INSTITUTIONAL ETHICS COMMITTEE-SHSRCKERALA

STANDARD OPERATING PROCEDURE

VERSION–07

STATE HEALTH SYSTEMS RESOURCE CENTRE-KERALA

2025

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ABBREVIATIONS

COI	Conflict of Interest
CV	Curriculum Vitae
DSMB	Data Safety Monitoring Board
EC	Ethics Committee
GCP	Good Clinical Practice
HMSC	Health Ministers Screening Committee
HOD	Head of the Department
HPSR	Health Policy and Systems Research
ICD	Informed Consent Document
ICMR	Indian Council for Medical Research
IEC	Institutional Ethics Committee
IND	Investigational Drug
LAR	Legally Authorized Representative
LGBTQI A	Lesbian, Gay, Bisexual, Transgender, Queer, Intersex and Asexual
MCR	Multi Center Research
MTA	Material Transfer Agreement
PI/Co-PI	Principal Investigator/Co-Principal Investigator
SAE	Serious Adverse Events
SHSRC-K	State Health Systems Resource Centre-Kerala
SOP	Standard Operating Procedure

Introduction

Kerala's health system has garnered international recognition for achieving health outcomes comparable to those of developed nations. The state's well-structured public health care system operates at three levels: Primary care is delivered through Family Health Centres (FHCs); Secondary care through Community Health Centres (CHCs) and Taluk Hospitals; and Tertiary care through District and General Hospitals. In addition, Medical Colleges under the Department of Medical Education provide advanced tertiary care, serve as referral centres, and play a key role in training medical professionals. Other systems of medicine under the Department of Health and Family Welfare also contribute significantly to the healthcare delivery landscape in the state.

The State Health Systems Resource Centre, Kerala (SHSRC-K) was established in 2008–09 as a technical support arm of the Department of Health and Family Welfare, Government of Kerala. Since 2013–14, SHSRC-K has been functioning as an autonomous body, modeled after the National Health Systems Resource Centre (NHSRC), New Delhi. As the state-level nodal agency for health systems research, SHSRC-K operates under the State Mission Director, National Health Mission, with the mandate to support the Department in policy formulation, strategic planning, health systems innovation, and knowledge management.

The core functions of SHSRC-K include:

1. Serving as the nodal agency for research activities within the Department of Health & Family Welfare.
2. Coordinating and guiding health research initiatives at all levels of the department.
3. Providing technical guidance and mentorship to staff interested in operational research and relevant studies.
4. Strengthening research capacity among health personnel across the system.
5. Promoting operational research among programme officers and frontline health workers to address context-specific health system challenges.

Information about disease trends and risk factors, outcomes of treatment or public health interventions, functionalities and patterns of care, health care costs and utilization are

important for informed policy-making. While such insight is available either through a robust data management system or through research studies, Kerala's current research output remains inadequate and disproportionate to the state's population health burden. The lack of sufficient data and evidence often constrains timely and effective decision-making in key areas of health policy and service delivery.

The establishment of an Institutional Ethics Committee (IEC) at SHSRC-K aims to ensure that all health systems research conducted under the Department adheres to the highest ethical standards, promotes scientific rigor, and ultimately contributes to equitable and evidence-informed health policy development in Kerala.

Objectives

The objective of this Standard Operating Procedure (SOP) is to support the effective and efficient functioning of the Institutional Ethics Committee (IEC) at SHSRC-Kerala. It aims to ensure the quality, consistency, and technical rigor of ethical review processes for all submitted biomedical, social, and health policy and systems research (HPSR) proposals, as well as for ongoing studies involving human participants.

This SOP is aligned with the ethical standards outlined in the following national guidelines and regulatory frameworks:

1. ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017)
2. ICMR National Ethical Guidelines for Biomedical Research Involving Children (2017)
3. National Guidelines for Ethics Committees Reviewing Biomedical and Health Research during the COVID-19 Pandemic (April 2020)
4. New Drugs and Clinical Trials Rules (2019)

Through this SOP, the IEC seeks to promote ethical research practices that protect the dignity, rights, safety, and well-being of research participants, while facilitating high-quality research that informs health policy and systems strengthening in Kerala.

Authority under which IEC is constituted

The Institutional Ethics Committee of the State Health Systems Resource Centre–Kerala (IEC SHSRC-K) is constituted as an independent body under the authority of the Executive Director, SHSRC-K. The IEC functions autonomously to ensure ethical oversight of biomedical, social, and health systems research involving human participants.

The Executive Director is responsible for appointing the Chairperson and all members of the Committee, based on their qualifications, experience, and demonstrated competence in reviewing the scientific and ethical dimensions of research proposals. The composition of the IEC will be in accordance with applicable national ethical guidelines.

The tenure of IEC members shall be three years from the date of appointment or until further orders, whichever is earlier. The Executive Director retains the authority to reconstitute the Committee or make changes to its membership as required, to maintain compliance with national regulations and institutional needs.

Revoking proposals

The IEC SHSRC-K has the right to revoke its approval accorded to scientific studies, and it has to record the reasons for doing so and communicate the same to the investigator as well as to the Licensing Authority or other relevant stakeholders. IEC SHRC-K may review the progress of the approved studies intermittently till the completion of the study through periodic study progress report and internal audit reports.

Requirements for IEC Membership

All members appointed to the IEC SHSRC-K must fulfill the following requirements:

1. **Documentation:** Submit an updated Curriculum Vitae with signature. Provide a signed consent/acceptance letter for EC membership and a Confidentiality along with COI Agreement
2. **Training Requirements:** Submit training certificates on Human Research Participant

Protection and Good Clinical Practice Guidelines.

- If not already trained, members must undergo mandatory training within 6 months of appointment and submit certificates accordingly.
- Be willing to undergo refresher training periodically as arranged by the EC.
- COI: Declare any COI, if applicable, as per EC policies, at the appropriate time during review or meetings.

3. **Public Disclosure:**
   - Be willing to have their full name, profession, and institutional affiliation disclosed in the public domain as part of the EC's commitment to transparency.
4. **Commitment to Ongoing Learning:**
   - Members must demonstrate willingness to update their knowledge and skills related to research ethics and ethical review during their tenure.

Conventions and Conduct of IEC meetings:

The Chairperson will conduct all meetings of the IEC SHSRC-K. In the absence of the Chairperson an alternate Chairperson will be elected from the other members on the day of the meeting by the members present, (or Chairperson should nominate a committee member as Acting Chairperson for that meeting) who will conduct the meeting. The alternate or acting chairperson should have the same powers as the Chairperson and should be a non-affiliated person.

The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all parties concerned. The Member Secretary will prepare the minutes of the meetings and get it approved by the Chairperson and all the members. In the absence of the Member Secretary, an alternate Member Secretary among the members will organize the IEC meeting. All proposals will be received at least two weeks before the meeting and after initial scrutiny by the Member Secretary the proposals will be circulated to the IEC members. The recommendations by the IEC SHSRC-K will be communicated to all the PIs and guides/HODs. If required, additional review meetings can also be conducted with a short notice period.

Review procedures

To ensure that all research involving human participants adheres to the highest ethical and scientific standards, the IEC SHSRC-K follows a systematic review process. This process is guided by national ethical guidelines and aims to assess the potential risks and benefits of proposed studies, safeguard participant rights and well-being, and promote responsible conduct of research. The following procedures outline the steps involved in the review and decision- making process of the Committee:

i. The IEC SHSRC-K shall convene regular meetings once every three months. Additional meetings may be scheduled at short notice as required, particularly when urgent or time-sensitive proposals are received. Meetings will typically be planned when a minimum of five proposals are pending review.
ii. Proposals must be submitted to the IEC atleast two weeks prior to a scheduled meeting, after incorporating the modifications suggested by the Institutional Review Committee (IRC) of SHSRC-K. This enables sufficient time for review by IEC members.
iii. The Member Secretary, with the assistance of the Secretariat, shall screen proposals for completeness and categorize them based on the level of risk involved into the following types of review:
    1. Exemption from Review
    2. Expedited Review
    3. Full Committee Review
iv. Decisions shall be taken by consensus following thorough discussion. In situations where consensus cannot be reached, decisions will be determined through voting.
v. The Principal Investigator (PI) or Research Scholar is expected to present the proposal during the IEC meeting. In the absence of the PI due to unavoidable circumstances, the Co-Principal Investigator (Co-PI) may present the proposal. Researchers may also be invited to offer clarifications on a case-by-case basis, if required.
vi. Deliberations and decisions during the review will be documented, and the minutes of the meeting will be formally approved by the Chairperson.
vii. The final decision of the IEC regarding the reviewed proposals must be recorded and confirmed on the same day as the meeting.
viii. The type of review to be undertaken shall be determined based on the level of risk

involved, categorized as follows:

Less than minimal risk:	No foresee able harm or discomfort. Includes research on anonymous or de-identified data/samples, data in the public domain, or systematic reviews/meta-analyses.
Minimal Risk	Harm or discomfort not greater than that encountered in daily life or during routine physical or psychological examinations. Examples: history taking, physical examinations, chest X-rays, non-invasive sample collection (e.g., saliva, urine, hair).
Minor Increase Over Minimal Risk (Low Risk)	Slightly above minimal risk threshold. Includes: routine research involving children or vulnerable populations, withholding of proven interventions in control/placebo groups in trials, minimally invasive procedures (e.g., minor blood draws), and use of identifiable personal data. May also include social or psychological risks, such as temporary distress.
More than Minimal Risk (High Risk)	Invasive procedures or significant probability of harm. Examples: interventional studies involving drugs, devices, or procedures such as lumbar punctures, biopsies, endoscopies, or sedation for diagnostics.

Types of reviews

The IEC SHSRC-K classifies research proposals into three categories for review, based on the level of risk involved and the nature of the research. These include: Exemption from Review, Expedited Review, and Full Committee Review. The categorization ensures that ethical oversight is proportional to the potential risk to research participants.

a. Exemption from review:

Proposals posing less than minimal risk and involving no identifiable information may be considered for exemption from ethical review. Examples include:

- Evaluation or monitoring of public health programmes by government agencies for the purpose of programme refinement or improvement, where no individual identifiers are collected.
- Research involving publicly available data, such as for systematic reviews or meta- analyses.
- Observation of public behaviour, provided that the information is not linked to identifiable individuals and disclosure would not harm the observed persons.
- Institutional quality control or quality assurance audits.

- Studies comparing instructional techniques, curricula, or classroom management methods.

b. Expedited Review:

Proposals involving no more than minimal risk may be subjected to expedited review by the Member Secretary, Chairperson, or a designated member/subcommittee of the IEC. The following types of proposals qualify for expedited review:

- Research based on non-identifiable clinical documentation, such as medical records or data.
- Minor modifications or amendments to previously approved protocols (e.g., administrative changes, typographical corrections, change in research personnel).
- Revised proposals, continuing reviews, or progress/annual reports where no new risk is introduced.
- Minor protocol eviations that do not increase risk.
- Expedited review of Serious Adverse Events (SAEs)/unexpected Adverse Events (AEs), conducted by the SAE subcommittee.
- Multi centre research where a designated main Ethics Committee has already reviewed and approved the protocol. In such cases, the local IEC may conduct an expedited review limited to site-specific aspects.
- Research conducted during emergencies or disasters, provided it meets ethical standards.
- Research using non-identifiable biological specimens (e.g., from blood/tissue banks or left over clinical samples).

Special ethical considerations for research during emergencies or disasters:

- Research must be essential, culturally appropriate, and specific, with potential for future application.
- Community engagement is vital before and during the research; representatives or advocates should be identified.
- Privacy and confidentiality must be strictly protected.
- The study should impose minimal additional risk.
- Research should yield direct or indirect benefits to participants or affected communities.
- Collaborative research with local partners is mandatory for international studies.

- Any transfer of biological material must comply with Government of India regulations and intellectual property considerations.

c. Full Review

Proposals that pose more than minimal risk or do not qualify for exemption or expedited review must undergo a full committee review. The review is conducted by all IEC members and is applicable in the following scenarios:

- Research involving vulnerable populations, even if the assessed risk is minimal.
- Studies with a minor increase over minimal risk, including procedures or populations requiring special protections.
- Research involving blinding, deception, or placebo controls.
- Any proposal previously reviewed under expedited or subcommittee review that requires ratification by the full committee, which reserves the right to modify or reverse prior decisions.
- Protocol amendments (e.g., changes to informed consent forms, investigator brochures, recruitment materials) that alter the level of risk.
- Major deviations or violations in approved protocols.
- Situations where new information arises that may alter the benefit–risk assessment, potentially requiring protocol suspension or termination.
- Research conducted during emergencies or disasters that require a full committee assessment, depending on the urgency and complexity, as determined by the Member Secretary.
- Advance approval of research protocols for foreseeable emergency or disaster scenarios, intended for implementation once the event occurs.

Review of proposals involving vulnerable population

Vulnerable populations are those who may have limited autonomy, diminished capacity to give informed consent, or are at higher risk of coercion or exploitation in the research context. These individuals or groups are either relatively or absolutely incapable of protecting their own interests and include, but are not limited to:

a. Economically, socially, or politically disadvantaged individuals.
b. Children (below18years of age).
c. Women in special situations (e.g., pregnant, lactating, widowed, or divorced women in certain contexts).
d. Tribal and other marginalized communities.
e. Gender and sexual minorities.
f. Refugees, migrants, the homeless, or individuals in conflict zones or disaster settings.
g. Persons with mental illness, cognitive impairment, or physical disabilities.
h. Terminally ill patients or individuals seeking new interventions after exhausting standard therapies.
i. Individuals with stigmatizing or rare diseases or those with compromised or impaired decision-making capacity.
j. Persons whose voluntariness or understanding may be affected due to dependency or hierarchical relationships (e.g., students, prisoners, subordinates, or institutionalized individuals).

Research involving vulnerable populations, even if minimal risk, shall undergo full committee review during both initial and continuing review processes.

The IEC SHSRC-K shall take the following measures to ensure additional protections:

A. Ethical Safeguards for Research Involving Vulnerable Groups:

- ***Children, Pregnant Women, Elderly in Particularly Vulnerable Tribal Groups:***
  - Avoid inclusion unless scientifically justified, with additional safeguards to minimize risk.
- ***Tribal Communities:***
  - Allow research only if it is therapeutic, diagnostic, or preventive in nature and directly benefits the community.

- Require approval from competent authorities (e.g., Tribal Welfare Commissioner or District Collector) before accessing tribal areas.
- Informed consent must be obtained in consultation with community elders or culturally appropriate gatekeepers, in the local dialect, and in the presence of appropriate witnesses.
- Individual consent must be obtained even when gate keeper permission is given.
- In areas without a panchayat system, a tribal leader or socially recognized authority may act as the gatekeeper.

- ***LGBTQIA+ Community:***
  - Encourage community engagement by sensitizing peer educators or community champions who can facilitate communication with potential participants.
- ***Individuals Lacking Capacity to Consent:***
  - Consent should be obtained from a Legally Authorized Representative (LAR) in the presence of an impartial witness.
  - Thorough explanation of risks, benefits, and procedures must be ensured.
- ***Institutional Settings:***
  - Protocols must detail mechanisms to prevent coercion or undue influence.
- ***Mental Illness and Cognitive Impairment:***
  - The IEC bears special responsibility to safe guard participants rights and dignity and ensure their participation is ethically justifiable.

B. Review and Oversight Measures

- ***Justification for Inclusion:***
  - The inclusion or exclusion of any vulnerable group must be clearly justified by the researcher and evaluated by the IEC.
- ***Benefit-Risk Assessment:***
  - Carefully examine the benefits, risks, and risk minimization strategies. Additional safety measures must be clearly articulated.
- ***Informed Consent Process:***
  - Must be voluntary, well-documented, and free from coercion or undue incentives.
  - In the case of children aged 7–18, assent must be recorded along with consent from a parent or LAR.
  - Re-consent must be obtained when applicable (e.g., a child turning 18 during the

study).

- ***Community Engagement:***
  - Whenever feasible, include empowered representatives or individuals familiar with the population under study during review deliberations.
- ***Conflict of Interest (COI):***
  - IEC must ensure that any COI does not increase risks or reduce benefits to vulnerable participants.
- ***Regulatory Compliance:***
  - All research must conform to applicable national and institutional guidelines/ regulations.
  - Any exception to standard procedures must be clearly justified by the researcher and approved by the IEC.
  - Such exceptions must be minimal, explicitly mentioned in the informed consent documents, and ethically defensible.

Identifying and managing Conflict of Interest

Conflict of Interest (COI) refers to a set of conditions in which professional judgement concerning a primary interest, such as participant welfare or research validity, is unduly influenced by a secondary interest (financial or non- financial; personal, academic or political). COI may present at the level of researches, Ethics Committee members, research institutions or sponsors.

Identification of Conflict of Interest

1. **Declaration Requirements**
   - All researchers and EC members must declare any potential conflicts of interest at the time of submitting research proposals or prior to EC meetings.
   - The Chairperson of the EC shall ensure that all members submit COI declarations before reviewing.
   - The declaration should include any financial relationships (consultancies, stock ownership, royalties, etc.), personal relationship, academic competition, or political affiliations that may affect the research process.
2. **Review process**
   - The EC shall review all submitted COI disclosures as part of the protocol evaluation process.
   - The EC must assess whether the declared interest could compromise the integrity of the research or the protection of participants.

Policy for Mitigation and Management of COI

1. **Recusal of members**
   - EC members with declared COI must recuse themselves from reviewing or decision- making for the protocol where a COI exists.
   - This applies specifically when they are Principal Investigator (PI), Co-investigators, or have any direct involvement in the research.
2. **Institutional Role**
   - Policies and SOPs shall address COI issues that are dynamic, transparent and actively communicated.

- Policies and procedures shall be implemented to address COI and conflicts of commitment, and staff shall be educated about such policies.
- Research and research results shall be monitored for accuracy and objectivity
- The functioning and decision making of the EC shall not be interfered with.

3. Documentation and Accountability.

- The policy, SOPs, and COI declaration forms must be actively communicated to all stakeholders.
- Public disclosure of research outcomes should indicate any COI as per the principle of transparency.

Types of Conflict of Interest (COI)

- Personal COI: If the investigator of a research proposal has close and immediate family relationship with the member of the institution (spouse, son/daughter, parents, sibling, dependent)
- If the IEC member is a collaborator, Principal investigator, co-investigator, financer, research staff, consultant for a research proposal which has come for review.
- Any committee member with a conflicting interest in a proposal will abstain from deliberations and in the decision-making process on that proposal, except to provide information as requested by the Committee. Such abstentions will be recorded in the minutes.
- An IEC member or consultant with either a financial or non-financial conflict of interest in a research project involving human participants may not participate in the IEC review of that research.

Identifying, Mitigating and Managing COI

IEC SHSRC- Kerala has developed policies and SOPs to address COI issues that are dynamic, transparent and actively communicated to researchers and members of IEC.

It shall,

- Require chairperson to seek COI declarations from members before each proposal review.
- At the beginning of each meeting, the Chairperson asks the members to disclose any COI concerning any of the items on the agenda.

- If the Chairperson has a conflict of interest for a particular project, this should be so declared and handled like any other member's conflict is handled.
- During the meeting, IEC member having conflict discloses the existence of the conflict just before the review begins.
- Ensure researchers submit a comprehensive disclosure of COI in their proposal documents.
- Evaluate each study in light of any disclosed COI and ensure appropriate action is taken to mitigate this.
- Encourage EC members to recuse themselves from reviewing of decision- making for proposals where they have direct involvement as PI, Co- investigator, or related secondary interest.
- Document all COI declarations and management decisions.
- Conduct periodic training on COI identification and management for EC members and researchers.
- Ensure the institution does not interfere in the EC's independent decision- making process.
- Monitor research results for accuracy and objectivity and address any detected COI at the researcher or institutional level.
- The IEC Chairperson has the final authority to determine whether a COI has been managed or eliminated appropriately for research participant protection.
- The IEC shall not approve a research study proposal where a COI is not managed or eliminated.
- The declaration and management of COI should be recorded in the proceedings of the IEC meetings.

Requirements for IEC Membership

Every EC member must:

- Provide an updated CV with signature
- Consent letter
- Submit training certificates on human research participant protection and good clinical practice (GCP) guidelines.
- If not trained must undergo training and submit training certificates within 6 months of appointment. Refresher training for existing members will be conducted periodically.
- Be willing to undergo training or update their skills/knowledge during their tenure
- Declare Conflict of Interest (COI) in accordance with the policy of the IEC, if applicable, at the appropriate time
- Sign a confidentiality and conflict of interest agreement/s;
- Be willing to place her/his full name, profession and affiliation to the EC in the public domain

Continuing training of EC Members

The ICMR National Ethical Guidelines emphasize that EC members should not only undergo initial training at the time of appointment but also continue receiving training through their tenure. This ensures that members remain updated with evolving ethical, regulatory and scientific developments

The continuing training involves:

- Human research protection: safeguarding the rights, safety and well- being of participants in biomedical and health research.
- Applicable EC SOPs: Familiarity with the institution's SOPs so members can apply consistent and transparent review processes.
- Regulatory requirements: Keeping up to date with changes in national laws, CDSCO rules, international guidelines like ICH- GCP and institutional policies.
- ICMR National Ethical Guidelines: Regular refresher on the ICMR guidelines, which for the ethical foundation for research involving human participants in India.

Frequency of training

Continuing education and refresher training sessions shall be conducted annually to ensure members remain updated throughout their tenure.

Review of multi-centric research

For multicentre researches conducted at more than one centre by different researchers usually following a common protocol, all sites are required to obtain approval from their respective ECs, which would consider the;

- Local needs and requirements of the population being researched and safeguard the dignity, rights, safety and well-being of the participants. The ECs/Secretariats of all participating sites should establish communication with one another
- If any EC does not grant approval for a study at a site the reasons must be shared with other ECs and deliberated upon. The EC can suggest site-specific protocols and informed consent modifications as per local needs.
- Separate review may be requested for studies with a higher degree of risk, clinical trials or intervention studies where conduct may vary depending on the site or any other reason which requires closer review and attention
- Common review for all participating sites in multi-centric research-In order to save time, prevent duplication of effort and streamline their view process, the ECs can decide to have one designated main EC, the decisions of which may be acceptable to other ECs.
- Common review process may be applied to research involving low or minimal risk, survey or multi-centric studies using anonymized samples or data or those that are public health research studies determined to have low or minimal risk.
- The common review is applicable only to ECs in India. In case of international collaboration for research and approval by a foreign institution, the local participating sites would be required to obtain local ethical approval.

Independent consultant/Invited subject experts

Subject experts will be called to provide special review for selected research proposals, if required. They can give their opinion/specialized views but they do not take part in decision making by IEC members.

Decision-making & Communication of decision

The IEC Members will discuss the various issues before arriving at a consensus. When consensus is not arrived at, the decision will be made by voting procedure.

- A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and the same should be conveyed to the Chairperson prior to the review of the application and recorded in the minutes.
- Decision will be made only in meetings where quorum is complete.
- Only the members can make the decisions. The expert consultants (subject experts) will only offer their opinions.
- The decision may be to approve, reject, or revise the proposals with minor modification and revise the proposals with major modifications. Specific suggestions for modifications and reasons for modifications and reasons for rejection will be given.
- In cases of conditional decisions, clear suggestions for revision and the procedure for having the application revised will be specified.
- Modified proposals will be reviewed by an expedited review through identified members.
- Decisions taken on the proposals will be communicated by the Member Secretary/ secretariat in writing to the PI/Research Scholar within two weeks after the meeting at which the decision was taken in the specified format
- IEC approval will be valid for one year or for the duration of the project whichever is less. Investigator has to get his or her project re- approved after one year, if required.

The communication of the decision will include:

1. Name and address of IEC.
2. The date, place and time of decision.
3. The name and designation of the applicant.
4. Title of the research proposal reviewed.
5. The clear identification of protocol number, version number, date, amendment number, date.
6. Along with protocol, other documents reviewed-Clear description of these documents along with Version number and Date.

7. List of EC members who attended the meeting-clear description of their role, affiliation and gender.
8. A clear statement of decision reached.
9. Any advice by the IEC to the applicant including the schedule/plan of ongoing review by the IEC SHSRC-K
10. In case of conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re- reviewed.
11. In case of rejection of the proposal, reason(s) for the rejection will be clearly stated.
12. Signature of the member secretary with date

Record keeping and archiving of documents

All Research proposals (one hard copy along with a soft copy) along with the information and documents submitted will be dated and filed. The documents will be archived for a minimum period of 3 years and for sponsored clinical trials for 5 years after completion/termination of the study. IEC members should not retain any documents with them after the meeting is over.

List of documents to be filed and archived

- Constitution of IEC
- SOP
- CV & consent of IEC members
- IEC Registration
- Honorarium details, Income and expenses
- Agenda & minutes of the meetings
- One copy of proposal
- Copy of recommendations/decision communicated to applicant
- Review reports, documents received during the follow up period and final reports of the study

Terms of reference

SHSRC-K being a research and technical support unit for the Department of Health and Family Welfare, Govt. of Kerala focuses on Health Policy and Systems Research (HPSR) towards strengthening the Health systems to achieve Sustainable Development Goals by 2030. In the context of the emerging challenges in health, there is a renewed interest in research across the state of Kerala. However, for there searchers within the health system there is lack of facilitating environment for the conduct of research. In this background an ethics committee is being constituted for the state's health system at SHSRC-Kerala. Therefore, the area of jurisdiction of the Institutional Ethics Committee (IEC) shall spam across all institutions under the Department of Health and Family Welfare, Government of Kerala. It shall take up academic or investigator- initiated projects under the purview of Biomedical and Health Research. It will accept proposals for review from outside provided the research is concerning the health system of Kerala.

The Institutional Ethics Committee (IEC) of the State Health Systems Resource Centre – Kerala (SHSRC-K) has been constituted to review biomedical and health research proposals involving human participants. The Terms of Reference are maintained by the IEC Secretariat and include:

1. Membership requirements
2. Terms of appointment, including duration, renewal, removal, and resignation procedures
3. Frequency of meetings
4. Fee structure for proposal processing, including honorarium or consultancy to members/invited experts

Appointments to the IEC, including the Chairperson and members, will be made by the Executive Director, SHSRC-K, based on qualifications and experience. The tenure of each member shall be three years, extendable for one more term. The committee will periodically revise its Standard Operating Procedures (SOPs) to reflect evolving requirements and ethical norms. The term of appointment of members could be extended for another term and a defined percentage (35 to 50%) of members could be changed on regular basis. Preferably, IEC would appoint persons trained in bioethics or persons familiar with ethical guidelines and laws of the country. The SOPs will be updated periodically based on the changing requirements.

Scope of Research Under the Purview of IEC, SHSRC-K

The IEC SHSRC-K shall review research proposals falling under the purview of Biomedical and Health Research, as defined by the Indian Council of Medical Research (ICMR). SHSRC-K undertakes a diverse set of studies, including:

1. Health systems and service delivery evaluations, such as assessments of public health institutions and government programmes
2. Implementation research on piloting and evaluating innovative models of care and public health interventions
3. Behavioral and psychosocial research, including studies on stigma, mental health, and health-seeking behavior
4. Community-based research and studies promoting health equity, especially among marginalized groups
5. Health Policy and Systems Research (HPSR) aimed at health system strengthening
6. Epidemiological and operational research, using retrospective and prospective designs, health records, biological data, and system-level indicators

Types of Projects Reviewed

The IEC will review the following types of projects:

1. Public health research
2. Investigator-initiated studies within the health system including academic research
3. Government-funded evaluations and commissioned studies
4. Externally submitted proposals, provided they are:
    1. Relevant to Kerala's health system
    2. Include at least one SHSRC-K affiliated person as co-investigator
    3. Undergo IEC review before publication

Roles and Responsibilities of IEC-SHSRC-K

The primary responsibility of IEC-SHSRC-K is to protect the dignity, rights, safety, and well- being of human research participants.

The IEC shall:

1. Ensure adherence to ethical principles such as autonomy, beneficence, non-maleficence, justice, and confidentiality
2. Review the scientific, ethical, medical, and social aspects of research before and during the study period

3. Verify that all research his conducted by qualified investigators and complies with ICMR/ICH-GCP/local laws
4. Ensure voluntary and informed consent from participants
5. Recommend compensation in cases of research-related injuries
6. Conduct site monitoring visits, review annual and final reports, and handle SAEs/AEs as applicable
7. Maintain confidentiality of documents and discussions
8. Participate in continuing education and remain updated on relevant guidelines
9. Promote harmonization of protocols and discourage duplicate submissions to multiple funders
10. Maintain a record of all projects, including decisions, amendments, and final outcomes

Scope, Tenure, and Renewal Policy

As the research and technical support unit to the Department of Health and Family Welfare, Government of Kerala, SHSRC-K focuses on HPSR and other public health research aligned with Sustainable Development Goals (SDGs).

The IEC will have jurisdiction across all institutions under the Department of Health and Family Welfare. This facilitates academic and investigator-initiated research and builds a supportive environment for ethical research across Kerala's health system.

Application Procedures

Proposals must be submitted to the IEC at least two weeks prior to a scheduled meeting, after incorporating the modifications suggested by the Institutional Review Committee (IRC) of SHSRC-K.

The submission process includes:

1. Electronic submission of the prescribed application form and documents via email
2. One hard copy of the signed application and full proposal, submitted to the IEC

Secretariat

1. Applications must be signed by the Principal Investigator (PI) and all collaborators
2. All submissions will be issued an IEC registration number for future reference
3. The PI may be invited to present the proposal and respond to queries in person or online
4. Revised versions, if required, must be resubmitted within a stipulated time

5. Online reviews and virtual presentations are permissible in special circumstances

IEC Review Fee

1. An administrative/processing fee of ₹6,000 will be charged for all research proposals
2. A fee waiver may be granted for non-funded, investigator-initiated studies by researchers within the health system, at the discretion of the Chairperson
3. The fee contributes to covering expenses for IEC's optimal functioning, documentation, archiving, and honorarium to non-affiliated members

Conditions for Accepting Studies from Outside Institutions

The IEC will consider external proposals only if:

1. The research directly concerns Kerala's health system
2. A SHSRC-K affiliated member is included as a co-investigator
3. IEC review is completed prior to publication or dissemination of findings

Administration and Secretariat Support

IEC SHSRC-K shall operate from a designated office space with adequate infrastructure and full- time staff to manage:

1. Documentation and record-keeping
2. Confidential filing of applications, reports, and meeting records
3. Scheduling and logistics of IEC meetings

The secretariat shall assist the Member Secretary and be trained in ethical review procedures. An honorarium per sitting will be provided to non-affiliated members, determined periodically by the institution.

Conditions of appointment of IEC members

1. Members should be selected in their capacities based on their qualifications, experience, interest, commitment and willingness to volunteer the required time and effort for the EC.
2. Members are appointed to the EC for a particular role. They cannot substitute for the role of any other member who is absent for a meeting. The role of Chairperson/ Member Secretary is an additional activity to their primary responsibility, based on their qualifications. Therefore, if the Chairperson is a lawyer, they can serve as both the

lawyer and the Chairperson.

3. The duration of the appointment is initially for 3 years, and all members must accept the appointment in writing.
4. At the end of 3 years, as the case may be, the committee will be reconstituted, and at least 50% of the members will be replaced by a defined procedure.
5. A member can be replaced in the event of death or long-term non-availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed fit for a member.
6. A member can tender a resignation from the committee with proper reasons to do so.
7. All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form.
8. An investigator can be a member of the committee; however, the investigator as a member cannot participate in their view of and approval process for any project in which he or she has presence as a PI, Co-PI or potential conflict of interest.
9. Members should be aware of local, social and cultural norms, as this is the most important social control mechanism. If required, subject experts could be invited to offer their views, for example, for drug trials, a pharmacologist, preferably a clinical pharmacologist, should be included. Similarly, based on the requirement of research area, for example, HIV, genetic disorders, etc., specific patient groups may also be represented in the Committee, and could be drawn from any public or private institute from anywhere in the country. These consultants should also sign the confidentiality agreement regarding the meeting, deliberations and related matters. These consultants or subject experts can share their views, but cannot vote for the decision.

Therefore, every EC member must:

a. Provide an updated CV with a signature.
b. Consent letter
c. Submit training certificates on human research participant protection and good clinical practice (GCP) guidelines.
d. If not trained, must undergo training and submit training certificates within 6 months of appointment. Refresher training for existing members will be conducted.
e. Be willing to undergo training or update their skills/ knowledge during their tenure
f. Declare Conflict of Interest (COI) in accordance with the policy of the IEC, if applicable, at the appropriate time.
g. Sign a confidentiality and conflict of interest agreement.

h. Be willing to place her/ his full name, profession and affiliation to the IEC in the public domain.

Composition of an Ethics Committee:

Ethics Committees must be multi-disciplinary and multi-sectoral, ensuring diverse perspectives in ethical review. The composition should reflect:

- Adequate representation of age and gender
- Preferably 50% of members being non-affiliated or from outside the institution
- A balanced mix of medical and non-medical, as well as technical and non-technical members, based on the institution's needs

Membership structure and responsibilities

The ideal size of an EC is between 7 and 15 members. The composition, affiliations, qualifications, member specific roles and responsibilities of the members in IEC SHSRC-K is given below:

Sl. No	Members of EC	Description of the role
1.	**Chairperson** *Non-affiliated* Qualifications: 1. A well-respected person from a scientific background 2. Prior experience of having served/serving in an EC	• Conduct EC meetings and be accountable for independent and efficient functioning of the committee • Ensure active participation of all members during meetings • Ratify the minutes of the previous meetings • Seek a Conflict of Interest (COI) declaration from members and ensure quorum and fair decision making • Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc. • In case of anticipated absence of Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting.
2.	**Member Secretary** *Affiliated* Qualifications: 1. Should be a staff member of the institution. 2. Should have knowledge and experience in clinical research	• Organise an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review • Schedule EC meetings, prepare the agenda and minutes

Sl. No	Members of EC	Description of the role
	and ethics, be motivated and have good communication skills. 3. Should be able to devote adequate time to this activity which should be protected by the institution	• Organise EC documentation, communication and archiving • Ensure training of the EC secretariat and EC members • Ensure SOPs are updated as required & adherence to EC functioning is maintained according to the SOPs. • Prepare for and respond to audits and inspections • Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review • Assess the need for expedited review/exemption from review or full review. • Assess the need to obtain prior scientific review, invite independent consultants, patients or community representatives. • Ensure quorum during the meeting and record discussions and decisions.
3.	**Basic Medical scientist** *Non-affiliated/affiliated* Qualifications: 1. Non-medical or medical person with qualifications in basic medical sciences	• Conduct scientific and ethical review with an emphasis on intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, protocol deviation, progress and completion report.
4.	**Clinician** *Non-affiliated/affiliated* Qualifications: 1. Should be individual/s with recognised medical qualification, expertise and training	• Scientific review of protocols, including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics • Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) • Review medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation. • Thorough review of protocol, investigator's brochure (if applicable) and all other protocol details and submitted documents
5.	**Legal expert** *Non-affiliated/affiliated* Qualifications: 1. Should have a basic degree in Law from a recognised university, with experience	• Ethical review of the proposal, Informed Consent Document (ICD) along with translations, MoU, regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol-specific other permissions (Departmental and

Sl. No	Members of EC	Description of the role
	2. Desirable, if trained in medical law	Institutional permissions, Health Ministers Screening Committee(HMSC), etc.), compliance with guidelines, etc. • The legal expert is also expected to confirm that the proposals are in tune with all the principles, norms and legal provisions laid down in relevant statutes as applicable.
6.	**Social Scientist/representative of NGO/Philosopher/ethicist/ theologian** *Non-affiliated/affiliated* Qualifications: 1. Should be an individual with a social/behavioural science/ philosophy/religious qualification 2. Trained and/or have expertise and be sensitive to local cultural and moral values. 3. Can be from an NGO involved in health-related activities	• Ethical review of the proposal, ICD, along with the translations. • Assess the impact on community involvement, socio–cultural context, religious or philosophical context, and any ethical and societal concerns. • Serve as a patient/participant/societal/community representative and bring in ethical and societal concerns.
7.	**Lay person** *Non-affiliated* Qualifications: 1. Literate person from the public or community 2. Has not pursued a medical science/health-related career in the last 5 years 3. May be a representative of the community from which the participants are to be drawn 4. Is aware of the local language, cultural and moral values of the community 5. Desirable: involved in social and community welfare activities	• Ethical review of the proposal, ICD, along with translation(s). • Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. • Serve as a representative of the patient/ participant/community and bring in ethical and societal concerns. • Assess societal aspects, if any.

Quorum requirements

1. A minimum of five members present in the meeting room.
2. The quorum should include medical, non-medical or technical and/or non-technical members.
3. Minimum one non-affiliated member should be part of the quorum
4. Preferably, the lay person should be part of the quorum.

5. No decision is valid without the fulfillment of the quorum.
6. The chairperson can take decisions along with the Member Secretary or a designated member of the Committee or Subcommittee of the EC for expedited reviews, which should be ratified in the next full committee.

Conditions of appointment of members

1. Members should be selected in their capacities based on their qualifications, experience, interest, commitment and willingness to volunteer the required time and effort for the EC.
2. Members are appointed to the EC for a particular role. They cannot substitute for the role of any other member who is absent for a meeting. The role of Chairperson/ Member Secretary is an additional activity to their primary responsibility, based on their qualifications. Therefore, if the Chairperson is a lawyer, they can serve as both the lawyer and the Chairperson.
3. The duration of the appointment is initially for 3 years, and all members must accept the appointment in writing.
4. At the end of 3 years, as the case may be, the committee will be reconstituted, and at least 50% of the members will be replaced by a defined procedure.
5. A member can be replaced in the event of death or long-term non-availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed fit for a member.
6. A member can tender a resignation from the committee with proper reasons to do so.
7. All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form.
8. An investigator can be a member of the committee; however, the investigator as a member cannot participate in the review of and approval process for any project in which he or she has presence as a PI, Co-PI or potential conflict of interest.
9. Members should be aware of local, social and cultural norms, as this is the most important social control mechanism. If required, subject experts could be invited to offer their views, for example, for drug trials, a pharmacologist, preferably a clinical pharmacologist, should be included. Similarly, based on the requirement of research area, for example, HIV, genetic disorders, etc., specific patient groups may also be represented in the Committee, and could be drawn from any public or private institute

from anywhere in the country. These consultants should also sign the confidentiality agreement regarding the meeting, deliberations and related matters. These consultants or subject experts can share their views, but cannot vote for the decision.

Procedure for resignation, replacement or removal of members

The membership will be renewed after the stated term. As and when the members retire from service, they will be replaced by other nominated members by an order from the appointing authority. If a regular member resigns or ceases to be a member due to disqualification or death, a new member will be appointed for the remaining term.

Resignation of members

The members who have resigned may be replaced at the discretion of the appointing authority. Members who decide to resign must inform the appointing authority and the chairperson. In case of resignation a new member shall be appointed, falling in the same category of membership.

Termination/disqualification procedure

A member may be relieved or terminated of his/her membership in case of conduct unbecoming for a member of the Ethics Committee, or repeated inability to participate in the IEC meetings. If a regular member fails to attend more than 3 meetings of the committee without valid reasons, the membership shall be reviewed by the appointing authority.

Administration and Management

The Institutional Ethics Committee of SHSRC-Kerala is supported administratively by a designated Secretariat, established under the authority of the Executive Director, SHSRC-Kerala, in consultation with the Member Secretary. The Secretariat plays a vital role in ensuring the smooth and compliant functioning of the IEC, in line with applicable national and institutional ethical guidelines.

The Secretariat is responsible for facilitating the conduct of IEC meetings, managing communication with researchers, maintaining records, and supporting documentation processes before, during, and after meetings. It also assists in the implementation of standard procedures related to submission tracking, protocol review, and correspondence management. All activities are carried out under the supervision of the Member Secretary.

The IEC office shall be equipped with adequate space, staffing, and secure systems for document storage and archiving, ensuring confidentiality and data integrity. Secretariat staffs are expected to maintain high standards of ethical conduct, confidentiality, and procedural consistency in all activities related to research review.

The organizational structure, staffing details, and specific operational responsibilities of the Secretariat are elaborated in the IEC Secretariat SOP (Annexure 16), which shall be referred to for all administrative processes related to Secretariat functioning.

Webpage for IEC SHSRC-K

A dedicated web page for the IEC SHSRC-Kerala will be created and regularly maintained on the official website of the State Health Systems Resource Centre–Kerala. This page will serve as a centralized and transparent platform for all information related to the functioning of the IEC. The web page will include the following details:

- Composition of the IEC
- SOPs
- Registration details and accreditation
- Circulars, notices, and updates related to IEC meetings
- Downloadable submission forms and templates
- Relevant ethical guidelines and resources
- Contact details for IEC-related communication

This initiative aims to enhance accessibility, streamline submission and review processes, and ensure transparency in the ethical oversight of research activities supported by SHSRC-K.

Contact details

For any queries or correspondence related to the Institutional Ethics Committee SHSRC- Kerala, may contact:

Dr. Jathavedus Mohanlal
Member Secretary
Institutional Ethics Committee
State Health Systems Resource Centre – Kerala
Thycaud, Thiruvananthapuram, Kerala-695014

Contact number: 9400063022
Email ID: iec.shsrc@shsrc.kerala.gov.in
Website: https://shsrc.kerala.gov.in/index.php/irc-iec/iec

ANNEXURES

ANNEXURE – 1

APPLICATION FOR INITIAL ETHICSREVIEW

Section A: Basic Information

Application No: …….…..…… **Date of Receipt: …….....**

Title of Study:

Month & year of likely commencement of study:

Duration of study:

Details of Principal Investigator (PI):

Name :

Qualification :

Designation :

Affiliation :

Details of Co-Principal Investigator (s):

1. Name :
   Qualification :
   Designation :
   Affiliation :

2. Name :
   Qualification :
   Designation :
   Affiliation :

Send correspondence to: [] PI [] Co-PI [] PI & Co - PI

Section B: Research Related Information

B 1. Background & objectives of the study (250 words):

B 2. Type of study (Please insert [□] wherever applicable)

[]	Biological samples/Data	[]	Clinical trials
[]	Cohort	[]	Cross sectional
[]	Case Control	[]	Mixed Method
[]	Multi-method	[]	Others

Please specify:

B3. Methodology (Please describe the study design, study setting, study subjects, sample size with justification, sampling method, inclusion & exclusion criteria in maximum 850 words)

B3. a Recruitment of study subject (who will do the recruitment & how?)

B3. b Data collection techniques (Please explain in sequence, the conduct of study and all data collection procedures. Please include information on (a) medical/surgical procedures and tests, (b) treatment, (c) interviews, discussions, observations, (d) follow up, (e) specific locations where they will be performed and (f) by whom. Specify if procedure involves banking of biological samples, HIV testing, genetic testing, and what is the procedure of transportation and management of leftover samples is done)

B4. Plan for data analysis (Please include by whom & how data analysis will be done. And also mention whether data will be analyzed to understand gender, caste, class, ethnicity and race differentials in maximum 100 words)

B5. Does your study require permissions from authorities? (Please enlist the departments/organisations/agencies from where permissions has to be obtained for the conduct of data collection)

Section C: Participant Related Information

C1. Type of participants in the study:

[] Healthy volunteers [] Patients

[] Vulnerable persons/Special groups [] Others

C1. a Will there be vulnerable persons/special groups involved?

[] Yes [] No [] NA

If yes, please mention insert □ wherever applicable

[] Children under18 years

[] Pregnant or lactating women

[] Differently abled (Mental/Physical)

[] Elderly

[] Economically and socially disadvantaged

[] Institutionalized/Hospitalised

[] Refugees/ Migrants/Homeless

[] Terminally ill (stigmatized or rare diseases)

[] Others Please specify:

C2. Is there any reimbursement to the participants?

[] Yes [] No

If yes,

[] Monetary [] Non-monetary

Please provide the details

C3. Are there any incentives to the participants?

[] Yes [] No

If yes,

[] Monetary [] Non-monetary

Please provide the details

C4. Are there any participant recruitment fees/incentives for the study provided to the PI/Institution?

[] Yes [] No

If yes,

[] Monetary [] Non-monetary

Please provide the details

Section D: Risks, Benefits, Privacy and Confidentiality

D1. Risks, discomfort and side effects

(Please describe all possible risks and discomfort for subject/participant due to use of intervention and/or interaction procedures/data collection methods proposed. Also describe expected degree and frequency of such risk, discomfort, side effect of drug etc.)

D2. Minimization

(Please describe steps you have taken or propose to take to minimize such risk, discomfort or for early recognition of side effects and their management)

D3. Privacy and confidentiality

(Please describe the following; (i) how you propose to provide privacy to subjects/ participants while conducting study, (ii) what level of confidentiality you propose to promise, what are the likely consequences to the subject/participant in the event of violation of confidentiality)

D4. Identifiers

(Please describe the following; (i) the types of identifiable information on subject/ participant you intend to collect, (ii) how you propose to mask/remove identifiers, (iii) how do you propose to ensure safe keeping and storage of identifiable data and how long the data will be stored)

D5. Benefits

(Please describe benefits to the subject/participant in participating in the study. Also describe the benefits, if any, to the society)

D6. Risk-benefit ratio

(Analyses the extent to which the benefits of the study out-weigh the risk to the subjects/participants)

Section E: Informed Consent Process

E.1 How informed consent is collected?

[] Signed witnessed consent [] Witnessed thumb impression

[] Verbal consent [] Recorded audio consent

[] Others [] Signed non-witnessed consent

[] Non-witnessed thumb impression

[] Consent from surrogate will be obtained (so specify from whom)

[] No consent will be obtained

E.2 Process

(Please describe how, where, when & by whom the informed consent will be obtained, how much time the study subject will be given to consider participation and decide describe additional plans & needs for inform concern in case the study involves special population included pregnant mothers, prisoners, minors etc, describe how will you assess that information is correctly understood by the participant)

E.3 Information content

(Please attach the information sheet & informed consent forms in English and in translated local language)

Section F: Payment/Compensation

F.1 Who will bear the costs related to participation & procedures?

[] PI [] Institution

[] Sponsor [] Other agencies [] NA

F.2 Is there a provision for free treatment of research related injuries?

[] Yes [] No [] NA

If yes, then who will provide the treatment?

F.3 Isthereanyprovisionformedicaltreatmentormanagementtilltherelatednessis determined for injury to the participants during the study period?

[] Yes [] No [] NA

If yes, please specify

F.4 Is there a provision for ancillary care for unrelated illness during the study period? If yes, please specify.

[] Yes [] NA [] No

Section G: Publication & Benefits Sharing

G.1 How will you disseminate the study findings

G.2 Additional information to add in support of the application, which is not included elsewhere in the form

Section H: Declaration & Check List

- ☐ I/we certify that the information provided in this application forms is complete & correct.
- ☐ I/we confirm that all investigators have approved the submitted version of proposal.
- ☐ I accept ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of the human subjects who are directly or indirectly involved in this project.
- ☐ I/we confirm that the study will be conducted in accordance with the latest ICMR national ethical guidelines for biomedical & health researches involving human participants & other applicable regulations & guidelines.
- ☐ I/we confirm that this study will be conducted in accordance with the Drugs & Cosmetics Act 1940 & its rules 1945, GCP guidelines and other applicable regulations & guidelines.
- ☐ I/we will comply with all policies & guidelines of the institute and affiliated/ collaborating institutions where this study will be conducted.
- ☐ I/we will ensure that personnel performing the study are qualified, appropriately trained and will adhere to the provisions of the IEC SHSRC-K approved protocol.
- ☐ I/we declare that the expenditure in case of injury related to the study will be taken care of, if applicable.
- ☐ I/we confirm that an undertaking of what will be done with the left over samples is enclosed, if applicable.
- ☐ I/we confirm that we shall submit any protocol amendments, adverse events if reported.
- ☐ I/we protect the privacy of participants & assure confidentiality of data & biological samples.
- ☐ I/we here by declared that I/ any of the investigators have no conflict of interest (financial/non- financial) with the sponsor(s)
- ☐ Details of conflict of interest:
- ☐ I/we declare/confirm that all necessary government approvals will be obtained as per requirements and copies will be submitted to the committee.
- ☐ I/we declare that the findings of the study will be disseminated to the concerned departments/institutions/agencies after the conduct of the study.
- ☐ I will ensure that personnel performing this study are qualified, appropriately trained

and will adhere to the provisions of the IEC SHSRC-K approved protocol. I will not modify this IEC SHSRC-K certified protocol or any attached materials without first obtaining approval for an amendment to the previously approved protocol.

Name & Signature of PI
Date:

Name & Signature of HOD/Institution
Date:

CHECK LIST

Sl. No	Items	Yes	No	NA	Remarks (If applicable)
1	Cover page				
2	Brief CV of all investigators				
3	Good clinical practice (GCP) training of investigators in last 3 years				
4	Approval of institutional research committee				
5	Agreement between collaborating partners*				
6	MTA between collaborating partners*				
7	Evidence of external laboratory credentials in case of an externally outsourced laboratory study				
8	Copy of contractor agreement signed with the sponsor/donor agency				
9	Previous decisions by others ethics committees or regulatory authorities for proposed study (including negative decisions or modified protocol in same location or elsewhere)				
10	Detailed research protocol				
11	Participants information sheets & participants informed consent form (both in English& translated in local language)				
12	Assent form for minors (12 to18) (both in English & translated in local language)				
13	Interview schedule/case report forms/interview guidelines/focus group discussion guidelines				

* For Multicentre research (MCR)

* Material Transfer Agreement (MTA)

ANNEXURE – 2

APPLICATION FORM FOR EXPEDITED REVIEW

EC Ref. No. (For office use):

Section A: Basic Information

Title of study:

Details of Principal Investigator (PI):

Name :

Qualification :

Designation :

Affiliation :

Section B: Research Related Information

1. Choose reasons why expedited review from EC is requested?

Involves non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples	
Involves clinical documentation materials that are non-identifiable (data, documents, records)	
Modification or amendment to approved protocol (administrative changes/ correction of typographical errors and change in researcher (s))	
Revised proposal previously approved through expedited review, full review or continuing review of approved proposal	
Minor deviation from originally approved research causing no risk or minimal risk	
Progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee	
For multicentre research where a designated EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review	
Research during emergencies and disasters *(See Section 12 of ICMR Ethical Guidelines, 2017)*	
Amendments to an approved project where such amendments do not affect the substance of the original protocol and where no major new ethical	

issues are raised.	
Protocol amendments for safety reasons, that is, in order to protect the welfare of participants in a trial	
Requests for extension for an approved project with no modification of protocol	
Approval of recruitment and publicity material for approved projects	
Provision of a retrospective statement that the quality assurance study has been conducted in an ethical manner to assist journal editors to assess articles presented for publication.	

Any other (please specify)

2. Is waiver of consent being requested?

[] Yes [] No

3. Does the research involve vulnerable persons?

[] Yes [] No

If yes, please provide details:

Name and Signature of PI (with date):

Comments of EC Secretariat:

Name and Signature of Member Secretary (with date):

CHECK LIST

Sl. No	Items	Yes	No	NA	Remarks (If applicable)
1	Cover page				
2	Brief CV of all investigators				
3	Good clinical practice (GCP) training of investigators in last3 years				
4	Approval of institutional research committee				
5	Agreement between collaborating partners*				
6	MTA between collaborating partners*				
7	Evidence of external laboratory credentials in case of an externally outsourced laboratory study				
8	Copy of contractor agreement signed with the sponsor/donor agency				
9	Previous decisions by others ethics committees or regulatory authorities for proposed study (including negative decisions or modified protocol in same location or elsewhere)				
10	Detailed research protocol				
11	Participants information sheets & participants informed consent form (both in English & translated in local language)				
12	Assent form for minors (12 to18) (both in English & translated in local language)				
13	Interview schedule/case report forms /interview guidelines/focus group discussion guidelines				

* For Multicentre research (MCR)

* Material Transfer Agreement (MTA)

ANNEXURE – 3

APPLICATION FORM FOR EXEMPTION FROM REVIEW

EC Ref. No. (For office use):

Section A: Basic Information

Title of study:

Details of Principal Investigator (PI):

Name :

Qualification :

Designation :

Affiliation :

Section B: Research Related Information

1. Choose reasons why exemption from ethics review is requested?

Public health programmes by government agencies	
Research on data in the public domain/systematic reviews or meta-analyses	
Observation of public behavior/information recorded without linked identifiers and Disclosure would not harm the interests of the observed person	
Quality control and quality assurance audits in the institution	
Comparison among instructional techniques, curriculum, or class room management methods	
Consumer acceptance studies related to taste and food quality	

Any other (please specify in 100 words):

Name and Signature of PI (with date):

Comments of EC Secretariat:

Name and Signature of Member Secretary (with date):

CHECK LIST

Sl. No	Items	Yes	No	NA	Remarks (If applicable)
1	Cover page				
2	Brief CV of all investigators				
3	Good clinical practice(GCP)training of investigators in last3 years				
4	Approval of institutional research committee				
5	Agreement between collaborating partners*				
6	MTA between collaborating partners*				
7	Evidence of external laboratory credentials in case of an externally outsourced laboratory study				
8	Copy of contractor agreement signed with the sponsor/donor agency				
9	Previous decisions by others ethics committees or regulatory authorities for proposed study (including negative decisions or modified protocol in same location or elsewhere)				
10	Detailed research protocol				
11	Participants information sheets & participants informed consent form (both in English & translated in local language)				
12	Assent form for minors (12 to18) (both in English & translated in local language)				
13	Interview schedule/case report forms/interview guidelines/focus group discussion guidelines				

* *For Multicentre research (MCR)*

* *Material Transfer Agreement (MTA)*

ANNEXURE – 4

CONTINUING REVIEW/ANNUAL REPORT FORMAT

EC Ref. No. (For office use):

Section A: Basic Information

Title of the study:

Details of Principal Investigator (PI):

Name :

Qualification :

Designation :

Affiliation :

Section B: Research Related Information

1. Date of EC Approval:
2. Validity of approval:
3. Date of Start of study:
4. Proposed date of Completion:
5. Period of Continuing Report: _ to _____
6. Does the study involve the recruitment of participants?

   ☐ Yes ☐ No

   a. If yes,

      i. Total number expected:

      ii. Number Screened:

      iii. Number Enrolled:

      iv. Number Completed:

   b. Enrolment status:

      i. Number on follow- up:

      ☐ Ongoing ☐ Completed ☐ Stopped

c. *Report of DSMB: (Note: In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA)*

☐ Yes ☐ No ☐ NA

d. *Any other remark:*

e. *Have any participants withdrawn from this study since the last approval?*

☐ Yes ☐ No ☐ NA

If yes, the total number withdrawn and reasons:

7. Is the study likely to extend beyond the stated period?

(Problems encountered since the last continuing review application with respect to the implementation of the protocol as cleared by the EC)

☐ Yes ☐ No

a. *If yes, please provide reasons for the extension:*

8. Have there been any amendments in the research protocol/Informed Consent Document (ICD) during the past approval period?

☐ Yes ☐ No

a. *If yes, date of approval for protocol and ICD:*

b. *In case of amendments in the research protocol/ICD, was re-consent sought from participants?*

☐ Yes ☐ No

If yes, when/how:

9. Is any new information available that changes the benefit-risk analysis of human participants involved in this study?

☐ Yes ☐ No

If yes, discuss in detail:

10. Have any ethical concerns occurred during this period?

☐ Yes ☐ No

If yes, give details:

11.a. Have any adverse events been noted since the last review?

☐ Yes ☐ No

Describe in brief:

11.b. Have any SAE's occurred since the last review?

☐ Yes ☐ No ☐ NA

If yes, number of SAE's: *Type of SAE's:*

11.c. Is the SAE related to the study?

☐ Yes ☐ No

11.d. Have you reported the SAE to EC?

☐ Yes ☐ No

If no, state reasons

11.e. Has there been any protocol deviations/violations that occurred during this period?

☐ Yes ☐ No

a. If yes, the number of deviations: ……..

b. Have you reported the deviations to EC?

☐ Yes ☐ No

If No, state reasons

13. In case of multi centric trials, have reports of off-site SAEs been submitted to the EC ?

☐ Yes ☐ No ☐ NA

14. Are there any publications or presentations during this period?

☐ Yes ☐ No

If yes give details

Any other comments:

Date: **Name and Signature of PI**

ANNEXURE- 5

APPLICATION/NOTIFICATION FORM FOR AMENDMENTS

EC Ref. No. (For office use):

Section A: Basic Information

Title of study:

Details of Principal Investigator (PI):

Name :

Qualification :

Designation :

Affiliation :

Section B: Research Related Information

1. **Date of EC approval:**
2. **Date of start of study:**
3. **Details of amendment(s):**

Sl. No	Existing Provision	Proposed Amendment	Reason	Location in the protocol/ICD

4. **Impact on benefit-risk analysis**

   [] Yes [] No

   If yes, describe in brief:

5. **Is any re-consent necessary?**

   [] Yes [] No

   If yes, has the informed consent undergone any necessary changes?

   [] Yes [] No

6. Type of review requested for amendment:

[] Expedited review (No alteration in risk to participants)

[] Full review by EC (There is an increased alteration in the risk to participants)

7. Version number of amended Protocol/Investigator's brochure/ICD:

Name and Signature of PI (with date):

CHECK LIST

Sl. No	Items	Yes	No	NA	Remarks (If applicable)
1	Cover page				
2	Brief CV of all investigators				
3	Good clinical practice (GCP) training of investigators in last3 years				
4	Approval of institutional research committee				
5	Agreement between collaborating partners*				
6	MTA between collaborating partners*				
7	Evidence of external laboratory credentials in case of an externally outsourced laboratory study				
8	Copy of contractor agreement signed with the sponsor/donor agency				
9	Previous decisions by others ethics committees or regulatory authorities for proposed study (including negative decisions or modified protocol in same location or elsewhere)				
10	Detailed revised research protocol				
11	Revised participants information sheets & participants informed consent form (both in English & translated in local language)				
12	Revised assent form for minors(12to18) (both in English & translated in local language)				
13	Revised interview schedule/case report forms/ interview guidelines/focus group discussion guidelines				

** For Multicentre Research (MCR)*

** Material Transfer Agreement (MTA)*

ANNEXURE – 6

PROTOCOL VIOLATION/DEVIATION REPORTING FORM (REPORTING BY CASE)

EC Ref. No. (For office use): ……

Section A: Basic Information

Title of the study:

Details of Principal Investigator (PI):

Name :

Designation :

Affiliation :

Section B: Research Related Information

1. Date of EC approval:
2. Date of start of study:
3. Participant ID:
4. Date of occurrence:
5. Total number of deviations/violations reported till date in the study:

6. Deviation/Violation identified by:
   - □ Principal Investigator/study team
   - □ Sponsor/Monitor
   - □ SAE Sub Committee/EC

7. Is the deviation related to (Please insert [✓] wherever applicable)
   - □ Consenting
   - □ Enrollment
   - □ Staff
   - □ Investigational Product

- ☐ Safety Reporting
- ☐ Source documentation
- ☐ Participant non-compliance
- ☐ Laboratory assessment
- ☐ Others (specify)

8. Provide details of Deviation/Violation:

9. Corrective action taken by PI/Co-I:

10. Impact on (if any):

☐ Study participant ☐ Quality of data

11. Are any changes to the study/protocol required?

☐ Yes ☐ No

If yes, give details:

Date: **Name and Signature of PI**

ANNEXURE – 7

SERIOUS ADVERSE EVENT REPORTING FORMAT (BIOMEDICAL HEALTH RESEARCH)

EC Ref. No. (For office use)…….

Section A: Basic Information

Title of the study:

Details of Principal Investigator (PI):

Name :

Qualification :

Designation :

Affiliation :

Section B: Details of the Participant

1. **Initial and ID:**
2. **Age at the time of event:**
3. **Weight in kg:**
4. **Gender:** □ **Male** □ **Female**
5. **Height in cms:**

Section C: Details of event

1. **Suspected SAE diagnosis**:
2. **Date of onset of SAE**: DD/MM/YYYY
3. **Date of reporting SAE**: DD/MM/YYYY
4. **Describe the event**
   (*Provide the duration, setting, site, signs, symptoms, severity, criteria for regarding the event serious)*

5. Details of suspected intervention causing SAE

Note: In case of academic clinical trial, mention name, indications, dosage, form and strength of the drug(s). Applicable to research intervention including basic, applied and operational research or clinical research, except for investigational new drugs.

6. Report type

☐ Initial ☐ Follow-up ☐ Final

a) If Follow-up report, state date of Initial report: DD/MM/YYYY

7. Have any similar SAE occurred previously in this study?

☐ Yes ☐ No

If yes, please provide details.

8. In case of a multi-centric study, have any of the other study sites reported similar SAEs? (Please list number of cases with details if available)

9. Tick whichever is applicable for the SAE

(*Kindly note that this refers to the Intervention being evaluated and NOT disease process)*

a. ☐ Expected event ☐ Unexpected event

b. ☐ Hospitalization ☐ Increased Hospital Stay

☐ Death ☐ Congenital anomaly/birth defect

☐ Persistent or significant disability/ incapacity

☐ Event requiring intervention (surgical or medical) to prevent SAE

☐ Event which poses threat to life

☐ Others

In case of death, state probable cause of death ……

……..……

c. ☐ No permanent/significant functional/cosmetic impairment

☐ Permanent/significant functional/cosmetic impairment

☐ Not Applicable

10. **Describe the medical management provided for adverse reaction (if any) to the research participant.** (Include information on who paid, how much was paid and to whom).

11. Provide details of compensation provided /to be provided to participants
(Include information on who pays, how much, and to whom)

12. Outcome of SAE

- ☐ Fatal
- ☐ Continuing
- ☐ Recovering
- ☐ Recovered
- ☐ Unknown
- ☐ Other (*specify*)

13. Provide any other relevant information that can facilitate assessment of the case such as medical history

14. Provide details about PI's final assessment of SAE relatedness to research.

Date: **Name and Signature of PI**

ANNEXURE - 8

PREMATURETERMINATION/SUSPENSION/ DISCONTINUATION REPORT FORMAT

Title of the study:

EC Ref. No. (For office use): …….

Section A: Basic Information

Details of Principal Investigator (PI):

Name:

Qualification:

Designation:

Affiliation:

Section B: Research Related Information

1. Date of EC approval:
2. Date of start of study:
3. Date of last progress report submitted to EC:
4. Date of termination/suspension/discontinuation:
5. Tick the appropriate
   - Premature Termination
   - Suspension
   - Discontinuation

   a) Reason for Termination/Suspension/Discontinuation:

   b) Action taken post Termination/Suspension/Discontinuation (if any):

6. Plans for post study follow up/withdrawal, if any
   (*Please describe post-termination/suspension/discontinuation follow up plans if any. Also describe any withdrawal plans for the study).*

7. Details of study participants

a. Total participants to be recruited: b. Screened:

c. Screen failures: d. Enrolled:

e. Consent Withdraw: f. Withdrawn by PI

Reason (*Give details*): Reason (*Give details*):

g. Active on treatment h. Completed treatment

i. Participants on follow-up j. Participants lost to follow up

k. Any other (provide details)

l. Number of drop outs

Reasons for each drop-out:

8. Total number of SAEs reported till date in the study:

Have any unexpected adverse events or outcomes observed in the study been reported to the EC?

☐ Yes ☐ No

9. Have there been participant complaints or feedback about the study?

☐ Yes ☐ No

If yes, provide details

10. Have there been any suggestions from the SAE Sub Committee?

☐ Yes ☐ No

If yes, have you implemented that suggestion?

☐ Yes ☐ No

11. **Do the procedures for withdrawal of enrolled participants take into account their rights and welfare?** (e.g., making arrangements for medical care of research participants):

☐ Yes ☐ No

If yes, provide details

Summary of results (if any):

Date **Name and Signature of PI**

ANNEXURE – 9

APPLICATION FORM FOR SOCIO-BEHAVIOURAL AND PUBLIC HEALTH RESEARCH

Title of the study:

EC Ref. No. (For office use):……..

Section A: Basic Information

Details of Principal Investigator (PI):

Name :

Designation :

Affiliation :

Section B: Research Related Information

1. Data collection method used in the study (Please insert [✓]wherever applicable) Focus group

   - ☐ Questionnaire/Survey
   - ☐ Observation
   - ☐ Interviews
   - ☐ Documents and records
   - ☐ Ethnographies/Oral
   - ☐ History/Case studies
   - ☐ Others

   a. Specify if others……

   b. If it is an interview, will there be audio-video recording of participants' interview?

      ☐ Yes ☐ No

      If yes, justify there a sons and storage strategies.

2. Type of informed consent used in the study. (Please insert [✓] wherever applicable)

   □ Individual consent □ Gate-keeper consent

   □ Community consent □ Others (specify)

3. Provide details of safeguards to ensure privacy and confidentiality of participants in the event of data sharing.

4. Describe strategies to manage if any patterns of behavior of self-harm or harm to the society are identified.(e.g.: Suicide or infanticide)

   □ Yes □ No □ NA

5. Are cultural norms/Social considerations/Sensitivities taken in to account while designing the study and participant recruitment?

   □ Yes □ No

6. Is there a use of an interpreter?

   □ Yes □ No □ NA

   If yes, describe the selection process

7. Describe any preparatory work or site preparedness for the study.

   □ Yes □ No □ NA

8. a. Type of risk related to procedures involved in the study. (Please insert [✓] wherever applicable)

      □ Invasive □ Potentially harmful

      □ Emotionally disturbing □ Involving disclosure

   b. Describe the risk minimization strategies.

   c. Justify reasons if individual harm is over riding societal benefit.

      □ Yes □ No □ NA

   d. Describe how do societal benefits outweigh individual harm.

9. Does the study use in complete disclosure or active deception or authorized deception? If yes, provide details and rationale for deception.

   □ Yes □ No

10. Describe the debriefing process that will be used to make participants aware of the incomplete disclosure or deception, including their right to withdraw any record of their participation.

Date: **Name and Signature of PI**

ANNEXURE – 10

STUDY COMPLETION/FINAL REPORT FORMAT

Title of study:

EC Ref. No. (For office use):

Section A: Basic Information

Details of Principal Investigator (PI):

Name :

Qualification :

Designation :

Affiliation :

Section B: Research Related Information

1. **Date of EC approval:**
2. **Date of start of study:**
3. **Date of study completion:**
4. **Please provide details of:**
   a) Total number of study participants approved by the EC for recruitment:
   b) Total number of study participants recruited:
   c) Total number of participants withdrawn from the study (if any):

Provide the reasons for withdrawal of participants:

5. **Describe in brief the publication/presentation/dissemination plans of the study findings.** (Also, mention if both positive and negative results will be shared)

6. **Describe the main ethical issues encountered in the study (if any)**

7. State the number (if any) of Deviations/Violations/Amendments made to the study protocol during the study period

Deviations:

Violation:

Amendments:

8. Describe in brief plans for archival of records/record retention

9. Is there a plan for post study follow-up?

[] Yes [] No

If yes, describe in brief:

10. Do you have plans for ensuring that the data from the study can be shared/accessed easily?

[] Yes [] No

If yes, describe in brief:

11. Is there a plan for post study benefit sharing with the study participants?

[] Yes [] No

If yes, describe in brief:

12. Describe results (summary) with Conclusion:

13. Number of SAEs that occurred in the study:

14. Have all SAEs been intimated to the EC?

[] Yes [] No

15. Is medical management or compensation for SAE provided to the participants?

[] Yes [] No

If yes, provide details

DECLARATION

Please read the following statement and insert a ✓mark in appropriate space provided.

[] I the undersigned solemnly declare that the study was conducted in adherence to the ethical considerations, and the protection of the rights and welfare of the human subjects who are directly or indirectly involved in the study as mentioned in the submitted proposal.

[] I have enclosed the completed study report along with this form.

Name and Signature of PI (with date):

ANNEXURE - 11

FORMAT FOR CURRICULUM VITAE FOR INVESTIGATORS

EC Ref. No. (For office use):

Name			
Present affiliation *Please mention your job title, department and organization*			
Address *Please mention your full work address*			
Telephone number		**Email address:**	
Qualifications: *Please list your educational background starting with your bachelor's degree in chronological order*			
Professional registration *Please include the name of body, registration number and date of registration*			
Previous and other affiliations *Please include previous affiliations in the last 5 years and other current affiliations*			

Projects under taken in the last 5 years
Relevant research training/experience in the area
Relevant publications *Please list the references of your relevant publications*

Name and Signature of Investigator (with date):

ANNEXURE - 12

REPORTING OF SITE VISITS BY TEAM FROM ON GOING STUDIES

SUB-COMMITTEEREVIEW

Title of study:

Details of Principal Investigator (PI):

Name :

Designation :

Affiliation :

Name of the Team Members:

1.

2.

SITE VISIT DETAILS

1. Date of visit
2. Time of visit
3. Date of EC approval:
4. Date of start of study
5. Date of study completion(proposed)
6. Total number of study participants approved by the EC for recruitment:
7. Total number of study participants recruited till date:
8. Total number of participants withdrawn from the study (If any):

Check whether the following are being done according to the protocol

1. Sampling process
2. Consent process
3. Consent form signatures
4. Allocation Concealment

5. Storage of intervention medicines
6. Case/Participant Record Form
7. Data storage & safety
8. Payment to participants for visits
9. Study Coordinators or Research Officers

Any other (as decided by the team)

Remarks on the quality of above processes, their methods and the documentation etc.,

Ensure that the PI provides the following:

- List of study participants enrolled in the study (name, age, sex, CRNo./OPD No./Study Registration Number, and contact number).
- Names, designation, qualifications, research experience and contact details of the study coordinators, Research Officers and other study staff.
- Any other documents as deemed necessary by the Team.

Remarks

a. Findings suggesting deviation from the approved protocol
b. Any suggestion given to the PI
c. Suggestions regarding the process of inspection/site visits
d. Recommendations, if any.

ANNEXURE 13

TEMPLATE OF INVITATION LETTER TO A MEMBER

(Letter head)

Letter Ref. No.:

From,
The Executive Director
SHSRC Kerala, Thycaud, Trivandrum

To,

Sub: Invitation to be a member for Institutional Ethics Committee (IEC) SHSRC-K, Thiruvananthapuram

Dear Madam/Sir,

Greetings from Institutional Ethics Committee of the State Health Systems Resource Centre- Kerala!

Based on your expertise in the field of medicine and research, you are cordially invited to be a member of our IEC for a period of three years or till further orders. I request you to kindly accept our invitation and confirm the same at the earliest. This is issued with approval of competent authority.

With Regards,

ANNEXURE – 14

TEMPLATE OF CONSENT LETTER FROM A MEMBER

To

The Executive Director

SHSRC Kerala, Thycaud, Trivandrum

Sub: Consent to be a member of Institute Ethics Committee (IEC)-Reg.

Ref: Your Letter No., dated:

Ref: Invitation to be a member for Institutional Ethics Committee (IEC) SHSRC-K from ED SHSRC-Kerala dated DD/MM/YYYY

Dear Sir/Madam,

With reference to your letter stated above, I hereby extend my willingness to become a member of IEC of SHSRC Kerala, Thycaud, Trivandrum. I shall regularly attend IEC meetings to review and give my unbiased opinion regarding the ethical aspects of research proposals involving human participants. I shall be willing for my name, profession and affiliation to be published. I shall not participate in quorum decisions where there is a conflict of interest. I shall maintain all the research project related information confidential and shall not share or reveal the same to anyone other than project related personnel. I here with enclose my CV.

Thanking you.

Yours sincerely,

Signature with date:

Name of the Member:

Address:

Telephone No.(Off) & (Res):

E-mail:

ANNEXURE – 15

APPOINTMENT ORDER

(Letterhead)

APPOINTMENT ORDER

Date:

Ref No:

Dr./Mr./Mrs.:

I am pleased to appoint you as the (designation) of the Institutional Ethics Committee (IEC)(Humanresearch)atSHSRCKerala,Thiruvananthapuramfollowingthereceiptofyour acceptance letter. The appointment shall be effective from _____ for a period of year/months or till further notice provided the following conditions are satisfied.

1. You should be willing to publicize your full name, profession & affiliation.
2. You are willing to record all reimbursement for work & expenses, if any, within or related to an EC & make it available to the public upon request.
3. You consent to sign confidentiality agreement between you & the IEC regarding meeting deliberations, applications, information on research participants, & related matters.
4. The renewal of your appointment will be by consensus & one-month notice on either side will be necessary prior to resignation/termination of appointment. Terms & Conditions regarding the resignation procedure, disqualification procedures, replacement procedures etc. may be found in the Standard Operating Procedures (SOPs) of SHSRC K - IEC.
5. You will be paid a sum of INR 2000/- per sitting as Honorarium for your services rendered towards attending the IEC meetings at SHSRC-K as per the institutional norms.

We sincerely hope your association with IEC SHSRC-K will be scientifically productive and beneficial to the Institute & the community at large.

Signature of the ED

ANNEXURE – 16
STANDARD OPERATING PROCEDURE FOR THE FORMATION AND FUNCTIONING OF THE IEC SECRETARIAT (IEC SHSRC-K)

1. Introduction

This Standard Operating Procedure (SOP) outlines the process for the formation, roles, responsibilities, and operational guidelines of the Institutional Ethics Committee (IEC) Secretariat within the State Health Systems Resource Centre-Kerala (SHSRC-Kerala), under the Department of Health and Family Welfare, Government of Kerala. The IEC Secretariat plays a crucial role in supporting the efficient and ethical functioning of the IEC, ensuring compliance with national and international ethical guidelines for human research.

2. Purpose

The purpose of this SOP is to:

2.1. Standardize the process of establishing and maintaining the IEC Secretariat at SHSRC- Kerala.

2.2. Clearly define the roles and responsibilities of the IEC Secretariat and its members.

2.3. Ensure efficient administrative and logistical support to the IEC.

2.4. Enable timely and organized facilitation of ethical reviews.

2.5. Maintain proper documentation and record-keeping for all IEC activities.

3. Scope

This SOP applies to all individuals involved in the formation, operation, and management of the IEC Secretariat within SHSRC-Kerala.

4. Definitions

- *IEC*: Institutional Ethics Committee.
- *Secretariat*: The administrative and support unit for the IEC.
- *Member Secretary*: The designated individual responsible for the overall functioning of the IEC and its Secretariat.
- *SOP*: Standard Operating Procedure.

5. Formation of the IEC Secretariat

5.1. *Authorization and Mandate*

The IEC Secretariat is constituted under the authority of the Executive Director, SHSRC- Kerala, in consultation with the Member Secretary of the IEC.

5.2. *Infrastructure and Resources*

SHSRC-Kerala shall provide the Secretariat with appropriate infrastructure, including dedicated office space, computers, internet access, printers, filing systems, and other communication tools.

5.3. *Budget Allocation*

A dedicated budget shall be allocated for the operational expenses of the IEC Secretariat, including training, stationery, communication, and other logistic expenditures.

5.4. *Appointment of Staff*

Appointments to the Secretariat shall be made in accordance with SHSRC-Kerala's recruitment protocols, ensuring that selected staff are qualified and possess an understanding of ethical principles in research.

5.5. *Team composition*

The IEC Secretariat will comprise the following key personnel:

Member Secretary (Ex-officio Head): The Member Secretary is responsible for the overall coordination of the IEC and its Secretariat. The role include sensuring compliance with ethical guidelines, approving official communications, and chairing or facilitating meetings. The Member Secretary should be a senior scientist, clinician, or public health expert with experience in research ethics and administration.

Secretariat Officer: The Secretariat Officer is in charge of managing daily Secretariat operations, serving as the main contact for IEC-related matters, and coordinating documentation, logistics, and internal communication. The individual should have a graduate or postgraduate degree in public health, life sciences, law, or administration, along with relevant experience in research or ethical review administration.

Administrative Assistant: The Administrative Assistant provides essential office support including data entry, filing, appointment scheduling, preparation of meeting materials, and general correspondence. Proficiency in MS Office tools and prior experience in administrative roles is desirable.

Legal/Ethical Advisor (Consultant): The Legal/Ethical Advisor is a consultant who provides legal and ethical guidance as needed. The role may be part-time or on-call and

should be filled by an individual with formal training in health law or bioethics and experience in research ethics.

6. Roles and Responsibilities of the IEC Secretariat

The IEC Secretariat plays a central role in ensuring the smooth functioning of the Institutional Ethics Committee. It is responsible for administrative, logistical, and documentation-related tasks before, during, and after IEC meetings. Its duties include managing communication with researchers, facilitating meetings, maintaining records, and ensuring compliance with ethical guidelines.

6.1. Pre-Meeting Responsibilities

Protocol Submission Management: Before each meeting, the Secretariat receives and acknowledges all research protocol submissions, including new applications, amendments, continuing reviews, and reports of adverse events. An initial screening is conducted to verify the completeness of submissions, using IEC checklists. In cases of incomplete submissions, researchers are promptly informed and guided on necessary revisions.

Meeting Preparation: The Secretariat prepares the meeting agenda in consultation with the Member Secretary. Meeting notices, agendas, protocols, prior minutes, and any reviewer comments are shared with IEC members in advance, allowing sufficient time for review. Arrangements for the meeting venue, refreshments, and required equipment (such as projectors or audio systems) are also managed at this stage.

Correspondence Management: All incoming and outgoing correspondence related to IEC activities is handled and documented systematically by the Secretariat.

6.2. During Meeting Responsibilities

Logistics and Support: During meetings, the Secretariat ensures smooth coordination and provides all necessary documents and logistical support to members. If a researcher is required to present their proposal, the Secretariat facilitates this process.

Minute Taking: Accurate minutes of the meeting are recorded in real time, capturing key discussions, decisions taken (approval, conditional approval, deferral, or rejection), any conditions imposed, and dissenting opinions where applicable.

6.3. Post-Meeting Responsibilities

Communication of Decisions: Following the meeting, the Secretariat drafts decision letters based on the IEC's conclusions and disseminates them to the respective researchers. These letters clearly communicate the decision and specify any

modifications, clarifications, or documentation required.

Record Keeping and Archiving: A secure and well-organized filing system is maintained for all IEC-related records. This includes submitted protocols, meeting agendas and minutes, correspondence, SOPs, training logs, and regulatory communications. Confidentiality and data security protocols are followed strictly, with access limited to authorized personnel only. A structured archiving process is implemented for completed or expired studies as per retention policy.

Follow-up and Compliance: The Secretariat also monitors the status of ongoing research, maintaining a database of approved protocols. It tracks compliance with reporting timelines, such as the submission of annual progress reports and final study summaries, and follows up with researchers on any pending approvals or conditions.

Training and Development: The Secretariat assists in organizing regular training and capacity-building sessions for IEC members and researchers, ensuring ongoing adherence to ethical standards and national/international guidelines.

7. Other Relevant Details

7.1. *Confidentiality and Data Security*

All members of the IEC Secretariat must sign a confidentiality agreement. Strict protocols for data security, both physical and digital, must be implemented to protect sensitive research information and participant data. Access to confidential documents should be restricted to authorized personnel only.

7.2. *Training and Continuing Education*

All Secretariat staff shall undergo regular training on research ethics, relevant national and international guidelines (e.g., ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICH-GCP), data management, and administrative procedures. Continuing education is crucial to keep staff updated with evolving ethical standards and regulatory requirements.

7.3. *Conflict of Interest*

Secretariat staff must declare any potential conflicts of interest that may arise in relation to submitted protocols. In case of a conflict, the staff member shall recuse themselves from handling the specific protocol.

7.4. *Communication Protocols*

Clear communication protocols shall be established for interaction with researchers, IEC members, institutional authorities, and regulatory bodies. All official

communications must be documented.

7.5. *Quality Assurance and Auditing*

The functioning of the IEC Secretariat shall be subject to periodic internal and external audits to ensure compliance with this SOP, relevant guidelines, and regulatory requirements. Findings from audits shall be used for continuous improvement.

7.6. *Record Retention Policy*

A clear record retention policy shall be established and adhered to, specifying the duration for which different types of IEC documents must be retained. This policy should align with national regulations and institutional policies.

8. Revision History

This SOP will be reviewed and updated periodically (every 2-3 years, or as needed due to changes in regulations or institutional policy) to ensure its continued relevance and effectiveness.

Version	Date	Description of Change
1.0	July 30, 2025	Initial Draft