SANDRA SHROFF COLLEGE OF NURSING, VAPI

SOP

FOR INSTITUTIONAL ETHICS COMMITTEE

TITLE:
ETHICS COMMITTIEE
SANDRA SHROFF COLLEGE OF NURSING VAPI (ECSSCN)

SOPs VERSION 1 JANUARY 2025

The SOP shall be valid from 01/01/25 valid up to 31/12/27

Prepared by **Mrs. Divya Pancholi** **Member Secretary** Associate Professor, HOD Mental Health Nursing Sandra Shroff College of Nursing, Vapi	**Signature** SECRETARY ETHICS COMMITTEE SANDRA SHROFF COLLEGE OF NURSING, VAPI
Reviewed by **Dr. Nancy Fernandes Pereira** **Chairperson** Former Principal Leelabai Thackersey College of Nursing, Mumbai	**Signature** CHAIRPERSON ETHICS COMMITTEE SANDRA SHROFF COLLEGE OF NURSING, VAPI
Approved by **Dr. Anita Nawale** **Incharge Principal** Sandra Shroff College of Nursing, Vapi	**Signature** IN CHARGE PRINCIPAL SANDRA SHROFF COLLEGE OF NURSING, VAPI
Dr. Anita Nawale **Incharge Principal** Sandra Shroff College of Nursing, Vapi	**Signature of Head of Institution** IN CHARGE PRINCIPAL SANDRA SHROFF COLLEGE OF NURSING VAPI

Sandra Shroff College of Nursing
Phone No. 0260-2467346

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STANDARD OPERATING PROCEDURES (SOPs) OF ETHICS COMMITTEE SANDRA SHROFF COLLEGE OF NURSING, VAPI

INTRODUCTION

SSCN has been established in the year 2003 by Mrs. Sandra Shroff, Founder & Chairperson with sole purpose of enabling girls from rural area of below average families to stand on their feet & support their families. SSCN is the 1st B.Sc. Self-finance Nursing college in Gujarat and 1st M.Sc., Self-finance Nursing College in South Gujarat.

SSCN has started Basic B.Sc. Nursing course in 2003. Later on, 2 years of M.Sc. Nursing & 3 years of General Nursing & Midwifery courses were started in the year 2011 & 2022 accordingly. G.N.M., B.Sc. Nursing and M.Sc. Nursing courses are recognized by Indian Nursing council (INC), Gujarat Nursing Council (GNC), & affiliated to Veer Narmad South Gujarat University, Surat.

Bio medical research involves a number of ethical issues that need to be addressed. The Institutional Human Ethics Committee (IHEC)/IEC plays an important role in guiding researchers in the ethical aspects associated with the biomedical research. Apart from ethical issues, EC will also review the research proposals for the scientific relevance and risk involved in research. EC functions as per the ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participant-2017 (ICMR National Ethical Guidelines)

I. PURPOSE

The standard operating procedures (SOPs) describes the terms of reference (TOR), which provide the frame work for constitution, responsibilities and activities of the Ethics Committee (EC).

The Ethics Committee (EC) of the Institute was established in order to provide independent guidance, advice and decision (in the form of "approval/Recommendation/ disapproval") on health research or other specific research proposals involving.

II. TITLE:

ETHICS COMMITTIEE SANDRA SHROFF COLLEGE OF NURSING VAPI

ADAPTATION:

Hence forth, ETHICS COMMITTIEE SANDRA SHROFF COLLEGE OF NURSING VAPI **Will be called as "ECSSCN" SOPs VERSION 1 JANUARY 2025**

III. (a) SCOPE

The SOP applies to the functioning of all activities under the "ECSSCN". This includes the basic responsibilities of the "ECSSCN", composition, appointment of the members and conduct of the meeting.

III. (b) OBJECTIVES OF SOP

The objective of this Standard Operating Procedures of ECSSCN is to maintain effective functioning of the EC and to ensure quality and technical excellence and consistent ethical review of all the submitted health and biomedical research proposals and ongoing approved research studies involving human participants in accordance with the ICMR ethical guidelines for biomedical research on human participants.

III. (c) AUTHORITY UNDER WHICH EC:

The Principal of SSCN, Vapi will appoint the Chairperson and all the committee members based on their competence, experience and integrity by request. Members will confirm their acceptance to the principal by providing all the required information for membership. The Chairperson will furnish any information or report to the Principal, SSCN, Vapi when required.

IV. COMPOSITION OF AN EC:

- ECs will be multi-disciplinary and multi-sectoral.
- There will be adequate representation of age and gender.
- Preferably 50% of the members will be non-affiliated or from outside the institution.
- The number of members in an EC will preferably be 14-15 and a minimum of 5 members shall be present to meet the quorum requirements.
- The EC will have a balance between medical and non-medical members/technical and non-technical members, depending upon the needs of the institution.

V. MEMBERSHIP REQUIREMENTS OF THE ETHICS COMMITTIEE

Sr No.	Members of EC	Definition/Description
1	**Chairperson** Non-affiliated Qualifications – M.Sc. /Ph.D. in Nursing • A well-respected person from nursing background with prior experience of having served/ serving in an EC	• Conduct EC meetings and be accountable for independent and efficient functioning of the committee • Chairperson will be responsible and lead all discussions and deliberations pertinent to the review of research proposal. • The chairperson will represent the IEC at various meetings and forums. • Ensure active participation of all members (particularly non-affiliated, non-medical/ non-technical) in all discussions and deliberations • Ratify minutes of the previous meetings • In case of anticipated absence of Chairperson at a planned meeting, the Chairperson will nominate a committee member as Acting Chairperson or

		the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson will be a non-affiliated person and will have all the powers of the Chairperson for that meeting. • Seek Conflict of Interest (COI) declaration from members and ensure quorum and fair decision making. • Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.
2	**Member Secretary** Affiliated Qualifications - M.Sc. in Nursing/Ph.D. Nursing • will be a staff member of the institution. • will have knowledge and experience in clinical research and ethics, be motivated and have good communication skills. • will be able to devote adequate time to this activity which shall be protected by the institution	• Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review • Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review. • Schedule & organize EC meetings, prepare the agenda and maintain minutes • Maintain EC documentation, communication and archiving • To sign documents and communications related to EC functioning. • To communicate with EC members and applicants/investigators. • To notify the principal investigator regarding EC decisions related to the submitted proposal. • Assess the need for expedited review/ exemption from review or full review. • Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives. • Ensure training of EC secretariat and EC members • Ensure SOPs are updated as and when, revise and distribution of SOP's guidelines, adherence of EC functioning to SOPs • To provide necessary administrative support for EC related activities to the chairperson. • To delegate various responsibilities to appropriate and authorized individuals. • Prepare for and respond to audits and inspections • Ensure quorum during the meeting and record

		discussions and decisions.
3	**Basic Medical Scientist(s)** Affiliated/ non-affiliated Qualifications - • Medical person with qualifications in basic medical sciences • In case of EC reviewing clinical trials with drugs, the basic medical scientist will preferably be a pharmacologist	• Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report • For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.
4	**Clinician(s)** Affiliated/ non-affiliated Qualifications - will be individual/s with recognized medical qualification, expertise and training with knowledge of research	• Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics • Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) • Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation. • Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
5	**Legal expert/s** Non-affiliated Qualifications -Will have a basic degree in Law from a recognized university, with experience	• Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial 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, HMSC for international collaboration, compliance with guidelines etc. • Interpret and inform EC members about new regulations if any
6	**Scientific member** Affiliated/ non-affiliated Qualifications – A postgraduate degree (MD/MS/MSC/PhD) in medical, clinical, or biomedical sciences, or allied health sciences.	• Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report • Examine study protocols, informed consent

	In case of EC reviewing clinical trials with drugs, the basic medical scientist will preferably be a pharmacologist	forms, data collection tools, and interventions for scientific accuracy and appropriateness. • Provide expert advice to the committee and researchers on technical or scientific issues.
7	**Social scientist** Non-affiliated Qualifications - will be an individual with social science 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	• Ethical review of the proposal, ICD along with the translations. • Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any. • Serve as a societal / community representative and bring in ethical and societal concerns.
8	**Lay person(s)** Non-affiliated Qualifications - • Literate person from the public or community • Has not pursued a medical science/ health-related career in the last 5 years • May be a representative of the community from which the participants are to be drawn. • Is aware of the local language, cultural and moral values of the community.	• Ethical review of the proposal, ICD along with translation(s). • Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. • Serve as a patient/participant/ community representative and bring in ethical and societal concerns. • Assess on societal aspects if any.

VI. ROLE & RESPONSIBILITIES OF EC MEMBERS:

- To attend EC meetings and participate in discussions and deliberations
- To review, discuss and consider research proposals submitted for evaluation.
- To review the progress and consider research proposals submitted for evaluation.
- To evaluate final report outcomes.
- The EC must ensure ethical conduct of research by the investigator team, protection of the dignity, rights, safety, local community value customs and well-being of the research participants.
- Declaration of conflicts of interest to the Chairperson observed by them.
- Ensure that privacy of the individual and confidentiality of data including the documents and deliberations of EC meetings.
- Participate in continuing education activities in research and ethics and get updated on

relevant guidelines and regulations.

- To provide information and documents related to training obtained in biomedical ethics and biomedical research to EC secretariat.
- To provide an updated CV when requested for by the EC secretariat
- To 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.
- To recommend appropriate compensation for research related injury, wherever required.
- To carry out monitoring/ visits of study sites as and when needed.
- To rule out same/similar research by different investigators from same institution and harmonized. 'Me too' research (replicative) (shall not to be encouraged and submission of same research to different funding agencies shall not be accepted.)

VII. REQUIREMENTS FOR EC MEMBERS

Every EC member must:

1. provide a recent signed CV and training certificates on human research protection and good clinical practice (GCP) guidelines, and submit training certificates within 1 month of appointment.
2. be willing to undergo training or update their skills/knowledge during their tenure as an EC member;
3. be aware of relevant guidelines and regulations;
4. read, understand, accept and follow the COI policy of the EC and declare it, if applicable, at the appropriate time;
5. sign a confidentiality and conflict of interest agreement/s;
6. be willing to place her/his full name, profession and affiliation to the EC in the public domain; and
7. be committed and understanding to the need for research and for imparting protection to research participants in research.

VIII. CRITERIA FOR SELECTION OF MEMBERS OF AN EC

- Members will be selected in their personal capacities based on their qualifications, experience, interest, commitment and willingness to volunteer the required time and effort for the EC.
- Members are appointed to the EC for a particular role. They cannot substitute for the role of any other member who is absent for a meeting. The role of Chairperson/ Member Secretary is an additional activity to their primary responsibility based on their qualifications.

TRAINING

- Members will be trained periodically regarding GCP guidelines.
- Any change in the relevant guidelines or regulatory requirements will be brought to the attention of all EC members.
- EC members will be made aware of local, social and cultural norms and emerging ethical issues.

CONFIDENTIALITY:

- All the members EC will sign a consent letter in which they declare their commitment for all activities of the committee, and maintaining confidentiality of activities and documents of ECSSCN
- The staff of institute of EC will sign an agreement of maintaining confidentiality.
- Chairperson of ECSSCN will sign on all the confidentiality forms of members and institute staff.

IX. QUORUM REQUIREMENTS FOR EC MEETINGS

1. A minimum of five members present in the meeting room.
2. The quorum shall include both medical, non-medical or technical or/and non-technical members.
3. Minimum one non-affiliated member shall be part of the quorum.
4. Preferably the lay person shall be part of the quorum.
5. The quorum for reviewing regulatory clinical trials shall be in accordance with current CDSCO requirements.
6. The quorum shall include special invitee from the concerned field if reviewing the research proposal from specific field if not a member of EC.
7. No decision is valid without fulfilment of the quorum.

X. CONVENTION AND CONDUCTION OF EC MEETING

- The chairperson will conduct all meetings of the EC. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned.
- Member Secretary will prepare the minutes of the meetings and get it approved by the chairperson and all members. In the absence of Member Secretary alternate Member Secretary among the members, will organize the EC meeting.
- All proposals after initial scrutiny by secretary the proposals will be circulated to the IEC along with tool and consent form It shall be sent to EC members at least 2 weeks before the meeting.
- The recommendation & suggestions of the EC will be communicated to all primary investigators and guides by the secretary. If required, additional review meeting can also be conducted with a short notice period.

XI. APPLICATION PROCEDURES:

- All proposals shall be submitted on any working day 2 weeks in advance of scheduled meeting. One hard copy and one soft copy of the proposal shall be submitted to EC. The date of EC meeting shall be intimated to the Principal investigator by the Secretary.
- Researcher has to make a brief presentation of the proposal.
- If revision is to be made, the revised proposal in required number of copies shall be submitted within stipulated period of time as specified in the communication or before the next meeting.

XII. SUBMISSION & REVIEW PROCEDURE:

- Researchers shall submit research proposals at least 2 weeks before the scheduled EC meeting.
- Submission shall include one hard copy (signed) and one soft copy (PDF) of the complete proposal and supporting documents in the prescribed format.
- Incomplete submissions will not be processed and shall be returned to the investigator for correction.
- The list of documents required is subject to modification depending on the type of research, EC SOPs, and institutional policies.

Details of Documents Required for EC Review

The following documents must be submitted, as applicable:

1. Covering letter addressed to the Member Secretary, EC
2. Type of review requested (Exempt/Expedited/Full Committee)
3. Application Form for Initial Review
4. Correct version of Informed Consent Document (ICD) in English and local language(s), along with translation and back-translation certificates (if applicable)
5. Case record form/questionnaire
6. Recruitment materials: advertisements, notices, posters (if applicable)
7. Participant instruction card, diary, or other tools (if applicable)
8. Investigator's Brochure (for drug/biological/device trials, if applicable)
9. Details of funding agency/sponsor and fund allocation (if applicable)
10. Brief curriculum vitae of all investigators
11. Statement of Conflict of Interest (COI), if any
12. Valid GCP training certificate (preferably within the last 5 years) for clinical trial investigators
13. Evidence of any other research ethics or related training
14. List of ongoing research studies undertaken by the Principal Investigator (if applicable)
15. Undertaking duly signed by all investigators
16. Relevant regulatory permissions (as applicable)
17. Administrative approvals (e.g., HMSC approval for international trials)
18. Institutional Committee for Stem Cell Research (IC-SCR) approval (if applicable)
19. Memorandum of Understanding (MoU) for collaboration with other institutions (if

applicable)

20. Clinical Trial Agreement between sponsor, investigator, and Head of Institution (if applicable)
21. Documentation of Clinical Trial Registration (preferable)
22. Insurance policy for study participants with coverage details (if applicable)
23. Indemnity policy with coverage details (if applicable)
24. Any additional documents required by EC (e.g., EC approvals for multicentric studies)
25. Protocol

Details of documents to be included in the protocol

The study protocol shall include the following components:

1. Title page with the title of the study and the signatures of the investigators
2. Brief summary / lay summary
3. Background and rationale justifying the need for human participants
4. Justification for inclusion/exclusion of vulnerable populations
5. Clear objectives and endpoints (if applicable)
6. Eligibility criteria and participant recruitment procedures
7. Detailed methodology including:
   - Study design
   - Sample size with justification
   - Data collection methods
   - Interventions, dosages, route, duration
   - Details of invasive procedures, if any
8. Duration of the study
9. Justification for placebo use, benefit–risk assessment, and withdrawal plans
10. Informed consent process including participant information sheet, consent forms (English and local language), AV recording (if applicable), and consent for stored samples
11. Statistical analysis plan
12. Measures to ensure privacy and confidentiality
13. Risk management plan for studies involving more than minimal risk
14. Compensation and reimbursement details, and management of research-related injury
15. Provision of ancillary care for unrelated illnesses during research
16. Data storage, retention, and security plan
17. Publication plan for dissemination of results while maintaining confidentiality
18. Ethical considerations and participant protection safeguards

- The Member Secretary 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.
- A researcher cannot decide that her/his proposal falls in the exempted, expedited or full review category. All research proposals shall be submitted to the EC. The decision on the type of review required rests with the EC and shall be decided on a case-to-case basis. Researchers shall approach the EC with appropriate justification for the proposal to be considered as exempt, expedited or if waiver of consent is requested.

- Expedited review will be conducted by Chairperson, Member Secretary and one or two designated members or as specified in SOPs.
- Approval granted through expedited review and the decisions of the SAE subcommittee shall be ratified at the next full committee meeting.
- EC members shall be given enough time (at least 1 week) to review the proposal and related documents, except in the case of expedited review.
- All EC members shall review all proposals.
- The EC shall adopt a system for pre-meeting peer review by subject experts and obtain clarifications from the researchers prior to the meeting in order to save time and make the review more efficient during the full committee meeting, especially in institutions where there are no separate scientific review committees.
- The EC shall have a system of appointing primary and secondary reviewers. The Member Secretary shall identify the primary and secondary reviewers for reviewing the scientific content and the ethical aspects in the proposal as well as the informed consent document, depending upon their individual expertise.
- The Member Secretary shall identify subject experts to review the proposal as per need. These experts shall be invited to the EC meeting or join via video/tele conference but will not participate in final decision making.
- The EC shall meet regularly, adopt best practices, try to reduce turnaround time or have procedures in place for early decision making so that research is not delayed.
- The designated (primary and secondary) reviewers and subject experts shall conduct the initial review of the study protocol and study related documents as per the pre- defined study assessment form.

XII. (a) TYPES OF REVIEW

i) Exemption From Review:

- Proposals with less than minimal risk where there are no linked identifiers,
  For example;
- Research conducted on data available in the public domain for systematic reviews or meta-analysis;
- Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person;
- Quality control and quality assurance audits in the institution;
- Comparison of instructional techniques, curricula, or classroom management methods;
- Consumer acceptance studies related to taste and food quality; and public health programmes by Govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers)

ii) Expedited review

- Proposals that pose no more than minimal risk may undergo expedited review,
  For example;

- Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples;
- Research involving clinical documentation materials that are non-identifiable (data, documents, records);
- Modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s);
- Revised proposals previously approved through expedited review, full review or continuing review of approved proposals;
- Minor deviations from originally approved research causing no risk or minimal risk;
- Progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected SAEs will be conducted by SAE subcommittee; and
- For multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review.
- Research during emergencies and disasters

iii) Full committee review

- All research proposals presenting more than minimal risk that are not covered under exempt or expedited review shall be subjected to full committee review,

Some examples are;

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

XII. (b) ETHICAL ISSUES RELATED TO REVIEWING A PROTOCOL

i) Social values

- The basic requirement for health research to be ethically permissible is that it must have anticipated social value. The outcome of the research shall be relevant to the health problems of society.
- All stakeholders, including sponsors, researchers and ECs must ensure that the planned research has social value.

ii) Scientific design and conduct of the study

- Although ECs shall obtain documentation from a prior scientific review, they shall also determine that the research methods are scientifically sound, and shall examine the ethical implications of the chosen research design or strategy.
- The EC shall raise scientific concerns (even if the study has prior approval of a scientific committee) if it may affect quality of research and or safety of research participants

iii) Benefit-risk assessment

- The benefits accruing from the planned research either to the participants or to the community or society in general shall justify the risks inherent in the research.
- Risks may be physical, psychological, economic, social or legal and harm may occur either at an individual level or at the family, community or societal level. It is necessary to first look at the intervention under investigation and assess its potential harm and benefits and then consider the aggregate of harm and benefits of the study as a whole.
- The EC shall review plans for risk management, including withdrawal criteria with rescue medication or procedures.
- The EC shall give advice regarding minimization of risk/discomfort wherever applicable.
- Adequate provisions shall be made for monitoring and auditing the conduct of the research, including the constitution of a Data and Safety Monitoring Board (DSMB) if applicable (for example in clinical trials)

iv) Selection of the study population and recruitment of research participants

- Recruitment shall be voluntary and non-coercive. Participants shall be fairly selected as per inclusion and exclusion criteria. However, selection of participants shall be distributive such that a particular population or tribe or economic group is not coerced to participate or benefit.
- Participants shall be able to opt out at any time without their routine care being affected.
- No individual or group of people must bear the burden of participation in research without accruing any direct or indirect benefits.
- Vulnerable groups shall be recruited after proper justification is provided.

v) Payment for participation

- Plans for payment for participation, reimbursement of incurred costs, such as travel or lost wages, incidental expenses and other inconveniences shall be reviewed.
- There is a need to determine that payments are not so large as to encourage prospective participants to participate in the research without due consideration of the risks or against their better judgement. No undue inducement shall be offered.

vi) Protection of research participants' privacy and confidentiality

- ECs shall examine the processes that are put in place to safeguard participants' privacy and confidentiality.
- Research records to be filed separately than routine clinical records such as in a hospital setting.

vii) Community considerations

- The EC shall ensure that due respect is given to the community, their interests are protected and the research addresses the community's needs.
- The proposed research should not lead to any stigma or discrimination. Harm, if any, shall be minimized.
- Plans for communication of results to the community at the end of the study shall be carefully reviewed.
- It is important to examine how the benefits of the research will be disseminated to the community.

viii) Qualifications of researchers and adequacy assessment of study sites

- The EC shall look at the suitability of qualifications and experience of the PI to conduct the proposed research along with adequacy of site facilities for participants.

xi) Disclosure or declaration of potential COI

- The EC shall review any declaration of COI by a researcher and suggest ways to manage these.
- The EC shall manage COI within the EC and members with COI shall leave the room at the time of decision making in a particular study.

x) Plans for medical management and compensation for study related injury

- The proposed plan for tackling any medical injuries or emergencies shall be reviewed.
- Source and means for compensation for study related injury shall be ascertained.

xi) Review of the informed consent process

The informed consent process must be reviewed keeping in mind the following:

- The process used for obtaining informed consent, including the identification of those responsible for obtaining consent and the procedures adopted for vulnerable populations;
- The adequacy, completeness and understandability of the information to be given to the research participants, and when appropriate, their lars;
- Contents of the patient/participation information sheet including the local language translations Back translations of the informed consent document in English, Wherever required;
- Provision for audio-visual recording of consent process, if applicable, as per relevant regulations; and If consent waiver or verbal/oral consent request has been asked for, this shall be reviewed by assessing whether the protocol meets the criteria.

XII. (c) FULL COMMITTEE MEETING

- All proposals that are determined to undergo full committee review shall be deliberated and the decision about the proposal taken at a full committee meeting.
- ECs shall conduct regular full committee meetings to deliberate proposals in

accordance with a pre-decided schedule, as described in the SOPs.

- A meeting will be considered valid only if the quorum is fulfilled. This shall be maintained throughout the meeting and at the time of decision making.
- If a member has declared a COI for a proposal then this shall be submitted in writing to the Chairperson before beginning the meeting and shall be recorded in the minutes.
- The member who has declared COI shall withdraw from the EC meeting (leave the room) while the research proposal is being discussed upon. This shall be minuted and the quorum rechecked.
- A list of absentee members as well as members leaving or entering in-between the meeting shall be recorded.
- Proposals shall be taken up item-wise, as given in the agenda.
- No of proposals reviewed in a meeting shall justify that there is ample time devoted for review of each proposal. If there are more number of proposals for consideration per meeting either meetings may be more frequent or more EC's to be constituted as per requirement of the institution.
- Time allotted for the meeting shall be reasonable to allow ample discussion on each agenda item.
- The minutes of the previous meeting and list of protocols that were exempt from review or underwent expedited review shall be ratified
- The researcher shall be called in to present a proposal or provide clarifications on the study protocol that has been submitted for review but shall not be present at the time of decision making.
- The primary and secondary reviewers can brief the members about the study proposal and review carried out as per EC SOPs.
- The comments of an independent consultant (if applicable) shall be presented by the Member Secretary or subject experts shall be invited to offer their views, but they shall not participate in the decision-making process. However, her/his opinion must be recorded.
- Representative(s) of the study group population shall be invited during deliberations to offer their viewpoint but shall not participate in the decision-making process.
- The EC shall utilize electronic methods such as video/conference calls for connecting with other subject experts/independent consultants during the meeting.
- All members of the EC (including the Chairperson and the Member Secretary) present in the room have the right to vote/express their decision and shall exercise this right.
- The decision must be taken either by a broad consensus or majority vote (as per SOP) and shall be recorded. Any negative opinion shall be recorded with reasons.

Types of decisions by EC:

The EC shall give one of the following decisions:

- Approved – with or without suggestions or comments;
- Revision with minor modifications/amendments – approval is given after examination by the Member Secretary or expedited review, as the case may be;
- Revision with major modifications for resubmission – this will be placed before the full committee for reconsideration for approval; or

- Not approved (or termination/revoking of permission if applicable) – clearly defined reasons must be given for not approving/terminating/revoking of permission.

- Approval may be granted for the entire duration of the proposed research or can be subject to annual review depending on the type of study. The EC shall review the annual report (counted from the day of approval or date of actual start of the study) for continuation as per SOP.
- Depending on the risk involved, the progress of the proposal may be monitored annually or at shorter intervals (quarterly, half yearly) as per EC decision. Approval shall be continued if progress is satisfactory.
- An EC may decide to reverse its positive decision on a study if it receives information that may adversely affect the benefit-risk assessment.
- The Member Secretary (assisted by the Secretariat) shall record the discussions and prepare the minutes which shall be circulated to all the members for comments before final approval by the Chairperson/Vice-Chairperson/designated member of the committee.
- The decision of the EC shall be communicated to the researcher along with suggestions, if any.
- The researcher shall have an opportunity to reply/clarify to EC comments or to discuss or present her/his stand.
- The researcher can also approach the head of the institute who serves as an appellate for EC matters.
- The head of the institute as appellate has the power to dissolve the EC or reappoint an EC.

XII. (d) REVIEW OF MULTICENTRIC RESEARCH

Multicentre research is conducted at more than one centre by different researchers, usually following a common protocol. Many clinical trials, clinical studies and public health research including surveys are conducted at several research centers within the country or at international sites. Multicentric research studies are carried out with the primary aim of providing a sound basis for the subsequent generalization of its results. 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. There are concerns, however, related to duplication of effort in the parallel review by the involved ECs, wastage of time and also those related to communication between the committees.

Separate review by ECs of all participating site

- The ECs/Secretariats of all participating sites shall establish communication with one another.
- If any EC does not grant approval for a study at a site the reasons must be shared with other ECs and deliberated upon.
- The EC can suggest site-specific protocols and informed consent modifications

as per local needs.

- Separate review may be requested for studies with a higher degree of risk, clinical trials or intervention studies where conduct may vary depending on the site or any other reason which requires closer review and attention.

Common review for all participating sites in 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. This is especially important for 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.
- The meeting of the designated main EC can be attended by nominated members of ECs of the participating centres to discuss their concerns, if any, about ethics or human rights and to seek solutions and communicate the decision of the main EC to their respective ECs.
- This EC shall be located in India and registered with the relevant authority (if applicable).
- Meetings shall be organized at the initial and, if required, intermediary stages of the study to ensure uniform procedures at all centres.
- The site ECs, however, retain their rights to review any additional site-specific requirements, ensure need-based protection of participants or make changes in the informed consent document (ICD), translations and monitoring research as per local requirements.
- The protocol may be modified to suit local requirements and shall be followed it is duly approved by the EC of the host institutes/decision of main EC is accepted.
- Adherence to protocols, including measures to terminate the participation of the erring local centres, if required, shall be monitored.
- The common review is applicable only for ECs in India. In case of international collaboration for research and approval by a foreign institution, etc., the local participating sites would be required to obtain local ethical approval.
- Sponsor/funding agencies shall be informed about any site-specific changes being made, and the modified version shall only be used by the site concerned.
- Plans for manuscript publication and a common final report with contributors from the participating sites shall be decided upon before initiation of the study.
- Site-specific data may be published only after the appropriate authorities accept the combined report and appropriate permissions are obtained.

XII. (e) CONTINUING REVIEW

- Ongoing research shall be reviewed at regular intervals, at least once a year, (or more often, if deemed necessary depending on the level of risk) or as may be specified in the SOP of the EC and at the time of according to approval, and as indicated in the communication letter.
- The EC shall continually evaluate progress of ongoing proposals, review SAE reports from all sites along with protocol deviations/violations and non-compliance, any new information

pertaining to the research and assess final reports of all research activities.

- Clinical trials under the purview of a licensing authority must comply with all regulations applicable to SAEs. The EC shall also ensure compliance by the researcher. For academic and other trials, an institutional policy shall be established.
- The EC shall examine the measures taken for medical management of SAEs. Participants shall not have to bear costs for the management of study-related injury whether they are in the intervention arm or the control arm.
- Compensation shall be given for research-related injuries if applicable, as determined by the EC and as per regulatory requirement (if applicable).
- For protocol deviations/violations the EC shall examine the corrective actions. If the violations are serious the EC may halt the study. The EC may report to the institutional head/government authorities where there is continuing non-compliance to ethical standards.
- Reports of monitoring done by the sponsor and DSMB reports may also be sought.

XII. (f) SITE MONITORING

- ECs shall follow mechanisms described in a SOP to monitor the approved study site until completion of the research to check for compliance
- Monitoring can be routine or "for cause" and must be decided at a full committee meeting. For research that involves higher risk or vulnerable participants or if there is any other reason for concern, the EC at the time of initial review or continuing review can suggest that routine monitoring may be conducted at more frequent intervals.

Causes for monitoring

The following situations may justify "for cause" monitoring:

- High number of protocol violations/deviations.
- Large number of proposals carried out at the study site or by the same researcher.
- Large number of SAE reports.
- High recruitment rate.
- Complaints received from participants.
- Any adverse media report.
- Adverse information received from any other source.
- Non-compliance with EC directions.
- Misconduct by the researcher; and
- Any other cause as decided by the EC.

XII. (g) RECORD KEEPING AND ARCHIVING

- All documentation and communication of an EC shall be dated, filed and preserved according to written procedures.
- Confidentiality shall be maintained during access and retrieval procedures by designated persons.
- All active and inactive (closed) files shall be appropriately labelled and archived separately in designated areas.

- Records shall be maintained in hard copies as well as soft copies.
- All records shall be archived for a period of at least 3 years after the completion/ termination of the study.
- Documents related to regulatory clinical trials shall be archived for 5 years after the completion/termination of the study or as per regulations.
- Records shall be archived for a longer period, if required by the sponsors/regulatory bodies.
- EC shall describe archival and retrieval mechanisms in SOPs.
- EC records shall be accessible for inspection by authorized representatives of regulatory agencies.
- ECs shall adopt methods for electronic storage of records wherever feasible.

Administrative documents

1. Constitution and composition of the EC
2. Appointment letters
3. Signed and dated copies of the most recent curriculum vitae of all EC members
4. Signed confidentiality agreements
5. COI declarations of members
6. Training records of EC members
7. Financial records of EC
8. Registration/accreditation documents, as required
9. A copy of national and international guidelines and applicable regulations
10. Regulatory notifications
11. Meeting-related documents
12. Agenda and minutes
13. All communications received or made by the EC
14. SOPs

Proposal-related documents

1. One hard copy and a soft copy of the initial research proposal and all related documents
2. Decision letters
3. Any amendments submitted for review and approval
4. Regulatory approvals
5. SAE, AE reports
6. Protocol deviations/violations
7. Progress reports, continuing review activities, site monitoring reports
8. All correspondence between the EC and researchers
9. Record of notification issued for premature termination of a study with a summary of the reasons
10. Final report of the study
11. Publications, if any

XIII. THE TYPE OF PROPOSALS TO BE REVIEWED BY INSTITUTIONAL ETHICS COMMITTEE

The research committee will review scientific and ethical aspects of all types of research studies in collaboration with international organization/university, all dissertation/research projects (undergraduate, post graduate nursing students and Ph.D. research project and individual faculty projects)

XIV. FEES CHARGES:

A reasonable fee for review may also be charged by the EC to cover the expense related to optimal functioning in accordance to Institutional policies. (for those outside the institution)

XV. HONORARIUM TO THE MEMBERS:

Reasonable honorarium for attending the meeting and reimbursement of travelling expense for attending the research ethical committee meeting will be given to the ethical Committee members.

XVI. PROCEDURE FOR RESIGNATION, REPLACEMENT OR REMOVAL OF MEMBERS:

Resignation and disqualification of members:

Resignation: Any member who wishes to resign may do so by submitting a letter of resignation to the chairperson. The resignation will come into effect from the day it is accepted by the chairperson.

Disqualification of EC member due to unbecoming conduct:

1. The process may be initiated if EC chairperson or secretary receives any communication in writing alleging misconduct by a member (provided by member of the public or EC member)

2. The chairperson on satisfying that a prima facie case exists before initiating action. If the chairperson's opinion is that the matter is of grave significance where the integrity of EC could be questioned, the chairperson may suspend the membership of the concerned member until final decision is taken. In this period of suspension, the member will avail any rights, privileges or responsibilities of the member and will not perform any duties as EC member.

3. The chairperson may convene meeting to specifically discuss this issue/matter. The meeting convened will follow the usual rules of quorum. The allegation will be discussed at the IEC meeting and the member alleged of misconduct will be provided adequate opportunity to defend themselves.

4. The member would stand disqualified if members present approve of disqualification by voting (2/3 majority of members present in the meeting and vote). The chairperson will communicate the decision to the member in writing regarding disqualification.

Disqualification due to failure to attend EC meeting:

A member may be disqualified if they fail to attend more than three regular consecutive EC meetings without prior permission or intimation.

Following process will be carried out:

i. Written intimation by the member secretary to the chairperson informing that the member has not attended more than three regular consecutive EC meetings.

ii. The chairperson will initiate the review process of membership of such a member by including in the agenda of the next regular meeting.

iii. A written communication will be sent to the concerned EC member informing them that the issue of disqualification would be discussed at the meeting, inviting the member to be present to put up their case. Alternately, the concerned EC member will be allowed to state his/her arguments regarding unauthorized absence in writing by a letter addressed to the chairperson.

iv. The matter will be discussed and reviewed at the EC meeting. The concerned will be provided adequate opportunity to represent his/her case. If a written communication is received from the concerned member, it will be read and reviewed

v. The chairperson/member secretary will inform the EC members about the cessation of membership by a confidential letter to other EC members or at the next upcoming meeting.

Conditions of appointment/replacement: Members will be appointed to the EC if they accept the following conditions.

1. Shall be willing to be member of EC.

2. Shall be willing to receive work related to the EC.

3. Shall be willing to sign the confidentiality and conflict of interest agreements

4. Meeting, deliberation, application, information on research participation and related matters.

XVII. STANDARD OPERATING PROCEDURES TO BE FOLLOWED BY THE COMMITTEE FOR VULNERABLE POPULATION

A vulnerable category of subjects includes children, prisoners, pregnant women, specially abled persons (physical and mentally), refugees and displaced persons who are likely to be vulnerable to coercion or undue influence. Projects to be subjected to full review by all members when it involves vulnerable and special groups of population.

Adequate justification shall be provided for involving such subjects. Rights and welfare of those unable/incapable to give informed consent shall be protected (individuals mentally challenged/behavioral disorder). Key principle to be followed with vulnerable group is that others will be responsible for protecting their interest because they cannot do so or are in a compromised position to protect their own interest.

Principles for research among vulnerable population:

1. Vulnerable populations have an equal right to be included in research so that they can accrue the benefits which is applicable to them too.

2. If the research focuses solely on the vulnerable group the study shall answer their health needs.

3. Participants shall be empowered /explained to the maximum level so to enable them to make informed consent or not to give assent for participation

4. Extra care shall be taken to ensure participants privacy and confidentiality, so that there is no breach of confidentiality as it would enhance their vulnerability further

5. All stake holders must ensure that safety and protection are in place to ensure the dignity, rights and wellbeing of the vulnerable population is safeguarded.

6. Researcher/s shall include justification if vulnerable population is included in their research.

Role of Ethics committee in case of vulnerable population

i. Ethics committee (EC) must record in their proceedings if they are satisfied with the given justification/s

ii. EC shall strictly review the safety (additional) measures.

iii. EC shall ensure consent process is well documented. Additional measures such as recording of assent and re-consent when applicable shall be ensured.

iv. EC shall carefully determine the benefits and risk/s of the research study and identify/examine strategies to minimize the risk

V. EC shall ensure there is no coercion, force, duress, undue influence, threat or misrepresentation or incentives for participation during the entire period of study as the potential participants are dependent on others.

vi. EC shall ensure protection of privacy, confidentiality and rights of vulnerable population at all times, i.e. during and even after completion of the research

XVIII. OBLIGATION/DUTIES OF STAKE HOLDERS

STAKEHOLDERS	OBLIGATION/DUTIES
Researcher/s	1. Recognize the vulnerability of population and ensure additional safeguards are in place for their protection. 2. Justify inclusion/exclusion of vulnerable population. 3. COI (conflict of interest) issues must be addressed. 4. Ensure a balanced benefit-risk ratio through well-defined procedure. 5. Ensure prospective participants are competent to give informed consent. 6. When a prospective participant in unable/lacks the ability to give consent then take consent from legally authorized representative (LAR). 7. Seek permission from the appropriate authorities where relevant (like for institutionalized individual/s, tribal communities, etc.) 8. Dissent from participant shall be respected. 9. Researcher shall be conducted within the purview of existing relevant regulation/guidelines.
Ethics committee	1. During review determine whether the prospective participant belong to vulnerable group for the proposed research. 2. Evaluate whether the inclusion/exclusion of the vulnerable population is adequately justified. 3. Ensure COI does not increase harm or lessen benefit to the participant. 4. Advice risk minimizing strategies whenever possible after carefully examining benefits and risk to the participants. 5. Suggest more frequent reviews and monitoring including visits for additional safety. 6. It is desirable to have empowered representatives from specific population during deliberation. Only the full ethical committee shall do initial and continuing reviews for such proposals. 7. EC have special responsibility when research is conducted on participants who are suffering from mental illness and/or cognitive impairment. The committee shall exercise caution and would require getting justification from researcher for any exception than the usual requirements of participants or essentiality of departure from the guideline governing research. EC shall ensure that these exceptions are as minimal as possible and clearly spelled out in the ICD. 8. EC shall have SOPs for handling proposals involving vulnerable population.

XIX. POLICY REGARDING TRAINING FOR NEW AND EXISTING COMMITTEE MEMBERS ALONG WITH STANDARD OPERATING PROCEDURES:

- Members shall be trained in human research protection, EC functions and SOPs, ICMR National Ethical Guidelines for Biomedical and Health Research involving Human participants 2017, GCP guidelines (if applicable), New Drugs and Clinical Trails Rules 2019 and relevant regulations of the country.
- EC members shall undergo initial and continuing training in human research protection, applicable EC SOPs and related regulatory requirements. All training shall be documented.
- Any change in the relevant guidelines or regulatory requirements shall be brought to the attention of all EC members.
- EC members shall be aware of local, social and cultural norms and emerging ethical issues.

XX. POLICY TO MONITOR OR PREVENT CONFLICT OF INTEREST ALONG WITH STANDARD OPERATING PROCEDURES:

- If a research scholar believes that an EC member has potential conflict, the researcher/investigator may request in writing to the chairperson to exclude this member from review of their protocol. The request must include substantial evident to justify their claim that a conflict of interest exists with the EC member.
- At the beginning of each meeting, the ECSSCN Chairperson will ask the members to disclose any COI concerning any of the items on the agenda. During the meeting, EC member having conflict discloses the existence of the conflict just before the review of the relevant item begins.
- The COI will be declared in the format provided in SOP of ECSSCN, and submitted to the member secretary.
- The EC members will not participate in discussing, or decision making on research proposals" applications reviewed at any level (exempt: expedited, or full- board) when they have conflicts of interest except to provide information requested by the EC.

XXI. (a) TERMS OF REFERENCE FOR EC

- This SOP includes clear roles and responsibilities of EC members and it will be provided to each one of them during the meeting.
- ECSSCN has formulated own SOPs VERSION 1 JANUARY 2025 based on ICMR guidelines 2017 and amendment will be done as and when required. It will be named as new version.
- A copy of the latest version of SOPs will be made available to each member and they will be trained on the SOPs. The SOPs will be available in the institute of the EC as both hard and soft copies.

- The EC will be registered with the DHR (Department of Health Research).

XXI (b) TERMS OF REFERENCE FOR EC MEMBERS

- The head of the institution will appoint all EC members, including the Chairperson.
- The appointment letter issued to all members will specify the TORs. The letter issued by the head of the institution will include the following:
  - Role and responsibility of the member in the committee
  - Duration of appointment
  - Conditions of appointment
- The SOPs will be updated periodically based on the changing requirements.
- The term of EC membership will be 2 years. The duration could be extended. One third of members can be changed after 2 years depends on availability of person.
- EC members will be given a reasonable honorarium for attendance at the meeting.
- EC would preferably appoint persons trained in bioethics or persons conversant with ethical guidelines and law of the country. Substitute member may be appointed/nominated if meetings have been continuously missed by member due to illness or other unforeseen circumstances.