STANDARD OPERATING PROCEDURES FOR SMHRC INSTITUTIONAL ETHICS COMMITTEE

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SMITA MEMORIAL
HOSPITAL AND RESEARCH CENTRE

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1. Control of the Manual

1.1 The holder of the copy of this manual is responsible for maintaining it in good and safe condition and in a readily identifiable and retrievable manner.

1.2 The holder of the copy of this Manual shall maintain it in current status by inserting latest amendments as and when the amended versions are received.

1.3 Head-Quality is responsible for issuing the amended copies to the copyholders, the copyholder should acknowledge the same and he /she should return the obsolete copies to the Head-Quality.

1.4 The amendment sheet, to be updated (as and when amendments received) and referred for details of amendments issued.

1.5 Date of implementation will be with effect from the date of issue.

1.6 The manual is reviewed once a year and is updated as relevant to the hospital policies and procedures. Review and amendment can happen also as corrective actions to the non-conformities raised during the self-assessment or assessment audits by NABH.

2. Authority over Control of Manual

Preparation	Review	Approval &Issue
Asst. Medical Superintendent [Academics]	Head -Quality	Chief Executive Officer

2.1 The procedure manual with original signatures of the above on the title page is considered as 'Master Copy', and the photocopies of the master copy for the distribution are considered as 'Controlled Copy' through Smita HIS" as Soft Copy.

3. Distribution List of the Manual

No.	Designation	Type
1	CEO	Controlled Copy
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PREAMBLE

"The most important human endeavor is striving for morality in our actions. Our inner balance and even our very existence depend on it. Only morality in our actions can give beauty and dignity to our lives"-Albert Eintein

Smita Memorial Hospital and Research Center is a 300 bedded multi-speciality hospital situated in Thodupuzha, Idukki District, Kerala, where, we provide compassionate healthcare that every individual deserves. “Service with Smile” is the motto of the hospital. We believe in ‘Sarvetra Santu Sukhinah : Sarve Santu Niramaya:’ which means ‘Let all be blissful, Let all stay healthy.’

Bio medical research involves a few ethical issues that need to be addressed. The Institutional Ethics Committee (IEC) plays an important role in guiding researchers in the ethical aspects associated with the biomedical research. In the modern era of healthcare services, we are not mere healers but we are also guardians and social engineers. This is an era in which research takes a front hand and development is progressive. At the same time, the benefits of research may overshadow the harms and side effects.

To ensure the safety of the participants in any research, it is imperative that we investigate the ethical aspects of the research and to address this, a research institution must have its own ethics committee. Apart from ethical issues, IEC will also review the research proposals for scientific relevance and risk involved in research. IEC functions as per the ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participant-2018 (ICMR National Ethical Guidelines).

Our “Institutional Ethical Committee Guidelines” is a culmination of team efforts working towards a more ethical world. We sincerely acknowledge all the organisations cited as references in our book, for their valuable guidance and help in our IEC formation. Any error is from our side, and purely unintentional. But to our immense satisfaction, we did put our best foot forward towards in formulating the IEC.

“Live as if you were to die tomorrow. Learn as if you were to live forever”! -

Mahatma Gandhi

1. SHORT TITLE AND SCOPE:

1.1 The following may be called as "Standard Operating Procedures for the SMHRC Institutional Ethics committee (IEC)." The present SOP covers functioning of Ethics Committee reviewing all research on human subjects done at SMHRC as well as those done at other locations under the aegis of a principal investigator / co-investigator employed at SMHRC.

2. NAME OF THE ETHICS COMMITTEE:

2.1 SMHRC Institutional Ethics Committee (IEC), Smita Memorial Hospital and Research Center, Thodupuzha.

3. ADDRESS OF THE OFFICE OF THE ETHICS COMMITTEE

The Member Secretary
SMHRC Institutional Ethics Committee, Smita Memorial Hospital and Research Center, Thodupuzha, Idukki dis. Kerala - 682058
Phone No: 0486-2208000 Mobile No. Off:9249092791
Email ID: ams@smitahospital.com

4. OBJECTIVES, PURPOSEAND SCOPE:

4.1 Objectives:

4.1.1 The objective of this SOP is to contribute to the effective functioning of the SMHRC Institutional Ethics Committee (IEC) for human research so that a consistent ethical review mechanism for health and biomedical research is put in place for all proposals dealt by the Committee, which ensures quality of research and technical excellence for ongoing approved research studies involving human participants in accordance with the ICMR National Ethical Guidelines and New Drugs and Clinical Trials Rules 2019.

4.1.2 IEC shall follow all the provisions in ICMR Ethical Guidelines 2018, as not everything can be included in these SOPs. This has also been mandated by the New Drug and Clinical Trials Rules, 2019.

4.2 Purpose and scope of the proposed Ethics Committee:

4.2.1 The Institutional Ethics Committee (IEC) of the SMHRC is established as an independent representative and competent body to provide independent guidance, advice and decision (in the form of "approval/recommendation /disapproval") and to ensure quality as well as technical excellence with consistent ethical review of all the submitted biomedical research proposals involving human participants in accordance with the ICMR ethical guidelines for biomedical research on human participants.

4.2.2 The primary purpose of this committee is to protect the rights, safety and well being of human subjects who participate in a research project. Apart from ethical issues, IEC will also review the research proposals for the scientific relevance and risk involved in research. IEC functions as per the ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participant-2019 (ICMR National Ethical Guidelines).

4.2.3 The present SOP covers functioning of Ethics Committee reviewing all research on human subjects done at SMHRC as well as those done at other locations under the aegis of a principle investigator / co-investigator employed at SMHRC.

4.3 Types of projects that will be reviewed under the purview of Biomedical and Health Research, if academic or external investigatorinitiated studies:

4.3.1 The types of projects that will be reviewed under the purview of Biomedical and health research means studies on basic, applied, and operational research or clinical research including drug trials, designed primarily to increase scientific knowledge about diseases and conditions (physical or socio-behavioural), their detection and cause, and evolving strategies for health promotion, prevention, or amelioration of disease and rehabilitation., community studies etc.

4.3.2 SMHRC IEC will also be analysing the thesis projects of DNB Residents who obtain admission in the Institution.

5. TERMS OF REFERENCE

5.1 Terms of reference will be maintained in the office of IEC. This includes:

5.1.1 Membership Requirements

5.1.2 Terms of Appointment with reference to the duration of the term

5.1.3 The policy for removal, replacement, resignation procedure

5.1.4 Frequency of meetings

5.1.5 Payment of processing fee to the IEC for review, honorarium/ consultancy to the members/ invited experts etc.

5.2 The head of the institution will appoint all EC members, including the Chairperson.

5.3 The appointment letter issued to all members should specify the TORs.

5.4 The letter issued by the head of the institution will include, at the minimum, the following:

5.4.1 Role and responsibility of the member in the committee

5.4.2 Duration of appointment

5.4.3 Conditions of appointment

5.5 The IEC is mandated to examine research proposals where research is to be wholly or partially carried out at SMHRC, to ensure that research is carried out in accordance with ethical principles.

5.6 It ensures that the research projects carried out at SMHRC:

5.6.1 Are sound in design, have statistical validity and are conducted according to the ICMR guidelines.

5.6.2 Do not compromise safety of the patients or volunteers.

5.6.3 Are conducted under the supervision of medical persons with the required expertise.

5.6.4 Include solely, patients who have given voluntary and informed consent.

5.7 Affiliated and non- affiliated members of SMHRC IEC will be paid a reasonable honorarium, for attending each IEC meeting.

5.8 The SOPs will be updated periodically based on the changing requirements. The term of appointment

5.9 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.

5.10 Term of EC membership will be 5 years. The duration could be extended as specified in the SOPs.

5.11 A defined percentage of EC members could be changed on a regular basis.

5.12 The TOR for the EC and its members will be clearly specified by the institution in the EC SOPs.

5.13 SMHRC IEC will have written SOPs according to which the committee would function.

5.14 The IEC will refer to ICMR guidelines in preparing the SOPs for all biomedical and health research and to CDSCO guidelines for drug and device trials under the purview of the licensing authority. The SOPs should be updated periodically to reflect changing requirements.

5.15 A copy of the latest version of SOPs should be made available to each member and they should be trained on the SOPs. The SOPs must be available in the secretariat of the EC as both hard and soft copies.

5.16 The scope, tenure and renewal policy of the EC should be stated.

5.17 Members of the EC should not have any known record of misconduct.

5.18 The EC should be registered with the relevant regulatory authorities, for example, ECs approving clinical trials under the ambit of Drugs and Cosmetics Act will be registered with CDSCO.

6. AUTHORITY UNDER WHICH IEC IS CONSTITUTED

6.1 SMHRC Institutional Ethics committee (IEC) is an Institutional standing ethics committee which functions independently.

6.2 The Chief Executive Officer of the Institution 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.

6.3 The tenure/ period of IEC members will be for 5 years or till further orders.

7. ROLES AND RESPONSIBILITIES OF IEC

7.1 The basic responsibility of an EC is to ensure protection of the dignity, rights, safety and well-being of the research participants.

7.2 The EC must ensure ethical conduct of research by the investigator team.

7.3 The EC is responsible for declaration of conflicts of interest to the Chairperson, if any,at each meeting and ensuring these are recorded in the minutes.

7.4 The EC should perform its function through competent initial and continuing review of all scientific, ethical, medical and social aspects of research proposals received by it in an objective, timely and independent manner by attending meetings, participation in discussion and deliberations.

7.5 The EC must ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.

7.6 The EC should 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.

7.7 Responsibilities of members should be clearly defined.

7.8 The SOPs should be given to EC members at the time of their appointment.

7.9 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.

7.10 The EC should ensure that privacy of the individual and confidentiality of data including the documents of EC meetings is protected.

7.11 The EC reviews progress reports, final reports and adverse effects/serious adverse effects (SAE) and gives needful suggestions regarding care of the participants and risk minimization procedures, if applicable.

7.12 The EC should recommend appropriate compensation for research related injury, wherever required.

7.13 The EC should carry out monitoring visits at study sites as and when needed.

7.14 The EC should participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations.

7.15 The EC may see that conduct of same/similar research by different investigators from same institution is harmonized. 'Me too' research (replicative) should not to be encouraged and submission of same research to different funding agencies should not be accepted.

7.16 IEC will conduct scientific, administrative, and ethical review of the research proposals, and can approve all types of research proposals involving human participants.

7.17 Human samples/material likely to affect human health will also come under the purview of the IEC. Internal audit and prescription audit will however, require only an intimation to the IEC. However, this does not preclude any administrative permissions wherever needed.

7.18 The goals of research, however important, should never be permitted to override the health and well being of the research participants.

7.19 The IEC will take care that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non - maleficence and Justice in planning, conduct 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.

7.20 It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures, for example annual reports, final reports and site visits for assessment of quality of conduct of research, documentation, reporting of SAEs, and data safety & storage, etc.

7.21 The committee will also examine compliance with all regulatory requirements, applicable guidelines, administrative & financial rules, and the relevant laws.

7.22 The mandate of the IECs will be to review all research projects involving human subjects (including any biological samples and behavioural issues) to be conducted at the Institute, irrespective of the funding agency or when no external funding agency is supporting the research.

7.23 The IEC members are responsible for declaration of Conflict of Interest to the Chairperson / Member Secretary at each meeting and it will be ensured that the same is recorded in the minutes

8. COMPOSITION

8.1 Number of members

8.1.1 The number of members in the IEC may range from 7 to 15.

8.1.2 The IEC will be multidisciplinary in composition and independent. As per the ICMR National EthicalGuidelines2018, SMHRC IEC should have the following categories of members.

8.2 Members of the IEC:

Institutional Ethics committee will be constituted with the following:

8.2.1 Chairperson, nominated by the Chief Executive Officer of the Institution, who is an expert from outside the institute.

8.2.2 Member secretary – Institutional - 1

8.2.3 Basic medical scientist - Non-affiliated/affiliated

8.2.4 Clinicians -Non-affiliated/affiliated

8.2.5 Legal expert -Non-affiliated/affiliated

8.2.6 Social Scientist / Ethicist

8.2.7 Philosopher / theologian-Nonaffiliated/affiliated

8.2.8 Lay person from the community -Non-affiliated/affiliated

8.2.9 Additional members

8.2.10 Alternate members

8.2.11 Supporting staff - not considered as members of the IEC

8.3 **Membership Requirements:**

8.3.1 All members are required to be Graduate.

8.3.2 Medical Scientists shall hold a Post Graduate Degree in Medicine of MD/ MS.

8.3.3 The Non-Medical Scientific members are required to have a any other professional degree / post graduate / Ph.D in Life Sciences / Technology

8.3.4 Legal Expert is required to be an Advocate with basic qualification of B.L. All members are required to have good moral character and should not have been convicted for any offense.

8.4 **Requirements for IEC Membership:**

8.4.1 Every EC member must:

8.4.1.1 Provide an updated CV with signature

8.4.1.2 Consent letter

8.4.1.3 Submit training certificates on human research participant protection and good clinical practice (GCP) guidelines

8.4.1.4 If not trained must undergo training and submit training certificates within 6 months of appointment (or as per institutional policy)

8.4.1.5 Be willing to undergo training or update their skills/knowledge during their tenure

8.4.1.6 Declare Conflict of Interest (COI)in accordance with the policy of the IEC, if applicable, at the appropriate time

8.4.1.7 Be aware of relevant guidelines and regulations

8.4.1.8 Read, understand, accept and follow the COI policy of the EC and declare it, if applicable, at the appropriate time;

8.4.1.9 Sign a confidentiality and conflict of interest agreement/s;

8.4.1.10 Be willing to place her/his full name, profession and affiliation to the EC in the public domain

8.4.1.11 Be committed and understanding to the need for research and for imparting protection to research participants in research.

8.5 **Responsibilities of each member:**

8.5.1 **Chairperson: Non Affiliated**

8.5.1.1 A well-respected person from any background with prior experience of having served/ serving in an EC

8.5.1.2 Conduct EC meetings and be accountable for independent and efficient functioning of the committee

8.5.1.3 The Chairperson of the Committee should be from outside the Institution to maintain the independence of the Committee.

8.5.1.4 The Chairperson is responsible for conducting all committee meetings, and leads all discussions and deliberations pertinent to the review of research proposals.

8.5.1.5 The Chairperson presides overall administrative matters pertinent to the committee's functions.

8.5.1.6 Conduct EC meetings and ensure active participation of all members during meeting (particularly non-affiliated, non-medical/ non- technical) in all discussions and deliberations

8.5.1.7 Ratify minutes of the previous meetings

8.5.1.8 Seek COI declaration from members and ensure quorum and fair decision making.

8.5.1.9 Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.

8.5.1.10 In case of anticipated absence of both Chairperson and Vice Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting.

8.5.1.11 The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting.

8.5.2 **Member Secretary: Affiliated**

8.5.2.1 The Member Secretary should be a Medical Scientist who belongs SMHRC and should conduct the business of the committee.

8.5.2.2 In consultation with the Chairperson, the Member Secretary will be responsible for the following functions.

8.5.2.2.1 Receiving all research proposals.

8.5.2.2.2 Forwarding all materials for review by the committee members.

8.5.2.2.3 Preparation and dissemination of agenda for all committee meetings (10 days prior to the meeting date)

8.5.2.2.4 Schedule EC meetings

8.5.2.2.5 Inviting special attendees/expert, from relevant specialities to the scheduled meetings, if needed.

8.5.2.2.6 Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review.

8.5.2.2.7 Preparation and circulation of minutes (within 14 days of the meeting).

8.5.2.2.8 Notification of review outcome to Principal Investigator of research proposals.

8.5.2.2.9 Organize EC documentation, communication, retention, safekeeping and archiving of all records and documentation.

8.5.2.2.10 Performance of other duties assigned by the Chairperson.

8.5.2.2.11 Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review

8.5.2.2.12 Ensure training of EC secretariat and EC members

8.5.2.2.13 Ensure SOPs are updated as and when required & adherence of EC functioning to the SOPs

8.5.2.2.14 Prepare for and respond to audits and inspections

8.5.2.2.15 Assess the need for expedited review/ exemption from review or full review.

8.5.2.2.16 Assess the need to obtain prior scientific review, invite independent consultant,patient or community representatives.

8.5.2.2.17 Ensure quorum during the meeting and record discussions and decisions

8.5.3 **Basic scientist: Affiliated / Non-affiliated**

8.5.3.1 Non-medical or medical person with qualifications in basic medical sciences

8.5.3.2 Scientific and ethical review - emphasis on intervention, benefit-risk analysis, Research design, methodology and statistics, continuing review process, SAE, Protocol deviation, progress and completion report

8.5.3.3 Drug safety and pharmacodynamics in case of clinical trials

8.5.3.4 In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a Pharmacologist.

8.5.4 **Clinician: Affiliated / Non-affiliated**

8.5.4.1 Should be individual/s with recognized medical qualification, expertise and

8.5.4.2 Training

8.5.4.3 Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics

8.5.4.4 Ongoing review of the protocol (SAE, protocol deviation or violation, progress and Completion report)

8.5.4.5 Review medical care, facility and appropriateness of the principal investigator,

8.5.4.6 Provision for medical care, management and compensation.

8.5.4.7 Thorough review of protocol, investigators brochure & all other protocol details

8.5.5 **Legal expert: Affiliated / Non-affiliated**

8.5.5.1 Should have a basic degree in Law from a recognized university, with experience

8.5.5.2 Desirable: Training in medical law.

8.5.5.3 Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial

8.5.5.4 Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions such as, stem cell committee for stem cell research, (NAC-SCRT, HMSC for international collaboration etc) compliance with guideline etc.

8.5.5.5 Interpret and inform EC members about new regulations if any

8.5.6 **Social scientist/ philosopher/ ethicist / theologian: Affiliated / Non-affiliated**

8.5.6.1 Should be an individual with social/ behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities.

8.5.6.2 Ethical review of the proposal, ICD along with the translations.

8.5.6.3 Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any.

8.5.6.4 Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns

8.5.7 **Lay person: Non-affiliated**

8.5.7.1 Literate person from the public or community

8.5.7.2 Has not pursued a medical science/ health related career in the last 5 years

8.5.7.3 May be a representative of the community of the participants are to be drawn

8.5.7.4 Is aware of the local language, cultural and moral values of the community

8.5.7.5 Desirable: involved in social and community welfare activities

8.5.7.6 Ethical review of the proposal, ICD along with translation(s).

8.5.7.7 Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks.

8.5.7.8 Serve as a patient/participant/ community representative and bring in ethical and societal concerns.

8.5.7.9 Assess on societal aspects if any.

8.6 **Procedure for appointment of Members:**

8.6.1 The Chief Executive Officer [CEO] after appointing the chairperson shall, in consultation with the Chairperson, nominate the members of IEC, who have the qualification and experience to review and evaluate the science, medical aspect and ethics of the proposed study.

8.6.2 The normal term for IEC member will be for 60 months [5 years].

8.6.3 The CEO can renew the appointment of the member on the basis of Contribution.

8.6.4 During the term, the CEO can disqualify any member if the contribution is not adequate and, or there is long period of (member) non availability.

8.6.5 Member can discontinue from membership of IEC after giving at least 1-month advance notice.

8.6.6 The CEO can replace the member of IEC as and when required.

8.6.7 Each member is required to sign the declaration and confidentiality agreement regarding IEC activities.

8.6.8 Non institutional committee members are paid an honorarium for each meeting.

8.6.9 Presence of at least one woman on the committee is compulsory.

8.7 **Independent consultants:**

8.7.1 IEC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be.

8.7.2 These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups or special interest groups e.g. Cancer patients, HIV/AIDS positive persons or ethnic minorities.

8.7.3 They are required to give their specialized views but do not take part in the decision making process which will be made by the members of the IEC.

8.7.4 Member Secretary can take comments of experts (preferably prior to the meeting) if it is likely to assist the IEC in the review of the project.

8.8 **PROCEDURE FOR APPOINTMENT, RESIGNATION AND RECONSTITUTION**

8.8.1 The Chief Executive Officer [CEO] after appointing the chairperson shall, in consultation with the Chairperson, nominate the members of IEC, who have the qualification and experience to review and evaluate the science, medical aspect and ethics of the proposed study.

8.8.2 The normal term for IEC member will be for 60 months [5 years].

8.8.3 The CEO can renew the appointment of the member on the basis of contribution.

8.8.4 During the term,the CEO can disqualify any member if the contribution is not adequate and, or there is long period of (member) non availability.

8.8.5 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 unfit for a member.

8.8.6 A member can tender resignation from the committee with proper reasons to do so.

8.8.7 Member can discontinue from membership of IEC after giving at least 1 month advance notice. The CEO can replace the member of IEC as and when required.

8.8.8 Each member is required to sign the declaration and confidentiality agreement regarding IEC activities.

8.8.9 Non institutional committee members are paid an honorarium for each meeting.

8.8.10 Presence of at least one woman on the committee is compulsory.

8.8.11 For appointment to the committee, a candidate should have had at least 10 years of work experience at positions of significant responsibility. Professional integrity and commitment to human welfare would be important criteria for inclusion as members.

8.8.12 After the initial constitution, subsequent appointment to the committee shall be guided by the quorum requirements and activity of the members involved. As per ICMR guidelines, the appointee will be informed of the rights and duties of the committee, and that the external members will receive honorarium for every consultative meeting held on the campus.

8.8.13 All Committee members shall sign a confidentiality agreement at the time of appointment, the terms of which shall be binding on them even after the term expires. Co-opted members are also expected to sign confidentiality agreement. All members, shall serve a maximum of a five-year term on the committee, after which a fresh panel of three names in the same category will be submitted to the SMHRC IEC, so that one out of the three may be appointed in place of the retiring person.

8.8.14 Extension of membership may be considered due to non-availability of members of similar stature, qualification and intent to contribute to ethical human testing.

8.8.15 Members may voluntarily resign from the Committee at a month's notice citing appropriate reasons, and in case of internal members, their membership would be considered withdrawn, if they resign from the Institution. A member who has direct involvement or self affirmed conflict of interest with a proposal being considered shall not form a part of the quorum.

8.8.16 If a member is found to have a conflict of interest with the results of decision and fails to declare the same, or is found to have drawn direct benefit arising out of the results of the research, or has involved self-interest with the sponsor(s) or investigators, his/her membership shall be terminated with provision of appropriate legal proceedings. In case a member breaches the confidentiality, his/her membership shall be terminated and the institution may initiate appropriate legal proceedings.

9. CONVENTION AND CONDUCT OF THE IEC MEETING

9.1 Members are expected to show their full commitment, responsibility and respect for divergent opinions.

9.2 Review proposals free from bias and without any external influences.

9.3 All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form.

9.4 All IEC members must be familiarized with guidelines related to research and ethics such as ICMR National Ethical Guidelines2017, New Drugs and Clinical Trials Rules 2019, ICH-GCP guidelines.

9.5 When there is any change in SOP the same will be communicated to the members and necessary training will be imparted. Record will be maintained regarding the training of members and change in the SOP/guidelines.

9.6 Members are expected to declare conflicts of interest, if any, before commencement of the meeting.

9.7 IEC members should not take part in discussion or decision making on research proposals in which they are PI or Co –investigators or if there are any other conflicts of interest.

9.8 The IEC has the rights to revoke its approval accorded to scientific study/clinical study protocol, and further, it has to record the reasons for doing so and communicate the same to the Investigator as well as to the Licensing Authority/ other relevant stakeholders.

9.9 IEC may review progress of the approved studies periodically till the completion of the study through periodic study progress report /internal audit reports.

9.10 The investigator is responsible for reporting all Serious Adverse Effects [SAE] including hospitalization or prolongation of hospitalization, clinical trial related injury or death, regardless of causal relationship to the EC within 24 hours of knowledge. Reporting of SAE may be done

9.11 through email or fax communication(including on non-working days).

9.12 A report on how the SAE was related to the research must also be submitted within 14 days.

9.13 SAEs must be reported for all trials and if applicable timelines as specified by regulators to be followed (within 24 hours to the sponsor, EC and regulator, if applicable, followed by a due analysis report in 14 days).

9.14 The IEC shall forward the report on any SAE(including, death), after due analysis, along with

9.15 Its opinion on the financial compensation, if any, to be paid by the sponsor or his representative, to the Chairman of the Expert Committee constituted by the Licensing Authority.

9.16 The copy of the report has to be submitted the Licensing Authority within twenty one calendar days of the occurrence of the SAE

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

9.18 The duration of appointment initially shall be for a period of 5 years.

9.19 At the end of 5 years, the committee should be reconstituted, and one-third of the members will be replaced by a defined procedure (those who have had the longest standing in the IEC shall be phased out and new members taken in against the vacant posts).

9.20 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 unfit for a member.

9.21 A member can tender resignation from the committee with proper reasons to do so.

9.22 Conflict of interest should be declared by members of the IEC if any is there at any time for any project or decision.

9.23 The Chairperson will conduct all meetings of the SMHRC IEC.

9.24 In the absence of the Chairperson, the alternate Chairperson from the other members (or Chairperson should nominate a committee member as Acting Chairperson for a meeting), who will conduct the meeting.

9.25 The alternate or acting chairperson should have the powers of the chair person and should be non-affiliated person.

9.26 Member Secretary will prepare the minutes of the meetings and get it approved by the Chairperson and all the members.

9.27 In the absence of Member Secretary alternate Member Secretary among the members, will organize the IEC meeting.

9.28 All proposals will be received at least 3 weeks before the meeting and after initial scrutiny by Member Secretary the proposals will be circulated to the IEC members.

9.29 The recommendations by the IEC will be communicated to all the PIs and guides/HODs in case of a research student's proposals

9.30 If required additional review meetings can also be conducted with a short notice period.

9.31 The records shall be archived for a period of 5 years from the end of the project.

9.32 Possibility of e-archiving should be explored in view of the space and cost constraints.

9.33 Where indicated, archiving may be done for a longer time.

9.34 The meetings can be held on virtual platform also.

9.35 The member Secretary will obtain administrative approval for the funded projects before issuing the approval letter.

9.36 The recommendations by the IEC will be communicated to all the PIs and guides/HODs in case of student's proposals

9.37 If required additional review meetings can also be conducted with a short notice period.

10. QUORUM REQUIRED

10.1 The quorum for reviewing regulatory clinical trials should be in accordance with current New Drugs and Clinical Trials Rules 2019 and current CDSCO requirements

10.2 The quorum required shall be a minimum of 5 members in the meeting room.

10.3 It should include both medical and non-medical members, or technical or/and non-technical, with at least one of the members present being not affiliated to SMHRC.

10.4 The quorum for review of clinical trial or bioavailability or bioequivalence protocol and related documents shall be at least five members with the following representations: (i) medical scientist (preferably a pharmacologist); (ii) clinician; (iii) legal expert; (iv) social scientist or representative of non- governmental voluntary agency or philosopher or ethicist or theologian or a similar person; (v) lay person.

10.5 Preferably the lay person should be part of the quorum.

10.6 No decision is valid without fulfilment of the quorum.

11. TYPE OF CLINICAL RESEARCH REVIEWED BY THE COMMITTEE

11.1 Drug trials, Prospective clinical studies, on both medical and surgical patients and blood and pathology specimens, epidemiological studies, retrospective studies

12. APPLICATION PROCEDURES

12.1 All proposals should be submitted in English language to the office of the Chairman, SMHRC IEC on any working day 3 weeks in advance of scheduled meeting, in the prescribed application form along with relevant documents.

12.2 Twelve (12) hard Copies 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 IEC

12.3 Principle Investigators shall forward their application to the Chairperson IEC, through Member Secretary and the receipt of the application will be acknowledged by the IEC office.

12.4 Every application will be allotted an IEC registration number to be used for all future Correspondence and reference.

12.5 The date of IEC meeting will be intimated to the PI to attend the meeting and to make a brief presentation of the proposal and to clarify the points raised by the members.IEC can suggest for online meetings and virtual presentations of the investigators in special situations such as COVID-19 pandemic, etc.

12.6 If revision is to be made, the revised proposal in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

12.7 All research proposals/clinical trials funded/sponsored by Pharmaceutical companies, Agencies, Multinationals etc. will be charged an administrative fee/ processing fee of 5% of their sanctioned budget Waiver of these fees is permissible for non-funded studies, departmental studies,

12.8 and studies funded by organizations like ICMR, UGC, DST Government of India, State Science & Technology Department, UNICEF, WHO, USAID, Non - Profitable Organizations etc.

12.9 Thesis of DM/M.Ch/MD/MS/Ph.D Courses involving ethical issues also need EC clearance.

12.10 Every application has to be routed through the concerned Head of the Department to the IEC.

13. DETAILS OF DOCUMENTS TO BE SUBMITTED FOR EC REVIEW

13.1 Cover letter to the Member Secretary

13.2 Type of review requested

13.3 Application form for initial review

13.4 Permission of using copyrighted proforma/ questionnaire
13.5 A complete protocol
13.6 Approval of the project for Institute Scientific Committee
13.7 The correct version of the informed consent document (ICD) in English and the local language(s).
13.8 Case record form/questionnaire
13.9 Recruitment procedures: advertisement, notices (if applicable)
13.10 Patient instruction card, diary, etc. (if applicable)
13.11 Investigator's brochure (as applicable for drug/biologicals/device trials)
13.12 Details of funding agency/sponsor and fund allocation (if applicable)
13.13 Brief curriculum vitae of all the study researchers
13.14 A statement on Conflict of Interest (COI), if any
13.15 GCP training certificate (preferably within 5 years) of investigators (Sponsored clinical trials)
13.16 Any other research ethics/other training evidence, if applicable as per EC SOP
13.17 List of ongoing research studies undertaken by the principal investigator (if applicable)
13.18 Undertaking with signatures of investigators
13.19 Regulatory permissions (as applicable)
13.20 Relevant administrative approvals (such as HMSC approval for International trials)
13.21 Institutional Committee for Stem Cell Research (IC-SCR) approval (if applicable)
13.22 MoU in case of studies involving collaboration with other institutions (if
13.23 applicable)
13.24 Clinical trial agreement between the sponsors, investigator and the head ofthe institution(s) (if applicable)
13.25 Statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants.
13.26 A description of the arrangements for insurance coverage for research participants (if applicable)
13.27 A description of the arrangements for indemnity [if applicable].
13.28 A statement of agreement to comply with ethical principles set out in relevant guidelines.
13.29 decisions (e.g., those leading to a negative decision or modified protocol) and by other regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of modification(s) to the protocol made on that account.The reasons for previous negative decisions must be provided.

14. DETAILS OF DOCUMENTS TO BE INCLUDED IN THE PROTOCOL

The protocol should include the following:

14.1 The first page carrying the title of the proposal with signatures of the investigators
14.2 Brief summary/ lay summary of the protocol
14.3 Background with rationale of why a human study is needed to answer the research question
14.4 Justification of inclusion/exclusion of vulnerable populations
14.5 Clear research objectives and end points/ outcome
14.6 Eligibility criteria and participant recruitment procedures
14.7 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, dosages of drugs, route of administration, duration of treatment and details of invasive procedures, if any;
14.8 Duration of the study

14.9 Justification for use of placebo, benefit–risk assessment, plans to withdraw and rescue medication. If standard therapies are to be withheld

14.10 10. Procedure for seeking and obtaining written informed consent with a sample of the patient/participant information sheet and informed consent forms in English and local languages. Informed consent for storage of samples;assent; re-consent

14.11 Plan for statistical analysis of the study

14.12 Plan to maintain the privacy and confidentiality of the study participants

14.13 .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 during and after research period and insurance policy

14.14 Provision of ancillary care for unrelated illness during the duration of research

14.15 An account of storage and maintenance of all data collected during the trial; and

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

14.17 Ethical considerations and safeguards for protection of participants

15. REVIEW PROCEDURES

15.1 The meeting of the IEC will be held periodically as required, unless otherwise specified by the member secretary. Additional review meetings can also be held with short notice as and when required. Meetings will be planned in accordance with the need of the work load.

15.2 The proposals should be sent to the IEC at least 3 weeks in advance of scheduled meeting.

15.3 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.

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

15.5 The PI / Research Scholar will then present the proposal in person 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 case to case basis,if needed. Applicant, sponsor or investigator may be invited to make a slide presentation on the proposal or elaborate on specific issues.

15.6 A decision will be taken only when sufficient time has been allowed to the Principal investigator for presentation of protocol and to the committee for review and discussion.

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

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

15.9 The proceedings of the meeting will be video recorded with prior permission from all the members attending the meeting.

15.10 The IEC will evaluate the possible risks to the subject with proper justifications, the expected benefit and adequacy of documentation for ensuring privacy, confidentiality and justice issue.

15.11 Decision will be taken only after reviewing a complete application with all the required documents necessary for the proposal.

15.12 A decision will only be taken at meetings where the quorum is complete.

15.13 Independent expert may be invited to the meeting or to provide written comment, subject to applicable confidentiality agreement.

15.14 Members will be given 10 days time in advance to review study proposals and the relevant documents.

15.15 IEC meetings will be minuted and all the proceedings and deliberation will be documented.

15.16 At the end of each IEC meeting, signatures from each member who has participated will be obtained on the final draft of the minutes of meeting.

15.17 Only members who participated in review and discussion will participate in decision.

15.18 Where ever possible, the decision will be arrived at through consensus not by vote, but when a consensus appears unlikely voting may be performed. Decision will be taken by simple majority of those attending.

15.19 Member having the conflict of interest will indicate to the chairman prior to the review of application and same will be recorded in the minutes.

15.20 Where there is conflict of interest, member will withdraw from the decision making procedure.

15.21 In case of conditional approval of a proposal the same will be communicated to the investigators, with clear suggestions for modifications and Re-review procedure.

15.22 Negative decision will be supported clearly by stated reasons.

16. RISK CATEGORIES

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

Type of risk	**Definition/description**
Less than minimal risk	Probability of harm or discomfort anticipated in the research is nil or not expected. Research on anonymous or non- identified data/samples, data available in the public domain, meta-analysis, etc
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
Minor increase over minimal risk or Low risk	Increment in probability of harm or discomfort is only a little more than theminimal 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. Research should have a social value. Use of personal identifiable data in research also imposes indirect risks. Social risks, psychological harm and discomfort may also fall in this
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

17. THE TYPE OF EC REVIEW BASED ON RISK INVOLVED IN THE RESEARCH, IS CATEGORIZED AS FOLLOWS TYPES OF REVIEWS

17.1 **Exemption from review**

17.1.1 Proposals which present "less than minimal risk" fall under this category

17.1.2 Following situations may come under this category:

17.1.2.1 Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

17.1.3 **Exceptions:**

17.1.3.1 When research on 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.

17.1.3.2 When interviews involve direct approach or access to private papers

17.2 **Expedited Review**

17.2.1 The proposals presenting "no more than minimal risk" to research participants may be subjected to expedited review.

17.2.2 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

17.2.2.1 Minor deviations from originally approved research protocol during the period of approval.

17.2.2.2 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.

17.2.2.3 Research activities that involve only procedures listed in one or more of the following categories

17.2.2.4 Clinical studies of drugs and medical devices only when -

17.2.2.5 Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or

17.2.2.6 Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.

17.2.2.7 Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.

17.2.2.8 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

17.3 **Research on interventions in emergency situation**

17.3.1 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.

17.3.2 Research in such instance of medical care could be allowed in patients -

17.3.2.1 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 be given to the relative/ legal guardian when available later;

17.3.2.2 When the intervention has undergone testing for safety prior to its use in emergency situations and sponsor has obtained prior approval of DCGI;

17.3.2.3 Only if the local IEC reviews the protocol since institutional responsibility is of paramount importance in such instances.

17.3.2.4 If Data Safety Monitoring Board (DSMB) is constituted to review the data

17.4 **Research on disaster management**

17.4.1 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:

17.4.1.1 Research planned to be conducted after a disaster should be essential, culturally sensitive and specific in nature with possible application in future disaster situations.

17.4.1.2 Disaster-affected community participation before and during the research is essential and its representatives or advocates must be identified.

17.4.1.3 Extra care must be taken to protect the privacy and confidentiality of participants and communities.

17.4.1.4 Protection must be ensured so that only minimal additional risk is imposed.

17.4.1.5 The research undertaken should provide direct or indirect benefits to the participants, the

17.4.1.6 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.

17.4.1.7 All international collaborative research in the disaster-affected area should be done with a local partner on equal partnership basis.

17.4.1.8 Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

17.4.1.9 Expedited review may also be taken up for nationally relevant proposals requiring urgent review.

17.5 **Procedure for expedited review:**

17.5.1 Only to be performed when there is no or minimum risk to the trial participants.

17.5.1.1 Re-examination of a proposal already examined by the IEC.

17.5.1.2 Study of minor nature eg., examination of case records.

17.5.1.3 Similar study proposal for which IEC had already given approvals earlier.

17.5.1.4 An urgent proposal of national interest having minimum risk.

17.5.1.5 Proposals with minimum risk to be reviewed when it may not be possible to convene a main ethics committee meeting with quorum- as for example during natural disasters, lockdowns, epidemics etc

17.5.2 All expedited approvals will be given in a meeting with quorum of at least 3 members (nominated by the Chairman) of IEC.

17.5.3 Quorum must have one expert or scientist having scientific knowledge in the field of proposal.

17.5.4 Should also include either the Member Secretary or the Chairman or both.

17.5.5 Decision taken by the committee on expedited approval however will be brought to the notice of the main committee members for ratification.

18. FULL REVIEW

18.1 All research presenting with "more than minimal risk", proposals/ protocols which do not qualify for exempted or expedited review and projects shall be subjected to full review by all the members.

18.1.1 Research involving vulnerable populations, even if the risk is minimal

18.1.2 Research with minor increase over minimal risk

18.1.3 Studies involving deception of participants;

18.1.4 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;

18.1.5 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;

18.1.6 Major deviations and violations in the protocol;

18.1.7 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

18.1.8 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;

18.1.9 Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

19. ELEMENTS OF REVIEW

Following are the elements to be reviewed by the IEC member

19.1 **Scientific design and conduct of the study:**

19.1.1 The appropriateness of the study design in relation to the objectives of the study, the statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest number of research participants.

19.1.2 The appropriateness of clinical trial site in terms of facilities to conduct the intended research and to take clinical care of the patients as per their requirements. This shall include investigations, treatment facilities, supportive staff follow-up facilities etc.

19.1.3 The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities.

19.1.4 The justification for the use of control arms.

19.1.5 Criteria for prematurely withdrawing the research participants

19.1.6 Criteria for suspending or terminating the research as a whole

19.1.7 The adequacy of provisions made for monitoring and auditing the conduct

19.1.8 of the research, including the constitution of a data and safety monitoring committee (DSMC).

19.1.9 The manner in which the results of the research will be reported and published

19.2 **Requirement of research participants:**

19.2.1 The characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status and ethnicity).

19.2.2 The means by which initial contact and recruitment is to be conducted.

19.2.3 The means by which full information is to be conveyed to potential research participants or their representatives.

19.2.4 Inclusion criteria for research participants.

19.2.5 Exclusion criteria for research participants

19.3 **Care and protection of research participants:**

19.3.1 Any plans to withdraw or withhold standard therapies for the purpose of the justification for such action

19.3.2 The medical care to be provided to research participants during and after the course of the research

19.3.3 The adequacy of medical supervision and psycho-social support for the research participants.

19.3.4 Steps to be taken if research participants voluntarily withdraw during the course of the research.

19.3.5 The criteria for extended access to the emergency use of and/or the compassionate use of study products.

19.3.6 The arrangements, if appropriate for informing the research participants general practitioner/consultant, including procedures for seeking the participant's consent to do so.

19.3.7 A description of any plans to make the study product available to the research participants following the research.

19.3.8 A description of any financial costs to research participants.

19.3.9 The rewards and compensations for research participants (including money, services, and /or gifts.

19.3.10 The provisions for compensation/treatment in the case of the injury disability/ death of a research participant attributable to participation in the research.

19.3.11 The insurance and indemnity arrangements.

19.3.12 The ethics committee shall look into the details of the protocol for formation of a data and safety monitoring board. In the absence of any such provision in the protocol, the IEC may insist on the same prior to approval or recommend to the CEO, SMHRC to constitute a Data and Safety Monitoring Board [DSMB] for monitoring the trial.

19.4 **Protection of research participant confidentiality:**

19.4.1 A description of the persons who will have access to personal data of the of the research participants, including medical records and biological samples;

19.4.2 The measures taken to ensure the confidentiality and security of personal information concerning research participants

19.5 **Informed consent process:**

19.5.1 A full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent.

19.5.2 Consent form in English and local language (Malayalam) in case of studies on human subjects will be reviewed.

19.5.3 The adequacy, completeness, and understandability of written and oral information to be given to the research participants and when appropriate, their legally acceptable representative(s).

19.5.4 Clear justification for the intention to include in the research individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals.

19.5.5 Assurances that research participants will receive information that becomes available during the course of the research relevant to their participation (including their rights, safety and well-being).

19.5.6 The provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project.

19.6 **Community considerations:**

19.6.1 The impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn.

19.6.2 The steps taken to consult with the concerned communities during the course of designing the research.

19.6.3 The influence of the community on the consent of individuals.

19.6.4 Proposed community consultation during the course of the research.

19.6.5 The extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research and the ability to respond to public health needs.

19.6.6 A description of the availability and affordability of any successful study product to the concerned communities following the research.

19.6.7 The manner in which the results of the research will be made available to the research participants and the concerned communities.

19.7 **Appropriateness of investigator:**

19.7.1 The ethics committee shall review the CV of the investigator, including qualifications, current designation and experience to determine whether he / she has appropriate capability to undertake the research in question (including clinical trials).

20. REVIEW OF RESEARCH PROPOSALS INVOLVING VULNERABLE POPULATION

20.1 **Vulnerable population:**

20.1.1 Individuals may be considered to be vulnerable if they are:

20.1.1.1 socially, economically, or politically disadvantaged and therefore susceptible to being exploited

20.1.1.2 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

20.1.1.3 able to give consent, but whose voluntariness or understanding is compromised due to their situational conditions or

20.1.1.4 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.

20.1.2 Individuals who are relatively or absolutely incapable of protecting their own interests and providing valid informed consent.

20.1.3 Examples of vulnerable population includes:

20.1.3.1 Economically and socially disadvantaged

20.1.3.2 Children (up to 18 years)

20.1.3.3 Women in special situations

20.1.3.4 Tribals and marginalized, communities

20.1.3.5 Refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations

20.1.3.6 Afflicted with mental illness and cognitively impaired individuals, differently abled–mentally and physically disabled

20.1.3.7 Terminally ill or are in search of new interventions having exhausted all therapies

20.1.3.8 Suffering from stigmatizing or rare diseases

20.1.3.9 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.

20.2 **Pregnant or nursing women:**

20.2.1 Pregnant or nursing women should in no circumstances be the subject of any research unless the research carries no more than minimal risk to the fetus or nursing infant and the object of the research is to obtain new knowledge about the foetus, pregnancy and lactation.

20.2.2 As a general rule, pregnant or nursing women should not be subjects of any clinical trial except such trials as are designed to protect or advance the health of pregnant or nursing women or fetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable subjects.

20.2.2.1 The justification of participation of these women in clinical trials would be that they should not be deprived arbitrarily of the opportunity to benefit from investigations, drugs, vaccines or other agents that promise therapeutic or preventive benefits. Example of such trials are, to test the efficacy and safety of a drug for reducing perinatal transmission of HIV infection from mother to child, trials for detecting fetal abnormalities and for conditions associated with or aggravated by pregnancy etc.

20.2.2.2 Women should not be encouraged to discontinue nursing for the sake of participation in research and in case she decides to do so, harm of cessation of breast feeding to the nursing child should be properly assessed except in those studies where breast feeding is harmful to the infant.

20.2.2.3 Research related to termination of pregnancy: Pregnant women who desire to undergo Medical Termination of Pregnancy (MTP) could be made subjects for such research as per The Medical Termination of Pregnancy Act, GOI, 1971.

20.2.2.4 Research related to pre-natal diagnostic techniques: In pregnant women such research should be limited to detect the foetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994 and not for sex determination of the foetus.

20.3 **Children:**

Before undertaking trial in children the investigator must ensure that –

20.3.1 Children will not be involved in research that could be carried out equally well with adults

20.3.2 The purpose of the research is to obtain knowledge relevant to health needs of children. For clinical evaluation of a new drug the study in children should always be carried out after the phase iii clinical trials in adults. It can be studied earlier only if the drug has a therapeutic value in a primary disease of the children

20.3.3 A parent or legal guardian of each child has given proxy consent

20.3.4 The assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors, adolescents etc.

20.3.5 Research should be conducted in settings in which the child and parent can obtain adequate medical and psychological support

20.3.6 Interventions intended to provide direct diagnostic, therapeutic or preventive benefit for the individual child subject must be justified in relation to anticipated risks involved in the study and anticipated benefits to society

20.3.7 The child's refusal to participate in research must always be respected unless there is no medically acceptable alternative to the therapy provided/ tested, provided the consent has been obtained from parents / guardian

20.3.8 Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child subject as any available alternative interventions

20.3.9 The risk presented by interventions not intended to benefit the individual child subject is low when compared to the importance of the knowledge that is to be gained.

20.4 **Full Review:**

20.4.1 All research presenting with more than minimal risk, proposals/ protocols which do not qualify for exempted or expedited review and projects that involve vulnerable population and special groups shall be subjected to full review by all the members.

20.5 **Obligations/duties of stakeholders**:

20.5.1 **Researchers:**

20.5.1.1 Recognize the vulnerability of the participant and ensure additional safeguards are in place for their protection.

20.5.1.2 Justify inclusion/exclusion of vulnerable populations in the study.

20.5.1.3 COI issues must be addressed.

20.5.1.4 Have well defined procedures (SOPs) to ensure a balanced benefit-risk ratio.

20.5.1.5 Ensure that prospective participants are competent to give informed consent.

20.5.1.6 Take consent of the LAR when a prospective participant lacks the capacity to consent.

20.5.1.7 Respect dissent from the participant.

20.5.1.8 Seek permission of the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities, etc.

20.5.1.9 Research should be conducted within the purview of existing relevant guidelines / regulations.

20.5.2 **Ethics committee:**

20.5.2.1 Special considerations would be taken while reviewing projects involving research on vulnerable population like pregnant women, children (up to 18 years), economically disadvantaged, sexual minorities, terminally ill, suffering from mental, stigmatizing, or rare diseases, tribals and marginalized communities, differently abled-mentally and physically disabled, have diminished autonomy due to dependency etc.

20.5.2.2 The institutional Ethics Committee during the review process of projects involving vulnerable population, will determine whether the prospective participants for a particular research are vulnerable.

20.5.2.3 The SMHRC IEC will examine whether inclusion/exclusion of the vulnerable population is justified.

20.5.2.4 Only the full Committee does initial and continuing review of such proposals.

20.5.2.5 If possible, empowered representatives from the specific populations are included during deliberations.

20.5.2.6 Efforts are made to ensure that individuals or communities who are economically or socially disadvantaged and are invited for research are selected in such a way to ensure a balanced benefit-risk and advise risk minimization strategies wherever possible.

20.5.2.7 Additional safeguards, such as more frequent review and monitoring, including

20.5.2.8 site visits are done.

20.5.2.9 When research is conducted on participants who are suffering from mental illness and/or cognitive impairment the SMHRC IEC exercises caution and require researchers to justify cases for exceptions to the usual requirements of participation or essentiality of

departure from the guidelines governing research. SMHRC IEC ensures that these exceptions are as minimal as possible and are clearly spelt out.

20.5.2.10 The rights and welfare of mentally challenged and differently abled persons who are incapable of giving informed consent or those with behavioral disorders are protected.

20.5.2.11 It is ensured that appropriate proxy consent from legal guardian is taken after the person is well informed about the study, need for participation, risks and benefits involved and the privacy and confidentiality procedures undertaken. It is ensured that the entire consent process is adequately

20.5.2.12 documented.

20.5.2.13 IEC must ensure that the informed consent process should be well documented and recording of assent in case of research studies involving children aged 7 to 18 years and reconsent, when applicable.

20.5.2.14 Informed consent from vulnerable populations may be obtained from LAR (Legally authorized representative)in presence of impartial witness after through explanation of risks and benefits,

20.5.2.15 Research on genetics should not lead to promotion of racial inequalities.

20.5.2.16 Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them;

20.5.2.17 Rights and welfare of mentally challenged and mentally differently able persons who are incapable of giving informed consent or those with behavioral disorders must be protected.

20.5.2.18 Adequate justification is required for the involvement of subjects such as prisoners, students, subordinates, employees, service personnel etc., who have reduced autonomy as research subjects.

20.5.2.19 Adequate care is taken while reviewing proposals involving patients such as prisoners, students, subordinates, employees, service personnel etc. who have reduced autonomy as research participants since the consent provided could be under duress or due to other compulsions.

20.5.2.20 The committee will ensure that COI do not increase harm or lessen benefits to the participants.

20.5.2.21 The committee will carefully determine the benefits and risks to the participants and advise risk minimization strategies wherever possible.

20.5.2.22 The committee will suggest additional safeguards, such as more frequent review and monitoring, including site visits.

20.5.2.23 Only the full committee will do initial and continuing review of such proposals. It is desirable to have empowered representatives from the specific populations during deliberations.

20.5.2.24 EC has special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment. The committee exercise caution and require researchers to justify cases for exceptions to the usual requirements of participation or essentiality of departure from the guidelines governing research. EC will ensure that these exceptions are as minimal as possible and are clearly spelt out.

20.5.2.25 EC has SOPs for handling proposals involving vulnerable populations.

20.5.3 **Sponsors:**

20.5.3.1 The sponsor, whether a government, an institution or a pharmaceutical company, should justify the inclusion of vulnerable groups in the protocol and make provisions for protecting their safety.

20.5.3.2 The sponsor must enable monitoring and ensure that procedures are in place for quality assurance (QA) and quality control (QC).

20.5.3.3 The sponsor should ensure protection of the participants and research team if the research is on sensitive topics

21. REVIEW OF MULTICENTRIC RESEARCH

21.1 Multicentre research is conducted at more than one centre by different researchers usually following a common protocol.

21.2 All sites are required to obtain approval from their respective ECs, which would consider the local needs and requirements of the populations being researched and safeguard the dignity, rights, safety and well-being of the participants.

21.3 The ECs/Secretariats of all participating sites should establish communication with one another

21.4 If any EC does not grant approval for a study at a site the reasons must be shared with other ECs and deliberated upon.

21.5 The EC can suggest site-specific protocols and informed consent modifications as per local needs.

21.6 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

21.7 Common review for all participating sites in multicentric 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.

21.8 Common review process may be applied to research involving low or minimal risk, survey or multicentric studies using anonymized samples or data or those that are public health research studies determined to have low or minimal risk.

21.9 The common review is applicable only for 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.

22. FOLLOW UP PROCEDURE

22.1 IEC will review the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of the research.

22.2 Progress of all the research proposals will be followed at a regular intervals of at least once in 6 months. But in a special situations, IEC will conduct the follow up review at shorter intervals basing on the need, nature and events of research project.

22.3 The committee shall seek from the investigators:

22.3.1 A progress report on six monthly basis or more frequently as the committee feels it.

22.3.2 A report of each serious event when observed during the conduct of the study.

22.3.3To be kept informed of amendments to any study-related document.

22.3.4To be kept informed of study discontinuation with reasons.

22.4 With regard to Clinical trials, Data Safety Monitoring Board (DSMB) will be constituted by the CEO, SMHRC or by the trial investigators to review the clinical trial notifications and to report the adverse events if any to the Institutional Ethics Committee. The board will review the clinical trial records for

serious adverse events and report periodically to the IEC. Also the investigators have to communicate the observations of DSMB to IEC periodically.

22.5 All the requirements and procedures for follow up review will be similar to that of initial and main review. Following instances and events will require the follow-up review

22.5.1 Protocol amendment, likely to affect, rights, safety or well being of research subject in conduct of study.

22.5.2 Serious or unexpected adverse reaction related to study or product, action taken by investigator, sponsor and regulatory authority.

22.5.3 Any event or information that may affect the benefit/risk ratio of the study.

22.5.3.1 A decision of a follow-up review will be issued and communicated to applicant indicating modification / suspension / termination / continuation of the project. IEC will also require the investigators to inform the committee about any SAE and payment of any compensation for the same. It shall also review the adequacy of treatment given to participants following an SAE.

22.5.3.2 In case of premature suspension/termination, the applicant must notify the IEC of the reasons for suspension/termination with a summary of results.

22.5.3.3 Applicant must inform at the time of completion of study and must send the result summary to IEC.

22.5.3.4 IEC must receive a copy of final summary of study completed from the applicant.

23. POLICY REGARDING TRAINING FOR NEW AND EXISTING COMMITTEE MEMBERS ALONG WITH SOPS

23.1 The Member Secretary of the Ethics committee collects the information on Drugs and Cosmetics rules, notifications and supplementary amendments from time to time and informs the committee members.

23.2 Formal training in Good Clinical Practice along with certification will be organized by SMHRC at regular intervals.

23.3 Guidelines in this document may be subjected to amendments as and when the need arises. The faculty/investigators from SMHRC, or any other concerned citizen from public can suggest the need to add/delete, alter/amend certain clauses in this document.

23.4 The SMHC Ethics Committee or a special committee constituted for that purpose shall discuss the suggestions made before recommending for the same or otherwise.

23.5 Member secretary will be responsible for tabling the amendments.

23.6 Amended version of the document will be put before the Executive Board of SMHRC for its consideration and approval.

24. DECISION-MAKING

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

24.2 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.

24.3 Only the members can make the decisions. The expert consultants (subject experts) will only offer their opinions.

24.4 Decision may be to approve, reject, or revise the proposals.

24.5 Specific suggestions for modifications and reasons for modifications and reasons for rejection will be given.

24.6 In cases of conditional decisions, clear suggestions for revision and the procedure for having the application revised will be specified.

24.7 Modified proposals will be reviewed by an expedited review through identified members.

24.8 Decision 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

24.9 IEC approval will be valid for one year or for the duration of the project whichever is less.

24.10 Investigator must get his or her project re- approved after one year, where required.

24.11 The communication of the decision will include:

24.11.1 Name and address of IEC.

24.11.2 The date, place, and time of decision.

24.11.3 The name and designation of the applicant.

24.11.4 Title of the research proposal reviewed.

24.11.5 The clear identification of protocol no., version no., date, amendment no., date.

24.11.6 Along with protocol, other documents reviewed- Clear description of these documents along with Version No. and Date.

24.11.7 List of EC members who attended the meeting- clear description of their role, affiliation and gender.

24.11.8 A clear statement of decision reached.

24.11.9 Any advice by the IEC to the applicant including the schedule / plan of ongoing review by the SMHRC IEC

24.11.10 In case of conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re-reviewed.

24.11.11 In case of rejection of the proposal, reason(s) for the rejection will be clearly stated.

24.11.12 Signature of the member secretary with date

25. PROCEDURE FOR COMMUNICATING THE DECISION OF IEC TO THE APPLICANT

25.1 The committee will give its opinion on the project in writing in one of the following ways;

25.1.1Approval

25.1.2Disapproval

25.1.3Modification before approval

25.1.4Discontinuation of previously approval project

25.2 The Chairman of the committee may provisionally approve without calling a full meeting in cases where only administrative amendment has been made. The Chairman will inform other members of the committee of the amendment and his decision. The decision will be ratified at the next full committee meeting and this will be minuted.

26. REVIEW OF PERFORMANCE OF ETHICS COMMITTEE

26.1 The Chief Executive Officer of SMHRC who is the constituting authority of the IEC shall periodically assess the performance of IEC members in consultation with the Chairperson and Member secretary of the IEC, in terms of attendance, punctuality, participation in discussion and willingness to learn.

26.2 The member secretary shall evaluate performance of the IEC itself in terms of time interval between submission of proposal and approval/rejection, maintenance of records, arrangements for meetings etc and shall carry out corrective action.

26.3 Records shall be maintained of the review and any corrective and preventive action.

27. PROCEDURE FOR DOCUMENTATION AND ARCHIVING

27.1 All the documents and communications of IEC will be dated, filed and archived in a secured place.

27.2 Only the person, who is authorized by the chairman of IEC will have the access to the various documents.

27.3 All the documents related to research proposals will be archived for a minimum period of 5 years in the Institute, following the completion of the study.

27.4 No documents (except agenda) will be retained by any IEC member.

27.5 At the end of each meeting every member will return all the research proposal documents to IEC office staff.

28. RECORD KEEPING AND ARCHIVING OF DOCUMENTS

28.1 All Research proposals (12 hard copies along with soft copy) along with the information and documents submitted will be dated and filed.

28.2 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.

28.3 IEC members should not retain any documents with them after the meeting is over.

28.4 List of documents to be filed and archived

28.4.1Constitution of IEC

28.4.2SOP

28.4.3CV & consent of IEC members

28.4.4IEC Registration

28.4.5Honorarium details, Income and expenses

28.4.6Agenda & minutes of the meetings

28.4.7One copy of proposal

28.4.8Copy of recommendations/decision communicated to applicant

28.4.9Review reports, documents received during the follow up period and final reports of the study

29. POLICY TO MONITOR OR PREVENT THE CONFLICT OF INTEREST ALONG WITH STANDARD OPERATING PROCEDURES

29.1 It is recognized that the potential for conflict of interest will always exist, but has steadfast faith in the IEC and its Chairperson, to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

29.2 No member may participate in review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the IEC.

29.3 The Member will immediately disclose to the Chairperson of the EC any actual or potential conflict of interest that he/she may have in relation any particular proposal submitted for review by the Committee, and to abstain from any participation in discussion or recommendation in respect of such proposals.

29.4 If an applicant submitting a protocol believes that an IEC/IRB member has a Potential conflict, the investigator may request that the member be excluded from the review the protocol. The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiate

the claim that a conflict exists with the member(s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict.

29.5 When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the IEC/IRB review or approval except to provide information requested by the Committee.

29.6 Examples of conflict of interest cases may be any of the following:

29.6.1 A member is involved in a potentially competing research programme.

29.6.2 Access to funding or intellectual information may provide an unfair Competitive advantage.

29.6.3 Any member with conflict of interest will disclose the same before the start of the meeting and abstain from discussion and voting .The same will be documented in the minutes of the meeting.

30. ADMINISTRATION AND MANAGEMENT

30.1 SMHRC, should have an office for the IEC which have adequate space, infrastructure and staff to the EC for maintaining full-time secretariat, safe archival of records and conduct of meeting.

30.2 A reasonable fee for review may be charged by the IEC to cover the expenses related to optimal functioning in accordance to Institutional policies for industry sponsored projects/funded projects. There should be provision for allocating reasonable amount of funds for smooth functioning of the IEC.

30.3 Honorarium of INR 5000/-per sitting will be paid by the institute to the Non affiliated members attending the meeting.

31. SPECIAL SITUATIONS

31.1 Institutions can have one or more than one EC. They can have multiple ECs to review large numbers of research proposals. Each EC can function as a stand-alone committee which should follow all the SOPs and TORs of that institution.

31.2 An institution that does not have its own EC (user institution) may utilize the services of the EC of another institution (host institution) preferably in the adjoining/nearby area. Relevant requirements must be fulfilled before they do so.

32. CONDITIONS OF REVIEW FOR UTILIZING THE SERVICES OF AN EC OF ANOTHER INSTITUTION AND ACCEPTING PROPOSALS FROM OUTSIDE THE INSTITUTION

32.1 The two institutions SMHRC and the other institution (host and user) will enter into a MoU for utilizing the services of the EC of the host institution or the user institution should provide a "No Objection Certificate" and agree to be overseen by the IEC of the SMHRC.

32.2 The SMHRC IEC should have access to all research records including the source documents and research participants for continuing review of the implemented project, including site visits.

32.3 The SMHRC IEC can undertake site monitoring and will have all the rights and responsibilities related to ethical review of the projects submitted by the user institutions.

32.4 MoU in case of studies involving collaboration with other institutions/agencies/ organizations/ companies etc. (if applicable) is necessary.

32.5 In case the research is planned in collaboration with an institute/ department / center outside the SMHRC, then the MoU should be between the 2 institutions, the signatories on the behalf of both institutions being the Head of the Institutions.

32.6 The MoU and the approval include duly signed (a) assent and approval for the proposed research project, (b) the name of the Co-PI from the department, and (c)publication plan for dissemination and authorship, and (d) any other terms and conditions.

32.7 Material Transfer Agreement (as in collaborative research) where any biological samples are to be transferred from the Institute to other institute or laboratories or other agencies for testing or storage or for any future use.

33. FEES

33.1 The Prescribed IEC fee for IEC review per study will be INR Rs 50,000/- to be remitted along with the application to SMHRC IEC for external research projects.

33.2 For studies like drug trials, the fees would be Rs 1,00,000/-

33.3 Clinical drug trials requiring expedited review, fee would be Rs 1,50,000/-.

33.4 There will be however no fees for theses protocols of in house DNB post graduate Residents.

33.5 A fees of Rs 20,000/- is to be paid for external Postgraduates pursuing any degree or doctoral studies related to health / healthcare / basic sciences.

33.6 The fee structure will be Rs 25,000/- additional for:

33.6.1 For changes/ amendments in the submitted documents for resubmission and re-approval

33.6.2 New patient safety information / additional information for reviewing and approval

33.6.3 changes or amendment made in inclusion/exclusion criteria or protocol including administrative or patient safety.

33.7 All research proposals/clinical trials funded/sponsored by Pharmaceutical companies, Agencies, Multinationals etc. will be charged an administrative fee/ processing fee of 5% of their sanctioned budget.

34. WEB PAGE FOR IEC

34.1 A dedicated webpage will be created and maintained for IEC.

34.2 Details of composition, SOP ,registration details, circulars/notifications related to IEC meetings and status of submitted proposals and ongoing projects, submission forms, guidelines and contact details will be displayed on this page.

35. CONTACT DETAILS / ADDRESS OF THE OFFICE OF THE ETHICS COMMITTEE

The Member Secretary
Smita Memorial Hospital and Research Center, Vengalloor, Thodupuzha
Idukki 685608
Phone No: 0486-2208000
Email ID: ams@smitahospital.com

36. ANNEXURE -1 – Template – Invitation Letter to a Member

Letter head
Letter ref no:

From

The Chief Executive Officer

Smita Memorial Hospital and Research Centre Thodupuzha

To

Dear Sir/Madam
Greetings!

Sub: **Invitation to be a member** for Institutional Ethics Committee (IEC) of SMHRC, Thodupuzha

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

From,

37. ANNEXURE 2 – TEMPLATE – CONSENT LETTER FROM A MEMBER

To

The Chief Executive Officer

Smita Memorial Hospital and Research Centre Thodupuzha

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 SMHRC, Thodupuzha. 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,

Address:

Telephone No: (Off) (Res) email: Signature
with date Name of the Member

38. ANNEXURE 3 – Template – 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 Smita Memorial Hospital and Research Centre [SMHRC], Thodupuzha 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
1. 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 SMHRC IEC, Thodupuzha.

You will be paid a sum of INR/...../- per sitting as Honorarium for your services rendered towards attending the IEC meetings at as per the institutional norms.

We sincerely hope your association with IEC, SMHRC, Thodupuzha will be scientifically productive and beneficial to the Institute & the community at large.

Signature with date

39. ANNEXURE 4– TEMPLATE – APPLICATION FOR INITIAL REVIEW

APPLICATION FOR INITIAL REVIEW

- **SECTION A -BASIC INFORMATION**

1. Title of the study: Acronym / Short title, (If any):
2. Name of Principal Investigator:
3. Department:
4. Date of submission:
5. Designation:
6. Email id:
7. Type of review requested:
   a. Exemption from review
   b. Expedited review
   c. Full committee review
8. (Protocol number (If any): Version number:
9. Details of Investigators:
   a. Name, Designation and Qualification
   b. Department and Institution
   c. Address for communication
   d. Principal Investigator/Guide
   e. Co-investigator/student/fellow
10. Number of studies where applicant is a:
    a. Principal Investigator at time of submission
    b. Co-Investigator at time of submission:
11. Duration of the study:

- **FUNDING DETAILS AND BUDGET**

1. Total estimated budget for site:
   a. At site
   b. Overall.
2. Funding
   a. Self-funding
   b. Institutional funding
   c. Funding agency (Specify)

- **SECTION B - RESEARCH RELATED INFORMATION**

OVERVIEW OF RESEARCH

1. Lay summary(within300words):
2. Objective of the study:
3. Type of study:
   (a) Basic Sciences

(b) Clinical
(c) Cross Sectional
(d) Retrospective
(e) Epidemiological/
(f) Case Control
(g) Prospective
(h) Public Health Cohort
(i) Qualitative
(j) Socio-behavioural
(k) Systematic Review
(l) Quantitative
(m) Biological samples/Data
(n) Mixed Method
(o) Any others (Specify)

4. justification for conduct of this study:

METHODOLOGY

1. Sample size/ number of participants At site : total sample size Control group / Study group
2. Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for saturation
3. Inclusion criteria:
4. Exclusion criteria:
5. Study design:
6. Investigations specifically related to projects:
7. Is there an external laboratory/outsourcing involved for investigations?Yes / No/ NA
8. How was the scientific quality of the study assessed?
9. Independent external review / Review by sponsor or Funder/Review within PI's institution/Review within multi-centre research group/ No review
10. Date of the Review:
11. Research Comments of scientific committee/IRC, if any (100 words)

- **SECTION C: PARTICIPANT RELATED INFORMATION -RECRUITMENT AND RESEARCHPARTICIPANTS**

1. Type of participants in the study:
   a. Healthy volunteers
   b. Patients
   c. Vulnerable persons/ Special group
   d. Others ,(Specify)
2. Who will do the recruitment? Participant recruitment methods used:
   a. Posters
   b. leaflets/Letters
   c. TV/Radioads/
   d. Social

e. Patients/ Family/Friends
f. Telephone
g. Others (Specify)

3. Will there be vulnerable persons / special groups involved?
   a. Yes
   b. No
   c. NA
4. If yes, type of vulnerable persons / special groups
   a. Children under18yrs
   b. Pregnant or lactating women
   c. Differently abled (Mental/Physical)
   d. Employees/Students/Nurses/Staff
   e. Elderly
   f. Institutionalize
   g. Economically and socially disadvantaged
   h. Refugees/Migrants/Homeless
   i. Terminally ill (stigmatized or rare diseases)
   j. Any other (Specify):
5. Provide justification for inclusion/exclusion
6. Are there any additional safeguards to protect research participants?
7. Is there any reimbursement to the participants?
   Yes ☐ No☐ If yes, Provide details Monetary☐Non-monetary☐
8. Are there any incentives to the participants?
   Yes ☐ No ☐ If yes,Monetary☐ Non-monetary☐ Provide details
9. Are there any participant recruitment fees/incentives for the study provided to the PI/Institution?
   If yes,Monetary☐ Non-monetary☐ Provide detailsYes ☐ No☐

BENEFITS AND RISKS

10. Are there any anticipated physical/social/psychological discomforts/ risk to participants?
    a. Yes
    b. No
    c. If yes, categorize the level of risk:
       i. Less than Minimal risk
       ii. Minimal risk
       iii. Minor increase over minimal risk or low risk
       iv. More than minimal risk or high risk
11. Describe the risk management strategy:

12. What are the potential benefits from the study?
    i. For the participant
    ii. For the society/community
    iii. For improvement in science Please describe how the benefit justify the risks
13. Are adverse events expected in the study?
    i. Yes
    ii. No

iii. NA

14. Are reporting procedures and management strategies described in the study?
    i. Yes
    ii. No
    iii. If Yes, Specify

INFORMEDCONSENT

15. Are you seeking waiver of consent? If yes, please specify reasons
    a. Yes
    b. No
16. Version number and date of Participant In formation Sheet(PIS): Version number and date of Informed Consent Form(ICF):
17. Type of consent planned for:
    a. Signed consent
    b. Verbal/Oral consent
    c. Witnessed consent
    d. Audio- Video (AV) consent
    e. Consent from L AR (If so, specify from whom)
    f. For children <7yrs parental/LAR consent
    g. Verbal assent from minor (7-12 yrs) along with parental consent
    h. Written assent from minor (13-18 yrs) along with parental consent
    i. Other (specify)
18. Who will obtain the informed consent?
    a. PI/Co-I
    b. Nurse/Counsellor
    c. Research Staff
    d. Other (Specify)
19. Any tools to be used e)Participant Information Sheet (PIS) and Informed Consent Form(ICF)

English ☐ Local language ☐ Other ☐(Specify) List the languages in which translations were done .If translation has not been done in local language, please justify

20. Provide details of consent requirements for previously stored samples if used in the study7 (g)Elements contained in the Participant Information Sheet(PIS) and Informed Consent Form (ICF) Others(Specify)

PAYMENT/COMPENSATION

21. Who will bear the costs related to participation and procedures?
22. PI ☐ Institution ☐ Sponsor ☐ Other agencies ☐ (specify)
23. Is there a provision for free treatment of research related injuries?Yes ☐ No☐N/A ☐ If yes,then
24. who will provide the treatment?
25. Is there a provision for compensation of research related SAE?If yes,specify. Yes ☐ No ☐N/A ☐
26. Sponsor ☐ Institutional/Corpusfund☐ Projecgtrant☐ Insurance☐
27. Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period?If yes,specify.Yes
28. ☐ No☐N/A ☐
29. (e)Is there a provision for ancillary care for unrelated illness during the study period?If yes,please specify
30. . Yes ☐ No ☐ N/A ☐

STORAGE ANDCONFIDENTIALITY

1. Identifying Information: Study Involves samples/data. Yes ☐ No ☐ NA ☐If Yes, specify Anonymous/Unidentified ☐ Anonymized: Reversibly coded ☐ Irreversibly coded
2. Identifiable ☐ If identifiers must be retained, what additional precautions will be taken to ensure that access is limited /data is safeguarded? (e.g. data stored in a cabinet, password protected computer etc.)
3. Who will be maintaining the data pertaining to this study?
4. Where will the data be analysed and by whom?
5. For how long will the data be stored?
6. Do you propose to use stored samples/data in future studies? Yes ☐ No ☐ Maybe ☐ If yes, explain how you might uses to red material/data in the future?

SECTION D: OTHER ISSUES

PUBLICATION, BENEFIT SHARING AND IPRISSUES

1. Will the results of the study be reported and disseminated? If yes, specify. Yes ☐ No ☐ NA ☐
2. Will you inform participants about the results of these study? Yes☐No☐NA☐
3. Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? If yes describe in brief(Max50words) Yes ☐ No ☐NA☐
4. Is there any plan for post research benefit sharing with participants? If yes, specifyYes No ☐ NA☐
5. Is there any commercial value or a plan to patent/IPR issues? If yes, please provide details Yes☐ No ☐ NA☐
6. Do you have any additional information to add in support of the application, which is not include ed elsewhere in the form? If yes, provide details. Yes ☐ No☐

SECTION E: DECLARATION AND CHECKLIST

DECLARATION (Please tick as applicable)

1. I/We certify that the information provided in this application is complete and correct.
2. I/We confirm that all investigators have approved the submitted version of proposal/related documents.
3. I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants and other applicable regulations and guide- lines.
4. I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, New drugs and Clinical Trial Rules 2019 GCP guidelines and other applicable regulations and guidelines.
5. I/Wewillcomplywithallpoliciesandguidelinesoftheinstituteandaffiliated/collaborating institutions where this study will be conducted.
6. I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the IEC approved protocol.
7. I/We declare that the expenditure in case of injury related to the study will be taken care of.
8. I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
9. I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports and a final report and also participate in any audit ofthe study if needed.
10. I/We confirm that we will maintain accurate and complete records of all aspects of the study.
11. I/We will protect the privacy of participants and assure confidentiality of data and biological samples.
12. I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.

13. I/We have the following conflict of interest (PI/Co-I):
14. I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.

Name of PI:

Signature with date:

Name of Co-PI:

Signature with date:

Name of Guide:

Signature with date
Name of HOD:

Signature with date

Administrative requirements:

SL. No	Items	Yes No	Enclosure No.	IEC Remarks
1.	Cover letter			
2.	Brief CV of all Investigators			
3.	Good Clinical Practice (GCP) training of investigators in last 3 years			
4.	Approval of scientific committee			
5.	IEC clearance of other centers			
6.	Agreement between collaborating partners			
7.	MTA between collaborating partners			
8.	Insurance policy/certificate			
9.	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification			
10.	Copy of contract or agreement signed with the sponsor or donor agency			
11.	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol			

Proposal related:

SL. No	Items	YES NO	Enclosure No.	IEC Remarks
	Copy of the detailed protocol			
	Investigators Brochure (If applicable for drug/biologicals/ Device trials)			

	Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated			
	Assent form for minors (12-18 years) (English and Translated)			
	Proforma/Questionnaire/Case Report Forms (CRF)/Interview guides/ Guides for Focused Group Discussions (FGDs)(English and translated)			
	Advertisement/material to recruit participants (fliers, posters etc)			

Permission from governing authorities

SL NO	Other permissions	Required	Not required	Received	Applied/ dd mm/yy
	CTRI				
	DCGI				
	HMSC				
	NAC-SCRT				
	ICSCR				
	RCGM				
	BARC				
	others (specify)				

Application Form for Exemption from Review

Title of Study:

Principal Investigator (Name, Designation, and Affiliation):

1. Choose reasons why exemption from ethics review is requested (tick all applicable):

i. Research on data in the public domain/systematic reviews or meta-analyses
ii. Observation of public behaviour/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
vii. Any other (please specify in 100 words):

Signature of PI with date:

.....

Comments of EC Secretariat:

.....

Signature of Member Secretary with date:

.....

40. ANNEXURE -5 – TEMPLATE – CONTINUING REVIEW / ANNUAL REPORT FORMAT

1. Title of study:
2. Principal Investigator (Name, Designation and Affiliation):
3. Date of IEC approval:
4. Validity of approval:
5. Date of start of study:
6. Proposed date of study completion:
7. Period of continuing report from to:
8. Does the study involve recruitment of participants Yes ☐ No ☐
    a. If yes, Total number expected: Number Screened: Number Enrolled: Number Completed: Number on follow up
    b. Enrolment status – ongoing /completed/stopped
    c. Report of DSMB Yes ☐ No ☐ NA
    d. Any other remark
    e. Have any participants withdrawn from this study since the last approval? Yes ☐ No☐ NA☐ If yes, total number withdrawn and reasons:
9. Is the study likely to extend beyond the stated period? Yes ☐No☐ If yes, please provide reasons for the extension.
10. Have there been any amendments in the research protocol /Informed Consent Document (ICD)during the past approval period?
    a. If no, skip to item no. Yes ☐ No☐
    b. If yes, date of approval for protocol and ICD:
    c. In case of amendments in the research protocol/ICD, was re-consent sought from participants? Yes ☐ No☐ If yes, when/how:
11. 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:
12. Have any ethical concerns occurred during this period?
    Yes ☐ No☐ If yes, give details
13. Have any adverse events been noted since the last review? Yes ☐ No☐ Describe in brief:

41. ANNEXURE -6 – TEMPLATE – APPLICATION/NOTIFICATION FORM FOR AMENDMENTS

1. Title of the study
2. IEC ref no:
3. PI – Name, Designation and Affiliation
4. Date of EC approval
5. Date of Start of study
6. Details of Amendments

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

   Impact on Benefit and risk analysis – Yes/No If yes describe in brief
7. Is any reconsent necessary? Yes/No
8. If yes, have necessary changes been made in the informed consent? Yes/No
9. 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)
10. Version number of amended Protocol/Investigator's brochure/ICD: Signature of PI:

42. ANNEXURE-7-TEMPLATE-PROTOCOL VIOLATION/DEVIATION REPORTING FORM (REPORTING BY CASE)

1. Title of the study
2. IEC ref no:
3. PI – Name, Designation and Affiliation
4. Date of EC approval
5. Date of Start of study
6. Participant ID
7. Total number of deviations /violations reported till date in the study:
8. Deviation/Violation identified by: Principal Investigator/study team/ Sponsor/Monitor/SAE Sub Committee/EC
9. Is the deviation related to (Tick the appropriate box):
   a. Consenting ☐
   b. Source documentation☐
   c. Enrollment ☐
   d. Staff ☐
   e. Laboratory assessment ☐
   f. Participant non-compliance ☐
   g. Investigational Product
   h. Safety Reporting ☐
   i. Others(specify)
10. Provide details of Deviation/Violation:
11. Corrective action taken by PI/Co-I:
12. Impact on (if any): Study participant/Quality of data/
13. Are any changes to the study/protocol required? Yes/No If yes, give details
14. Signature of PI with date

43. ANNEXURE-8-TEMPLATE- SERIOUS ADVERSE EVENT REPORTING FORMAT (BIOMEDICAL HEALTH RESEARCH)

1. Title of the study
2. IEC ref no:
3. PI – Name, Designation and Affiliation
4. Date of EC approval
5. Date of Start of study
6. Participant details:
   Initials/ID
   Age at the time of event Gender: Male/Female Weight (Kgs) :
   Height (cms) :
7. Suspected SAE diagnosis
8. Date of onset of SAE:
9. Describe the event
10. Date of reporting SAE
11. Details of suspected intervention causing SAE
12. Report type: Initial/Follow-up/Final
13. If Follow-up report, state date initial report
14. Have any similar SAE occurred previously in this study? Yes/NO If yes, please provide details.
15. 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)
16. 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 defects ☐
    Persistent or significant disability/incapacity ☐Event requiring intervention (surgical or medical) to prevent SAE☐ Event which poses threat to life☐ Others☐
17. In case of death, state probable cause of death.
18. No permanent/significant functional/cosmetic impairment ☐ Permanent/significant functional/cosmetic impairment
    Not Applicable
19. 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).
20. Provide details of compensation provided / to be provided to participants (Include information on who pays, how much, and to whom
21. Outcome of SAE
    Fatal ☐Recovered ☐ Continuing ☐ Unknown ☐ Recovering ☐Other(specify) ☐
22. Provide any other relevant information that can facilitate assessment of the case such as medical history
23. Provide details about PI's final assessment of SAE relatedness to research.
    Signature of PI with date

44. ANNEXURE-9 TEMPLATE PREMATURE TERMINATION /SUSPENSION/ DISCONTINUATION REPORT FORMAT

1. Title of the study
2. IEC ref no:
3. PI – Name, Designation and Affiliation
4. Date of EC approval
5. Date of Start of study
6. Date of last progress report submitted to EC
7. Date of termination/suspension/discontinuation:
8. Reason for Termination/Suspension/Discontinuation
9. Action taken post Termination/Suspension/Discontinuation (if any):
10. Plans for post study follow up/withdrawal (if any)
11. Details of study participants
    Total number of participants to be recruited Screened Screen failures Consent with drawn – reason with drawn by PI- reason Active on treatment / Completed treatment/ Participants on follow-up: Participants lost to follow up Number of drop outs Reasons for each drop-out Any other
12. Total number of SAEs reported till date in the study
13. Have any unexpected adverse events or outcomes observed in the study been reported to the EC? Yes/No
14. Have there been participant complaints or feedback about the study? Yes/No If yes provide details
15. Have there been any suggestions from the SAE Sub Committee? Yes/No. If yes have you implemented that suggestion? Yes/No
16. Do the procedures for withdrawal of enrolled participants take into account their rights and welfare?
    Yes ☐ No☐ (e.g., making arrangements for medical care of research participants):
    If Yes, provide details Summary of results: Signature of PI with date

45. ANNEXURE-10-TEMPLATE- APPLICATION FORM FOR CLINICAL TRIALS

1. Title of the study
2. PI details
3. Type of Clinical trial – Regulatory trial / Academic trial
   CTRI registration number:
   NABH accreditation number:
   EC registration number
   If regulatory trial, provide status of CDSCO permission letter
4. Approved and letter attached/ Applied, under process/ Not applied (State reason)
5. Tick all categories that apply to your trial
6. Phase-I ☐ Phase II☐ Phase III ☐ Phase IV or Post Marketing Surveillance☐
   Investigational medicinal products ☐ Investigational New drug ☐
   Medical devices☐ New innovative procedure ☐ Drug/device combination
   Bioavailability/Bioequivalenc estudies ☐ Non-drug intervention☐ Repurposing an existing intervention ☐ Indian system of (AYUSH)medicine Phytopharmaceutical drug Others (specify) ☐Stem

cells Approved drug for any new indication or new route of administration ☐
Trial design of the study
I.Randomized ☐ Factorial ☐
Non randomized ☐ Stratified ☐
Parallel ☐ Adaptive ☐
Cross-over ☐ Comparison trial ☐ Cluster ☐ Superiority trial ☐ Matched-pair ☐
Non-inferiority trial ☐
Others (specify)☐ Equivalence trial ☐
II.If there is randomization, how will the participants be allocated to the control and study group(s)?
III.Describe the method of allocation concealment (blinding / masking), if applicable.

7. List the primary / secondary outcomes of the trial.
8. Is there a Contract Research Organization (CRO) /Site Management Organisation (SMO) / Any other agency such as public relation/human resource? Yes ☐ No ☐
   If yes, Name and Contact details:
9. State how the CRO/SMO/agency will be involved in the conduct of the trial (tick all that apply) Project management ☐ Clinical and medical monitoring ☐Regulatory affairs ☐ Data management ☐ Statistical support ☐ Medical writing ☐ Site management ☐ ☐
10. Please provide the following details about the intervention being used in the protocol
    a. Drug/s, device/s and/or biologics; Yes ☐ No ☐ NA ☐ if yes, provide regulatory approval details.
    b. Already approved drugs or a combination of two or more drugs with new indications / change in dosage form / route of administration. Yes ☐ No ☐ NA ☐If yes, provide details.
    c. Provide contact details of who prepared and /or is manufacturing the drug/s, device/s and biologics.
    d. Provide details of patent of the drug/s, device/s and biologics.
11. Describe in brief any preparatory work or site preparedness for the protocol? Yes ☐ No ☐ NA ☐If yes, provide details
12. Is there an initial screening/use of existing database for participant selection? Yes☐ No☐ NA☐ If Yes, provide details
13. Is there any anticipated incidence, frequency and duration of adverse events related to the intervention?Yes ☐ No ☐ NA ☐ If yes, provide details of arrangements made to address them.
14. Does the study use a placebo?Yes ☐ No ☐ NA ☐ If yes, justify the use of the placebo and risks entailed to participants.
15. Will current standard of care be provided to the control arm in the study? Yes ☐ No ☐ NA ☐ If no, please justify.
16. Are there any plans to withdraw standard therapy during the study? Yes ☐ No ☐ NA ☐ If yes, please justify
17. Are there any rules to stop the protocol in case of any adverse events?. Yes ☐ No ☐ NA ☐ If yes, please specify
18. Does the study have a Data and Safety Monitoring Plan? Yes ☐ No ☐ NA ☐ If no, please justify.
19. Participant Information Sheet(PIS) and Informed Consent Form (ICF)
    English Local language Other(Specify) ☐
    (certified that local version (s) is/are a true translation of the English version and can be easily understood by the participants)
20. Involvement/consultation of statistician in the study design Yes ☐ No ☐ NA ☐

21. Is there any insurance coverage of the trial? If yes, provide details. Yes ☐ No ☐
22. Is the PI registered with Medical Council of India (MCI) or the State Medical Council registration? Yes ☐ No ☐ Please provide details.
23. Is the PI trained in GCP in last 3 years? If yes, Please enclose certificate Yes ☐ No ☐

Signature of PI with date

46. ANNEXURE-11-TEMPLATE- SERIOUS ADVERSE EVENT REPORTING FORMAT (CLINICAL TRIALS)

1. Title of the study
2. PI details: Participant details Initials and Case No Subject ID
   Age at the time of event Gender: Male/Female Weight (Kgs) Height (cms)
3. Report type: Initial ☐ Follow-up ☐ Final ☐
4. If Follow-up report, state date of Initial report
5. What was the assessment of relatedness to the trial in the initial report?
   By PI – Related ☐ By Sponsor – Related☐ By EC –Related ☐
   Unrelated ☐ Unrelated ☐ Unrelated ☐
6. Describe the event and specify suspected SAE diagnosis
7. Date of onset of SAE: Date of reporting:
8. Onset lag time after administration of intervention:
9. Location of SAE (Clinic/Ward/Home/Other)
10. Details of suspected study drug/device/investigational procedure causing SAE:
    I. Suspect study drug (include generic name) device/intervention:
    II. Indication(s) for which suspect study drug was prescribed or tested:
    III. Route(s) of administration, daily dose and regimen, dosage form and strength
    IV. Therapy start date: Stop date:
11. Was study intervention discontinued due to event? Yes ☐ No ☐
12. Do the reaction decline after stopping or reducing the dosage of the study drug / procedure? Yes☐ No ☐If yes, provide details about the reduced dose
13. Did the reaction reappear after reintroducing the study drug / procedure?Yes ☐ No ☐ NA ☐If yes, provide details about the dose
14. Concomitant drugs history and lab investigations:
    I. Concomitant drug (s) and date of administration:
    II. Relevant test/laboratory data with dates:
    III. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)
15. Have any similar SAE occurred previously in this study? Yes ☐ No If yes, please provide details
16. Seriousness of the SAE: Death ☐Congenital anomaly ☐ Life threatening ☐ Required intervention to prevent Hospitalization-initial or prolonged☐ permanent impairment / damage ☐ Disability☐ Others (specify) ☐
17. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include infor- mation on who paid, how much was paid and to whom).
18. Outcome of SAE:
    Fatal ☐ Recovered ☐
    Continuing ☐ Unknown ☐

Recovering ☐ Other (specify) ☐

19. Was the research participant continued the trial? Yes ☐ No ☐ NA ☐
20. Provide details about PI's final assessment of SAE relatedness to trial.
21. Has this information been communicated to sponsor/CRO/regulatory agencies?Yes ☐
22. Provide details if communicated (including date)
23. Does this report require any alteration in trial protocol? Yes ☐ No ☐No ☐
24. Provide details of compensation provided / to be provided the participants (Include information on who pays, how much, and to whom)

Signature of PI with date

47. ANNEXURE-12-TEMPLATE- STUDY COMPLETION/FINAL REPORT FORMAT

1. Title of study:
2. PI (Name, Designation and Affiliation):
3. Date of EC Approval:
4. Date of Start of Study:
5. Date of study completion:
6. Provide details of:
   a. Total no. of study participants approved by the EC for recruitment:
   b. Total no. of study participants recruited:
   c. Total number of participants withdrawn from the study (if any):
   d. Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared)-
   e. Describe the main Ethical issues encountered in the study (if any):
   f. State the number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study period
   g. Describe in brief Plans for archival of records / Record Retention:
   h. Is there a plan for post study follow-up –
   i. Do you have plans for ensuring that the data from the study can be shared/ accessed easily?
   j. Is there a plan for post study benefit sharing with the study participants? 11.Describe results (summary) with Conclusion:
   k. Number of SAEs that occurred in the study
   l. Have all SAEs been intimated to the EC:
   m. Is medical management or compensation for SAE provided to the participants?

48. ANNEXURE-13-TEMPLATE- PARTICIPANT INFORMATION SHEET

i. Statement that the study involves research and explanation of the purpose of the research. In simple language
ii. Expected duration of the participation of subject.
iii. Description of the procedures to be followed, including all invasive procedures. (iv)Description of any reasonably foreseeable risks or discomforts to the Subject.
iv. Description of any benefits to the participant or others reasonably expected from research. If no benefit is expected participants should be made aware of this.
v. Disclosure of specific appropriate alternative procedures or therapies available to the participant.

vi. Statement describing the extent to which confidentiality of records identifying the participant will be maintained and who will have access to participant's medical records.
vii. Trial treatment schedule and the probability for random assignment to each treatment (for randomized rials).
viii. Statement describing the financial compensation and the medical management as under:
   a. In case of an injury occurring to the subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.
   b. In the event of a trial related injury or death, the sponsor or his representative or the investigator or centre, as the case may be, in accordance with the rule 39, as the case may be, shall provide financial compensation for the injury or death.
ix. An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury.
x. The anticipated prorated payment, if any, to the participant for participating in the trial.
xi. Responsibilities of subject on participation in the trial.
xii. Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled.
xiii. Statement that there is a possibility of failure of investigational product to provide intended therapeutic effect.
xiv. Statement that in the case of placebo-controlled trial, the placebo administered to the subjects shall not have any therapeutic effect.
xv. Any other pertinent information.
xvi. Additional elements, which may be required:
   a. Statement of foreseeable circumstances under which the participation of the subject may be terminated by the Investigator without his or her consent.
   b. Additional costs to the participant that may result from participation in the study.
   c. The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by Subject.
   d. Statement that the Participant or participant's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the participant's willingness to continue participation will be provided.
   e. A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or foetus, if the participant is or may become pregnant), which are currently unforeseeable.
   f. Approximate number of participants enrolled in the study.

49. ANNEXURE-14-TEMPLATE- INFORMED CONSENT FORM

Study Title:
Study Number:
Participant's Initials:
Participant's Name:
Date of Birth/Age:
Address of the Participant:
Qualification:
Occupation: Student / Self-Employed / Service / Housewife/ Others (Please click as appropriate).

Annual Income of the subject:

Name and address of the nominees and his relation to the subject (for the purpose of compensation in case of trial related death).

Place Initial box (Subject)

i. I confirm that I have read and understood the information [] Sheet dated for the above study and have had the opportunity to ask questions.

ii. I understand that my participation in the study is voluntary and [] that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

iii. I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

iv. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purposes []

v. I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative: Date:/ / Signatory's Name:

Signature of the Investigator: Date: / /

Study Investigator's Name:

Signature of the Witness Date: / / Name of the Witness:

50. ANNEXURE-15-TEMPLATE- UNDERTAKING BY THE INVESTIGATOR

1. Full name, address, and title of the Principal Investigator (or Investigators when there is no Principal Investigator).
2. Name and address of the medical college, hospital, or other facility where the research will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, or any other statements of qualifications).
3. Name and address of all clinical laboratory facilities to be used in the study.
4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.
5. Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigations.
6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.
7. Commitments:

(i) I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained. I inform that no work has been started for this research yet.

(ii) I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval or favourable opinion from the ethics committee of the amendment, except where necessary to eliminate an immediate hazard to the trial subject or when the changes involved are only logistical or administrative in nature.

(iii) I agree to personally conduct or supervise the clinical trial at my site.

(iv) I agree to inform all trial subject, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.

(v) I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s)in accordance with the regulatory requirements and Good Clinical Practices guidelines.

(vi) I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.

(vii) I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.

(viii) I agree to maintain adequate and accurate records and to make those records available for audit or inspection by the Sponsor, ethics committee, Central Licencing Authority or their authorised representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorised representatives of the Sponsor.

(ix) I agree to promptly report to the ethics committee all changes in the clinical trial activities and all unanticipated problems involving risks to human subjects or others.

(x) I agree to inform all serious adverse events to the Central Licencing Authority, sponsor as well as the ethics committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licencing Authority along with the report of the serious adverse event.

(xi) The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licencing Authority, the Chairperson of the ethics committee and the Head of the institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.

(xii) I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data.

(xiii) I agree to comply with all other requirements, guidelines, and statutory obligations as applicable to clinical Investigators participating in clinical trials.

Signature of Investigator with date.

51. ANNEXURE-16- DECLARATION OF CONFLICT-OF-INTEREST FORM

Investigator/Sponsor / CRO; Protocol No.: Protocol Title:

S. No.	**Member's Name**	**Designation**	**Conflict of Interest declared**		**Signature and Date**
			Yes	**No**	

52. MEMBERS IN ETHICS COMMITTEE

S.No.	Name	Qualification with Specialization	Current Organization	Designation/ role of member in Ethics Committee	Affiliation of member with institute that has constituted the Ethics Committee
1	Dr. RAJEEVAN K	Other (PHYSICAL EDUCATION AND SPORTS)	NSS COLLEGE CHERTALA Retired College Principal	Chair Person	No
2	Dr. SHOBHA P	MBBS (DNB FAMILY MEDICINE PG DIP BIOETHICS HUMAN RIGHTS)	SMITA MEMORIAL HOSPITAL AND RESEARCH CENTRE	Member Secretary - Clinician (Dual Role)	Yes
3	Dr. DONA SUSAN MATHEW	MBBS (MD - Pathology & Microbiology)	SMITA MEMORIAL HOSPITAL AND RESEARCH CENTRE	Basic Medical Scientist	Yes
4	Dr. Sachin Mathew Jose	MBBS (MD - Paediatrics)	SMITA MEMORIAL HOSPITAL AND RESEARCH CENTRE	Clinician - Alt Member Secretary (Dual Role)	Yes
5	Dr. SANKAR KUMAR	MBBS (MD - Anesthesiology)	SMITA MEMORIAL HOSPITAL AND RESEARCH CENTRE	Clinician	Yes
6	Dr. AJAI P	MBBS (MS - Orthopedics)	SMITA MEMORIAL HOSPITAL AND RESEARCH CENTRE	Clinician	Yes
7	Mr. MATHEWS MALIECKAL	Bachelor in Theology (B. Philosophy)	St Thomas Forane Church, Mylacombu	Social Scientist	No
8	Mr. PRINCE J PANANAL	LLB (Master of Laws (LL.M.))	Private Legal Firm	Legal Expert	No
9	Mr. GEORGEKUTTY K T	B. COM (DIM, A. F.S)	Retired Govt Official	Lay Person	No
10	Ms. Gagan Gopalan	BA (Pre Primary TTC, Fashion Designing)	De Paul Public School	Lay Person	No
11	Ms. ANUMOL T J	Other (M. TECH)	SMITA MEMORIAL HOSPITAL AND RESEARCH CENTRE	Other Supporting Staff	Yes

53. Provisional Registration of Ethics Committee

File No. - EC/NEW/INST/2024/4552

सत्यमेव जयते

Government of India
Ministry of Health & Family Welfare
Department of Health Research

2nd Floor, IRCS Building,
New Delhi - 110001
Dated : 13-Feb-2025

Provisional Certificate

Subject: Provisional registration of the Ethics Committee relating to Biomedical and Health Research with the National Ethics Committee Registry for Biomedical and Health Research (NECRBHR), Department of Health Research (DHR).

In exercise of the powers conferred by sub-rule (3) of rule 17 of the New Drugs and Clinical Trials Rules, 2019, the designated authority in the Department of Health Research, Ministry of Health & Family Welfare, hereby provisionally registers and permits the following Ethics Committee to perform the duties of ethics committee as specified in Chapter–IV of the New Drugs and Clinical Trials Rules, 2019.

Name :	**SMHRC INSTITUTIONAL ETHICS COMMITTEE**
Address :	**SMITA MEMORIAL HOSPITAL AND RESEARCH CENTRE, VENGALLOR THODUPUZHA IDUKKI DIST KERALA, THODUPUZHA, Idukki, Kerala - 685608**
Contact No:	**0486-2208000**
Fax :	**-NA-**

2. The Ethics Committee shall observe all the conditions as stipulated in Chapter-IV of the aforesaid Rules, i.e., New Drugs and Clinical Trials Rules, 2019 and the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, specified by the Indian Council of Medical Research (ICMR).

3. The designated authority shall scrutinize the documents and information furnished with the application by the Ethics Committee for the issue of final registration certificate.

4. The above provisional registration shall be valid for a maximum period of two years from the date of its issue or till grant of final registration or rejection of provisional registration, whichever is earlier.

Note: EC registration number provided by DHR should be displayed on every certificate of approval issued by the Ethics committee

ANU NAGAR
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Date: 2025.02.13 16:10:08 +05'30'

(Anu Nagar)
Joint Secretary
Department of Health Research
Designated Authority

54. AMENDMENT SHEET

SL No.	Page No	Date	Details of the Amendment	Reasons	Signature of the Preparatory Authority	Signature of the Approval Authority