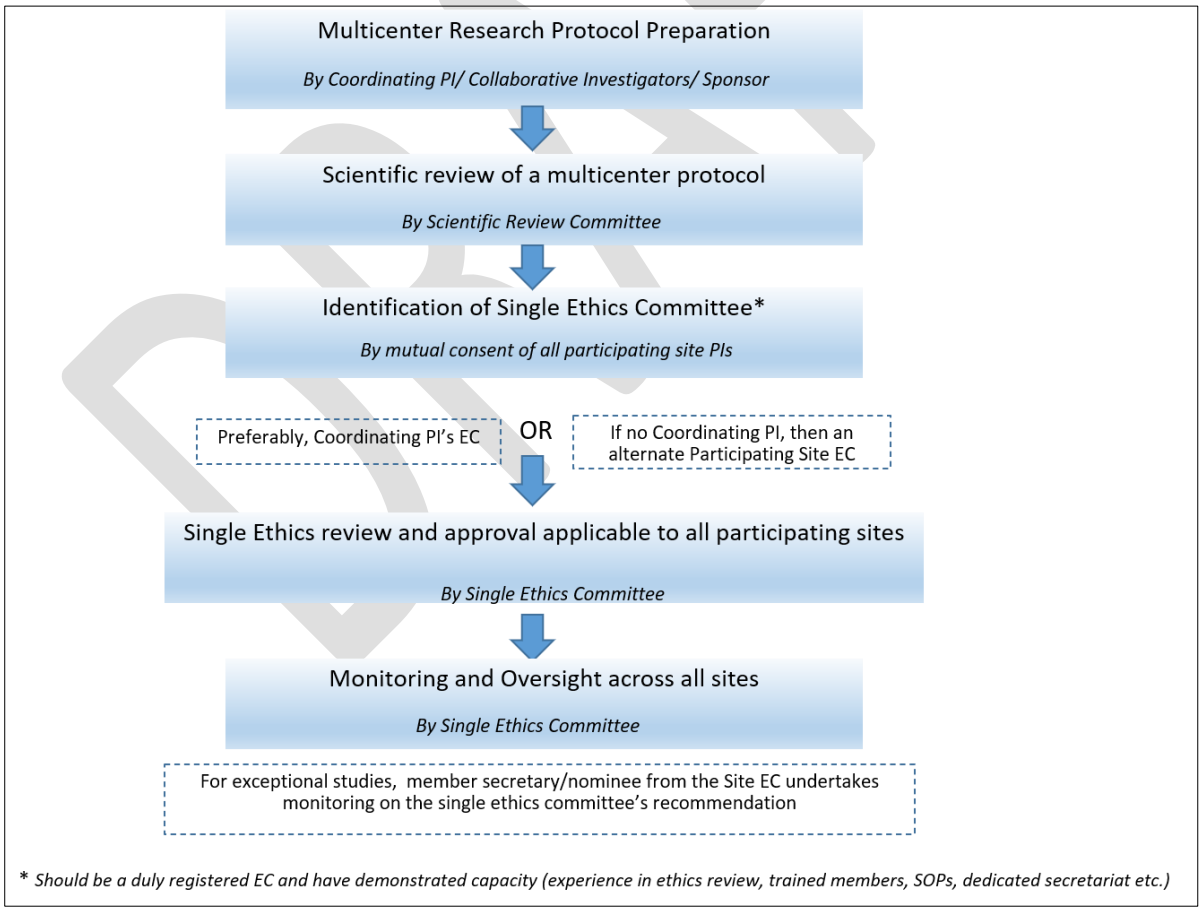
A single ethics committee, identified from among the participating sites, would undertake a comprehensive ethics review of the complete multicentre research protocol, including all core and site-specific documents. The review would consider national, regional, and local contexts, ensure scientific robustness while focusing on strengthening the ethical and participant-protection aspects of the study across all participating sites.

Following the review, the single ethics committee would provide consolidated comments and recommendations to the principal investigator who would address these comments,

revise the protocol and related documents as required, and resubmit them for further consideration.

Upon receipt of satisfactory responses, the single ethics committee would grant an ethics approval, which would be applicable to all participating sites of multicentre research. This approach must be anchored in trust in the competence, independence, and impartiality of a single ethics committee, and in a shared commitment among participating sites to recognise, rely upon, and implement its decisions. Effective implementation requires mutual trust, cooperation, and coordination among all participating institutions, while noting the fact that the ethics committees are duly registered with the central authority and thereby have established composition with set ethics review procedures to undertake a quality ethics review. Figure 1 illustrates the proposed process flow for conducting a single ethics review in multicentre research studies.

Figure1: Framework for Single Ethics Review and Oversight of Multicentre Research



It is particularly advantageous for research conducted in settings without formal institutional structures, such as field sites, community-based locations, or outreach centres,

by enabling their inclusion under a uniform and robust ethical oversight framework that complies with applicable regulatory requirements.

Single ethics review is a responsibility to be undertaken by the Ethics Committee (EC) at the study coordinating site, and all other participating study sites must support the process and accept the decisions taken. This approach requires all participating sites to respect each other, build mutual trust and cooperation to work together and facilitate the process of ethics review. It can effectively streamline ethics review and improve overall research coordination, which will ultimately benefit the people of the country. The primary role of the EC around the protection of the rights, safety, and well-being of research participants must be upheld by ensuring that the research is high-quality and employs robust tools and methods. Creating a supportive research environment in the country will go a long way in improving health research outcomes for the population.

Further, any multicentre studies involving international collaborations must adhere to additional requirements as per existing norms.

4. Limitations of Single Ethics Review

While the single ethics review model offers significant benefits, its effective implementation requires careful management of certain considerations:

4.1. The single ethics committee may initially have limited familiarity with the socio-cultural, institutional, and operational contexts of all participating sites. This may result in inadequate consideration of site-specific ethical issues related to participant vulnerability, community engagement practices, language and literacy barriers, and variations in local healthcare and research infrastructure.

4.2. With primary ethical review and oversight responsibility vested in a single ethics committee, participating institutions may perceive reduced involvement in decision-making and monitoring of research activities conducted at their own sites. This may raise concerns related to accountability, institutional responsibility, and the ability to promptly identify and address site-level ethical or operational issues.

4.3. The single ethics committee may experience increased administrative and technical burden due to the volume, complexity, and scale of multicentre research submissions.

4.4. Effective coordination and coordination among ethics committee, investigators, and participating sites may be challenging, particularly in large or geographically dispersed

multicentre studies. Communication gaps may lead to delays, inconsistent implementation of approved protocols, and misunderstandings regarding roles and responsibilities.

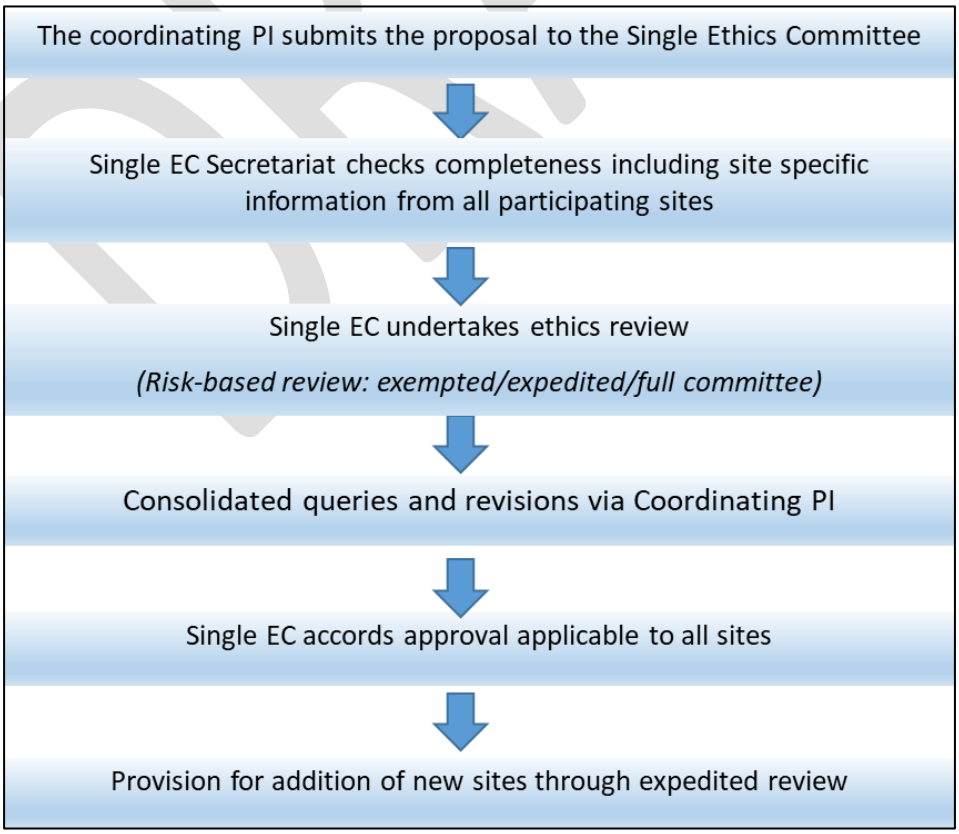
4.5. Ensuring effective continuing review, safety monitoring, reporting of adverse events, management of protocol deviations, and oversight of amendments across multiple sites may be operationally complex under a single ethics review framework.

The subsequent sections of this document present structured mechanisms and operational provisions designed to strengthen implementation, address these challenges, and support the effective and responsible functioning of the single ethics review model.

5. Implementation steps for Single ethics review

This section describes the implementation steps for conducting a single ethics review in multicentre research studies. It presents the sequence of actions involved from submission of the multicentre research proposal through ethics review, approval. Figure 2 provides an overview of the single ethics review workflow, illustrating key stages such as administrative completeness checks, risk-based ethics review, consolidated queries and revisions, and approval applicable across all participating sites.

Figure2: Implementation Steps for Single Ethics Review in Multicentre Research



5.1 Multicentre research protocol development

5.1.1. In investigator-led research, the Coordinating PI (if present) or the participating investigators collectively shall integrate and harmonise inputs from all participating sites into a common multicentre research protocol. Conversely, where the study is sponsor-driven, the sponsor is responsible for providing a complete, standardised common protocol to be implemented uniformly across all research sites.

5.1.2. The multicentre research protocol must be finalised and mutually accepted by all participating site investigators before its submission for single ethics review and it must include a list of all participating institutions, along with the names and contact details of the site principal investigators.

5.1.3. The protocol (with version number and date) must undergo a thorough scientific review and approval through an appropriate expert group, committee, or peer-review process before submission to the single ethics committee. The scientific review comments and the approval letter must be submitted as part of the submission made to the single ethics committee. This ensures scientific robustness and saves time for ethics review.

5.1.4. The protocol must state whether the inclusion of additional participating sites is anticipated at a later stage. Where applicable, the protocol shall outline a predefined mechanism for the inclusion of new sites, including submission of site-specific information, investigator details, and any local context considerations, through a formal protocol amendment (administrative) for review by the single ethics committee prior to study initiation at the new site[1]. Refer to Annexure 4 - Application form for Amendments - (https://ethics.ncdirindia.org/PDF/ApplicationNotificationformforAmendments.pdf)

5.1.5. The protocol must address mechanisms for study coordination, communication, or handling conflicts arising from differing institutional policies or operational practices across participating sites.

[1] No newly added site shall initiate study activities until approval for site inclusion has been granted by the single ethics committee and all applicable institutional permissions have been obtained.

5.1.6. The study budget should also include adequate provisions to cover costs related to a single ethics review, multicentre coordination and communication activities.

5.2. Identification of the Single Ethics Committee

5.2.1. A single ethics committee shall be identified from among the participating sites with mutual consent[2] of all stakeholders and the name and details of the single ethics committee must be clearly stated in the study protocol to ensure that all stakeholders are aligned and informed

5.2.2. In multicentre research protocols with a coordinating Principal Investigator or coordinating site, the single ethics review of multicentre research protocols must be undertaken by the ethics committee of the coordinating site (provided it meets the eligibility criteria specified in Box 2).

5.2.3. In case there is no Coordinating PI or Site, or where the ethics committee of the Coordinating Site does not meet the eligibility criteria or is unable to undertake the role, the other participating sites shall mutually agree and identify another participating site's ethics committee to undertake the single ethics review. Provided it meets the eligibility criteria specified in Box 2.

Box 2: Eligibility Criteria for Single Ethics Committee

The ethics committee designated to function as the single ethics committee shall meet all of the following minimum requirements:

1) Valid registration with the Department of Health Research (DHR) and/or the Central Drugs Standard Control Organisation (CDSCO), as applicable, through the Naitik or Sugam portal.
2) Demonstrated experience in ethics review, including a proven track record based on years of functioning
3) Adequately trained ethics committee members, including training in biomedical and health research ethics, SOP's, GCP, NDCT Rules as applicable.
4) A dedicated EC secretariat with defined roles and responsibilities.
5) Adequate administrative capacity and technological infrastructure to support efficient communication, documentation, and the timely conduct of ethics review.

[2] *Institutions should adopt and incorporate these guidelines into their EC Standard Operating Procedures (SOPs), for implementation.*

5.2.4. In such cases, the Principal Investigator from the institution whose ethics committee is identified to undertake this role shall thereafter be designated as the Coordinating Principal Investigator for the purposes of the single ethics review process under these guidelines.

5.2.5. It is important to note that the designation of a single ethics committee 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.

5.3. Initial review form for single ethics review

The Initial Review Form provides a standardised framework for submitting multicentre research proposals to a Single Ethics Committee. It ensures that the ethics committee receives complete and consistent information across all participating sites, while capturing both common and site-specific ethical considerations. (Refer to Annexure 15- ICMR Initial Review Form for Multicentric Research https://ethics.ncdirindia.org/PDF/Initial_Review_Multicentric_Research.pdf)

5.3.1. The initial review form must clearly mention the names and roles of each participating site, along with their contact details.

5.3.2. The initial review form must include any unique site-specific or local ethical concerns, in addition to the common considerations applicable to all sites, to ensure that no local issues are overlooked. ***Refer to Table 1***

Table 1: Requirements for Single Ethics Review of Multicentre Research Studies

S. No.	Document to be submitted by the Coordinating PI to the Single Ethics Committee
1	Multicentre research protocol (Version No. & Date) applicable across participating sites with Scientific Committee approval letter to be enclosed.
2	Initial Review Form for Single Ethics Review – includes site names, roles and contact details
4	Informed consent documents including Master ICF and site-specific / translated versions, as applicable along with recruitment materials
5	Investigators' curriculum vitae and training certificates (e.g., GCP) at each participating site
6	Budget, funding, and compensation details including site-wise budgets and insurance / funds for compensation
7	Data management, access and data sharing plan

8	Monitoring plan (including DSMB, if applicable)
9	Conflict of interest declarations from investigators at all participating sites
10	Authorship, publication, and dissemination plan

5.4. Single ethics review process

5.4.1. The Coordinating Principal Investigator shall formally approach the identified single ethics committee with a request to undertake an ethics review for the proposed multicentre research study which would be applicable to all participating sites.

5.4.2. On receipt of the formal submission, the Secretariat shall verify the administrative completeness of the application and ensure that all required documents, including site-specific information for all participating sites, have been submitted.

5.4.3. Depending on the risk involved, the Member Secretary/Secretariat categorises them into three types, namely, exemption from review, expedited review, and full committee review as outlined in Tables 2.1 and 4.2 of the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017).

5.4.4. Single ethics committee would conduct a comprehensive ethics review of the complete multicentre research protocol, including study design, recruitment methods, informed consent documents, site-specific considerations, payment for participation, compensation, long-term storage of samples/ data and any other relevant study materials. ***Refer to Table 2*** for the elements to be reviewed.

Table 2: Ethical Considerations Specific to Multicentre Research for Review by the Single Ethics Committee

This table should be read in conjunction with Table 4.3 of the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017), which describes general ethical considerations applicable to all research proposals.

Ethical consideration	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, and external validity

Ethical consideration	Role of the Single Ethics Committee
	• 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.
2. Benefit–Risk Assessment	• Evaluates the overall benefit- risk of the multicentre research as a whole. • In addition, evaluates additional site-wise risk, if any, due to variations in population group, social sensitivities, infrastructure, healthcare access and emergency care availability. • Ensures that risk-mitigation strategies are adequate, feasible, and uniformly implemented across all participating sites.
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.
4. 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 contact information of the single ethics committee, and the secretariat is available. • Ensure that site-specific scientific, technical, or ethical considerations are addressed and that all translated versions are accurate and fully consistent with the ethics committee-approved English informed consent form. • Seeks inputs, if required, from the member secretary of site ECs, when necessary, to address local scientific, ethical, or cultural concerns.

Ethical consideration	Role of the Single Ethics Committee
5. Privacy and Data/ sample sharing	• Reviews plans for collection, storage, and sharing of biological samples and/or data, including identifiable information. • Ensure that the proposed sample and data sharing arrangements are consistent with participant consent, ethical approvals, and governance frameworks. • Evaluates plans for long-term storage, secondary use, access control, and accountability for shared samples/data in compliance with applicable data protection and regulatory requirements.
6. 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. • Reviews transparency of financial arrangements and accountability mechanisms among sponsor, coordinating centre, and participating sites, including timelines for reimbursements and liability for research-related injury.
7. Community Engagement	• Reviews site-specific community engagement plans to manage inter-site variability in local norms, gatekeeper roles, and community power dynamics. • Ensures that engagement strategies respect regional sociocultural norms while maintaining uniform ethical standards across all sites.
8. Investigator Qualifications & Site Capability	• Assesses adequacy and comparability of investigator expertise, infrastructure, facilities, and resources across sites. • Ensures that all sites are capable of implementing the protocol uniformly and safely.
9. Conflicts of Interest (COI)	• Reviews COI disclosures across all participating sites to identify site-specific, institutional, or sponsor-related conflicts that may not be apparent when sites are reviewed independently. • Assesses cross-site inconsistencies in COI disclosures and management plans, and requires harmonised mitigation

Ethical consideration	Role of the Single Ethics Committee
	measures where similar roles or relationships exist across multiple centres. • Monitors changes in COI during the course of the multicentre study and requires timely cross-site disclosure and revision of COI management plans when new financial, professional, or institutional relationships arise.
10. Dissemination and post-trial access	• Reviews plans for dissemination of study results and equitable post-trial access to interventions or benefits to participants, communities, and relevant stakeholders across all sites. • Ensures dissemination strategies and feasibility of post-trial commitments are culturally appropriate and accessible to diverse populations irrespective of geographic location • Ensures consistency in the content and timing of result dissemination across participating sites, so that no site or community receives partial, delayed, or preferential access to study findings in a multicentre setting.

5.4.5. To ensure that contextual, cultural, and community-specific perspectives are adequately considered, inputs may be sought from a community representative or the Member Secretary of the site Ethics Committee. In addition, subject matter experts may be consulted, as required, to address site-specific scientific, technical, or ethical issues that fall beyond the core expertise of the reviewing committee.

5.4.6. Due to exceptional reasons of local ethical concerns, the single EC may have to refer the matter to seek comments of site EC for the ethical concerns that are unclear to single EC upon review.

5.4.7. In general, it may be assumed that ethical consideration would be similar across all participating sites. However, it is possible that for some types of research there may be variable degrees of risk based on the local socio-economic conditions.

5.4.8. After the initial review, the single ethics committee shall communicate its queries, comments, and provisional decisions to the Coordinating PI.

5.4.9. The Coordinating PI shall address the committee's comments, incorporate required amendments into the core protocol, after discussing internally with the respective Site Principal Investigators. The Coordinating PI shall then resubmit the amended protocol, along with all site-specific revisions, to the ethics committee for further review.

5.4.10. The ethics review and approval process by single EC should avoid 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

5.5. Approval letter

5.5.1. Upon satisfactory review of the responses to its comments, the single ethics committee shall issue an approval letter applicable to all participating sites.

5.5.2. The approval letter must specify the list of all approved participating sites, the approved protocol (with version number and date), all other reviewed and approved documents, and the validity period of the approval.

5.5.3. Where necessary, site-specific conditions for implementation at individual sites may be stated in the approval letter without altering the approved core protocol or documents. Such conditions may relate to local feasibility, participant recruitment, variations in the standard of care, additional safeguards for vulnerable populations, or site-specific operational and logistical considerations.

5.5.4. The approval letter may include a recommended ethics oversight plan (see section 5.6), either uniform across all sites or tailored to individual sites, detailing the frequency, scope, and reporting requirements for site-level oversight, thereby ensuring consistent implementation of the approved protocol and effective multicentre coordination.

5.5.5. The single ethics committee shall communicate the final approval to the coordinating principal investigators, who in turn would inform the site principal investigators. The Site Principal Investigators shall keep their institutional authorities, as well as their respective site Ethics Committees, informed about the study, in order to ensure transparency, alignment, and effective local implementation of the research

5.6. Addition of new sites post ethics approval

5.6.1. The single ethics committee may review and approve participating sites that are ready at the time of initial submission, while permitting additional participating sites to be submitted subsequently for expedited review in view of the administrative implications by the same committee. In such cases, site-specific documents, as

specified in Table 1, including but not limited to investigator curricula vitae, site feasibility assessments, and confidentiality agreements, shall be submitted and reviewed by the single EC.

5.6.2. The Member Secretary of the single ethics committee may remain vigilant when a new site is proposed for inclusion, particularly where local factors or conditions may pose additional risks to participants. In such circumstances, the submission may require a full re-review by the single ethics committee.

5.7. Monitoring and Oversight

5.7.1. Monitoring and oversight by a single ethics committee refers to ongoing ethical oversight conducted across all participating sites to ensure participant safety and welfare, adherence to the approved protocol, and appropriate site functioning. This form of oversight is uniform, coordinated, and ethics-focused, and is distinct from statutory regulatory inspections or audits, which fall outside the committee's mandate.

5.7.2. A clear and comprehensive oversight and monitoring plan shall be developed for all participating sites, specifying the monitoring methods (including periodic reports, annual/continuing review reports, random or "for cause" site visits, follow-up calls, or other appropriate mechanisms), frequency, roles and responsibilities, and communication channels to be followed by all sites.

5.7.3. Site principal investigator shall submit a site-specific continuing review form, annual progress report to the Coordinating PI, who shall collate the report and submit it to the single ethics committee. The single ethics committee shall review this plan to ensure consistent ethical conduct across sites.

5.7.4. In determining the nature and intensity of monitoring across all participating sites, the single ethics committee 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.

5.7.5. Based on the study design, risk profile, site characteristics, sponsor requirements, and participant safety considerations, the single ethics committee may determine

the need for a Data and Safety Monitoring Board (DSMB) as appropriate to the nature of the research.

5.7.6. The contact details of the single ethics committee Secretariat shall be clearly included in the informed consent documents and prominently displayed at the study site. All complaints shall be reviewed by the single ethics committee, which shall recommend corrective actions as necessary.

5.7.7. For exceptional multicentre research, depending on the nature, scale, and complexity of the study, the single ethics committee may require more frequent or intensive monitoring. In such cases, upon the recommendation of the single ethics committee, the Member Secretary of the site Ethics Committee may serve as the primary liaison between the single ethics committee and the site Principal Investigators and may undertake closer monitoring in circumstances such as:

- **Research involving vulnerable persons**: Ensure consistent voluntariness and appropriate language translations are used across sites for adequate understanding and protection of research participants.
- **High-risk interventions (SAE likelihood above minimal risk)**: Ensure harmonised SAE reporting, conduct targeted monitoring of sites to ensure adherence to complex procedures and safety checklists across sites.
- **Studies with complex logistics or operational constraints**: implement risk-based monitoring with frequent on-site or remote reviews and provide targeted support to strengthen site operations and compliance.
- **Research involving sensitive personal data or a high risk of breach of confidentiality/ misuse of data**: ensure uniform data governance practices, monitor secure handling and anonymisation, and verify compliance during data transfer.

5.8. Serious Adverse Event reporting

5.8.1. All Serious Adverse Events (SAEs) shall be reported and reviewed in accordance with the ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants (2017) and any study-specific reporting requirements defined in the multicentre research protocol. A key advantage of centralised SAE review is the early identification of patterns or safety signals that may be missed when SAEs

are reviewed in isolation by multiple participating ethics committees in multicentre research.

5.8.2. The site principal investigator, through the Coordinating PI shall notify the single ethics committee and the site ethics committee within 24 hours of becoming aware of a Serious Adverse Event. (Refer to the Serious Adverse Event Reporting Format (Biomedical Health Research) - Annexure 6 https://ethics.ncdirindia.org/PDF/SeriousAdverseEventReportingFormatBiomedicalHealthResearch.pdf)

5.8.3. Following causality assessment, the site PI shall submit the detailed SAE report to the Single Ethics Committee within 14 days. The procedures shall remain as applicable.

5.8.4. The single ethics committee shall promptly review the SAE to assess participant safety, adequacy of site response, corrective and preventive actions, need for protocol modification, and compensation requirements, as applicable. The committee's findings and recommendations shall be communicated to the site principal investigator and Sponsor, as appropriate. A single review enables the single ethics committee to issue consistent SAE recommendations and harmonised safety decisions applied uniformly across all participating sites, thereby strengthening participant protection.

5.9. Annual/ Progress Reporting, Documentation, Amendments/ deviations and Record-Keeping

5.9.1. The site principal investigator shall report protocol deviations, adverse events and violations to the single ethics committee for review and recommendations.

5.9.2. Completion of study reports to the single ethics committee focusing on ethical aspects of the study. (Study completion/Final report format - Annexure 12 https://ethics.ncdirindia.org/PDF/StudycompletionFinalreportformat.pdf).

5.9.3. The Coordinating PI, must prepare a consolidated report covering all participating sites covering work done at all participating sites and submit this to the single ethics committee. The single ethics committee may require the coordinating Principal Investigator to present this report, as appropriate.

5.9.4. The single ethics committee shall maintain a secure centralised repository of all study-related documents, communications, decisions, and amendments.

5.10. Study Completion and Dissemination

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

5.10.2. Site principal investigators shall disseminate study results to local participants and communities through appropriate mechanisms (e.g., community meetings, participant letters, local media), as approved.

5.10.3. The protocol shall include a clear timeline for publication as well as fair, transparent, and timely dissemination of study findings or policy conversion plans.

5.11. Communication and Training

5.11.1. Communications between participating sites and the single ethics committee are crucial and must be efficient and timely, with mutual respect for all stakeholders.

5.11.2. Digital platforms such as email, video conferencing, and online portals may be utilised to facilitate communication and harmonisation of efforts.

5.11.3. All investigators and ethics committees must remain updated with ethical guidelines and regulatory requirements, and receive specialised training on operational aspects of single ethics review. Investigators and ethics committees may support one another to facilitate efficient implementation and the timely and amicable resolution of conflicts arising during the review or conduct of the study.

6. Roles and responsibilities of stakeholders in Multicentre research

Table 3: Stakeholder Responsibilities in Multicentre Research

Key Responsibilities
Coordinating Site or Research Institution Hosting the Single Ethics Committee
• Support the single ethics review process for timely and efficient multicentre research. • Ensure the ethics committee is duly registered with DHR/CDSCO (Naitik/Sugam), as applicable. • Provide infrastructure, administrative, logistical, and financial support for the single ethics review process.

- Facilitate inter-site coordination and communication.
- Support implementation of single ethics committee recommendations and oversight activities, including DSMB or other monitoring mechanisms.

Single Ethics Committee/Member Secretary or coordinating site EC

- Conducts a comprehensive single ethics review of multicentre protocol and study documents and issues an ethics approval applicable to all participating sites in the multicentre research.
- Provide ethics oversight and monitoring across all participating sites, as per the approved monitoring plan.
- Review and recommend actions on protocol amendments, SAEs, protocol deviations, and violations to ensure harmonised decisions across sites.
- Oversee disclosure and management of conflicts of interest across all sites.
- Maintain a secure, centralised repository of all study-related submissions, approvals, decisions, and communications.

Coordinating Principal Investigator

- Act as primary liaison between site PIs and the single ethics committee. Coordinate communication among investigators, sponsors, and ethics committees.
- Maintain communication with the single ethics committee's Member Secretary/Secretariat and support timely review and oversight by fulfilling requirements and timely submission.
- Share approved protocol, ethics approval letter, and committee recommendations with all site PIs.
- Ensure timely communication of amendments, SAEs, and study updates to the single ethics committee.
- Consolidate site-level reports (progress, deviations) and submit to the single ethics committee.
- Coordinate dissemination of study results, implementation of follow-up actions and translations to policy/public health
- Keep site principal investigators informed, who in turn keep respective site Ethics Committees and institutions informed and updated of the study.

Participating Site Institutions

- Implement the study locally under a single ethics committee approval, accepting suggestions and decisions of single EC.
- Ensure compliance with local institutional policies and applicable regulations.
- Facilitate monitoring and oversight by the single ethics committee and monitoring officer.
- Manage site-level administrative and financial responsibilities, including participant compensation, in line with ethics approval and agreements.

Site Ethics Committee (Local ECs)

- No role in reviewing or approving the multicentre study protocol under a single ethics review system
- Receive updates/ information only from site investigator regarding receipt of the study, final approval, major amendments, and other significant milestones, with no expected action.
- Expected to facilitate and support single ethics review process.
- May undertake site-specific review in exceptional studies involving high risk to participants due to local circumstances.

Site Principal Investigator

- Implement the study at the site according to the single ethics committee–approved protocol and timelines.
- Report protocol deviations, violations, and SAEs to the single ethics committee via coordinating PI.
- Facilitate monitoring activities conducted by the single ethics committee or monitoring officer.
- Ensure proper storage, handling, and security of study materials and participant data
- Disseminate study results and address community feedback at the site.
- Keep the respective Site Ethics Committee of the institution regarding receipt of the multicentre study, final ethics approval granted by the Single Ethics Committee, and other significant study milestones.

Member Secretary of the participating site

- Serve as the primary liaison between the single ethics committee and site PIs for monitoring activities.
- Conduct site-level monitoring (on-site or remote) in accordance with the monitoring plan.
- Report findings to the coordinating PI to inform single ethics committee for oversight and corrective action.
- Ensure consistent application of monitoring standards across all sites.
- Support implementation of single ethics committee recommendations regarding participant safety and compliance.

Initial challenges in implementing a single ethics review process are expected but likely to be short-term. Once the single ethics review is established, its benefits—enhanced efficiency, consistency, and stakeholder support—will outweigh the limitations, ultimately benefiting participants, researchers, ethics committees, and other relevant stakeholders involved in multicentre research.

Logo of the Institute	**Annexure 15- Initial Review Form for Multicentric Research** ***(Name of the Institution)*** **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 Single Ethics Committee

SECTION A - BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

(a) Name of Institute under which Single 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.)*

Sl.No	Participating Institution	Site PI (Name, Designation Details)

(f) Details of Site participating in multicenter research

(g) Type of review requested[1]:

Exemption from Review ☐ Expedited Review ☐ Full Committee Review ☐

(h) Title of the study:

Acronym/ Short title, (If any):

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

(j) Number of studies where applicant is a:

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

(k) Duration of the study:

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

2. FUNDING DETAILS AND BUDGET

(a) Total estimated budget for study:

At site | In India | Globally

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

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 ☐

[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.*

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)

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	☐	For children<7 yrs parental/LAR	☐	Verbal assent from minor (7-	☐	Written Assent from Minor (13-	☐

[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.*

whom)	consent	12 yrs) along with parental consent	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

(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 requiremnts can be found at National Ethical Guidelines for Biomedical & Health Research Involving Human Particpants 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: reversibly coded ☐ Irreversibly coded ☐ Identifiable ☐

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

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						
18.		☐	☐	☐		

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

PART 2 (Local Context Form for -Site Names)

General Instruction:

a) Tick one or more as applicable. Mark NA if not applicable. Attach additional sheets if required

1. ADMINISTRATIVE DETAILS

SECTION A - BASIC INFORMATION

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**:** h) 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) Any declaration of conflicts of Interest. Yes ☐ No ☐

b) 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.	MTA between collaborating partners	☐	☐	☐		
5.	Insurance policy/certificate	☐	☐	☐		
PROPOSAL RELATED						
6.	Copy of the modified protocol	☐	☐	☐		

7.	Participant Information Sheet (PIS) and Informed Consent Form (ICF) (English and translated)	☐	☐	☐		
8.	Assent form for minors (12-18 years) (English and Translated)	☐	☐	☐		
9.	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)	☐	☐	☐		
10.	Advertisement/material to recruit participants (fliers, posters etc)	☐	☐	☐		
11.	Any other relevant information/documents related to the study	☐	☐	☐		