Institutional Ethics Committee

State Health Systems Resource Centre Kerala

Standard Operating Procedure (SOP)

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INSTITUTIONAL ETHICS COMMITTEE - SHSRC KERALA

STANDARD OPERATING PROCEDURE

VERSION – 06

STATE HEALTH SYSTEMS RESOURCE CENTRE-KERALA

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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
LGBTQIA	Lesbian, Gay, Bisexual, Transgender, Queer, Intersex and Asexual
MCR	Multicenter 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

1. Introduction

The health system in Kerala has received international acclaim for its achievements in health indices, which are at par with developed countries. The public health care system in the state is well developed, having three levels of care, with Family Health Centres at the Primary level, Community Health Centres and Taluk hospitals at secondary level and District and General Hospitals at tertiary care level. The Medical Colleges, coming under the Department of Medical Education provide tertiary care and act as referral care centres, while also providing training for medical students. Other systems of medicine as well come under Department of Health and Family Welfare and contribute to the healthcare sector in the state.

The State Health Systems Resource Centre, Kerala (SHSRC-K), was established as a technical support organization for the Department of Health & Family Welfare, Government of Kerala in 2008-09. Since 2013-14, SHSRC- K has been functioning as an autonomous body under the Department of Health & Family Welfare with the objective of supporting the government on policy and strategy development and to mobilize technical assistance for specific health system issues. It is created on the lines of National Health Systems Resource Centre (NHSRC), New Delhi, which is the technical support organization to the Ministry of Health & Family Welfare.

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 arriving at policy decisions and plan for future actions. Such information is available either through a robust data management system or through research studies. However, the research output of the state till date is not sufficient and is inconsistent with the magnitude and disease burden of the state. Paucity of data often hinders policy decisions in important issues.

2. Objectives

The objective of this SOP is to contribute to the effective functioning of the IEC SHSRC-K and to ensure quality and technical excellence, with consistent ethical review of all submitted biomedical/social/HPSR research proposals and ongoing approved research studies involving human participants in accordance with the ICMR's National Ethical Guidelines for Biomedical and Health Research involving Human Participants 2017, National Ethical Guidelines for Biomedical Research Involving Children 2017, National Guidelines for Ethics Committees Reviewing Biomedical & Health Research during COVID-19 Pandemic-April 2020 and the New Drugs and Control trials rules 2019.

3. Authority under which IEC is constituted

State Health Systems Resource Centre-Kerala - Institutional Ethics Committee (IEC SHSRC-K) is an ethics committee which functions independently. The Executive Director of SHSRC-K will appoint the Chairperson and all the committee members, based on their qualifications, competence and experience in reviewing and evaluating the scientific and ethical aspects of biomedical research proposals. The tenure/period of IEC members will be for 3 years or till further orders.

3.1 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.

3.2 Requirements for IEC Membership

Every EC member must:

a. Provide an updated CV with 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 periodically.
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/s;
h. Be willing to place her/his full name, profession and affiliation to the EC in the public domain

4. 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 Chair person 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.

5. Details of documents to be submitted for EC review

The following documents are to be submitted for EC review.

i. Covering letter to the Member Secretary
ii. Application form for initial review
iii. Permission to use copyrighted proforma/questionnaire
iv. A complete protocol in the specified format
v. Approval of the project from Institutional Research Committee of SHSRC-Kerala
vi. The correct version of the informed consent document (ICD) in English and the local language(s).
vii. Tools (Questionnaire, interview schedule, guidelines, checklist etc.) in English and local language
viii. Recruitment procedures: advertisement, notices (if applicable)
ix. Patient instruction card, diary, etc. (if applicable)
x. Details of funding agency/sponsor and fund allocation (if applicable)
xi. Brief curriculum vitae of the PI
xii. A statement on Conflict of Interest, if any
xiii. Any research ethics/other training evidence, if applicable as per EC/SOP
xiv. List of ongoing research studies undertaken by the principal investigator (if applicable)
xv. Undertaking with signatures of investigators
xvi. Regulatory permissions (as applicable)
xvii. Relevant administrative approvals (such as HMSC approval for studies with international collaboration/funding)
xviii. MoU in case of studies involving collaboration with other institutions (if applicable)
xix. Insurance policy (if applicable)

6. Details of documents to be included in the protocol

The protocol should include the following:

i. The first page carrying the title of the proposal with signatures of the investigators

ii. Brief summary/lay summary of the protocol

iii. Background with rationale of why a human study is needed to answer the research question

iv. Justification of inclusion/exclusion of vulnerable populations

v. Clear research objectives and end points/outcome

vi. Eligibility criteria and participant recruitment procedures

vii. Detailed description of the methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded, etc.), types of data collection, intended intervention and details of invasive procedures, if any

viii. Duration of the study

ix. Procedure for seeking and obtaining written informed consent/ assent/ re-consent with the patient/participant

x. Participant information sheet and informed consent forms in English and local languages.

xi. Informed consent for storage of samples if applicable

xii. Plan for statistical analysis of the study

xiii. Plan to maintain the privacy and confidentiality of the study participants

xiv. For research involving more than minimal risk, an account of management of risk or injury; proposed compensation, reimbursement of incidental expenses and management of research related injury/illness/discomfort during and after research period and insurance policy

xv. An account of storage, maintenance and management of all data including the biological samples collected during the study

xvi. Plans for publication of results – positive or negative – while maintaining confidentiality of personal information/ identity.

xvii. Ethical considerations and safeguards for the protection of participants

7. Review procedures

i. The meeting of the IEC SHSRC-K will be held every three months. Additional review meetings can also be held with short notice as and when required. The meetings will be planned in accordance with a minimum of five proposals pending review.

ii. The proposals should be sent to the IEC members at least two weeks in advance of scheduled meeting.

iii. The Member Secretary with the support of the secretarial staff shall screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely, exemption from review, expedited review and full committee review.

iv. Decisions will be taken by consensus after discussion, and whenever needed voting will be done.

v. The PI/Research Scholar will then present the proposal in the meeting. When the PI is not available due to unavoidable reasons the Co-PI will be allowed to present the proposal. Researchers will be invited to offer clarifications on a case to case basis, if needed

vi. The review discussions/decisions will be charted down and the final minutes will be approved by the Chairperson.

vii. After the IEC meeting, the decision of the IEC members regarding the discussed proposals has to be obtained on the same day of the meeting.

viii. The type of EC review based on risk involved in the research, is categorized as follows

1. Less than minimal risk: Probability of harm or discomfort anticipated in the research is nil or not expected such as research on anonymous or non- identified data/samples, data available in the public domain, meta-analysis, etc.
2. Minimal risk: Probability of harm or discomfort anticipated in the research is not

greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely. Research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc.

3. Minor increase over minimal risk or Low risk: Increment in probability of harm or discomfort is only a little more than the minimal risk threshold. Routine research on children and adolescents; research on persons incapable of giving consent; delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials; use of minimally invasive procedures that might cause no more than brief pain or tenderness, small bruises or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing; trying a new diagnostic technique in pregnant and breastfeeding women etc. Use of personal identifiable data in research also imposes indirect risks. Social risks, psychological harm and discomfort may also fall in this category.
4. More than minimal risk or High risk: Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. Examples include research involving any interventional study using a drug, device or invasive procedure such as lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures

7.1 Types of reviews

A. Exemption from review:

Proposals which present "less than minimal risk" fall under this category. The following situations may come under this "less than minimal risk" category: Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exceptions:

a. When research on the use of educational tests, survey or interview procedures, or observation of public behavior can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.

b. When interviews involve direct approach or access to private papers

B. Expedited Review:

The proposals presenting "no more than minimal risk" to research participants may be subjected to expedited review. The Member- Secretary and the Chairperson of the IEC or designated member of the Committee or Subcommittee of the IEC may do expedited review only if the protocols involve;

- Minor deviations from originally approved research protocol during the period of approval.
- Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.
- Research activities that involve only procedures listed in one or more of the following categories

1. *Clinical studies of drugs and medical devices only when*
    - Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or
    - Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.
    - When in emergency situations like serious outbreaks or disasters, a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and the same participants should not be included in the clinical trial that may be initiated later based on the findings of the pilot study.
2. *Research on interventions in emergency situation*
    - When proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, physicians may use new intervention as investigational drug (IND)/devices/vaccine to provide emergency medical care to their patients in life threatening conditions. Research in such instances of medical care could be allowed in patients –
    - When consent of person/patient/responsible relative or custodian/ team of designated doctors for such an event is not possible. However, information about the intervention should be given to the relative/legal guardian when available later;

- When the intervention has undergone testing for safety prior to its use in emergency situations and sponsor has obtained prior approval of DCGI;
- Only if the local IEC reviews the protocol since institutional responsibility is of paramount importance in such instances.
- If Data Safety Monitoring Board (DSMB) is constituted to review the data;

3. *Research on disaster management*
    - It may also be unethical sometimes not to do research during disaster. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:
    - Research planned to be conducted after a disaster should be essential, culturally sensitive and specific in nature with possible application in future disaster situations.
    - Disaster-affected community participation before and during the research is essential and its representatives or advocates must be identified.
    - Extra care must be taken to protect the privacy and confidentiality of participants and communities.
    - Protection must be ensured so that only minimal additional risk is imposed.
    - The research undertaken should provide direct or indirect benefits to the participants, the disaster affected community or future disaster- affected population and a priori agreement should be reached on this, whenever possible, between the community and the researcher.
    - All international collaborative research in the disaster-affected area should be done with a local partner on equal partnership basis.
    - Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.
4. *Expedited review may also be taken up for nationally relevant proposals requiring urgent review.*

C. Full Review

All research proposals/protocols presenting with “more than minimal risk”, which do not qualify for exempted or expedited review shall be subjected to full review by all the members, including:

- Research involving vulnerable populations, even if the risk is minimal;
- Research with minor increase over minimal risk
- Studies involving blinding of participants
- Research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee;
- Amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, case record forms etc.) involving an altered risk;
- Major deviations and violations in the protocol;
- Any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment;
- Research during emergencies and disasters either through an expedited review/scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need
- Prior approval of research on predictable emergencies or disasters before the actual crisis is needed for implementation later when the actual emergency or disaster occurs.

8. Review of research proposals involving vulnerable population

Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests and providing valid informed consent and include:

a. Economically politically and socially disadvantaged people; and therefore, susceptible to being exploited
b. Children (up to 18 years);
c. Women in special situations;
d. Tribal and marginalized communities;
e. Refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations;
f. Those afflicted with mental illness and cognitively impaired individuals, differently abled–mentally and physically disabled;
g. Terminally ill or people who are in search of new interventions having exhausted all therapies;
h. Those suffering from stigmatizing or rare diseases; those incapable of making a voluntary informed decision for themselves or whose autonomy is compromised temporarily or permanently, for example people who are unconscious, differently abled;
i. Those who are able to give consent, but whose voluntariness or understanding is compromised due to their situational conditions; or those who have diminished autonomy due to dependency or being under a hierarchical system and unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent.

Initial and continuing reviews of research involving vulnerable populations, even if the risk is minimal; shall be subjected to full committee review by all the members. The IEC SHSRC- K shall;

- Take additional precautions to avoid inclusion of children, pregnant women and elderly people belonging to particularly vulnerable tribal groups
- Ensure that research on tribal populations is conducted only if it is of a specific therapeutic, diagnostic and preventive nature with appropriate benefits to the that

particular population.

- Ensure that the researcher obtain approval from competent administrative authorities, like the tribal welfare commissioner or district collector, before entering tribal areas
- Carefully determine the benefits and risks of the study and examine the justification provided and risk minimization strategies. Additional safety measures should be strictly reviewed and approved by the IEC.
- Ensure that the informed consent process is well documented. There should not be any undue coercion or incentive for participation. A person's refusal to participate should be respected and there should be no penalty. Also ensure that recording of assent in case of research studies involving children aged 7 to 18 years and re-consent, when applicable is done.
- In studies involving LGBTQIA community, ensure that peer educators or champions among the community could be educated and sensitized first. They would in turn explain the details to the potential participants from the community who would then understand them better.
- Ensure that informed consent from vulnerable populations may be obtained from Legally Authorized Representative (LAR) when a prospective participant lacks the capacity to consent in presence of impartial witness after thorough explanation of risks and benefits.
- Ensure that mechanisms to avoid coercion due to being part of an institution or hierarchy should be described in the protocol of studies involving terminally ill patients
- Examine whether inclusion/exclusion of the vulnerable population is justified.
- Ensure that COI do not increase harm or lessen benefits to the participants.
- Make it desirable to have empowered representatives from the specific populations during deliberations.
- Have special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment.
- Ensure that the research is being conducted within the purview of existing relevant guidelines/regulations.

- Justify with researchers the cases for exceptions to the usual requirements of participation or essentiality of departure from the guidelines governing research. It shall ensure that these exceptions are as minimal as possible and are clearly spelt out in the ICD.
- Ensure that Informed consent from tribal population should be taken in consultation with community elders and persons who know the local language/dialect of the tribal population and in the presence of appropriate witnesses. Even with permission of the gatekeeper, consent from the individual participant must be sought
- Ensure that wherever a panchayat system does not exist, the tribal leader, other culturally appropriate authority or the person socially acceptable to the community may serve as the gatekeeper from whom permission to enter and interact should be sought.

9. Identifying, mitigating and managing COI

IEC SHSRC-K has developed policies and SOPs to address COI issues that are dynamic, transparent and actively communicated to the researchers and the members of IEC. It shall;

- Evaluate each study in the light of any disclosed COI and ensure appropriate action is taken to mitigate this
- Ensure that the Chairperson seek Conflict of Interest (COI) declaration from members before the commencement of review of each proposal.
- Require their members to disclose their own COI and encourage IEC members to take appropriate measures to recuse themselves from reviewing or decision making on research proposals in which they are Principal Investigator (PI) or Co – investigators or have other potential conflicts of interest.
- Make appropriate suggestions for management, if COI is detected at the institutional or researchers' level.

10. Review of multi-centric research

Multicentre research is 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 the review 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.

11. 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.

12. 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

13. 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

14. Terms of reference

14.1 Scope, tenure and renewal policy

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 the researchers 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.

IEC SHSRC-K will function as per the Indian Council for Medical Research (ICMR) National Ethical Guidelines for Biomedical and Health research involving human participants 2017, and New Drugs and Clinical Trials Rules 2019

Terms of reference will be maintained in the office of IEC SHSRC-K. This includes

- Membership Requirements
- Terms of Appointment with reference to the duration of the term,
- The policy for removal, replacement, resignation procedure
- Frequency of meetings, and
- Payment of processing fee to the IEC for review, honorarium/ consultancy to the members/invited experts etc.

The Executive Director, SHSRC-K will appoint the Chairperson and all the committee members, based on their qualifications, competence and experience in reviewing and evaluating the scientific and ethical aspects of biomedical research proposals. The tenure of IEC members will be for 3 years or till further orders. 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.

14.2 Application procedures

All proposals should be submitted to IEC on any working day 2 weeks in advance of scheduled meeting in the prescribed application form along with relevant documents via email. One hard copy of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co- investigators/ Collaborators should be submitted to the IEC secretariat. Principle Investigators shall forward their application to the Chairperson of IEC SHSRC-K, through Member Secretary and the receipt of the application will be acknowledged by the IEC office. Every application will be allotted an IEC registration number to be used for all future correspondence and reference. The date of IEC meeting will be intimated to the PI through email. The PI may be directed to attend the meeting online/offline to make a brief presentation of the proposal if needed and to clarify the points raised by the members. IEC can recommend online meetings and virtual presentations in special situations. If revisions are to be made, the revised proposal (soft and hardcopies as specified) should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

All research proposals will be charged an administrative fee/processing fee of Rs.6000/-. A Waiver of this fee is permissible for non-funded studies by independent researchers from within the health system, at discretion of the chairperson.

14.3 Conditions for accepting studies from outside

In order to accept studies from external sources, the study must be relevant to the health system of Kerala. Additionally, one affiliated member from SHSRC-K should be included as a co-investigator of the study.

14.4 Quorum requirements

- A minimum of 50 percent of members + 1 must be present in the meeting for the fulfillment of the quorum.
- The quorum should include medical, non-medical or technical or/ and non- technical members. Minimum one non-affiliated member should be part of the quorum. Preferably the lay person should be part of the quorum.

- The quorum for reviewing regulatory clinical trials should be in accordance with current New Drugs and Clinical Trials Rules 2019 requirements.
- No decision is valid without fulfillment of the quorum.
- Chairperson can take decisions along with the Member- Secretary or designated member of the Committee or Subcommittee of the IEC for expedited reviews which should be ratified in the next full committee.

14.4.1 Composition

The number of members in an IEC may range from 7 to 15. The IEC will be multi-disciplinary in composition and independent. IEC SHSRC-K should have the following categories of members

Chairperson	-	Non-affiliated
Member Secretary	-	Affiliated
Basic medical scientist	-	Non-affiliated/affiliated
Clinicians	-	Non-affiliated/affiliated
Legal expert	-	Non-affiliated/affiliated
Social Scientist/representative of NGO/ Philosopher/ethicist/ theologian	-	Non-affiliated/affiliated
Lay person from the community	-	Non-affiliated/affiliated

14.4.2 Conditions of appointment of members

- The duration of appointment is initially for a period of 3 years
- Members must accept the appointment in writing
- Members must provide a one-page Curriculum vitae
- Members of the EC should not have any known record of misconduct.
- At the end of 3 years, as the case may be, the committee will be reconstituted, and 50% of the members will be replaced by a defined procedure.
- 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.

- A member can tender resignation from the committee with proper reasons to do so.
- The members including subject experts will receive an honorarium of Rs 2000/- per sitting for attending the meetings
- All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form.
- An investigator can be a member of the committee; however, the investigator as 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.
- Conflict of interest should be declared by members of the committee.
- 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 decision.

14.4.3 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.

14.4.4 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.

14.4.5 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.

14.5 Roles and responsibilities of IEC SHSRC-K

The main responsibility of IEC SHSRC-K is to review all types of Biomedical/ Social/HPSR research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellbeing of research participants before approving the research proposals.

IEC SHSRC-K shall;

1. Ensure that all ethical principles of research such as autonomy, beneficence, non – maleficence, respect for free and informed consent, respect for human dignity, respect for vulnerable persons, respect for privacy and confidentiality and justice are taken care of in planning, conducting and reporting of the proposed research. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required. In order to carry out these responsibilities, it will review the proposals for scientific, ethical, medical and social aspects before start of the study as well as monitor the research throughout the study period until and after completion of the study through appropriate well documented procedures, such as annual reports, final reports and site visits.
2. See that the research is sound in scientific design, has statistical validity and is conducted according to guidelines of ICMR/International Conference on Harmonization - Good Clinical Practices (ICH- GCP) as well as local regulatory requirements and laws.
3. See that the research is conducted/supervised by persons with the required expertise
4. Ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.
5. Assist in the development and education of the research community in the given institute (including researchers, clinicians, students and others), responsive to local healthcare requirements).
6. Ensure that privacy of the individual and confidentiality of data including the documents of IEC meetings is protected.
7. Review progress reports, final reports and Adverse events/Serious adverse events and give needful suggestions regarding care of the participants and risk minimization procedures, if

applicable.

8. Recommend appropriate compensation for research related injury, wherever required
9. Carry out monitoring visits at study sites as and when needed.
10. Participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations.
11. See that conduct of same/similar research by different investigators from same institution is harmonized.
12. Not accept submission of same research to different funding agencies.
13. See that the studies include only those participants who have given voluntary and informed consent.
14. Review all new and ongoing research projects at intervals appropriate to the degree of risk to the study participants.
15. Maintain a list of projects submitted, approved/disapproved and the final outcome of each.

14.6 Responsibilities of the members

Members are expected to show their full commitment, responsibility and respect for divergent opinions, maintain confidentiality and review proposals free from bias, without any external influences. All IEC members must be familiarized with guidelines related to research and ethics such as National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, National Ethical Guidelines for Biomedical Research Involving Children, 2017, National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During COVID-19 Pandemic (April 2020), the New Drugs and Control trials rules, 2019 and ICH-GCP guidelines. When there is any change in SOP the same will be communicated to the members and necessary training will be imparted. Records will be maintained regarding the training of members and changes in the SOP/ guidelines. Members are expected to declare conflicts of interest, if any, before commencement of the meeting. IEC members should not take part in discussion or decision making on research proposals in which they are Principal Investigator (PI) or Co –investigators or if there are any other conflicts of interest.

Members of IEC are expected to attend all IEC meetings and prior information should be provided if a member is unable to attend a meeting.

Responsibilities of each member is mentioned below

Chairperson

- Conduct Ethics Committee (EC) meetings and ensure active participation of all members during meetings
- Ratify minutes of the previous meetings
- Seek 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.

Member Secretary

- Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review
- Schedule EC meetings, prepare the agenda and minutes
- Organize EC documentation, communication and archiving
- Ensure training of EC secretariat and EC members
- Ensure SOPs are updated as and when required & adherence of EC functioning 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

Basic scientist

- 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.

Clinician

- Conduct 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 (protocol deviation or violation, progress and completion report) should also be ensured.

- Review medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation. Thorough review of protocol, investigators brochure & all other protocol details should be done.

Legal expert

- 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 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.

Social scientist/philosopher/ethicist/theologian

- Ethical review of the proposal, ICD along with the translations.
- Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any
- Serve as a patient/participant/societal/community representative and bring in ethical and societal concerns.

Lay person

- 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 patient/participant/community representative and bring in ethical and societal concerns.
- Assess societal aspects if any.

15. Administration and management

IEC SHSRC-K should have an office for the IEC which has adequate space, infrastructure and staff for maintaining a full-time secretariat, safe archival of records and conduct of meetings. The Secretariat should support the Member Secretary and Alternate Member Secretary (if applicable) in all their functions and should be trained in documentation and filing procedures under confidentiality agreement. A reasonable fee for review may be charged by the IEC for all the projects to cover the expenses related to optimal functioning in accordance to Institutional policies. This is important for smooth functioning of the IEC. An honorarium per sitting will be paid by the institute to the non- affiliated members attending the meeting. This will be decided by the institution from time to time.

16. Web page for IEC SHSRC-K

A dedicated webpage will be created and maintained for IEC on the SHSRC-K website. Details of composition, SOP, registration details, circulars/notifications related to IEC meetings and the status of submitted proposals and ongoing projects, submission forms, guidelines and contact details will be displayed on this page

17. Contact details

Dr. Ameena SR

Member Secretary,

IEC SHSRC-K,

Thycaud,

Thiruvananthapuram,

Kerala 695014

Contact number: 9400063022

Email ID: iec.shsrc@shsrc.kerala.gov.in

18. Annexures

ANNEXURE 1: Template of Invitation letter to a member

(Letter head)

Letter ref no:

From,

The ED

SHSRC Kerala, Thycaud, Trivandrum

To

_____

Dear Sir/Madam

Greetings from IEC SHSRC-K

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

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 2: Template of Consent Letter from a Member

To

The ED

SHSRC Kerala,

Thycaud, Trivandrum

Sub: Consent to be a member of Institute Ethics Committee (IEC) - Reg. Ref: Your Letter No: dated:

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 herewith enclose my CV.

Thanking you, Yours sincerely,

Signature with date

Name of the Member :

Address :

Telephone No. (Off) & (Res) :

E-mail :

ANNEXURE 3: Appointment order

(Letter head)

APPOINTMENT ORDER

Date:

Ref No:

Dr./Mr./Mrs.:

I am pleased to appoint you as the __of the Institutional Ethics Committee (IEC) (Human research) at SHSRC Kerala, Thiruvananthapuram following the receipt of your 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. Further, 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. 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 with date:

ANNEXURE 4: Application for Ethics Review

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:

B 3. Methodology (Please describe the study design, study setting, study subjects, sample size with justification, sampling method, inclusion & exclusion criteria in maximum 850 words)

B 3.a Recruitment of study subject (who will do the recruitment & how?)

B 3.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)

B 4. 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)

B 5. Does your study require permissions from authorities? (Please enlist the departments/ organisations/ agencies from where permissions have to be obtained for the conduct of data collection)

Section C: Participant Related Information

C1. Type of participants in the study:

[ ] Healthy volunteers
[ ] Vulnerable persons/Special groups
[ ] Patients
[ ] Others

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

[ ] Yes
[ ] NA
[ ] No

If yes, please mention insert ☑ wherever applicable

[ ] Children under 18 years
[ ] Pregnant or lactating women

[ ] Differently abled (Mental/Physical)
[ ] Elderly
[ ] Economically and socially disadvantaged
[ ] Refugees/ Migrants/ Homeless
[ ] Terminally ill (stigmatized or rare diseases)
[ ] Others

[ ] Institutionalized/ Hospitalised

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 Is there any provision for medical treatment or management till the relatedness is 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

[ ] No

[ ] NA

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 contract or 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 to 18) (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 5: Application Form for Expedited Review

(Name of the Institution) 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?**
   i. Involves non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples
   ii. Involves clinical documentation materials that are non-identifiable (data, documents, records)
   iii. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s))
   iv. Revised proposal previously approved through expedited review, full review or continuing review of approved proposal
   v. Minor deviation from originally approved research causing no risk or minimal risk
   vi. 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
   vii. 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

viii. Research during emergencies and disasters (*See* Section 12 of ICMR Ethical Guidelines, 2017)

ix. 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.

x. Protocol amendments for safety reasons, that is, in order to protect the welfare of participants in a trial

xi. Requests for extension for an approved project with no modification of protocol

xii. Approval of recruitment and publicity material for approved projects

xiii. 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):

CHECKLIST

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 contract or 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 to 18) (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 6: Application Form for Exemption from Review

(Name of the Institution) **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?

i. Research on data in the public domain/systematic reviews or meta-analyses
ii. Observation of public behavior/information recorded without linked identifiers and disclosure would not harm the interests of the observed person
iii. Quality control and quality assurance audits in the institution
iv. Comparison among instructional techniques, curricula, or classroom management methods
v. Consumer acceptance studies related to taste and food quality
vi. Public health programmes by government agencies

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):

CHECKLIST

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 contract or 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 to 18) (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 7: Application/ Notification Form for Amendments

(Name of the Institution) **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):**

. No	isting Provision	osed Amendment	Reason	ocation 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 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 contract or 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 (12 to 18) (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 8: Study Completion/ Final Report Format

(Name of the Institution) **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. **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):

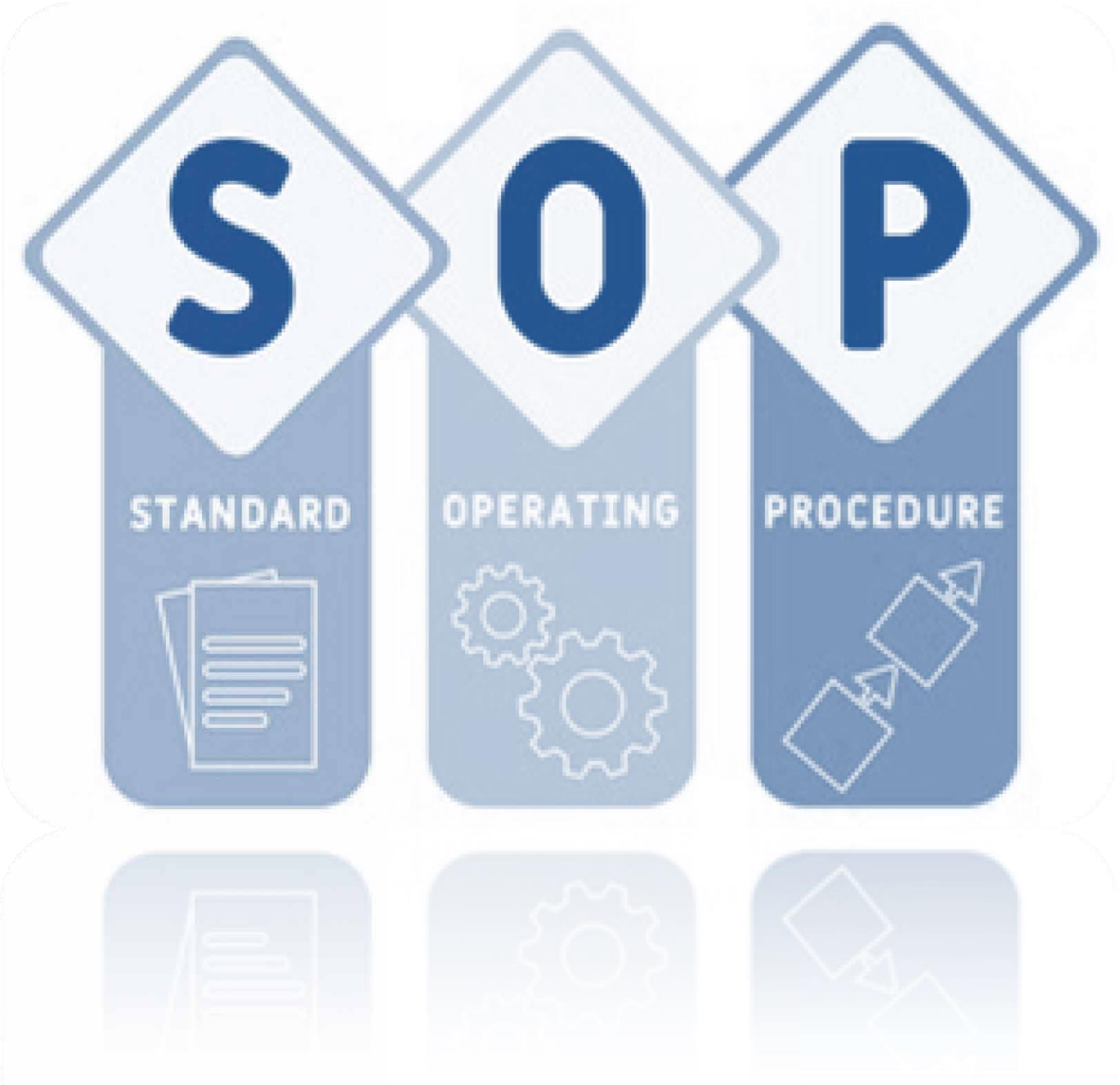
ANNEXURE 9: Format for Curriculum Vitae for Investigators

(Name of the Institution) **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 undertaken 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):



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