SRI NARAYANI HOSPITAL
& RESEARCH CENTRE

Standard Operating Procedure (SOP)

For

Sri Narayani Hospital and Research Centre Ethics Committee (SNHRCEC)

Version 2

SRI NARAYANI HOSPITAL
&
RESEARCH CENTRE ETHICAL COMMITTEE SOP

Version:02
Effective date:19.02.2024
Effective upto:19.02.2029

SOP prepared by	Reviewed by	Approved by
Dr Ramprasad Srinivasan Senior Scientist, SNHRC.	Dr. N. Balaji Director, SNHRC.	Dr R Magesh Babu Member Secretary, SNHRCEC.

Contents

1. Name of the Ethical Committee

Sri Narayani Hospital and Research Centre Ethical Committee (SNHRCEC)

2. Authority under which the ethics committee has been constitute

The Director of the Institute as advised by the governing council of SNHRC has constituted the IEC

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3. MEMBERSHIP REQUIREMENTS OF THE ETHICS COMMITTEE

3.1. PURPOSE

This document outlines the process of identifying and composition of members inSNHRCEC.

3.2. SCOPE

This document helps the chairperson and member secretary in maintaining thecomposition of members in SNHRCEC as mandated by Indian GCP and Schedule Y

3.3. RESPONSIBILITY

Chairperson and Member Secretary are responsible for identifying new members and in maintaining the composition of the IEC

Membership requirements of the Ethics Committee

Chairperson/ Vice Chairperson (optional) Non-affiliated Qualifications - A well-respected person from any 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 • 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 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. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting. • Seek COI declaration from members and ensure quorum and fair decision making. • Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.
Member Secretary/ Alternate Member Secretary (optional) Affiliated Qualifications - • Should be a staff member of the institution • Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills Should be able to devote adequate time to this activity which should be protected by the institution	Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review • Schedule EC meetings, prepare the agenda and minutes • Organize EC documentation, communication and archiving • Ensure training of EC secretariat and EC members • Ensure SOPs are updated as and when required • Ensure adherence of EC functioning to the SOPs • Prepare for and respond to audits and inspections • Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review. • Assess the need for expedited review/ exemption from review or full review. Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives. • Ensure quorum during the meeting and record discussions and decisions.

Basic Medical Scientist(s) Affiliated/ non-affiliated Qualifications - • Non-medical or medical person with qualifications in basic medical sciences • In case of EC reviewing clinical trials with drugs, the basic medical scientist should 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.
Clinician(s) Affiliated/ non-affiliated Qualifications - • Should be individual/s with recognized medical qualification, expertise and training	Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics • Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) • Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation. • Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
Legal expert/s Affiliated/ non-affiliated Qualifications - • Should have a basic degree in Law from a recognized university, with experience • Desirable: Training in medical law.	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
• Ethical review of the proposal, ICD along with the translations. • Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any • Serve as a patient/participant/ societal /	• Ethical review of the proposal, ICD along with the translations. • Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any • Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.

community representative and bring in ethical and societal concerns.	
Lay person(s) Non-affiliated Qualifications - • Literate person from the public or community • Has not pursued a medical science/ healthrelated 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 • Desirable: involved in social and community welfare activities	• Ethical review of the proposal, ICD along with translation(s). • Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. • Serve as a patient/participant/ community representative and bring in ethical and societal concerns. • Assess on societal aspects if any.

3.4. REFERENCES

- Schedule Y (Drugs and Cosmetic Act 1940) amendment 2013
- ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR(2017*)*

4. Terms of Reference of the Committee

Purpose:

Sri Narayani Hospital and Research Centre Ethics Committee (SNHRCEC) is involved in continuous oversight of Research and allied activities in its premises. The purpose of this SOP is to provide guidelines that helps in maintaining higher ethical standards, safety practices, protection of study volunteer interest and to maintain higher standards of clinical research

SCOPE

With increase in capacity of clinical research at the hospital, the Director is instituting an SNHRC Ethical Committee called SRI NARAYANI HOSPITAL AND RESEARCH CENTRE ETHICAL COMMITTEE OR SNHRCEC in short. Review of scientific proposals for scientific vigor and safeguarding highest ethical standards will form the core guiding principles of SNHRCEC. The SNHRCEC will review clinical research including student research, investigator-initiated research, extramural, intramural funded research and multi-centric multinational research

- Ensuring the highest scientific and ethical practices are followed at all the trials conducted at SNHRC
- Providing oversight/monitoring in ensuring that protocols are followed without any deviation
- Review applications for scientific and ethical practices on proposal of clinical, basic, translational research project and make decisions of approval, rejection or recommend suitable amendments.
- Review and approve, or withhold approval from amendments to previously approved protocols.
- To review reported Serious Adverse Events and inform appropriate regulatory bodies. Also, make decisions to continue, hold or close the study
- The Ethics Committee shall meet at least quarterly and at such other times as the Chair of the Ethics Committee shall require only if there is reason to conduct.
- The Ethics Committee shall have access to sufficient resources in order to carry out its duties.
- The Ethics Committee is authorised by the Board to obtain outside legal or other independent professional advice.

- Periodical updating SOPs as and when required in accordance to changes in policies of regulatory authorities or by the government or as mandated by the law
- Documents, if any, proving that the members of the committee are conversant with the provisions of clinical trials as per the provisions of D & C Rules and Good Clinical Practice Guidelines for clinical trials in India.

5. Conditions of Appointment and the Quorum Required

- The IEC members name, brief professional details and affiliation shall be published in SNHRC website
- Members must submit a short resume before appointment
- Any conflict of interest must be disclosed
- Members must undergo training related to ethics in clinical research whenever possible and must apprise themselves with the Schedule Y, GCP for clinical trials in India, ICH GCP guidelines and the ICMR guidelines and SNHRCEC SOPs
- Members must sign the conflict of interest declaration form (SNHRCEC/IEC/SOP/17 Version 1) disclosure before the start of their term
- Members must maintain strict adherence to confidentiality about the projects at all times
- Any financial interest must be disclosed
- Other non-financial interest such as participation in the research project as PI, Co-PI or in any other form must be disclosed
- Co-author in a publication of research project submitted to IEC

- The Quorum Requirements are as follows

The number of persons in an Ethcis Committee should have atleast seven members. Ethics Committee should appoint, from among its members, a Chairperson (who is from outside the institution) and a Member Secretary. Other members should be a mix of medical/non-medical, scientific and non-scientific persons, including lay public, to reflect the different viewpoints.

For review of each protocol the quorum of Ethics Committee should be atleast 5 members with the' following representations:

(a) basic medical scientists (preferably one pharmacologist).
(b) clinicians
(c) legal expert
(d) social scientist / representative of non-governmental voluntary agency / philosopher / ethicist / theologian or a similar person
(e) lay person from the community.

In any case, the ethics committee must include at least one member whose primary area of interest / specialization is nonscientific and at least one member who is independent of the institution / trial site. Besides, there should be appropriate gender representation on the Ethics Committee. If required, Subject experts may be invited to offer their views. Further, based on the requirement of research area, e.g. HIV AIDS, genetic disorders etc. specific patient groups may also be represented in the Ethics Committee as far as possible. Only those Ethics Committee members. who are independent of the clinical trial and the Sponsor of the trial should vote / provide opinion in matters related to the study.

6. Procedure for Resignation, Replacement and Removal of Members

- Members who wants to resign should provide prior intimation and communicate the decision by written or through electronic forms well in advance to the Member Secretary that will help him/her to find a suitable replacement
- Member Secretary shall appoint a new member based on the criteria for membership mentioned in SNHRCEC/IEC/SOP/01 Version: 01
- The member can be relieved of his duty if he/she has been found to be involved in misconduct, breach of confidentiality or any other actions that violates the basic structure of IEC
- Members will be automatically disqualified if they fail to attend 3 consecutive meeting without giving prior notice to member secretary
- Disqualification of members shall be communicated to the member in writing and shall be filed and archived in the secretariat
- At the end of the tenure around 50% of the existing members will be replaced with newer members without compromising on the combined expertise of the IEC

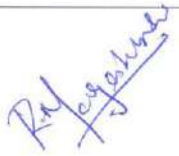
7. Address of the office of the Ethics Committee.

SRI NARAYANI HOSPITAL AND RESEARCH CENTRE
'E' BLOCK, ROOM NO.2,
SRIPURAM, VELLORE-632055, TAMIL NADU, INDIA
PHONE (OFFICE): +91-416-2206300

CONSTITUTION OF ETHICS COMMITTEE

SOP Number: SNHRCEC/IEC/SOP/01 Version: 02

Effective Date : 19.02.2024
Effective Upto : 19.02.2029

SOP prepared by	Dr. Ramprasad Srinivasan Senior Scientist, SNHRC.	
Reviewed by	Dr. N. Balaji Director, SNHRC.	
Approved by	Dr. R. Magesh Babu Member Secretary, SNHRCEC.	

8. Constitution & Composition of Institutional Ethics Committee

SNHRCEC/IEC/SOP/01 Version: 02

Sri Narayani Hospital and Research Centre (SNHRC) is one of the premier hospitals and research facility in Vellore district. SNHRC has been carrying out various research activities under the approval and monitoring of the institution review board since 2009. Thus far no research pertaining to humans were carried out. However, with the pursuit of advancing scientific knowledge with experimental vigor while maintaining safety and ethical standard, SNHRC is registering the ethical committee with CDSCO as mandated for the safety of human participants by the Indian law (Schedule Y).

With increase in capacity of clinical research at the hospital, the Director is instituting an SNHRC Ethical Committee called **SRI NARAYANI HOSPITAL AND RESEARCH CENTRE ETHICAL COMMITTEE OR SNHRCEC** in short. Review of scientific proposals for scientific vigor and safeguarding highest ethical standards will form the core guiding principles of SNHRCEC. The SNHRCEC will review clinical research including student research, investigator-initiated research, extramural, intramural funded research and multi-centric multinational research

A subcommittee of SNHRCEC is also formed known as The Data Safety Monitoring Subcommittee (DSMSC) and will be responsible for monitoring patient safety and assessing data during the course of the study in a manner that contributes to the scientific and ethical integrity of the study**.**

The Institutional Ethics Committees (SNHRCEC) is constituted by the Director of Sri Narayani Hospital and Research Centre (SNHRC) under authority vested by the Governing Council of the Sri Narayani Hospital and Research Centre

8.1. PURPOSE

- Sri Narayani Hospital and Research Centre Ethics Committee (SNHRCEC) is involved in continuous oversight of Research and allied activities in its premises. The purpose of this SOP is to provide guidelines that helps in maintaining higher ethical standards, safety practices, protection of study volunteer interest and to maintain higher standards of clinical research
- The documents will offer guidelines to identify and report and resolve potential conflict of interest

- This document will outline guidelines in maintaining strict confidentiality of identity of study volunteers, study sponsor's intellectual property, and in maintaining confidentiality over study results.

8.2. SCOPE

The SOP is applicable to all the research activities that are planned at SNHRC and comes under the purview of SNHRCEC

8.3. RESPONSIBILITY

- DIRECTOR
  - Responsible for appointing chairperson from outside of institute
  - Responsible for appointing member secretary within institute

- CHAIRPERSON
  - Responsible for head the SNHRCEC meetings and actively engage in the functioning of IEC
  - Coordinate with member secretary in all the activities related to IEC

- MEMBER SECRETARY
  - Responsible that all members sign CDA before any information is shared with the IEC members
  - Responsible for obtaining signature from observers before they attend the meeting
  - Responsible for administrative activities such receipt of proposals, setting up of agenda for IEC meetings, and record minutes of the meetings
  - Member Secretary will be the point person for various stake holders including principal investigators, sponsors, study volunteers and regulatory bodies
  - Responsible for finances and audit of IEC

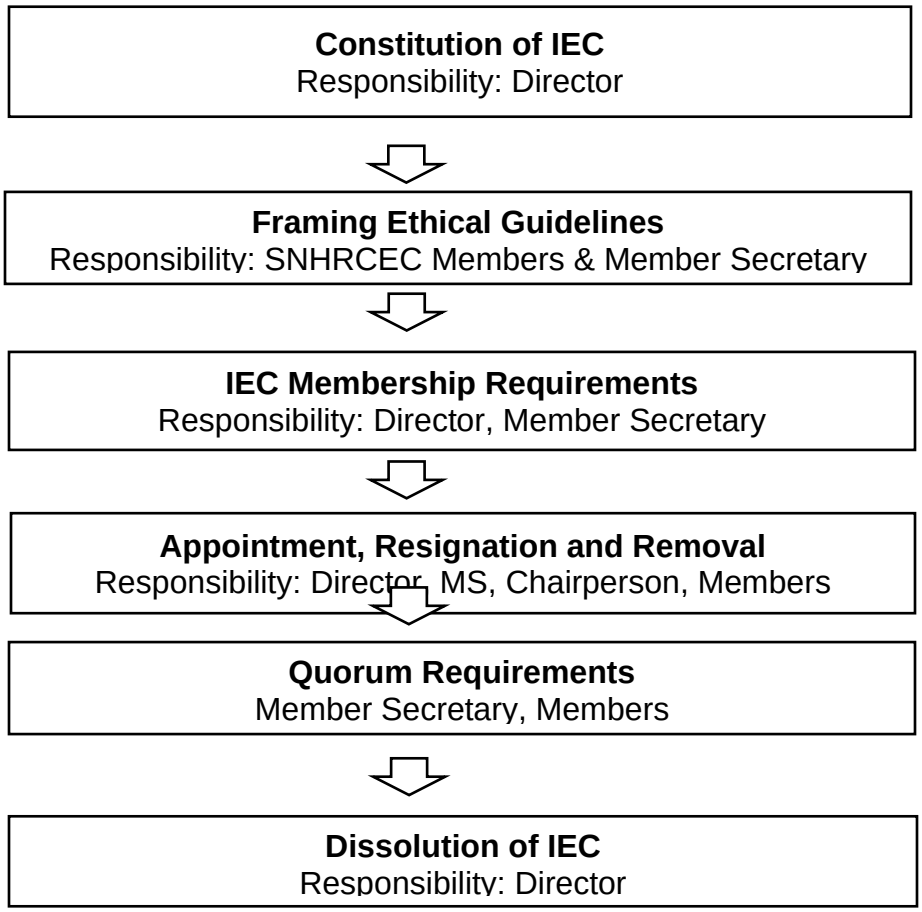
- IEC CO-ORDINATOR
  - IEC Co-Ordinator will assist Member Secretary in all the administrative activities of the IEC

- IEC MEMBERS
  - Complete understanding of the SOP and strict adherence to it
  - Attend IEC meetings regularly

- Understand the scientific proposal and ensure proper scientific and ethical guidelines are followed
- Review and discuss the proposal and seek any clarifications from the principal investigator/sponsor and ensure ethical principles are adhered to.
- Must be willing to undergo trainings/workshop on ethics from time to time
- In the event that the chairperson is absent for a meeting the IEC members can elect an interim chairperson for conducting the meeting

- IEC SECRETARIAT
  - Co-ordinates all administrative activities of IEC
  - Maintains SOP on file
  - Maintains training log of IEC members
  - Maintains minutes of the meetings

8.4. FLOW CHART FOR CONSTITUTION OF SOP



8.5. DETAILED PROCEDURE

- Ethical Framework

  The SNHRCEC will be diligent follow the best practices in the functioning of IEC. The SNHRCEC has formed its own guidelines based on the following publications by national and international bodies. The SNHRCEC is committed to follow rules and guidelines in accordance to national and international requirements.

  - Ethical Guidelines for Biomedical Research on Human participants, ICMR, 2006
  - National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017)
  - National Ethical Guidelines for Bio-Medical Research Involving Children
  - National Guidelines for Stem Cell Research (2017)
  - Good Clinical Practice & Guidelines for Clinical Trials on Pharmaceutical products in India, CDSCO, DGHS, MoHFW, Govt of India, including Schedule Y, 2005
  - Declaration of Helsinki, 2013
  - International Ethical Guidelines for Biomedical Research involving human subjects, Council for International Organizations of Medical Sciences CIOMS, 2002
  - Guideline for Good Clinical Practice E6 (R1), ICH Harmonised Tripartite Guideline, 1996
  - National Committee for Ethics in Social Science Research in Health (NCESSRH)

- **COMPOSITION OF IEC MEMBERS**

  - IEC members will be from various stream and disciplines in order to assess applications with thorough understanding
  - IEC members will from various backgrounds to peruse the application from multiple angles

- One scientific member with specialization in medical science, one non-scientific member and one person from outside of the institution
- The professional shall be from various background such as doctors, lawyers, statistician
- The director shall appoint Chairperson who will be an eminent person outside of the hospital and well versed with the ethical affairs
- Member Secretary shall be a person within the institute and is responsible for all the administrative activities regarding the IEC
- Members suitability shall be assessed by chairperson and member secretary based on their capacity to allot time, expertise and knowledge of ethical principles in research
- The members must sign a CDA and conflict of interest disclosure before sitting on a meeting for a specific project proposal
- All IEC members shall undergo training/workshops related to ethics to keep abreast of changing rules/guidelines i research

- **Membership requirements of SNHRCEC**

  - Members should have good understanding of ethical and/or scientific knowledge and expertise in the scientific or medical domain

  - The members of scientific or clinical experts must have adequate experience and have a post graduate education

  - Members must be willing to allocate time for the review of proposals and attending meetings and workshops that are required to satisfy the efficient functioning of IEC

  - Conflict of interest must be avoided at all times and in the event of unavoidable conflict of interest, a full disclosure must be made in a transparent manner

- **APPOINTMENT, TERMS AND TENURE OF IEC**

  - Director shall appoint Chairperson from outside of institute
  - Director shall appoint Member Secretary from within the institute
  - Director shall receive nomination for regular members from within and institute and is responsible for appointment of members
  - Member Secretary does not have voting rights

- The tenure of appointments shall be 3 years and renewal can be done after the completion of the tenure
- Members must give advance notice to Member Secretary if they wish to be not part of the IEC
- Members must sign CDA and Conflict of Interest disclosure at the beginning of the term
- Other than the member secretary, no member can hold more than 4 terms

- **THE QUORUM REQUIREMENT FOR IS AS FOLLOWS FOR DRUG TRIALS**

  - One basic medical scientist (pharmacology expert preferred)
  - One Clinician
  - One Legal Expert/Retired Judge
  - One social scientist/ representative of non-governmental organization/philosopher/ ethicist/ theologian
  - One Lay person

- **PROCEDURE FOR RESIGNATION, REPLACEMENT OR REMOVAL OF MEMBERS**

  - Members who wants to resign should provide prior intimation and communicate the decision by written or through electronic forms well in advance to the Member Secretary that will help him/her to find a suitable replacement
  - Member Secretary shall appoint a new member based on the criteria for membership mentioned in sections 6.1 and 7
  - The member can be relieved of his duty if he/she has been found to be involved in misconduct, breach of confidentiality or any other actions that violates the basic structure of IEC
  - Members will be automatically disqualified if they fail to attend 3 consecutive meeting without giving prior notice to member secretary
  - Disqualification of members shall be communicated to the member in writing and shall be filed and archived in the secretariat

- **DISSOLVING OF IEC**

  - The IEC can be dissolved at any time by the Director with a written communication to all the members involved. The communication can be documented and archived at the IEC Secretariat

- **SELF ASSESMENT OF IEC FUNCTIONING**

  - SNHRCEC will perform self-assessment on its functional capacity every year

- The self-assessment is based on the risk anticipated by the IEC and on the risk reported by the Principal Investigator
- The self-assessment report shall be prepared by the Member Secretary and presented during the first IEC meeting of every year

- **FINANCIAL RENUMERATION**

  - Institutional policy will determine the financial remuneration for all of its IEC members for review of protocols in the category of full review/exempted/expedited review.

8.6. **ANNEXURE**

- Appointment letter for Chairperson
- Appointment letter of IEC member/Member Initiate

8.7. **REFERENCES**

- ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006*)*
- National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017)
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000. (Geneva 2000)

8.8. **Annexure 1 - Appointment letter for Chairperson**

SNHRCEC/IEC/ANNEXURE/01 Version 01

Director:

Date: DD/MM/YYYY

Dear Dr _____

I am pleased to confirm your appointment as the Chairperson/Member of SNHRCEC. The term of your appointment is for three years effective from date _____. As an Chairperson/Member of SNHRCEC your name will appear in the website of Institution and IEC related records. Your willingness to contribute is greatly appreciated. Please note that your absence of three consecutive IEC meetings shall be considered as your inability to continue as a member of IEC.

Thanking You

Sincerely

Signature of the Director

8.9. Annexure 2 - Appointment letter of IEC member/Member Initiate

SNHRCEC/IEC/ANNEXURE/02 Version: 01

Director:

Date: DD/MM/YYYY

Dear Dr _____

I am pleased to confirm your appointment as the “Member Initiate” of SNHRCEC. The term of your appointment is for three years effective from date _____. As an Chairperson/Member of SNHRCEC your name will appear in the website of Institution and IEC related records. Your willingness to contribute is greatly appreciated. Please note that your absence of three consecutive IEC meetings shall be considered as your inability to continue as a member of IEC.

Thanking You

Sincerely

Signature of the Director

WRITING SOP

SOP Number: SNHRCEC/IEC/SOP/02 Version: 01

Effective Date : 19.02.2024
Effective Upto : 19.02.2029

SOP prepared by	Dr. Ramprasad Srinivasan Senior Scientist, SNHRC.	
Reviewed by	Dr. N. Balaji Director, SNHRC.	
Approved by	Dr. R. Magesh Babu Member Secretary, SNHRCEC.	

ABBREVIATIONS:

S.NO	ABBREVIATION	EXPANDED FORM
1	SOP	Standard Operating Procedure
2	ICMR	Indian Council of Medical Research
3	GCP	Good Clinical Practice
4	SNHRCEC	Sri Narayani Hospital Research Centre's Ethical Committee
5	IEC	Institutional Ethical Committee
6	IRB	Institutional Review Board
7	CRO	Contract Research Organization
8	CDA	Confidentiality Disclosure Agreement
9	GCP	Good Clinical Practice
10	ICH	International Conference on Harmonization
11	CTA	Clinical Trial Agreement
12	SAE	Serious Adverse Event
13	NCE	New Chemical Entity
14	NME	New Molecular Entity
15	DCGI	Drug Controller General of India
16	DGFT	Director General of Foreign Trade

9. WRITING SOP: STANDARD TEMPLATE FOR WRITING, REVIEWING PROCESS, APPROVAL AND AMENDMENT PROCESS FOR INSTITUTIONAL ETHICS COMMITTEE

SNHRCEC/IEC/SOP/02 Version: 01

9.1. PURPOSE

- This document outlines the process of writing Standard Operating Procedures (SOP) on how to write SOP, a standard format for writing SOP, the review of SOP, amendment of SOP from time to time in the institutional ethics committee.

- The SOP will provide clear instruction on writing SOPs and other allied processes in an effort to standardize activities in line with the Ethical Guidelines for Biomedical Research on Human Participants - ICMR (2006), National Ethical Guidelines For Biomedical Research Involving Children: ICMR (2017), National Guidelines for Stem cell Research – ICMR (2017) , Indian GCP and Schedule Y, WHO Operating Guidelines for Ethical Review Committee that review Biomedical Research and ICH (International Conferences on Harmonization) Good Clinical Practice (GCP)

9.2. SCOPE

This document provides the details on the procedure to be followed in writing SOP of SNHRCEC, review, and the amendment process.

9.3. RESPONSIBILITY

- CHAIRPERSON
  - Responsible for appointing a SOP writing team
  - Oversee and finalize the list of SOPs
  - Review and approve SOP by Signing and Dating

- MEMBER SECRETARY
  - Responsible for appointing a SOP writing team
  - Oversee and finalize the list of SOPs
  - Review and approve SOP by Signing and Dating
  - Responsible of adherence of SOP writing team to the prescribed format and contents
  - Appoint IEC/IRB secretariat

- IEC CO-ORDINATOR
  - Co-ordinate all activities regarding SOP writing, review, distribution, SOP management, archiving and amendment of SOP
  - Management of SOP up to date
  - Distribute SOP to all IEC members
  - Upload and maintain SOP on institutional website
  - Monitor and report that all IEC members are following the laid-out SOP

- IEC SECRETARIAT

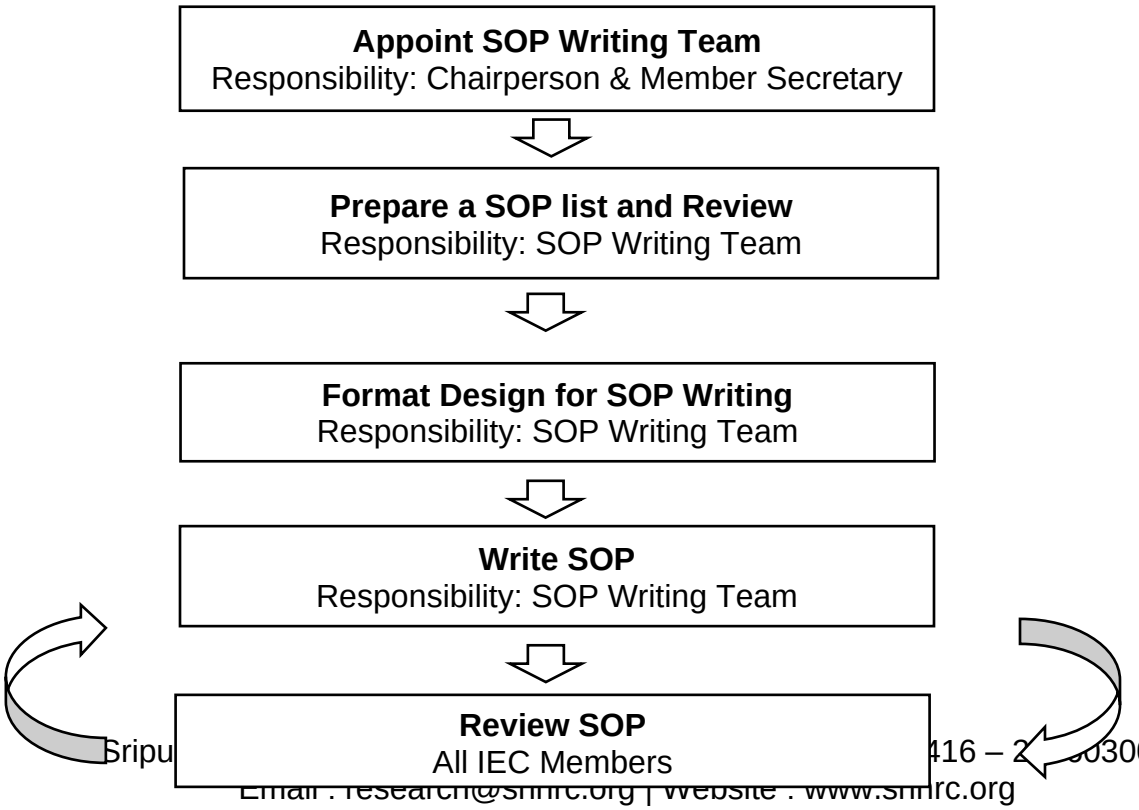
- Co-ordinate activities related to writing, review, distribution and approval
- Maintain SOP files
- Engage with IEC members in conducting meetings
- Maintain minutes of the meetings
- Perform archiving and retrieval of SOP and other documents

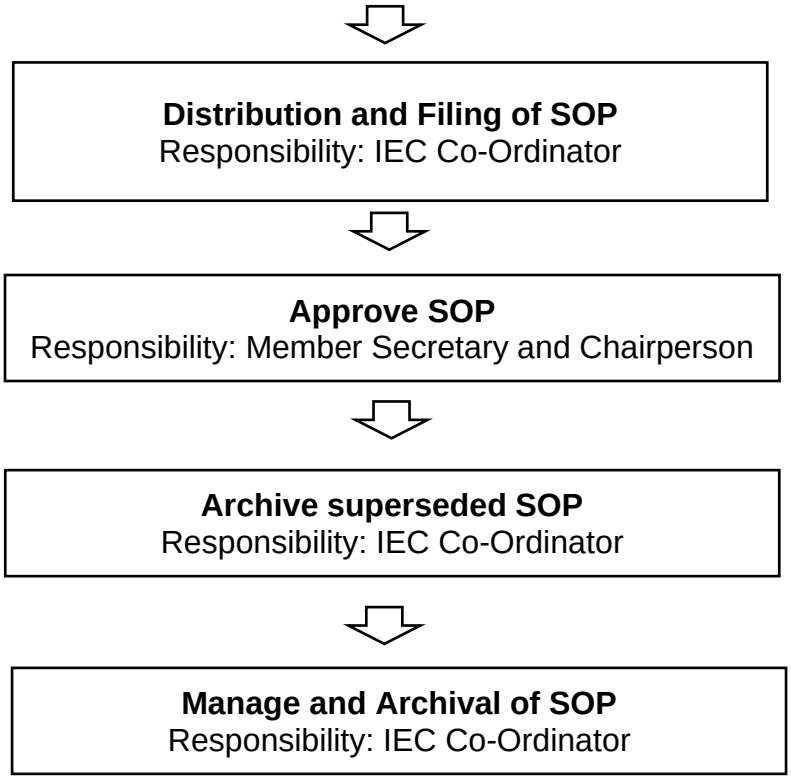
- SOP WRITING TEAM

  - Read and understand published guidelines for writing SOP
  - Responsible for preparing of SOP draft and submit it to Member Secretary
  - Responsible for review, amendment of SOP

- IEC MEMBERS
  - Review SOP
  - Discuss SOP in the IEC meeting
  - Approve, sign and date

9.4. FLOW CHART





9.5. DETAILED PROCEDURE

- TITLE PAGE
    - The first page or the title page should contain the title of the SOP that is concise and unambiguous
    - The title page must contain the SOP number in the format SNHRCEC/IEC/SOP/XX (XX are number starting from 01)
    - The version number post approval of the SOP must be written in the format Version XX (XX are numbers starting from 01)
    - The title page will have signed date and signatures of person responsible for writing and review
    - The title page will also have signed date and signatures of person responsible for approving the SOP

- SOP LAYOUT

- The SOP shall begin with a list of abbreviations that are commonly used in the SOP
- Any changes from the superseded SOP must be highlighted
- The next section will be titled as “Purpose” that will clearly state the purpose of this SOP
- The next section will be titled as “Scope” that clearly states the goal, responsibilities, SOP applicability.
- The next section will be titled as “Procedure” that will give clear, sufficient and precise details of the SOP.
- The next section will be titles as “Appendix” that will provide additional details regarding the SOP. The appendix page will be labelled with a unique number in the format SNHRC/IEC/SOP/XX Appendix XX Version XX Dated DDMMYYYY

- SOP FORMAT

  - Write SOP in a bulleted step wise manner
  - Follow a coherent order and use simple language
  - Present a flow chart for easy understanding
  - Avoid usage of gender wherever applicable and use common reference such as they, their and them.
  - Use date format DDMMYYY throughout the document
  - The given SOP template as in SNHRCEC/IEC/ANNEXURE/01 Version.01 shall be used

- SOP REVIEW AND FINALIZATION

  - A SOP review committee must be formed by the chairperson and member secretary
  - The SOP review committee will be responsible for careful reading of SOP and must provide comments in writing
  - The SOP writing committee must implement the suggestions by the SOP review committee and send it back to SOP review committee
  - SOP review committee must finalize the SOP ifthey find it satisfactory
  - After finalization, SOP review committee must send the SOP to the Chairperson and Member Secretary for approval
  - The SOP must be presented in the IEC meeting and finalized subject to the approval of IEC members
  - The SOP will be effective from the date of approval

- DISTRIBUTE AND IMPLEMENT SOP

- The SOP will be distributed among ethical committee members and applicable personnel by the IEC Co-Ordinator
- The SOP will be filed at the IEC office by the IEC Co-Ordinator
- The SOP shall be uploaded onto the institute website by the IEC Co-Ordinator

- AMENDMENT OF SOP

  - Any IEC member can request to amend the SOP if they feel that the SOP can be improved or if they can find any inherent flaw in the SOP
  - The amendment must be requested in SOP change request form as in SNHRCEC/IEC/ANNEXURE/02 Version.01
  - Member secretary shall discuss the SOP request and accept the request for change if the IEC members agree
  - No action will be taken if the IEC members do not agree. Approval of the amendment will be taken up in a meeting when there is sufficient quorum when both Chairman and Member Secretary are present.
  - The decision of Member Secretary and Chairperson will be final

- SOP MANAGEMENT AND ARCHIVAL

  - The current and active version of SOP shall be maintained in a master file at the IEC office by the IEC Co-Ordinator
  - All SOP of the IEC must be uploaded in the IEC website for public viewing
  - Superseded SOP must be clearly marked and archived in a separate master file.

- DEVIATION

  - SOP that are not followed or that are difficult to follow could be identified by internal or external audits by the Sponsors/CROs/regulatory authorities. The SOP that cannot be followed must be reported to IEC Co- Ordinator or the member secretary

9.6. ANNEXURES

- SOP template
- SOP change request form
- List of SOP
- Training log

9.7. REFERENCES

- Schedule Y (Drugs and Cosmetic Act 1940) amendment 2013

- ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR
- (2006*)*
- National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017)
- National Ethical Guidelines for Bio-Medical Research Involving Children National Guidelines for Stem Cell Research (2017)
- European Convention on Human rights and Biomedicine (1997).
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000. (Geneva 2000)

9.8. Annexure 3 - SOP Template

SNHRCEC/IEC/ANNEXURE/03 Version.01

1. TITLE PAGE
   - SOP Title
   - SOP Number
   - SOP Version
   - Superseded Version
   - Written by – Sign the Date of person responsible for writing SOP
   - Reviewed by – Sign and Date of person responsible for SOP review
   - Approved by – Sign and Date of Member Secretary or Chairperson with designation name
   - Effective Date

2. BODY OF THE SOP

   - Abbreviations
   - Purpose – A brief statement on the purpose of the SOP
   - Scope – A brief statement on the situation in which the SOP is applicable, responsibilities and state the range of activities
   - Responsibility – Name the person(s) or group responsible for complying with the SOP
   - Flow Chart
   - Procedures – Provide a clear step by step protocol
   - Appendix – Provide any ancillary information including templates
   - Deviations – Provide details on reporting process if an SOP cannot be followed

9.9. Annexure 4 – SOP change request form

SNHRCEC/IEC/ANNEXURE/04 Version 01

SOP Number
Title of the SOP
Details of Problems or Deficiency
Name and Designation of the Member Date:
Details to be Filled by Member Secretary
Presented the Problem during IEC meeting on : Date: DDMMYYYY
Recommend SOP revision: ☐ Yes ☐ No
If No, Give Reason
New SOP to be Written ☐ Yes ☐ No
Signature of Member Secretary Date: DDMMYYYY

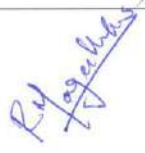
Annexure 5 – List of SOP
SNHRCEC/IEC/ANNEXURE/05 Version 02

S.No	Title	SOP Code	Version
1	Constitution of Ethics Committee	SNHRCEC/IEC/SOP/01	02
2	Writing SOP	SNHRCEC/IEC/SOP/02	01
3	Confidentiality Agreement	SNHRCEC/IEC/SOP/03	01
4	Receipt of application and Initial review process	SNHRCEC/IEC/SOP/04	01
5	Protocol Review	SNHRCEC/IEC/SOP/05	01
6	Expedited Review	SNHRCEC/IEC/SOP/06	01
7	Exempted Review	SNHRCEC/IEC/SOP/07	01
8	Resubmission of Amended Protocol and Review Process	SNHRCEC/IEC/SOP/08	01
9	Reviewing of Ongoing Study Protocols	SNHRCEC/IEC/SOP/09	01
10	Submission Final Report and Review	SNHRCEC/IEC/SOP/10	01
11	Reporting, Monitoring and Evaluation of Serious Adverse Events	SNHRCEC/IEC/SOP/11	01
12	Site Monitoring	SNHRCEC/IEC/SOP/12	01
13	Agenda, Procedures and Recording of Minutes of IEC Meeting	SNHRCEC/IEC/SOP/13	01
14	Maintenance of Ongoing Study Files, Archiving, Disposal and Retrieval of Documents	SNHRCEC/IEC/SOP/14	01
15	SOP for Review of Studies Involving Vulnerable Populations	SNHRCEC/IEC/SOP/15	01
16	Training of Ethical Committee Members	SNHRCEC/IEC/SOP/16	01
17	Conflict of Interest Declaration	SNHRCEC/IEC/SOP/17	01
18	Online Meeting	SNHRCEC/IEC/SOP/18	02
19	Application Review Fee	SNHRCEC/IEC/SOP/19	02

CONFIDENTIALITY AGREEMENT

SOP Number: SNHRCEC/IEC/SOP/03 Version: 01

Effective Date : 19.02.2024
Effective Upto : 19.02.2029

SOP prepared by	Dr. Ramprasad Srinivasan Senior Scientist, SNHRC.	
Reviewed by	Dr. N. Balaji Director, SNHRC.	
Approved by	Dr. R. Magesh Babu Member Secretary, SNHRCEC.	

10. CONFIDENTIALITY AGREEMENT

SNHRCEC/IEC/SOP/03 Version: 01

10.1. PURPOSE

- To protect the Sponsor/Investigators and Study Volunteers interest in ensuring confidentiality and thereby protecting their interests

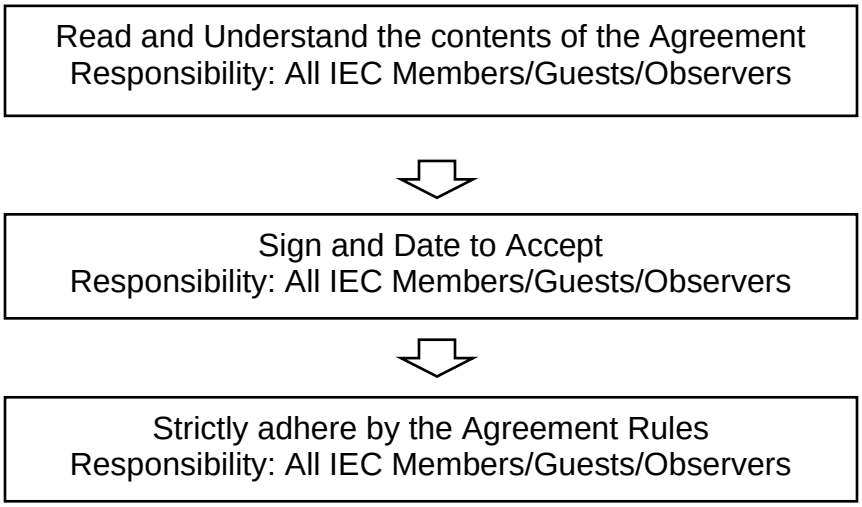
10.2. SCOPE

- Reading and signing of the Confidentiality agreement by all SNHRCEC members concerned

10.3. RESPONSIBILITY

- All SNHRCEC members must sign the Confidentiality Agreement in the beginning of their tenure as IEC members
- Chairperson and Member Secretary must sign the Confidentiality Agreement at the beginning of IEC constitution
- All Guest attendees and Observers must sign the Confidentiality Agreement before attending the IEC meeting
- Member Secretary must file the Confidentiality Agreement and must be available with the IEC Secretariat

10.4. FLOWCHART



10.5. DETAILED PROCEDURE:

- Members at the beginning of their tenure will carefully read the agreement and clarify doubts if any with Member Secretary and Chairperson
- Sign and Date the agreement
- Strictly adhere to the spirit of the agreement
- Member Secretary is responsible for filing the agreement with the IEC Secretariat

10.6. ANNEXURE

- Confidentiality agreement template

10.7. REFERENCES

- Schedule Y (Drugs and Cosmetic Act 1940) amendment 2013
- ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006*)*
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

10.8. ANNEXURE 7 - CONFIDENTIALITY AGREEMENT

SNHRCEC/IEC/ANNEXURE/07 Version 01

I _____ appointed as _____ of the SNHRCEC agree to not divulge any confidentiality and proprietary information pertaining to SNHRCEC to any third party for personal or other gains. I also agree not to copy, reproduce or disclose any information to any medium except when required by law. I understand that this agreement is binding on me indefinitely even after I part services from that SNHRCEC.

Member Name Member Signature

Date: _____

RECEIPT OF APPLICATION AND INITIAL REVIEW PROCESS

SOP Number: SNHRCEC/IEC/SOP/04 Version: 01

Effective Date : 19.02.2024
Effective Upto : 19.02.2029

SOP prepared by	Dr. Ramprasad Srinivasan Senior Scientist, SNHRC.	
Reviewed by	Dr. N. Balaji Director, SNHRC.	
Approved by	Dr. R. Magesh Babu Member Secretary, SNHRCEC.	

11. RECEIPT OF APPLICATIONS IN PRESCRIBED FORMAT

SNHRCEC/IEC/SOP/04 Version 01

11.1. PURPOSE

- To receive applications in the prescribed format with complete details for the review of the study protocol by the SNHRCEC

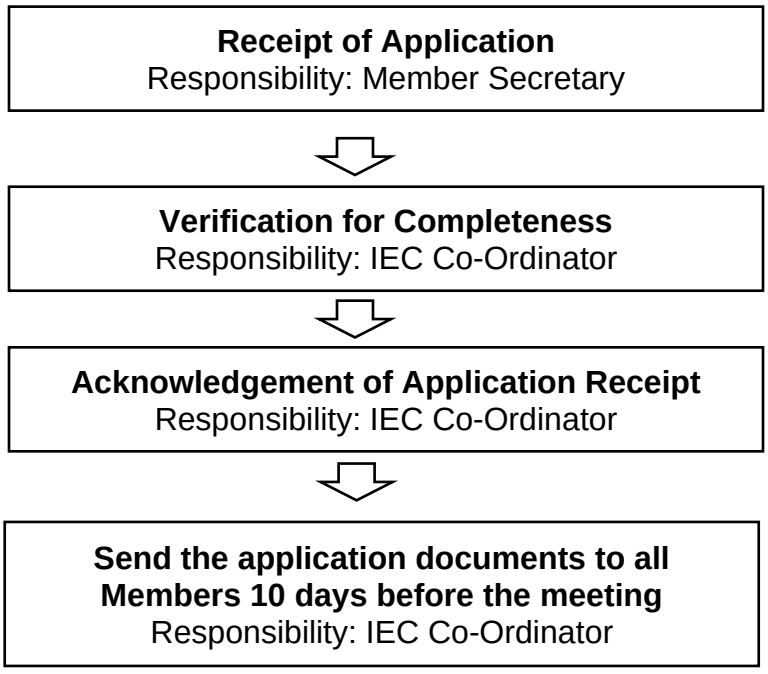
11.2. SCOPE

- The procedure to receive applications for review at the SNHRCEC

11.3. RESPONSIBILITIES

- Member Secretary shall be responsible for receipt of applications
- Members Secretary shall appoint IEC Co-Ordinator for coordinating with the sponsors/investigators on receipt of applications
- IEC Co-Ordinator facilitates the receipt of applications in the prescribed format

11.4. FLOW CHART



11.5. DETAILED PROCEDURE

- The PI must submit three hard copies of the protocol along with required forms (SNHRCEC/IEC/ANNEXURE/08 Version 01, SNHRCEC/IEC/ANNEXURE/09 Version 01, SNHRCEC/IEC/ANNEXURE/10 Version 01). PI must also submit a electronic copy of the protocol and associated documents
- For Ongoing/completed study PI shall use annexure SNHRCEC/IEC/ANNEXURE/11 Version: 01
- IEC Coordinator/Member Secretary will verify the documents for completeness (SNHRCEC/IEC/ANNEXURE/12 Version 01)
- Since the funding agencies now require an approval process on a concept proposal, before a full proposal is developed, the SNHRCEC has this provision. Concept proposals showing full budget and investigators list are to be presented. If the concept proposal is approved by the funding agency, the investigators may develop a full proposal. In the full proposal, appropriate consent form and clinical questionnaire should be provided with translation in local languages (Tamil). The review process will be as decided by the chairman and member secretary.
- Consent form for adults and assent form for minors are mandatory to submit along with the application.
- All Clinical Trials must go through a full application process, before the study is initiated.

- A cover letter in the prescribed format must be enclosed along with the protocol (SNHRCEC/IEC/ANNNEXURE/10 Version 01)
- If the application is incomplete the IEC Coordinator will intimate the PI
- IEC meeting takes place every three months and the timelines are given below
- 1st meeting - Between Jan 1 – Jan 15, 2nd meeting – Between April 1 – April 15, 3rd meeting – Between July 1 – July 15, 4th meeting – Between October 1st – October 15.
- Applications must be 3 weeks before the IEC meeting

11.6. ANNEXURE

- Letter for Submission of Application for Initial Review/Resubmission
- Documents Checklist submission for Initial Review
- Details of Ongoing/Completed/Terminated Study
- Checklist for verifying completeness of submission

11.7. REFERENCES

- Schedule Y (Drugs and Cosmetic Act 1940) amendment 2013
- ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006)

- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

11.8. Annexure 8 - Letter for Submission of Application for Initial Review/Resubmission

SNHRCEC/IEC/ANNNEXURE/08 Version 01

Date: [DD/MM/YYYY]
Place:

From
Name [Principal Investigator]
Designation, Department & Affiliation

To,
The Member Secretary
SNHRCEC
Sri Narayani Hospital and Research Centre, Thirumalaikodi, Vellore
Sub: Protocol submission for IEC review

Dear Sir/Madam

We are interested in carrying out research on a project entitled "_____" in SNHRC. We are submitting the duly filled application herewith as hard copy document along with a softcopy. We request you take up this proposal for a discussion in the next IEC meeting.

Sincerely

(Sign here)

Name of the Principal Investigator

11.9. ANNEXURE 9 - UNDERTAKING BY THE INVESTIGATOR

SNHRCEC/IEC/ANNNEXURE/09 Version 01

1. Full name, address and title of the Principal Investigator (or Investigator(s) when there is no Principal Investigator)

2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, and / or any other statement(s) of qualification(s)

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 investigation (s).

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.
(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 *I* favorable opinion from the Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard(s) to the trial Subjects or when the changers) involved are only logistical or administrative in nature.

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

(iv) I agree to inform all Subjects; 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 OCP 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 and CGP 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 / inspection by the Sponsor, Ethics Committee, Licensing Authority or their authorized representatives, in accordance with regulatory and OCP provisions. I will fully cooperate with any study related audit conducted by regulatory officials or authorized 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 unexpected serious adverse events to the Sponsor as well as the Ethics Committee within seven days of their occurrence.

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

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

8. Signature of Investigator with Date

11.10. ANNEXURE 10 - Documents Checklist submission for Review

SNHRCEC/IEC/ANNEXURE/10 Version 01

S.No	Description	Particulars	
1	Title of the Research Proposal		
2	Protocol number		
3	Type of Submission:	☐ Initial Review ☐ Resubmission ☐ Protocol Amendments ☐ Ongoing Review ☐ Completed Study ☐ Termination of Protocol	
3	Name of the PI, Designation, Department		
4	Name of Co-PI, Designation, Department		
5	Funding Source		
6	Duration of the proposed study		
	Will the research proposal be submitted to Health Ministry Screening Committee (HMSC) for International Collaboration	☐ Yes ☐ No	
	Does the research proposal require ICMR central ethics committee approval	☐ Yes ☐ No	
7	Information about the study for Volunteers		
	English	☐ Yes	☐ No
	Tamil	☐ Yes	☐ No
	Hindi	☐ Yes	☐ No
	Bengali	☐ Yes	☐ No
8	Informed Consent from Study Volunteers		
	English	☐ Yes	☐ No
	Tamil	☐ Yes	☐ No
	Hindi	☐ Yes	☐ No

	Bengali	☐ Yes	☐ No
9	Translation of Informed Consent		
	Tamil	☐ Yes	☐ No
	Hindi	☐ Yes	☐ No
	Bengali	☐ Yes	☐ No
10	Back translation of Informed Consent		
	Tamil to English	☐ Yes	☐ No
	Hindi to English	☐ Yes	☐ No
	Bengali to English	☐ Yes	☐ No
11	Translation Certificate	☐ Yes	☐ No
12	Back Translation Certificate	☐ Yes	☐ No
13	Give details on anticipated risks and mitigation strategy		
14	Will the study participants receive compensation for travel, accommodation and incidental expenses? If yes give details	☐ Yes	☐ No
15	Indemnity insurance	☐ Yes	☐ No
16	Clinical Trial Insurance	☐ Yes	☐ No
17	Clinical Trial Agreement	☐ Yes	☐ No
18	Undertaking by the Investigator	☐ Yes	☐ No
18	Any other relevant information	☐ Yes	☐ No
19	DCGI approval/submission letter	☐ Yes	☐ No
20	CV of Principal Investigator	☐ Yes	☐ No
21	Soft copy submission	☐ Yes	☐ No
22	Signature of Principal Investigator		

11.11. ANNEXURE 11 - DETAILS OF ONGOING/COMPLETED/TERMINATED STUDY

SNHRCEC/IEC/ANNEXURE/11 Version: 01

S.No	Description	Particulars
1	SNHRCEC Protocol Number	
2	Title of the Research Proposal	
3	Name of PI, Designation, Department	
4	Name of Co-PI, Designation, Department	
5	Funding Source	
6	Duration of the proposed study	
7	Date of Study Approval	
8	Name of Study Sponsor	
9	Name of CRO	
10	Study Initiation Date	
11	Study End Date	
12	DCGI approval Date	
13	Central Trial Registry of India Date	
14	Number of Volunteers/Patients from SNHRC	
	Screened	
	Recruited	
	Dropout	
15	Any Serious Adverse Events, if Yes, Provide Details	
16	Were there deviations from protocol, if yes, provide details of submission of revised protocol/amendment and approval date	
17	Publications if any, provide details	
18	Does the study require Extension, if Yes provide justification	
19	Signature of Principal Investigator	

11.12. ANNEXURE 12 - CHECKLIST FOR VERIFYING COMPLETENESS OF SUBMISSION

SNHRCEC/IEC/ANNEXURE/12 Version 01

1. SNHRCEC Protocol Number:

2. Type of Submission:

   ☐ Initial Review
   ☐ Resubmission
   ☐ Protocol Amendments
   ☐ Ongoing Review
   ☐ Completed Study
   ☐ Termination of Protocol

3. Protocol Title:

4. Name of PI

5. Designation, Department

6. Institute

7. Initial Review Packet

   ☐ Initial Review Form/ Re-Submission Form
   ☐ Protocol
   ☐ Protocol Related Documents
   ☐ Patient Information Sheet
   ☐ Informed Consent
   ☐ Informed Consent (Vernacular)
   ☐ Case Report Form
   ☐ Data Collection Form
   ☐ Investigative Brochure if applicable

☐ Others

8. Resubmission after Initial Review Packet

☐ SNHRCEC Initial Review decision letter
☐ Initial Review Form/ Re-submission form
☐ Revised protocol with date
☐ Protocol Summary page listing changes from previous versions
☐ Protocol Related Documents with version and date

☐ Patient Information Sheet
☐ Case Report Form
☐ Data Collection Form
☐ Investigative Brochure if applicable
☐ Informed Consent
☐ Informed Consent (Vernacular)
☐ Others

9. Re-Submission after Initial Review Packet

☐ SNHRCEC Initial Review decision letter
☐ Initial Review Form/ Re-submission form
☐ Revised protocol with date
☐ Protocol Summary page listing changes from previous versions
☐ Protocol Related Documents with version and date

☐ Patient Information Sheet
☐ Case Report Form
☐ Data Collection Form
☐ Investigative Brochure if applicable
☐ Informed Consent
☐ Informed Consent (Vernacular)
☐ Others

10. Protocol Amendment Packet

☐ Letter of Request for amendment from PI
☐ Ongoing/Completed/Terminated protocol review form
☐ List the amendments and audit as annexure
☐ Reasons for Amendments

☐ Anticipated risk to the study subjects
☐ Protocol Summary page listing changes from previous versions
☐ Protocol Related Documents with version and date

☐ Patient Information Sheet ☐ Informed Consent
☐ Case Report Form ☐ Informed Consent (Vernacular)
☐ Data Collection Form ☐ Others
☐ Investigative Brochure if applicable

11. Ongoing Review Packet

☐ Ongoing / completed / terminated protocol Review Submission Form
☐ Protocol amendment if any
☐ Study completed / terminated, if applicable

12. Completed Study Packet

☐ Ongoing / completed / terminated protocol Review Submission Form
☐ Final report

13. Study Termination Packet

☐ Ongoing / completed / terminated protocol Review Submission Form
☐ Reasons for termination
☐ Final Report if available

PROTOCOL REVIEW

SOP Number: SNHRCEC/IEC/SOP/05 Version: 01

Effective Date : 19.02.2024
Effective Upto : 19.02.2029

SOP prepared by	Dr. Ramprasad Srinivasan Senior Scientist, SNHRC.	
Reviewed by	Dr. N. Balaji Director, SNHRC.	
Approved by	Dr. R. Magesh Babu Member Secretary, SNHRCEC.	

12. SOP ON PROTOCOL REVIEW PROCESS

SNHRCEC/IEC/SOP/05 Version: 01

12.1. PURPOSE

- The purpose of this document is to guide the IEC members on the important aspects to be considered while reviewing a protocol

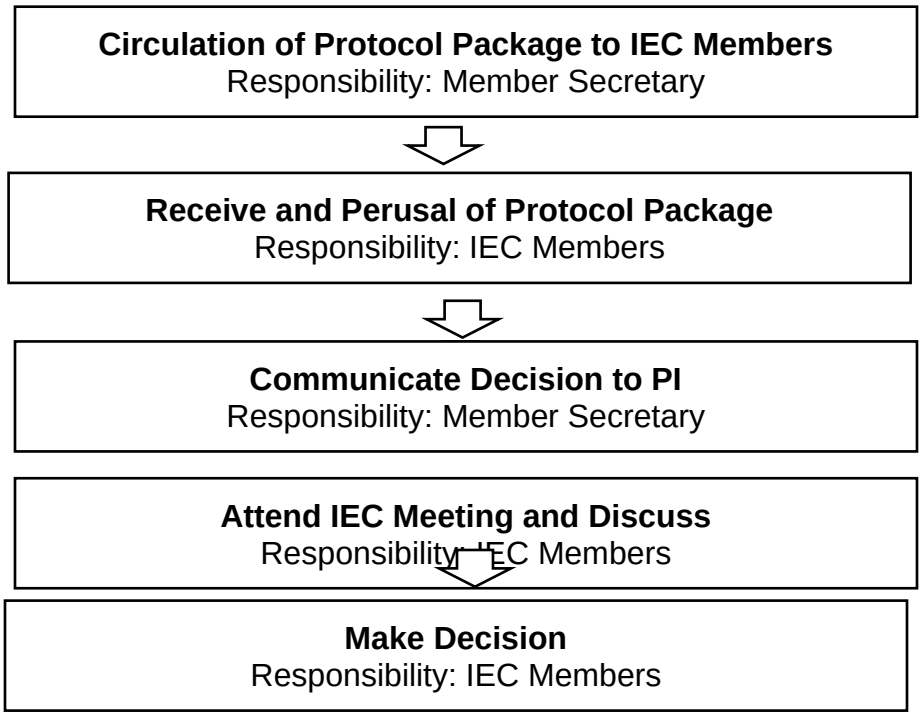
12.2. SCOPE

- The process to be followed by the IEC members for application review and applies to all IEC members

12.3. RESPONSIBILITY

- Member Secretary shall circulate among members all the applications that will be discussed in the forthcoming meeting
- All members shall carefully read the application and give their comments during the IEC meeting

12.4. FLOW CHART



File and Archive Documents
Responsibility: IEC Secretariat

12.5. DETAILED PROCEDURE

- All IEC Members will receive the protocol package 2 weeks in advance to the IEC meeting
- Depending on the nature and risk of trial, Member Secretary will categorize the protocol for
  - a) Initial Review
  - b) Expedited Review
  - c) Exempted Review
- Members receive the package and check for completeness
- In general, the IEC/IRB will review proposals for Science, Ethics and Finance.
- Members read and evaluate the proposal for its usefulness, risk/benefit to the population, study design (SNHRCEC/IEC/SOP/05 Version 01)
- Members discuss the proposal during the IEC meeting

The IEC is responsible to review protocols based specific guidelines issued by ICMR, with special focus on scientific merit, informed consent, and feasibility of the study. The following sections provide a general framework on the review process to be followed.

12.6. DECISION MAKING PROCESS GUIDELINES

- SCIENTIFIC DESIGN AND FEASIBILTY
  - Is the proposal new or novel?
  - Does it add incremental or paradigm shift to the scientific knowledge?
  - Is the study design sound?
  - Does the study justify the use of human participants?
  - Does the number of participants used in the trial justified?
  - Has statistical analysis methods well defined?
- RISK/BENEFIT ANALYSIS

  As per the ICMR guidelines, the following situations can be considered as minimal risk

Collection of blood samples either from finger prick, heel prick, ear prick or venipuncture from

- Healthy adults and non-pregnant women who weigh normal for their age and not more than 500 ml blood is drawn in an 8 week period and frequency of collection is not more than 2 times per week.

- From other adults and children, where the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected has been considered and not more than 50 ml or 3 ml per kg whichever is lesser, is drawn in an 8-week period and not more than 2 times per week

- From neonates depending on the haemodynamics, body weight of the baby and other purposes not more than 10% of blood is drawn within 48 – 72 hours.

Prospective collection of biological specimens for research purposes by noninvasive means. For instance:

- skin appendages like hair and nail clippings in a non-disfiguring manner;
- dental procedures - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction of permanent teeth; supraand subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth;
- excreta and external secretions (including sweat);
- un cannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum or by applying a dilute citric solution to the tongue
- placenta removed at delivery;
- amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
- mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
- sputum collected after saline mist nebulization and bronchial lavages.

Collection of data through noninvasive procedures routinely employed inclinical practice. Where medical devices are employed, they must be cleared/approved for marketing, for instance -

- physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy in to the participant or an invasion of the participant's privacy;
- weighing or testing sensory acuity;
- magnetic resonance imaging;
- electrocardiography, echocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow,
- moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Research involving clinical materials (data, documents, records, or specimens) that will be collected solely for non-research (clinical) purposes.

Collection of data from voice, video, digital, or image recordings made for research purposes.
Research on individual or group characteristics or behavior not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

12.7. Role and Responsibilities of IEC Members

A. SNHRCEC Member -Clinician

The Clinician Member of IEC shall evaluate the protocol for the risk/benefit analysis that includes but not limited to the following

- Standard of Care
- Placebo Use
- Dosing
- Medications
- Age Group
- Inclusion and Exclusion Criteria
- Study Procedures

B. SNHRCEC Member- Pharmacologist/Basic Medical Scientist

The Pharmacologist/Basic Medical Scientist Member of IEC shall evaluate the protocol for the risk/benefit analysis that includes but not limited to the following

- Investigator Brochure
- Drug Safety Data
- Pharmacokinetics/Pharmacodynamics of the drug
- Laboratory Procedures
- Use of biological samples

C. SNHRCEC Member- Legal Expert

The SNHRCEC Member- Legal Expert Member of IEC shall evaluate the protocol for the risk/benefit analysis that includes but not limited to the following

- Clinical Trial Agreement (CTA)
- Insurance
- Indemnity
- Confidentiality
- Any other legal issues pertaining to IEC

D. SNHRCEC Member- Social Scientist/Other Members

The SNHRCEC Member- Legal Expert Member of IEC shall evaluate the protocol for the risk/benefit analysis that includes but not limited to the following

- Informed Consent Process
- Compensation
- Vulnerable populations
- Post study access to data
- Community requirements

E. SNHRCEC Member- Lay Person

- Participant perspective
- Informed consent
- Community benefit

12.8. General Review Considerations of the study protocol:

- Whether the scientific rational is clear and adequate
- Whether statistical aspects such as sample size, statistical tests have been clearly defined
- Whether the study end points are measurable, interpretable and meets the study objective
- Whether research design is appropriate

- Whether study reporting process has been clearly established

12.9. General Review Guidelines for Participant Protection

- Whether the investigator is competent and infrastructure required for the study is present
- Whether there is provision of medical care for the study volunteers
- Whether there is a SOP for SAE events
- Whether there are provision of the study volunteers need to withdraw from the study
- Whether adequate information is available regarding the compensations of study subjects
- Whether there is clear mention on compensation owing to injury

12.10. General Review Guidelines for Informed Consent Process

- Whether informed consent form is available in languages know to the study participants
- Ensuring that audio visual recording of the informed consenting process is available for trials involved with New Chemical Entity or New Molecular Entity
- In the event that the trial involves participants in the age group of 7-12, the participants informed consent and parents informed consent are obtained
- An impartial witness must be made available if the participant is illiterate
- Whether Informed Consent Process is adequate for vulnerable population

12.11. General Review Guidelines for Budget, Compensation, Insurance and other Financials

The legal expert- Member IEC will be responsible for reviewing the clinical trial agreement for financials

- Whether adequate information is given on budget details under various heads
- Whether trial insurance is in place to cover the study subjects for injury due to all clauses mentioned in Rule 122DAB
- Screen CTA for validity of Insurance, Coverage, liability limit
- Budget for indemnity that covers liability of the investigator and sponsor
- Whether liabilities and indemnities are clearly defined

12.12. General Review Guidelines for review for protection of vulnerable population

- Whether the inclusion of vulnerable population is justified
- Any study that includes vulnerable population must be subjected to a full review
- Study subject who are economically weaker must not be used to benefit the economically affluent section
- Proper justification must be provided if the study involves participants from students, employees, prisoners etc..

12.13. DECISION MAKING

- After discussion on the study protocol the following decisions shall be taken with a complete consensus by IEC members. If no consensus is reached, a decision shall be taken by voting

- The decision shall be either a) Approval b) resubmission with minor modifications c) resubmission with major modifications d) not approved

- The committee shall then determine the frequency of ongoing review for approved protocols

- If the study is recommended for re-submission after a minor or major review, the committee shall decide whether the re-submitted application is to be taken through an expedited review or a full review

- Communication of decision to PI
    - The IEC secretariat shall communicate the decision of the IEC to the PI with a copy to the Director of SNHRC (SNHRCEC/IEC/ANNEXURE/15 Version: 01)
    - The certificate of IEC full board approval shall be given to the PI once approved (SNHRCEC/IEC/ANNEXURE/14 Version 01)
    - If the decision is for resubmission or not approved a communication shall be sent along with the appropriate reasons for the decision (SNHRCEC/IEC/ANNEXURE/15 Version 01)

12.14. ANNEXURE

- Protocol Assessment Form
- Certificate of Institute Ethics Committee
- IEC Initial Review Decision Letter

12.15. REFERENCES

- Schedule Y (Drugs and Cosmetic Act 1940) amendment 2013
- ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006*)*
- National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017)
- National Ethical Guidelines for Bio-Medical Research Involving Children National Guidelines for Stem Cell Research (2017)
- European Convention on Human rights and Biomedicine (1997).
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000. (Geneva 2000)
- Tata Memorial Centre SOP - 2016

12.16. ANNEXURE 13 - PROTOCOL ASSESSMENT FORM

SNHRCEC/IEC/SOP/13 Version 01

Protocol Number	Date (DD/MM/YYYY)
Protocol Title	
Principal Investigator	
Co-Investigator	
Type of Review	☐ New ☐ Revised ☐ Amended
Number of Sites	
Number of Participants at the site	
Duration of the Study	
Reviewer Name	
Objectives of the Study	☐ Clear ☐ Not Clear Comments:
Need for Human Participants	☐ Yes ☐ No
Methodology	☐ Clear ☐ Not Clear Comments:
Background Information and Data	☐ Sufficient ☐ Not Sufficient Comments:
Inclusion Criteria	☐ Appropriate ☐ Not Appropriate Comments:
Exclusion Criteria	☐ Appropriate ☐ Not Appropriate Comments:

Study has Vulnerable Population	☐ Yes ☐ No Comments:
Does PI qualify and has experience to conduct study	☐ Yes ☐ No Comments:
Availability of Similar Studies	☐ Yes ☐ No Comments:
Discontinuation and withdrawal criteria / Inappropriate	☐ Appropriate ☐ Inappropriate Comments:
Justification and use of placebo	☐ Yes ☐ No Comments:
Is Informed Consent Process appropriate?	☐ Appropriate ☐ Inappropriate Comments:
Adequate measures for Privacy and Confidentiality protection	☐ Yes ☐ No Comments:
Provision for Medico/Phycological support	☐ Yes ☐ No Comments:
Provision for Treatment of Study-Related Injuries	☐ Appropriate ☐ Inappropriate Comment
Provision for Compensation	☐ Appropriate ☐ Inappropriate Comment:

Provision for post-trial access	☐ Appropriate ☐ Inappropriate Comment
Provision for payments	☐ Appropriate ☐ Inappropriate Comment
Provisions for monitoring the data to ensure the safety of participants	☐ Yes ☐ No Comment

12.17. ANNEXURE 14 - Certificate of Institute Ethics Committee

SNHRCEC/IEC/ANNEXURE/14 Version 01

A proposal entitled "_____

_____

_____

SNHRCEC Protocol Number _____Submitted by PI _____

_____ to the Institutional Ethics Committee was reviewed at the

meeting held on DD/MM/YYYY under the chairmanship of _____

The following members of IEC were present during the meeting

Name of the Member	Affiliation

After deliberation the committee, the IEC approves/rejects the proposal with the following recommendations. Please note the approval is subject is following conditions. The failure to meet the following conditions may result in the termination of the study.

Terms of Approval:

1. The study had been approved for a term of _____ years. If an extension is required, please apply for extension with justifications and summary of findings that needs to presented at a IEC meeting

2. Reporting of SAE must be done with 24 hours of an adverse event.
3. A detailed report on SAE must be submitted within 7 days.
4. IEC approval must be obtained for any change or amendment in the protocol
5. IEC shall monitor the study at any time during the course of the project without any intimation

Member Secretary

Copy to PI: Name, Designation
Copy to: Director, SNHRC
Copy to File at IEC Secretariat

12.18. ANNEXURE 15 - IEC Initial Review Decision Letter

SNHRCEC/IEC/ANNEXURE/15 Version: 01

To,

The Principal Investigator
Affiliation
Institution

Sub: Decision on IEC initial review for the proposal number – (SNHRCEC Protocol no)

Dear Sir/Madam,

A proposal entitled "_____

_____

_____

SNHRCEC Protocol Number _____Submitted by PI _____

_____ to the Institutional Ethics Committee was reviewed at the

meeting held on DD/MM/YYYY under the chairmanship of _____

The following members of IEC were present during the meeting

S.No	Name of the Member	Affiliation

After deliberation the committee, the IEC requires a re-submission addressing the following comments

OR

After deliberation the committee, the IEC rejects the proposal for the following reasons

Member Secretary

Copy to PI
Copy to Director
Copy to file at IEC Secretariat

EXPEDITED REVIEW

SOP Number: SNHRCEC/IEC/SOP/06 Version: 01

Effective Date : 19.02.2024
Effective Upto : 19.02.2029

SOP prepared by	Dr. Ramprasad Srinivasan Senior Scientist, SNHRC.	
Reviewed by	Dr. N. Balaji Director, SNHRC.	
Approved by	Dr. R. Magesh Babu Member Secretary, SNHRCEC.	

13. SOP ON EXPEDITED REVIEW

SNHRCEC/IEC/SOP/06 Version: 01

13.1. PURPOSE

- To define the criteria in choosing study protocols for expedited review and management, review and approval process

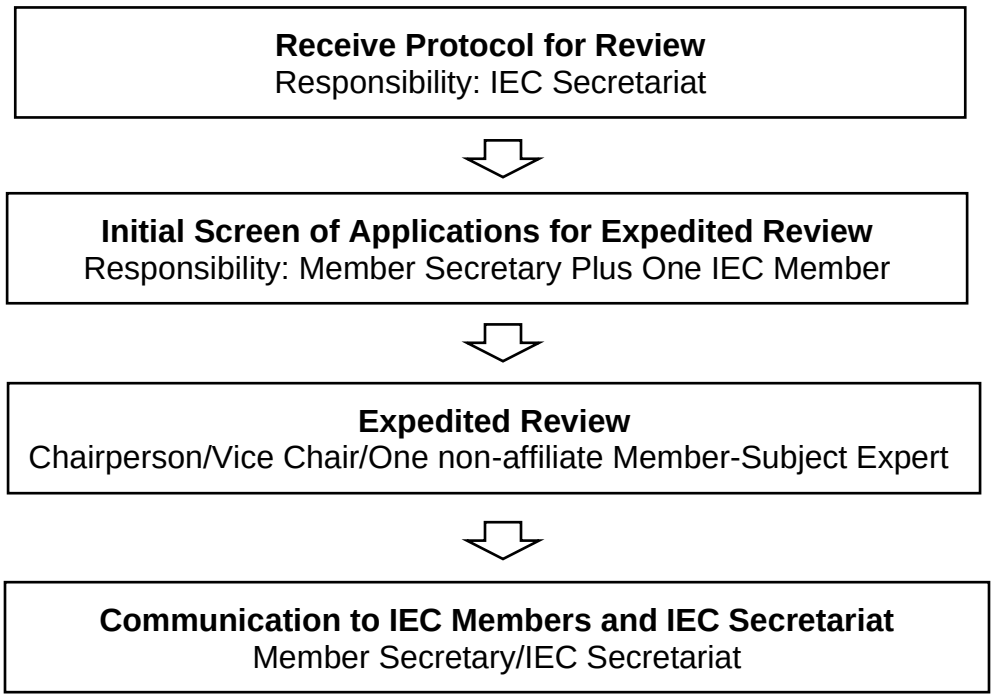
13.2. SCOPE

- This scope of the SOP is to provide guidelines in identifying select submitted protocols that have minimal risk to participants

13.3. RESPONSIBILITY

- IEC Member Secretary and one IEC member will initially screen applications that may qualify for exempted review

13.4. FLOW CHART



13.5. DETAILED PROCEDURE

- IEC Secretariat receives the application submitted by the Investigator/Sponsor
- IEC Secretariat reviews the application for completeness
- IEC informs Member Secretary
- Member Secretary and One affiliate member will review whether the application can be considered for expedited review as per the below guidelines
- Resubmission of protocol with minor modifications carried out based on initial review
- Minor protocol revisions that does not pose risk to the participants such as visits, minor changes in volume of blood drawn
- Change of Principal Investigator
- Data analysis
- Research involving data, documents or biological specimens that have been already collected and unlinked from personal identifiers or information of study participants
- Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.

13.6. EXPEDITED REVIEW PROCESS

- Re-submitted protocol shall be checked whether the PI has addressed the queries presented during the initial review process by the Member Secretary
- Member Secretary shall send, the documents submitted for expedited review, IEC member expedited review decision letter to Chairperson, Vice Chair and one non-affiliate member
- Protocol assessment form (SNHRCEC/IEC/SOP/10 Version: 01)
- The Expedited reviewers shall take decision unanimously and if consensus is not reached the protocol shall be sent to full board review
- The decision taken by the reviewers shall be communicated to the IEC Secretariat along with the protocol assessment form

- Communication of the Decision to PI (SNHRCEC/IEC/ANNEXURE/17 Version 01)
- On approval of the study, MS will issue the Certificate of Institutional Ethics Committee Expedited approval (SNHRCEC/IEC/ANNEXURE/16 Version 01) to the PI
- If the study is not approved, MS will communicate the decisions to the PI (SNHRCEC/IEC/ANNEXURE/17 Version 01
- MS will inform the SNHRCEC on the approved/not approved applications of the exempted review)

13.7. ANNEXURE:

- Certificate of Institute Ethics Committee – Expedited Review Approval
- Protocol Amendments – Expedited Review Approval
- Protocol Amendments – Expedited Review – Resubmission/ Not Approved

13.8. REFERENCES

- Schedule Y (Drugs and Cosmetic Act 1940) amendment 2013
- ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006*)*
- European Convention on Human rights and Biomedicine (1997).
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

13.9. ANNEXURE 16 - Certificate of Institute Ethics Committee – Expedited Review Approval

SNHRCEC/IEC/ANNEXURE/16 Version 01

A proposal entitled "_____

_____

_____

SNHRCEC Protocol Number _____Submitted by PI _____

_____ to the Institutional Ethics Committee was expediently reviewed

at the meeting held on DD/MM/YYYY under the chairmanship of _____

The following members of IEC were present during the meeting

Name of the Member	Affiliation

After Deliberation it was decided to approve the proposal through expedited process

Member Secretary

Copy to Principal Investigator
Copy to Director
Copy to file at IEC Secretariat

13.10. ANNEXURE 17 - Protocol Amendments – Expedited Review Approval

SNHRCEC/IEC/ANNEXURE/17 Version 01

To,

The Principal Investigator
Affiliation
SNHRC

Sub: Decision on IEC protocol review for the proposal number – (SNHRCEC Protocol no)

Dear Sir/Madam,

A proposal entitled "_____

_____

_____

SNHRCEC Protocol Number _____Submitted by PI _____

_____ to the Institutional Ethics Committee for protocol amendment

was reviewed at the meeting held on DD/MM/YYYY under the chairmanship of

_____

The following members of IEC were present during the meeting

Name of the Member	Affiliation

After deliberation the committee, approves the amended protocol

OR

After deliberation the committee, the IEC rejects the amendment of the protocol for the following reasons

Member Secretary

Copy to PI
Copy to Director
Copy to file at IEC Secretariat

13.11. ANNEXURE 18 - Protocol Amendments – Expedited Review – Resubmission/ Not Approved

SNHRCEC/IEC/ANNEXURE/18 Version 01

To,
The Principal Investigator
Affiliation
SNHRC

Sub: Decision on IEC Expedited protocol review for the proposal number – (SNHRCEC Protocol no)

Dear Sir/Madam,

A proposal entitled "_____

_____

_____

SNHRCEC Protocol Number _____Submitted by PI _____

_____ to the Institutional Ethics Committee for protocol amendment

was reviewed at the meeting held on DD/MM/YYYY under the chairmanship of

_____

The following members of IEC were present during the meeting

Name of the Member	Affiliation

After deliberation the committee, the IEC requires the protocol to be re-submitted addressing the following recommendations

OR

After deliberation the committee, the IEC rejects the approval of amendment to the protocol

Member Secretary

Copy to PI
Copy to Director
Copy to file at IEC Secretariat

EXEMPTED REVIEW

SOP Number: SNHRCEC/IEC/SOP/07 Version: 01

Effective Date : 19.02.2024
Effective Upto : 19.02.2029

SOP prepared by	Dr. Ramprasad Srinivasan Senior Scientist, SNHRC.	
Reviewed by	Dr. N. Balaji Director, SNHRC.	
Approved by	Dr. R. Magesh Babu Member Secretary, SNHRCEC.	

14. EXEMPT REVIEW

SNHRCEC/IEC/SOP/07 Version 01

14.1. PURPOSE:

- The purpose of this SOP is to identify protocols that pose minimal risk to the participants and shall be subjected to a exemption from IEC review.

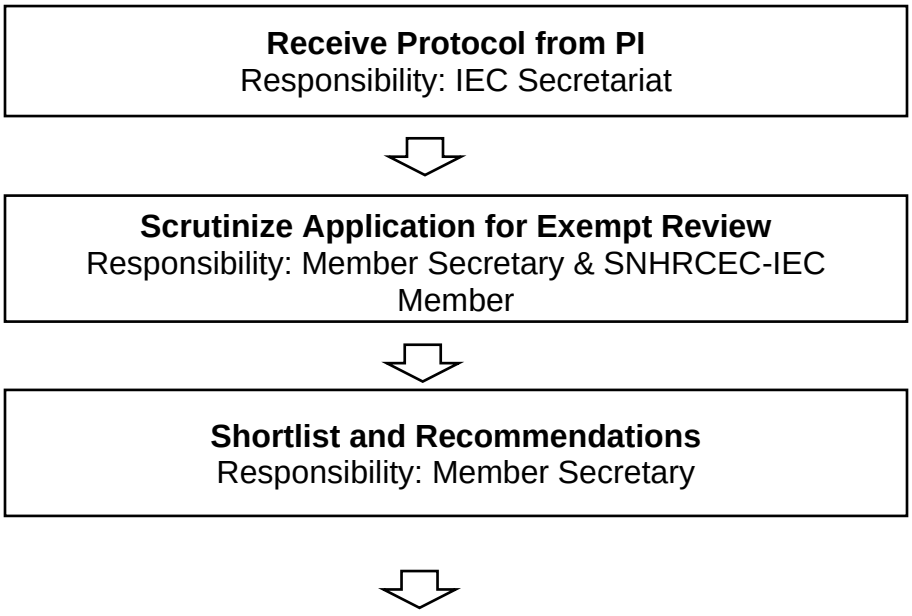
14.2. SCOPE:

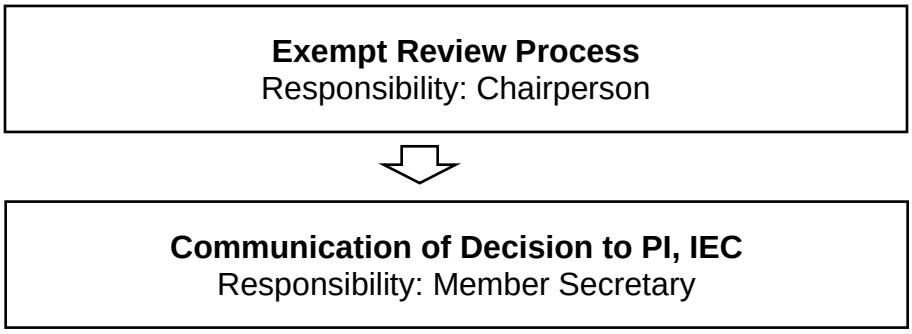
- The scope of this SOP is to provide certain guidelines in identifying proposals that pose minimal risk to the stud participants.

14.3. RESPONSIBILTY

- Member Secretary shall screen and determine the protocol that can be subjected to exempt review and send it to Chairperson for approval
- IEC Members – one affiliate member shall work with member secretary to determine the protocols for exempt review
- Chairperson shall approve the protocol for exempt review based on its merits and communicate the decision to all IEC member during the following IEC meeting

14.4. FLOW CHART





14.5. DETAILED PROCEDURE

- Guidelines for Exempt Review Determination
  - Protocols that pose very minimal risk for the study participants such as research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods
  - Studies that involve immortalized cell lines, microbes that can be cultured in laboratory, research on data availability in the public domain, research on cadavers or death certificates without identifying personal data
- Exceptions:
  - 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.
  - When interviews involve direct approach or access to private papers.
- The protocol cannot be considered for exempt review if it involves the following situations
  - Harm to Dignity, Psychological and emotional harm, Social harm and Informational risk
  - Cannot obtain informed consent involving human participants
  - Vulnerable population

- Breaches privacy and Confidentiality
- Studies based on Deception
- Audio/Video recording without consent

- Exempt Review Process

  - IEC Secretariat receives protocol and associate documents from the PI (SNHRCEC/IEC/ANNEXURE/08-11 Version: 01)
  - IEC Secretariat check the protocol for its completeness (SNHRCEC/IEC/ANNEXURE/12)
  - IEC Secretariat passes the protocol to Member Secretary for review process
  - Member Secretary and one affiliate IEC member scrutinize protocols and determine whether the protocol falls under exempt review based on the guidelines from the previous section
  - Member Secretary delegates the IEC secretariat to send a packet of protocols and documents to Chairperson that qualifies the screening process of exempt review
  - The Chairman receives the packet and determines whether the protocol qualifies for exempt review or for a full review
  - Chairman communicates his decision to IEC secretariat (SNHRCEC/IEC/ANNEXURE/20)
  - The Member Secretary will issue an Exempt Review Certificate to the PI (SNHRCEC/IEC/ANNEXURE/21)
  - The MS will inform the PI by sending a decision letter if the proposal is not approved for exempt review
  - The MS will communicate the Exempt Review approved and not approved proposals to all IEC members in the following IEC meeting

14.6. ANNEXURE

- Cover letter for Sending Protocols to Chairperson for Exempt Review
- Report of Exempted Review
- Certificate of Institute Ethics Committee- Exempt Review

14.7. REFERENCES

- Schedule Y (Drugs and Cosmetic Act 1940) amendment 2013
- ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006*)*

- European Convention on Human rights and Biomedicine (1997).
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000. (Geneva 2000)

14.8. ANNEXURE 19 - Cover letter for Sending Protocols to Chairperson for Exempt Review

SNHRCEC/IEC/ANNEXURE/19

Date:

To
Chairperson
SNHRCEC

Dear Sir/Madam

Please find herewith the proposal attached for consideration for exempt review. Kindly revert with your decision. The exempt review decision form is attached herewith.

Proposal Title: _____

_____

_____

SNHRCEC Protocol No: _____

Documents Enclosed:

Member Secretary

CC: Director

14.9. ANNEXURE 20 - Report of Exempted Review

SNHRCEC/IEC/ANNEXURE/20

1. Project Title

2. SNHRCEC Protocol Number

3. PI Name:

4. Name of the Reviewer:

5. Comments:

6. Decision ☐ Approved for Exempt Review

☐ Resubmit for expedited Review

☐ Resubmit for Full Board Review

Signature:

Date:

14.10. ANNEXURE 21 - Certificate of Institute Ethics Committee- Exempt Review

SNHRCEC/IEC/ANNEXURE/21

A proposal entitled "_____

_____

_____

SNHRCEC Protocol Number _____Submitted by PI _____

_____ to the Institutional Ethics Committee was reviewed under Exempt review. Since the proposed work involves minimal risk to study participants, the study is exempted from SNHRCEC review

Name of the Member	Affiliation
	Chairperson
	Member Secretary

After deliberation the committee, the IEC approves/rejects the proposal with the following recommendations. Please note the approval is subject is following conditions. The failure to meet the following conditions may result in the termination of the study.

Member Secretary Date:

RESUBMISSION OF AMENDED PROTOCOL AND REVIEW PROCESS

SOP Number: SNHRCEC/IEC/SOP/08 Version: 01

Effective Date : 19.02.2024
Effective Upto : 19.02.2029

SOP prepared by	Dr. Ramprasad Srinivasan Senior Scientist, SNHRC.	
Reviewed by	Dr. N. Balaji Director, SNHRC.	
Approved by	Dr. R. Magesh Babu Member Secretary, SNHRCEC.	

15. AMENDED PROTOCOL REVIEW PROCESS

SNHRCEC/IEC/SOP/08 Version 01

15.1. PURPOSE:

- This document outlines the procedure of receipt of documents for protocol amendment and the ensuing review process

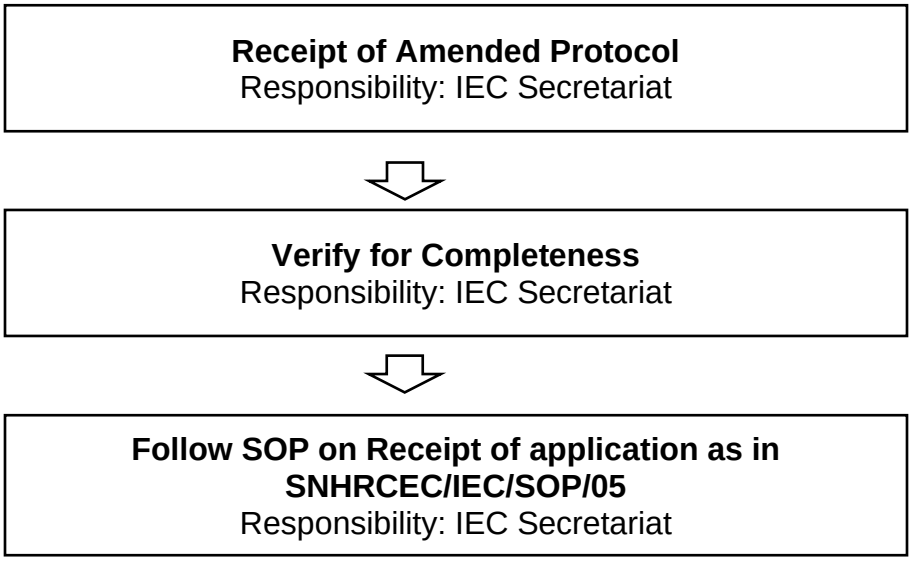
15.2. SCOPE:

- This SOP scope applies to the IEC review process of an amended protocol that may include administrative or technical. The IEC review of amended protocol is required process before the start of the project

15.3. RESPONSIBILITY

- IEC Secretariat – Receive the submission documents and verify for its completeness and make sure that the changes are highlighted along with the summary of changes
- IEC Secretariat will follow the procedures of SOP - SNHRCEC/IEC/SOP/08

15.4. FLOW CHART



15.5. DETAILED PROCEDURE:

- PI submits the amended protocol to IEC Secretariat highlighting the sections that have been changed from the initially submitted protocol and provides a summary of the changes in the first page
- IEC Secretariat checks the documents for its completeness
- IEC Secretariat sends the document to Member Secretary
- Member Secretary along with one affiliate member reviews the amended protocol based on the following guidelines

  - ❖ If the amendments detailed in the protocol do not carry any risk to the participants, data quality, credibility, privacy, then the protocol shall be reviewed by expedited review process (SNHRCEC/IEC/SOP/08). Examples of minor amendments are such as administrative changes to the protocol, notes on Insurance policy, approvals from DCGI and DGFT

  - ❖ If the amendment detailed in the protocol are technical in nature that may add risk to the participants, credibility of data, privacy, then it shall be subjected to a full board review (SNHRCEC/IEC/SOP/05).

  - ❖ The Member Secretary shall communicate the decision to the PI on whether the protocol is approved/need to re-submit addressing IEC comments/not approved

  - ❖ If the amended protocol is not approved the Member Secretary shall communicate the decision to the PI with the reasons for rejection

15.6. ANNEXURES:

- Receipt of application as in SNHRCEC/IEC/SOP/04

15.7. REFERENCES

- ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006)
- European Convention on Human rights and Biomedicine (1997).
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000. (Geneva 2000)

REVIEWING OF ONGOING STUDY PROTOCOLS

SOP Number: SNHRCEC/IEC/SOP/09 Version: 01

Effective Date : 19.02.2024
Effective Upto : 19.02.2029

SOP prepared by	Dr. Ramprasad Srinivasan Senior Scientist, SNHRC.	
Reviewed by	Dr. N. Balaji Director, SNHRC.	
Approved by	Dr. R. Magesh Babu Member Secretary, SNHRCEC.	

16. REVIEWING OF ONGOING STUDY PROTOCOLS

SNHRCEC/IEC/SOP/09
Version: 01

16.1. PURPOSE:

- The purpose of this SOP is set guidelines for the review process of any ongoing study that has been approved by the IEC

16.2. SCOPE:

- The SOP covers all the approved protocols the study status of which is ongoing in order to ensure that there is no deviation for the proposed protocol

16.3. RESPONSIBILITY:

- SNHRCEC Secretariat – Shall send reminders to the PI to send the “Ongoing Protocol Review Form”
- SNHRCEC - Responsible for carrying out review and discuss in the meeting

16.4. FLOW CHART

Determine Studies that have to be Reviewed

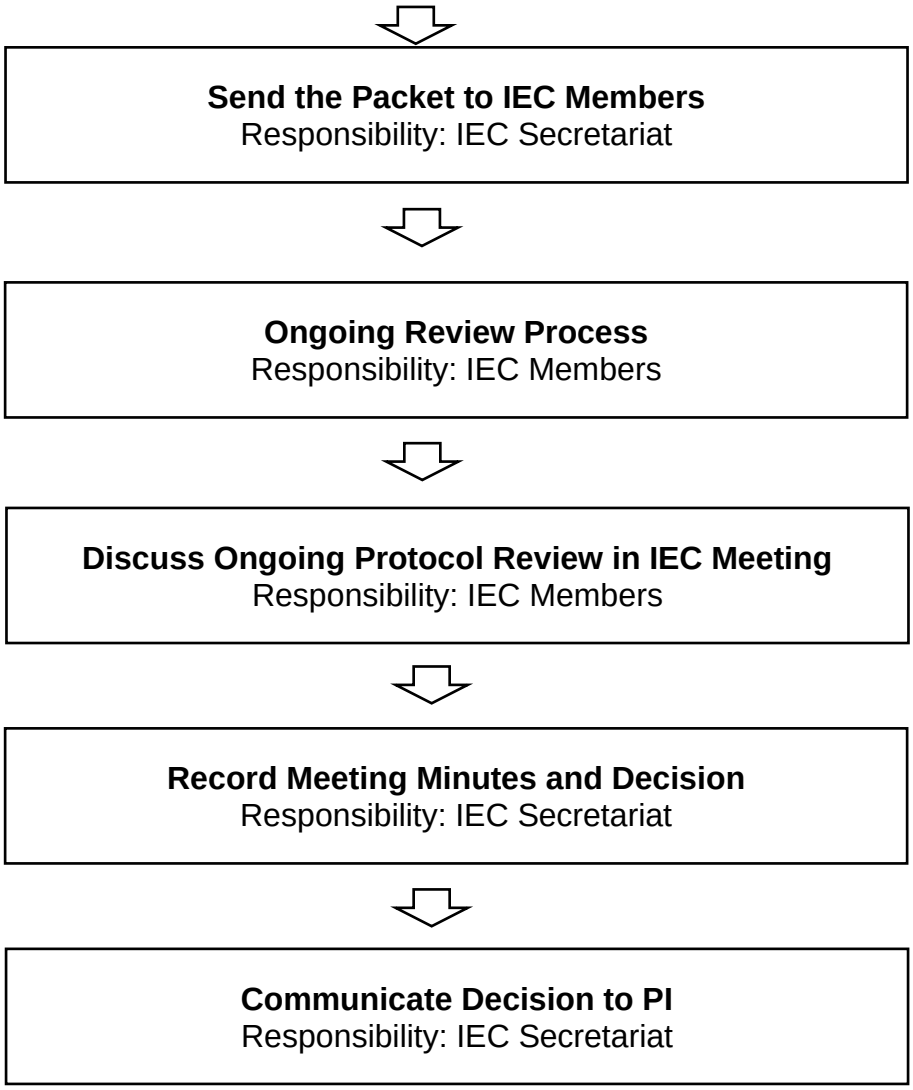
Responsibility: IEC Secretariat

⇩

Communicate to PI for Sending Ongoing Protocol Review Form
Responsibility: IEC Secretariat

⇩

Receive Ongoing Protocol Review Form and Other Documents
Responsibility: IEC Secretariat



16.5. DETAILED PROCEDURE:

- RECEIPT OF ONGOING PRTOCOL REVIEW FORM
  - IEC Secretariat shall determine the due date of protocols that needs ongoing review
  - IEC Secretariat shall plan at least 45 days prior to the next scheduled IEC meeting
  - IEC Secretariat shall inform the PI at least 45 days prior to the IEC meeting (SNHRCEC/IEC/ANNEXURE/22 Version 01)
  - PI shall submit ongoing protocol review form along with any support documents (SNHRCEC/IEC/ANNEXURE/23 Version 01)

- IEC Secretariat shall receive the ongoing protocol form and any associated documents and verify the contents for completion
- IEC Secretariat ensures that the following are completely filled out
    - ❖ Adverse events, drop-outs if applicable
    - ❖ If the study has not been initiated inform the reasons
    - ❖ If the study has been completed include a final report
    - ❖ If there are any changes to the protocol or consent forms, submit relevant documents and details
- IEC Secretariat shall make a packet containing the following and send it to all IEC members 15 days in advance to the next IEC meeting
    - ❖ Cover letter from Member Secretary indicating the meeting schedule
    - ❖ List of Protocols for the Ongoing Review
    - ❖ Ongoing Review Documents
- IEC Secretariat shall prepare meeting agenda

16.6. PROTOCOL REVIEW PROCESS

- IEC Members will review the ongoing protocol review form and study the associated documents
- IEC Members can seek clarification or raise any queries regarding the study
- After review, IEC shall decide on accepting the submission or shall recommend re-submission and give details on the clarification sought from the PI
- PI shall request extension of study while nearing study completion and IEC shall review extending the study subject to proper justification
- IEC Secretariat shall file the forms and minutes of the meeting
- IEC Secretariat shall communicate the decision of the ongoing protocol review as one of the followings
    - ❖ Accepted for Continuation
    - ❖ Resubmission
    - ❖ Approval of study extension

16.7. ANNEXURES

- Intimation to the PI Regarding Ongoing Review
- Ongoing/completed/terminated protocol review form
- Documents submission checklist for submission by PI

16.8. REFERENCES

- Schedule Y (Drugs and Cosmetic Act 1940) amendment 2013
- ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006*)*
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000. (Geneva 2000)

16.9. ANNEXURE 22 - INTIMATION TO THE PI REGARDING ONGOING REVIEW

SNHRCEC/IEC/ANNEXURE/22 Version 01

Dear Sir/Madam,

This is reference to the study entitled_____,
Protocol number _____ approved by the IEC on _____. This study is due for the ongoing review process as mandated by SNHRCEC. Please submit the Ongoing Protocol Review Form along with any supported documents to this office latest by date_____.

Member Secretary Date:

Copy to: Director

16.10. ANNEXURE 23 - ONGOING/COMPLETED/TERMINATED PROTOCOL REVIEW FORM

SNHRCEC/IEC/ANNEXURE/23 Version 01

SNHRCEC Protocol No	
Title of the Study	
Name of the PI	
Name of the Co-PI	
Duration of the Project	
Funding Source	
Site Name and Address where the study is conducted	
Satellite Centers if any	
Study Approval Date	
Number of Ongoing Review	
State the study Objectives	
State the Sample Size	
Has the Project been initiated	
Has the Subject Recruitment begun	
How many subjects have been screened	
How many subjects have been recruited	
Is study participant recruitment continuing? If no, give reason	Yes/No
Are there drop out? If yes state the reasons	Yes/No
Are study participants still receiving intervention? If yes, state the reasons	Yes/No
Has there been SAE, if yes state the number of SAE and action taken	Yes/No
Is there any new risk or benefit information? If yes, give details	Yes/No
Protocol Amendments approved by IEC	Yes/No
Any Protocol Deviations	Yes/No
Publications/Presentations	Yes/No
Do you require a study extension	Yes/No
List of additional documents for review	
Remarks	
Signature of the PI, Date	

SUBMISSION FINAL REPORT AND REVIEW

SOP Number: SNHRCEC/IEC/SOP/10 Version: 01

Effective Date : 19.02.2024
Effective Upto : 19.02.2029

SOP prepared by	Dr. Ramprasad Srinivasan Senior Scientist, SNHRC.	
Reviewed by	Dr. N. Balaji Director, SNHRC.	
Approved by	Dr. R. Magesh Babu Member Secretary, SNHRCEC.	

17. SUBMISSION OF FINAL REPORT AND REVIEW

SOP Number: SNHRCEC/IEC/SOP/10 Version 01

17.1. PURPOSE

- The purpose of this review is to provide IEC with instructions on the review process of the final report submissions

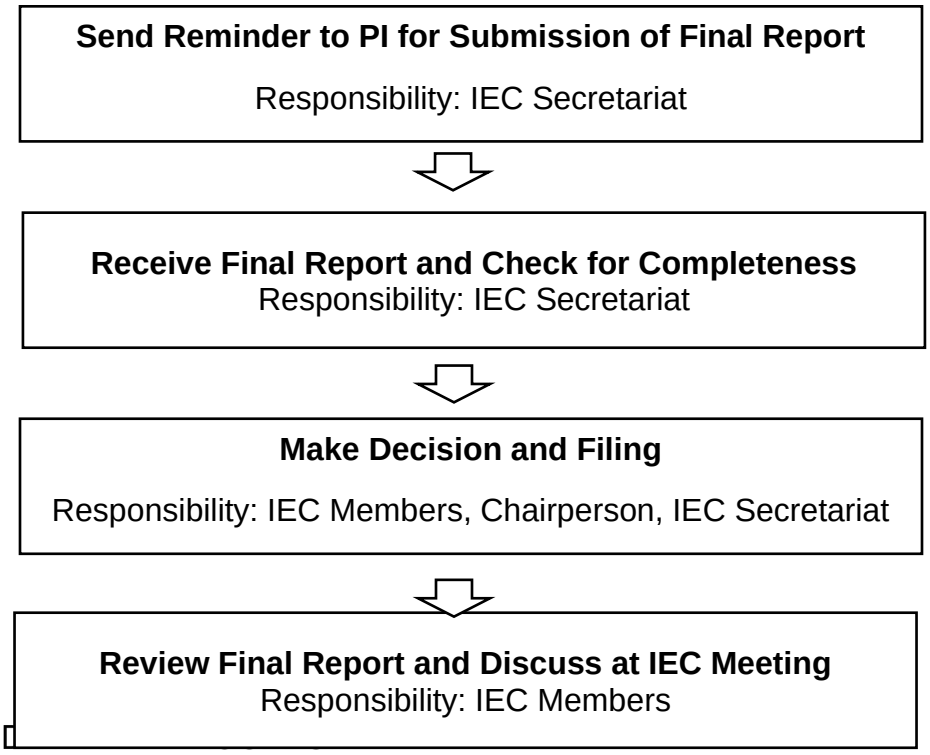
17.2. SCOPE

- This SOP applies to all SNHRCEC approved protocols that are either Ongoing or terminated

17.3. RESPONSIBILITY

- IEC Secretariat – Shall remind PI to submit final report
- IEC Members – Shall review the report and discuss in the meeting

17.4. FLOW CHART



17.5.

- The IEC Secretariat receives the protocol submission form SNHRCEC/IEC/ANNEXURE/11,12,13 Version: 01) and final report form (SNHRCEC/IEC/ANNEXURE/24 Version 01)
- IEC Secretariat makes a packet of documents with approved protocol, final report
- IEC Secretariat sends the packet to all IEC members
- PI/Co-PI makes a presentation in the IEC meeting
- IEC members review the documents and presentation and may raise queries
- IEC may take a decision on the final report as either study closed or requires further information
- Member Secretary shall inform the decision to the PI
- IEC Secretariat shall archive all the study related files

17.6. ANNEXURES

- Final Report Template

17.7. REFERENCES

- Schedule Y (Drugs and Cosmetic Act 1940) amendment 2013
- ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006*)*
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000. (Geneva 2000)

17.8. ANNEXURE 24 - FINAL REPORT TEMPLATE

SNHRCEC/IEC/ANNEXURE/24 Version 01

SNHRCEC Protocol No	
Title of the Study	
Name of the PI, Designation, Department	
Site Address	
Source of Funding	
Multicentric Study	Yes/No
Date of Study Initiation	
Date of Study Completion	
Objectives	
Methods	
Results	
Conclusion	
Ethical Issues, if any?	
Risk to Participants	
Deaths	
Unanticipated issues	
Benefit to participants/community	
Publications/Presentations	

REPORTING, MONITORING AND EVALUATION OF SERIOUS ADVERSE EVENTS

SOP Number: SNHRCEC/IEC/SOP/11 Version: 01

Effective Date : 19.02.2024
Effective Upto : 19.02.2029

SOP prepared by	Dr. Ramprasad Srinivasan Senior Scientist, SNHRC.	
Reviewed by	Dr. N. Balaji Director, SNHRC.	
Approved by	Dr. R. Magesh Babu Member Secretary, SNHRCEC.	

18. Reporting, Monitoring and Evaluation of Serious Adverse Events

SNHRCEC/IEC/SOP/11 Version 01

18.1. PURPOSE

- The purpose of this review is to provide instructions on the reporting process of SAE and receipt and review process of SAE by SNHRCEC

18.2. SCOPE

- This SOP applies to all the approved protocols that may have reported SAE and unexpected onsite and offsite reports submitted by PI. The review process must be based on the amended Drugs and Cosmetics Rule, dated Jan 30, 2013 that includes the Appendix XII of the amendments

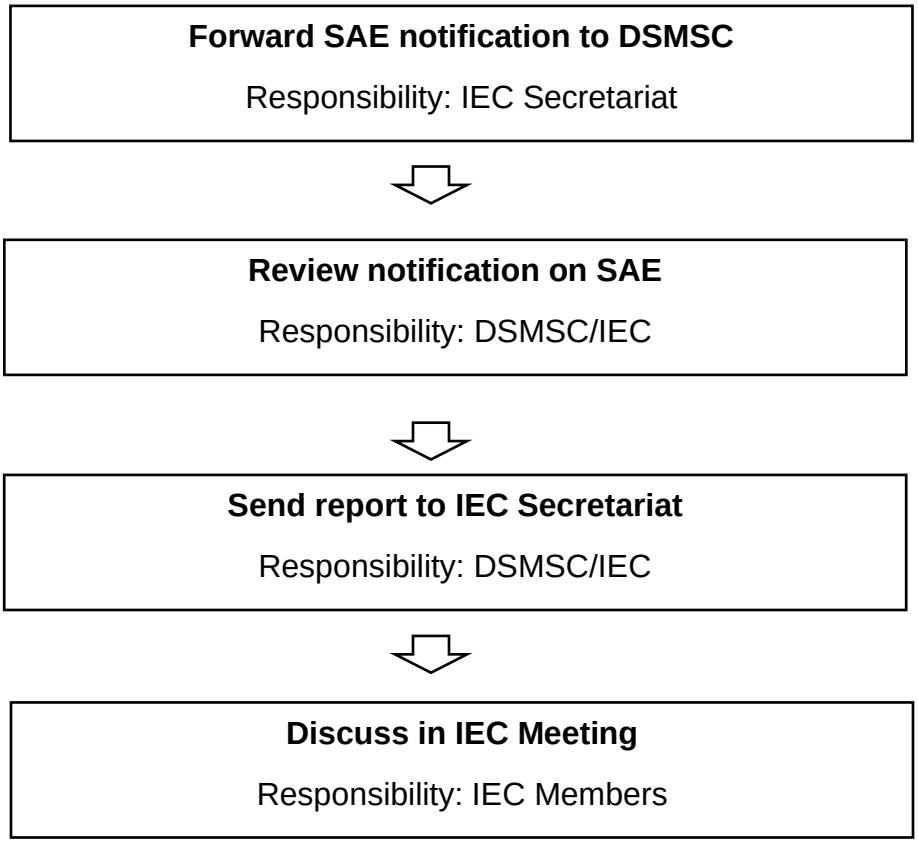
18.3. RESPONSIBILITY

- IEC Members – Review SAE events that involves risk to the human participants make decision. May offer to mediate compensation
- IEC Secretariat – Responsible for receiving SAE notifications from the PI and swiftly sending them to DSMSC for review.
- DSMSC – Review the SAE notification and sends their decision to IEC Secretariat/IEC. IEC will then take this matter for discussion in the subsequent meeting
- PI – In addition to notifying IEC, PI is responsible for notifying the sponsor and regulatory agencies on SAE

18.4. FLOW CHART

Receive SAE/AE notification

Responsibility: IEC Secretariat



18.5. DETAILED PROTOCOL

- All SAE must be reported within 24 hours of occurrence by the PI to a) IEC, b) sponsor c) CDSCO, if the trial has been approved by CDSCO.

- A report of SAE of death after a thorough analysis must be sent within 10 days to a) Sponsor, b) Chairman of IEC, c) CDSCO, if the trial has required prior approval from CDSCO d) Chairman, Expert committee, CDSCO e) Head of the institute where the SAE or death took place

- A report of SAE aside from death after a thorough analysis must be sent within 10 days to a) Sponsor, b) Chairman of IEC, c) CDSCO, if the trial has required prior approval from CDSCO d) Chairman, Expert committee, CDSCO e) Head of the institute where the SAE or death took place

- In situations where SAE is associated with death, then it must be reported to IEC in SAE notification form (SNHRCEC/IEC/ANNEXURE/25 Version 01)
- Although, the patient is out of trial and or on survival follow up, SAE-death must be reported in the SAE notification form
- An original and 2 copies along with a soft copy of the SAE report must be submitted to IEC secretariat
- SAE must be graded as per CTCAE Ver 4.02, US Dept of Health and Human Services, published May 28, 2009.
- The criteria for grades as per CTCAE Ver 4.02 is as follows

- Grades

Grade refers to the severity of the AE. The CTCAE displays Grades 1 through 5 with unique clinical descriptions of severity for each AE based on this general guideline:

Grade 1	Mild; asymptomatic or mildsymptoms; clinical or diagnosticobservations only; intervention notindicated.
Grade 2	Moderate; minimal, local ornoninvasive intervention indicated; limiting age-appropriateinstrumental ADL*.
Grade 3	Severe or medically significant butnot immediately life-threatening;hospitalization or prolongation ofhospitalization indicated; disabling;limiting self-care ADL**.
Grade 4	Life-threatening consequences;urgent intervention indicated.
Grade 5	Death related to AE.A Semi-colon indicates ‘or’ within the descriptionof the grade.

Activities of Daily Living (ADL)
*Instrumental ADL refer to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.
**Self-care ADL refer to bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden.

- SAE Report Review Before IEC Meeting

- SAE are received by the IEC Secretariat which duly forward it to DSMSC after checking for the completeness of the report
- SAE reports must be received with 24 hours of event occurring and it is the responsibility of the PI to send the report within 24 hours to the IEC Secretariat

- In the event of SAE-death, the hard copy is reviewed by the DSMSC and other SAE are reviewed can be reviewed with the soft copy
- The SAE report shall mark the first page with a remark as “DEATH” for easy identification

- Instructions to the Member Secretary for SAE review process before IEC Meeting

  - Member Secretary shall review the SAE report and forward it to DSMSC Secretary
  - If the SAE event is death, Member Secretary shall forward the report to DSMSC within 24 hrs and review it along with DSMSC either in person, email or telephone and inimate Chairperson, IEC on the meeting outcome
  - An emergency IEC meeting shall be conducted if there is an urgency owing to the SAE or if it is not deemed urgent, it shall be discussed in the next IEC meeting
  - The meeting agenda is then prepared to include SAE for a discussing in the next IEC meeting

- Post Review Action of DSMSC

  - After review, DSMSC send a letter to PI on the actions to be taken
  - The IEC Secretariat files the letter in the master file of the research protocol
  - The reply from the PI are reviewed by the DSMSC
  - The PI’s reply is discussed in the next IEC meeting
  - Member Secretary prepares the agenda for discussion of the SAE and AE reports, action taken in the next full board IEC meeting

- IEC Review and Actions for studies that have required approval of CDSCO
  - In the event of SAE -Death, the IEC shall review and send a report on SAE-Death, along with its view of financial compensation if any to the Chairman of Expert Committee, CDSCO within 21 calendar days of the occurrence of SAE-Death
  - In the event of SAE other than death, the IEC shall review and send a report on SAE-Death, along with its view of financial compensation if any to CDSCO within 21 calendar days of the occurrence of SAE-Death
- SAE Review during IEC Meetings

- Secretary of DSMSC will inform all the IEC members on the SAE event, review of SAE and actions taken. The review process shall apply for both on-site and off-site reported review

- Based on this a discussion shall take place and any of the decisions shall be taken based on the consensus of IEC members.

- Note the SAE report in the IEC records if information submitted isfound to be adequate

- Instruct the PI to inform all other participants enrolled in the study regarding the SAE and request them to undergo additional checkup as per recommendation

- Instruct the PI to inform all other participants enrolled in the study about the SAE and obtain their consent for continuous participation in the study

- Request further follow up information

- Request additional details

- Recommend whether or not compensation should be paid to the patient /his nominee for trial related injury / death as per institutional policy.

- Suspend certain activities under the protocol (while going on with activities intended to protect the safety, well-being of participants who have already been enrolled);

- Suspend enrolment of new research participants;

- Suspend the study till amendments requested for by the IEC are accepted

- Suspend the study till review is completed;

- Terminate the study

- Any other action

18.6. ANNEXURE

- Serious Adverse Event Report

18.7. REFERENCES

- Schedule Y (Drugs and Cosmetic Act 1940) amendment 2013
- ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006*)*
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000. (Geneva 2000)

18.8. ANNEXURE 25 - SERIOUS ADVERSE EVENT REPORT

SNHRCEC/IEC/ANNEXURE/25 Version 01

Protocol Number:
Title of the Proposal:
Copy of clinical trial permission obtained from CDSCO
CTRI Registration No.
Name of the PI, Designation, Dept
Site Address
Sponsor Name, Address, Contact
CRO Name, Address, Contact
Report Type: Initial Follow-up Final In Case of Follow-up, Date of Initial report In Case of Final, Dates of Initial and Follow-up
SAE Report of Death
SAE Report Other than Death
Patient Case No. Age: Gender: Patient Trial ID:
Total Number of SAE (prior) occurred in this site
Mention SAE Event Term CTCAE grade Refer CTCAE v4.2 where applicable
Whether the SAE occurred was a) Expected b) Un-expected

Whether SAE resulted in ☐ Death ☐ Hospitalization Increased Hospitalization stay ☐ Yes ☐ No In the event of death, state the cause of death
Cost of treatment borne by ☐ Patient ☐ Institute ☐ Sponsor/CRO
Drug Generic Name
Route of Administration
Indication for which the drug was administered
Dosage form and strength
Daily dose and Regimen
Starting date and time
Stopping date and time
Provide information on concomitant drugs including OTC drugs and non-drug therapies
Full Description of event including body site, severity and the diagnosis for the event
Start time and date of oneset of reaction
Stop time and date or duration of reaction
Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted.
If the event is death, post mortem findings
Any other information to prevailing illness that will helpful in assesment

SITE MONITORING

SOP Number: SNHRCEC/IEC/SOP/12 Version: 01

Effective Date : 19.02.2024
Effective Upto : 19.02.2029

SOP prepared by	Dr. Ramprasad Srinivasan Senior Scientist, SNHRC.	
Reviewed by	Dr. N. Balaji Director, SNHRC.	
Approved by	Dr. R. Magesh Babu Member Secretary, SNHRCEC.	

19. SITE MONITORING

SNHRCEC/IEC/SOP/12 Version 01

19.1. PURPOSE

- The purpose of this SOP is to provide instruction on the process of site monitoring visit for monitoring the compliance of an approved protocol

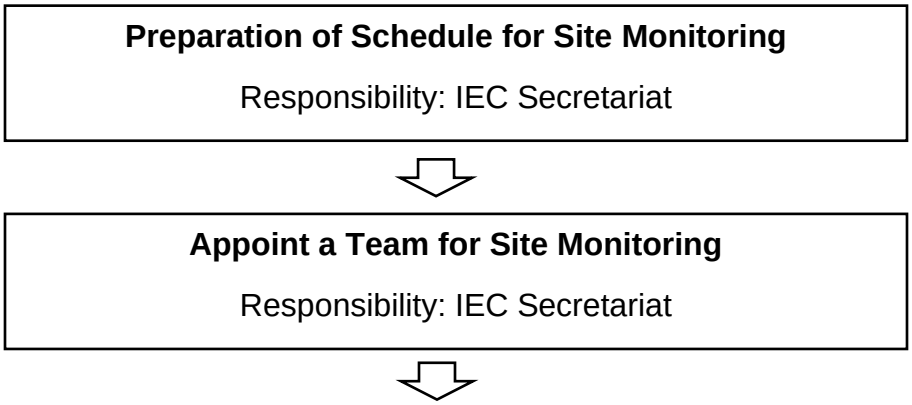
19.2. SCOPE

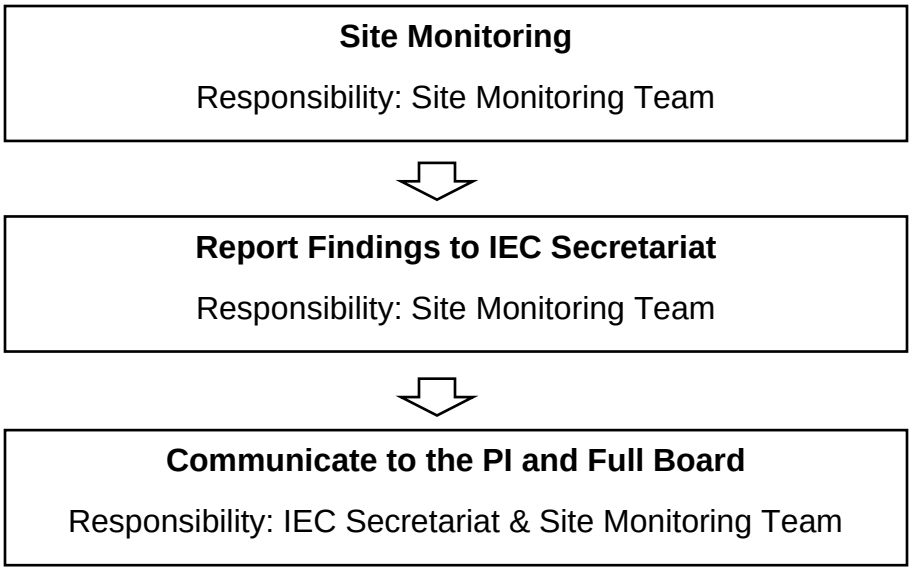
- This SOP applies to all the IEC members who visit the study implementation site for monitoring and to all the IEC approved protocols

19.3. RESPONSIBILITY

- IEC Secretariat – In consultation with Member Secretary appoints a team of IEC members or external consultants for on-site monitoring. Also make a schedule for on-site monitoring and communicates with PI and IEC site monitoring team
- IEC Members – Evaluate the compliance to the approved protocol and report any deviation back to the IEC Secretariat. Also, present the findings to the full board if required

19.4. FLOW CHART





19.5. DETAILED PROCEDURE

- IEC Secretariat shall identify the studies that require site monitoring and prepare a schedule for site monitoring
- The frequency of site monitoring shall be for every six months or if there reports of SAE, non-compliance or any other suspicion
- Member Secretary shall appoint a team of IEC Members or representative for site monitoring visit
- IEC Secretariat shall notify the site monitoring team and site PI of the impending site monitoring visit

19.6. INSTRUCTIONS FOR SITE MONITORING TEAM

- Review the consent forms to ensure that it is up to date and for compliance
- Review the site facilities for compliance
- Review study related documents to ensure the documents are filed correctly
- Review the protocol and ensure compliance
- Report on the site visit within 2 weeks and send it to IEC Secretariat (SNHRCEC/IEC/ANNEXURE/26 Version 01)
- Present the findings of site monitoring to the full board

  - AFTER SITE VISIT

- IEC Secretariat shall send the report of site visit to PI

- File the copy of report in IEC Secretariat file

19.7. ANNEXURE

- Site Monitoring Visit Report

19.8. REFERENCES

- Schedule Y (Drugs and Cosmetic Act 1940) amendment 2013
- ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006)
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000. (Geneva 2000)

19.9. Annexure 26 - SITE MONITORING VISIT REPORT

SNHRCEC/IEC/ANNEXURE/26 Version 01

SNHRCEC Protocol number	
Name of the PI, Designation, Address	
Name of the Sponsor	
Number of subjects approved	
Number of subjects enrolled	
Whether the consent forms are up to date	☐ Yes ☐ No Comments:
Whether there are any Deviation	☐ Yes ☐ No Comments:
Is there any non-compliance	☐ Yes ☐ No Comments:
Were there any SAE reported	☐ Yes ☐ No Comments:
Are the case record form up to date	☐ Yes ☐ No Comments:
Any other comments	
Name of IEC Member/Team/Representative	
Signature	
Date	

AGENDA, PROCEDURES AND RECORDING OF MINUTES OF IEC MEETING

SOP Number: SNHRCEC/IEC/SOP/13 Version: 01

Effective Date : 19.02.2024
Effective Upto : 19.02.2029

SOP prepared by	Dr. Ramprasad Srinivasan Senior Scientist, SNHRC.	
Reviewed by	Dr. N. Balaji Director, SNHRC.	
Approved by	Dr. R. Magesh Babu Member Secretary, SNHRCEC.	

20. AGENDA, PROCEDURES AND RECORDING OF MINUTES OF IEC MEETING

SOP Number: SNHRCEC/IEC/SOP/13 Version 01

20.1. PURPOSE

- The purpose of this SOP is to provide instructions on the process of conducting IEC meeting. This involves setting up of agenda in discussing the topics in IEC meetings, procedure of conducting the meeting and preparing of minutes of the meetings

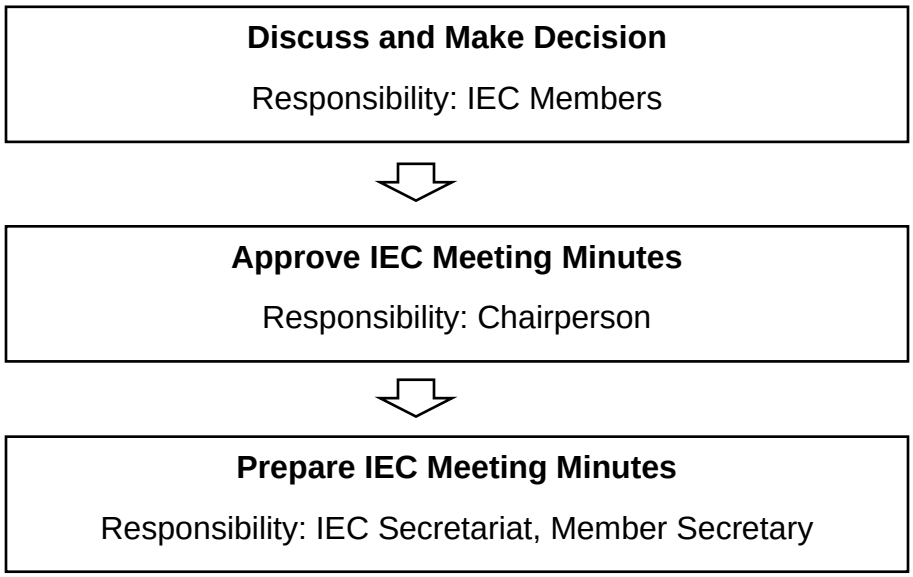
20.2. SCOPE

- This SOP allies to all items that will be discussed in the IEC meeting

20.3. RESPONSIBILITY

- IEC Secretariat – Preparation of agenda
- Member Secretary – Review of agenda
- IEC Members – Discuss the item and decision making
- Chairperson – Review and approval of minutes of the meeting

20.4. FLOW CHART



20.5. DETAILED PROCEDURE

- AGENDA PREPARATION AND BEFORE IEC MEETING PROCEDURES
    - IEC Secretariat will compile the list of protocols and submissions to prepare a meeting agenda (SNHRCEC/IEC/ANNEXURE/27 Version 01)
    - Member Secretary shall review the agenda and approve
    - Send the agenda to all IEC members
    - Send the protocol and other reports to all IEC members
    - Ensure the meeting room is available with facilities for a video presentation
    - Inform the Principal Investigators regarding the meeting and request them to have materials ready for presentation if required

- DURING THE IEC MEETING
    - IEC Secretariat and Member Secretary ensure that the quorum is met
    - Member Secretary and Chairperson given their opening remarks on the meeting
    - The previous meeting minutes are ratified by all IEC members
    - IEC members fill the COI form and if there are any COI, they leave the room
    - PI makes the presentation; answers queries raised by members and leaves the room once the presentation is complete

- In the event that the PI cannot be present for the meeting, he/she may send the representative for presenting the study
- After the discussion of each study, MS summarizes the discussion
- Decision shall be taken by consensus of all IEC members

- AFTER THE MEETING

- IEC Secretariat along with Member Secretary compile the meeting minutes (SNHRCEC/IEC/ANNEXURE/28 Version 01)
- IEC Secretariat send the meeting minutes to Chairperson for approval
- Chairperson review and approves the meeting minutes
- IEC Secretariat will send the minutes to all IEC members
- IEC Secretariat will keep a copy for its records

20.6. ANNEXURE

- Format for Scheduled meeting agenda
- Minutes of the Meeting Template

20.7. REFERENCES

- Schedule Y (Drugs and Cosmetic Act 1940) amendment 2013
- ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006*)*
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000. (Geneva 2000)

20.8. ANNEXURE 27 - FORMAT FOR SCHEDULED MEETING AGENDA

SNHRCEC/IEC/ANNEXURE/27 Version 01

1. Date and Time of meeting:
2. Venue of meeting:
3. Approval of the minutes of the meeting held in previous meeting
4. Date of forthcoming scheduled IEC meeting
5. Review of New Protocols / re-submissions

   SNHRCEC Protocol No:
   Name of the PI, Designation
   Title of the Study

6. Review of Protocol amendments

   SNHRCEC Protocol No:
   Name of the PI, Designation
   Title of the Study

7. Review of Ongoing protocols

   SNHRCEC Protocol No:
   Name of the PI, Designation
   Title of the Study

8. Review of Completed protocols

   SNHRCEC Protocol No:
   Name of the PI, Designation
   Title of the Study

9. Ratification of new protocols approved by expedited / exempt process

   SNHRCEC Protocol No:

   Name of the PI, Designation

   Title of the Study

10. Ratification of protocol amendments approved by expedited process

    SNHRCEC Protocol No:

    Name of the PI, Designation

    Title of the Study

11. Review of SAE, ratification of SRC meeting minutes and compensation , perusal of Central SAE Committee decision (if applicable)

    SNHRCEC Protocol No:

    Name of the PI, Designation

    Title of the Study

12. Review of protocol deviations

    SNHRCEC Protocol No:

    Name of the PI, Designation

    Title of the Study

13. Any other

20.9. ANNEXURE 28 - MINUTES OF THE MEETING TEMPLATE

SNHRCEC/IEC/ANNEXURE/28 Version 01

The following members attended the meeting held at SNHRC Conference room on _____ at _____ AM/PM

S.No	Name of the Member, Designation

- The quorum of the meeting was met with the attendance of _____ IEC Members
- Member Secretary and Chairperson gave their opening remarks

Member Secretary Remarks

Chairperson Remarks

- Ratification of the previous meeting minutes was completed
- It was decided that the next meeting will be held on _____

1. Review of New Protocols / re-submissions

   SNHRCEC Protocol No:

   Name of the PI, Designation

   Title of the Study

   Discussion Summary

   Decision

2. Review of Protocol amendments

   SNHRCEC Protocol No:

   Name of the PI, Designation

   Title of the Study

   Discussion

   Decision

3. Review of Ongoing protocols

   SNHRCEC Protocol No:

   Name of the PI, Designation

   Title of the Study

Discussion

Decision

4. Review of Completed protocols

   SNHRCEC Protocol No:

   Name of the PI, Designation

   Title of the Study

   Discussion

   Decision

5. Ratification of new protocols approved by expedited / exempt process

   SNHRCEC Protocol No:

   Name of the PI, Designation

   Title of the Study

   Discussion

   Decision

6. Ratification of protocol amendments approved by expedited process

   SNHRCEC Protocol No:

   Name of the PI, Designation

   Title of the Study

   Discussion

   Decision

7. Review of SAE, ratification of SRC meeting minutes and compensation , perusal of Central SAE Committee decision (if applicable)

   SNHRCEC Protocol No:

   Name of the PI, Designation

   Title of the Study

   Discussion

   Decision

8. Review of protocol deviations

   SNHRCEC Protocol No:

   Name of the PI, Designation

   Title of the Study

   Discussion

   Decision

9. Any other

   Discussion

   Decision

The meeting was adjourned on time.

Signature of Member Secretary
Date:

Signature of Chairperson
Date:

MAINTENANCE OF ONGOING STUDY FILES, ARCHIVING, DISPOSAL AND RETRIEVAL OF DOCUMENTS

SOP Number: SNHRCEC/IEC/SOP/14 Version: 01

Effective Date : 19.02.2024
Effective Upto : 19.02.2029

SOP prepared by	Dr. Ramprasad Srinivasan Senior Scientist, SNHRC.	
Reviewed by	Dr. N. Balaji Director, SNHRC.	
Approved by	Dr. R. Magesh Babu Member Secretary, SNHRCEC.	

21. MAINTAINENCE OF ONGOING STUDY FILES, ARCHIVING, DISPOSAL AND RETRIEVAL OF DOCUMENTS

SNHRCEC/IEC/SOP/14 Version 01

21.1. PURPOSE

- To provide instructions on the process of storage and maintaining study files that are ongoing at SNHRC, archiving of files after close of study, retrieval of documents and disposal

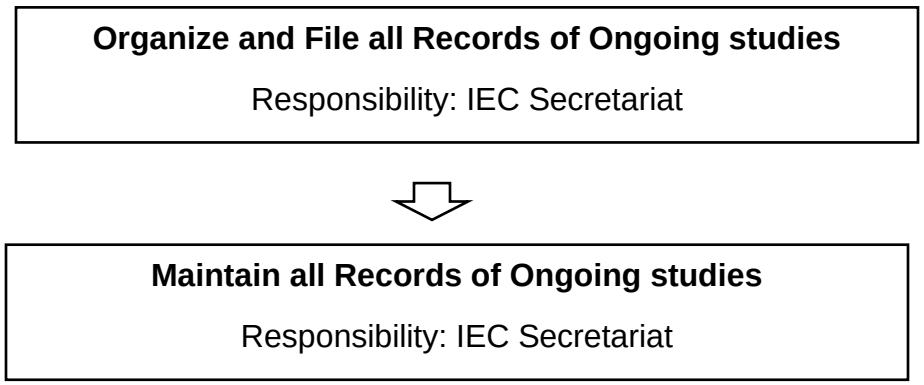
21.2. SCOPE

- This SOP applies to all the approved studies by the SNHRCEC,

21.3. RESPONSIBILITY

- IEC Secretariat – Responsible for filing and maintaining all files related to the study for a period of 5 years after the close of the study

21.4. FLOWCHART



21.5. DETAILED PROCEDURE

- Maintenance of Ongoing study files

- A Study master file must be created for each study at the time of initial submission of study protocol. This master file must contain all records and correspondence related to the study
- The study file shall be labelled using an unique identifier or using the study protocol number
- All documents related the study must be filed in an organized manner
- All files must be a stored in a closed cabinet and must be secured with a lock
- The file access must be only with IEC Secretariat
- All files shall be stored for a period of 5 years after the close of the study
- After the close of the study, send the files for archiving

- Archiving of study files
  - Once the study is closed the IEC Secretariat makes arrangement to archive study
  - All the files will be stored in an archive boxes clearly labelled with the protocol number, project title, PI name and archiving date
  - The access of files shall be restricted to IEC Secretariat and regulatory authorities
  - The archived files shall be stored in a separate room that is secured
  - The details of archiving location shall be maintained in a separated record at the IEC Secretariat
  - Any electronic records must be backed up on a regular interval and be kept by the IT manager
- Retrieval of Documents
  - Master files shall be made available to regulatory authorities by IEC after receiving a request in writing
  - If PI needs a copy of documents, he/she shall submit a written request and it shall be made available to the PI within a week (SNHRCEC/IEC/ANNEXURE/29 Version 01)
  - IEC Secretariat is authorized to retrieve documents from the archive. The IEC Secretariat must maintain a log of retrieval documents and must be available at IEC office for inspection
- Disposal of Closed files
  - All the files and records will be maintained for a period of 5 years after the close of the study
  - After 5 years of archiving, the files shall be shredded and soft copies will be deleted.
  - A log of files being destroyed must be kept at the IEC Secretariat (SNHRCEC/IEC/ANNEXURE/30 Version 01)

21.6. ANNNEXURES

- Document requisition form
- Template for disposal register

21.7. ANNEXURE 29 - DOCUMENT REQUISITION FORM

SNHRCEC/IEC/ANNEXURE/29 Version 01

Protocol Number	
Project Title	
PI Name, Designation, Contact	
Documents Requested	
Reason	
PI Signature, Date	
Requesting Person Name	
Requesting Person Signature, Date	
Documents Approved by IEC Secretariat	☐ Yes ☐ No
Signature of IEC Secretariat, Date	

21.8. ANNEXURE 30 - TEMPLATE FOR DISPOSAL REGISTER

SNHRCEC/IEC/ANNEXURE/30 Version 01

Protocol number	PI Name	IEC approval date	Study Closure Date	Date of Disposal	Name and Sign of Authorized person

SOP FOR REVIEW OF STUDIES INVOLVING VULNERABLE POPULATIONS

SOP Number: SNHRCEC/IEC/SOP/15 Version: 01

Effective Date : 19.02.2024
Effective Upto : 19.02.2029

SOP prepared by	Dr. Ramprasad Srinivasan Senior Scientist, SNHRC.	
Reviewed by	Dr. N. Balaji Director, SNHRC.	
Approved by	Dr. R. Magesh Babu Member Secretary, SNHRCEC.	

22. SOP FOR REVIEW OF STUDIES INVOVING VULNERABLE POPULATIONS

SNHRCEC/IEC/SOP/15

22.1. PURPOSE:

- To provide instructions on the process of review of vulnerable population. This SOP provides detailed instructions on the review process of a study protocol involving vulnerable population

22.2. SCOPE:

- This SOP applies to all studies that involves vulnerable population participation in the study. The IEC must consider that extra protection must be provided to these groups as these subject cannot consent to the study or may not be fully equipped to comprehend about the benefits or harms of the study.

22.3. RESPONSIBILITY

- IEC Secretariat – Responsible for receiving of the study protocol and must have updated forms that shows that the vulnerable subjects are involved in the study

- Member Secretary – Responsible for assigning members who completely understand the ethics standpoint of involving vulnerable population in the study. The assigned members must be well trained in the ethical concepts and guidelines of studies involving vulnerable population

- Chairperson/Member Secretary - Responsible in ensuring that IEC members are converse in reviewing study protocols through regular training

22.4. DETAILED PROCEDURE

- Study involving vulnerable population must undergo a full review process
  The review process is detailed as in SNHRCEC/IEC/SOP/05 Version 1

22.5. GUIDELINES FOR REVIEW OF VULNERABLE POPULATION

The Belmont Report (1972) Vulnerable populations as those groups that might “bear unequal burdens in research” because of their “ready availability in settings where research is conducted”, such as prisons, hospitals, institutions, and camps, and called for extra protection for these groups.

ICMR code ch111 –

22.6. Vulnerable groups - Categories

- The following list of subjects are classified under vulnerable groups
- Children
- Prisoners
- Pregnant Women
- Handicapped subjects
- Mentally disabled persons
- Refugees
- Displaced people
- Economically or Educationally weaker subjects
- HIV/AIDS Patients
- Terminally ill Patients
- Geriatric subjects

22.7. Vulnerable groups – Ethical Considerations

- Effort may be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed.
- Research on genetics should not lead to racial inequalities;
- Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them;
- 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;
- 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.
- Research using vulnerable participants is not prohibited by international ethical codes or regulations but their inclusion needs to be justified and special precautions need to be implemented for their protection.

22.8. Respect for individuals

The principle of respect for individuals incorporates two fundamental ethical principles:

- Respect for autonomy
- Protection of vulnerable people.
- These principles are commonly addressed by procedures to obtain individual informed consent that ensure that respondents understand

- the purpose of the research,
- the risks and benefits of participation
- and that their participation is voluntary

22.9. Research using children and adolescents

The purpose of including children in research is to gain knowledge relevant to the health needs of children. The ICMR guidelines state:

"Before undertaking trial in children the investigator must ensure that

- Children will not be involved in research that could be carried out equally well with adults;
- 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;
- A parent or legal guardian of each child has given proxy consent;
- The assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors from the age of seven years up to the age of 18 years.;
    - Research should be conducted in settings in which the child and p can obtain adequate arent medical and psychological support;
    - Interventions intended to provide direct diagnostic, therapeutic or preventive benefit for the individual child participant must be justified in relation to anticipated risks involved in the study and anticipated benefits to society;
    - 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;
    - Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child participant as any available alternative interventions;
    - The risk presented by interventions not intended to benefit the individual child participant is low when compared to the importance of the knowledge that is to be gained."

Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them. The economically disadvantaged have limited access to health care, may enrol in research to receive treatment, or enrol for compensation, are often educationally disadvantaged too with limitations in understanding and the potential for undue influence or manipulation. It is, therefore, important that the informed consent process uses simple language and enlists the help of family and significant others to explain the potential for risks, the uncertainty of personal health benefits, if appropriate, and clearly delineates those aspects of the study that are purely for research and those that are part of standard care. Undue financial inducements should be avoided. Particularly for illiterate and vulnerable participants in research, the informed consent process should be witnessed by an impartial witness, who is not part of the research team.

22.10. Research using students and employees

Research involving trainees of any description or employees including faculty often confers no therapeutic advantage for the participant. However, students and employees have the same rights as any other potential recruit to participate in a research project, irrespective of the degree of risk, provide certain conditions are met:

- The research must not bestow upon participating employees or students any competitive academic or occupational advantage over other staff and students who do not volunteer, and the researchers must not impose any academic or occupational penalty on those or staff who do not volunteer.
- Students and employees must not be systematically treated differently from non-employee or non-student participants as part of the project.
- Due to the potential for perceived or real coercion to participate, students and employees who desire to participate in the research (especially those under the direct supervision of the principal investigator or listed research collaborators) should ideally have a witness of their choice present during the informed consent process to ensure that participation was voluntary. A suitable representative may be invited to be present during the ethics review of the proposal. The Declaration of Helsinki states that, “When obtaining informed consent for the research project the physician should be particularly cautious if the participant is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship” (Clause 23). If at all possible, this approach is to be preferred to the immediately previous suggestion. Research involving people with life threatening diseases or who are medically vulnerable Prospective participants in a study which has a therapeutic component who are by reason of mental or behavioral disorders

not capable of giving adequately informed consent, persons with serious, potentially disabling, or life-threatening diseases, and persons rendered incapable of informed consent by an acute condition [emergency], are also vulnerable to exploitation, as are people who by virtue of progressive cognitive impairment may become vulnerable during the process of research (e.g., long term studies of those with cognitive decline who develop dementia). Participants with serious medical diseases are vulnerable to (possibly) misplaced therapeutic optimism. For such participants, attempts should be made to include them only if there is minimal risk if non - therapeutic research; for therapeutic research potential risks should be emphasized, as should realistic estimates of benefits. If the disease cannot otherwise be treated, a "compassionate use" of the experimental intervention is ethically justified.

- The Declaration of Helsinki states that, "For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons (Clause 24). Being mentally ill does not automatically render a person incompetent to consent and this must be ascertained for every participant. In people with major mental disorders such as schizophrenia, severe depression, mania, or people with mental retardation, even if the patient consents to participate, consent to permit participation should be additionally obtained from a responsible relative or legal guardian.

- The Declaration of Helsinki also states, that "Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population. The specific reasons for involving research participants with a condition that renders them unable to give informed consent should be stated in the experimental protocol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from the individual or a legally authorized surrogate" (Clause 26).

22.11. Research on Pregnant or nursing women

- The ICMR guidelines state, “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 foetus or nursing infant and the object of the research is to obtain new knowledge about the foetus, pregnancy and lactation. 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 participants.

i. 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 infe ction from mother to child, trials for detecting foetal abnormalities and for conditions associated with or aggravated by pregnancy etc. 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.

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

iii. **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”.

TRAINING OF ETHICAL COMMITTEE MEMBERS

SOP Number: SNHRCEC/IEC/SOP/16 Version: 01

Effective Date : 19.02.2024
Effective Upto : 19.02.2029

SOP prepared by	Dr. Ramprasad Srinivasan Senior Scientist, SNHRC.	
Reviewed by	Dr. N. Balaji Director, SNHRC.	
Approved by	Dr. R. Magesh Babu Member Secretary, SNHRCEC.	

23. TRAINING OF ETHICAL COMMITTEE MEMBERS

SNHRCEC/IEC/SOP/16 Version: 01

23.1. PURPOSE

- It is important that all ethical members undergo periodic training that ensures efficient functioning of IEC. Continuous training on ethics will help in keeping abreast of changes in rules or guidelines

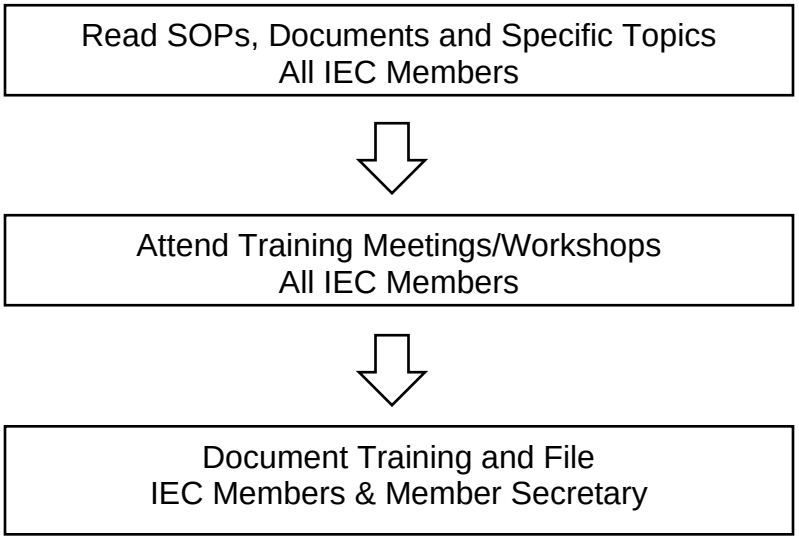
23.2. SCOPE

- All IEC members shall undergo periodic ethics related training

23.3. RESPONSIBILITY

- All IEC members must self-train or attend training/workshops
- Member Secretary shall file all training records of members

23.4. FLOW CHART



23.5. DETAILED PROCEDURE

- SNHRCEC shall conduct training to all new members joining IEC by an internal or external member of SNHRCEC
- Member Secretary shall make SOPs and guideline documents available to all IEC members for training
- The guideline documents are Ethical Guidelines for Biomedical Research on Human Participants - ICMR (2006), Indian GCP and Schedule Y, WHO Operating Guidelines for Ethical Review Committee that review Biomedical Research and ICH (International Conferences on Harmonization) Good Clinical Practice (GCP)
- Member Secretary shall encourage all IEC members to attend seminars/workshops on ethics
- Member Secretary shall file a copy of certificates of training workshop attended by IEC members
- Member Secretary shall file training logs for internal training of IEC members

23.6. ANNEXURE

- IEC Member Training Record Form

23.7. REFERENCES

- Schedule Y (Drugs and Cosmetic Act 1940) amendment 2013
- ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006*)*
- National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017)
- National Ethical Guidelines for Bio-Medical Research Involving Children
  National Guidelines for Stem Cell Research (2017)
- European Convention on Human rights and Biomedicine (1997).
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000. (Geneva 2000)

23.8. ANNEXURE 31 - IEC Member Training Record Form

SNHRCEC/IEC/ANNEXURE/31 Version 1

Ethics related Courses/Workshops/ Meeting attended _____

_____

_____

Organized by: _____

Place held: _____

Duration: _____

Key Topics Covered: _____

_____

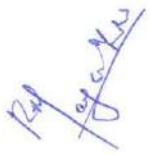
Member Signature Date:

Name of the Member

CONFLICT OF INTEREST DECLARATION

SOP Number: SNHRCEC/IEC/SOP/17 Version: 01

Effective Date : 19.02.2024
Effective Upto : 19.02.2029

SOP prepared by	Dr. Ramprasad Srinivasan Senior Scientist, SNHRC.	
Reviewed by	Dr. N. Balaji Director, SNHRC.	
Approved by	Dr. R. Magesh Babu Member Secretary, SNHRCEC.	

24. CONFLICT OF INTEREST DECLARATION

SOP Number: SNHRCEC/IEC/SOP/17 Version: 01

24.1. PURPOSE

- SNHRCEC is committed to ensuring its faculty an open and productive environment in which to conduct teaching, patient care, and research. Conflicts of interest, in the most conventional sense, arise because faculty members may have the opportunity to influence the institution's business decisions in ways productive of personal gain and thereby may compromise the integrity of SNHRCEC. The purpose of this SOP is to identify and declare any Conflict of Interest of the members pertaining to any submitted protocol

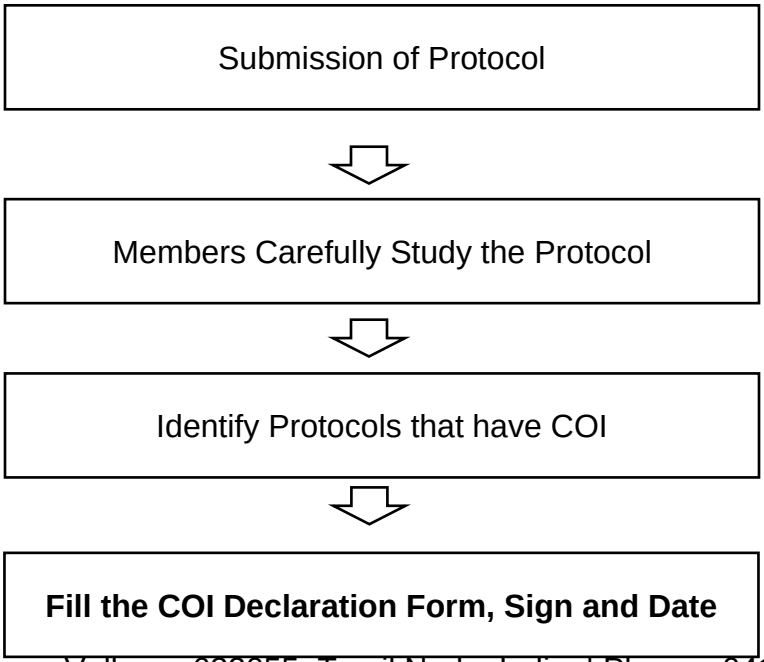
24.2. SCOPE

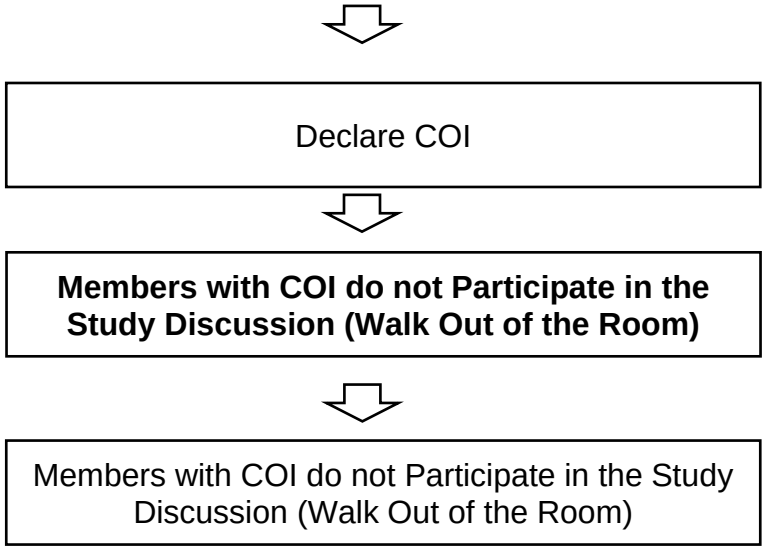
- Procedures regarding self-declaration of Conflict of Interest by SNHRCEC members

24.3. RESPONSIBILTY

- All members are responsible for declaring Conflict of Interest form before they attend the meeting
- Member Secretary is responsible in ensuring that all the IEC members sign COI declaration form

24.4. FLOWCHART





24.5. DETAILED PROCEDURE

- Members carefully go through the protocol to identify any potential or real Conflict of Interest pertaining to submitted protocols
- Before attending the meeting fill in the COI declaration form, Sign and Date
- Submit a copy of COI declaration form to Chairperson and Member Secretary
- Member must leave the room during the IEC discussion of the protocol to which the member(s) have conflict of interest

24.6. GUIDELINES TO IDENTIFY CONFLICT OF INTEREST

- Conflict of Interest include financial interest such as compensation from the study sponsor, shareholder of the study sponsor
- Other potential areas include grants from the study sponsor, publication, involvement of immediate relatives of the study sponsor,
- Personal, academic and political considerations

24.7. ANNEXURE

- CONFLICT OF INTEREST DISCLOSURE

24.8. ANNEXURE 32 - CONFLICT OF INTEREST DISCLOSURE FORM

SNHRCEC/IEC/ANNEXURE/32 Version 1

☐ I/We here certify the we have no Conflict of Interest for the proposals that are being discussed in today's meeting

☐ I/We declare Conflict of Interest for the protocol(s) discussed in this meeting

Name of the Member	Conflict of Interest for Protocol number, version	Signature/Date

Give Details of Conflict of Interest

_____

_____

_____

_____

Signature of Member Secretary Date:

ONLINE MEETING

SOP Number: SNHRCEC/IEC/SOP/18 Version: 02

Effective Date : 19.02.2024
Effective Upto : 19.02.2029

SOP prepared by	Dr. Ramprasad Srinivasan Senior Scientist, SNHRC.	
Reviewed by	Dr. N. Balaji Director, SNHRC.	
Approved by	Dr. R. Magesh Babu Member Secretary, SNHRCEC.	

25. Online Meeting sop
SNHRCEC/IEC/SOP/18/Version:02

25.1. Purpose:

This SOP is designed to describe how the SNHRCEC meetings are to be conducted in 'online/hybrid mode.' SNHRCEC meetings will be conducted to discuss the ethical issues in the submitted study proposals and issue decisions on the same. The term 'online' refers to a mode of meeting where the participants, who are physically present in different locations due to unavoidable situations, meet on a common virtual internet-based platform.

25.2. Scope:

The scope of this SOP is applied to the planning, communication, and organization of the regular, ad-hoc/emergency and expedited SNHRCEC meetings in an online platform. All other SOPs applicable to a physical meeting shall also apply to the online ethics committee meeting.

25.3. Responsibility:

The Chairperson is responsible for calling the online meetings, which will be conducted on the first Saturday of month of every quarter. The member-secretary with the help of the coordinator as the responsibility of intimating all the members and investigators.

25.4. Detailed instructions:

1. The member-secretary will finalize the meeting date in consultation with the Chairperson. Unless circumstances dictate otherwise, planned meetings will be conducted on the first Saturday of the first month of every quarter. The date may be changed due to public holidays or other reasons, which will be intimated to the Chairperson, members and investigators.

2. The invitation for the meeting will be sent to the members in advance by the SNHRCEC Secretariat. The final date will be fixed by the member-secretary and Chairperson.

3. The SNHRCEC secretariat will receive, scrutinize and distribute via email the final copies of proposals to all SNHRCEC members. The investigators are required to submit the PowerPoint presentation along with the proposal documents. This PowerPoint file will be used to for projection at the time of the online meeting. In case the investigator wants any changes in the file, they can submit a revised file 7 days prior to the meeting.

4. The member-secretary will contact the members and confirm their availability for the meeting. In the email communication sent to the members for confirming their availability, the member-secretary shall intimate them about the online platform that will be used, the requirements for such an online meeting (for e.g., laptop with mic and camera or specifications of the phone, software and the type of internet connection required.) and the ‘dos’ and ‘don’ts’ document specific to online meetings.

5. On the day of the meeting, an online meeting link will be setup and sent to the members. The meeting will start as per the timing mentioned in the agenda. The meeting host (Chairperson) will

monitor the entry of the members into the online platform. The Chairperson will obtain verbal consent from the attendees for video recording the meeting. The Chairperson shall assess and confirm the required quorum for the meeting. The members will be requested to confirm the minutes of the previous meeting. The Chairperson will request the members to declare any conflict of interest with regard to the proposals to be discussed. The investigator will present the proposal in person at the meeting

6. The minutes of the meeting will be recorded by the member-secretary along with coordinator. The video recording may be sent to the members by the member-secretary after obtaining the permission of the Chairperson with the understanding that the members will not share it to anyone else outside the ethics committee.

7. In case of technical issues such as a member not being able to join the meeting, or lost in between due to internet connectivity issues, the member-secretary with the permission of the Chairperson shall take the decision so as to postpone their concerned presentation until such time that they can join the meeting. Any member who wants to leave the meeting shall do so with the permission of the Chairperson after stating appropriate reasons. The member-secretary shall monitor the quorum continuously and intimate the Chairperson if it fails the meet the minimum requirement. The meeting shall be stopped until such time the quorum is reached. The member-secretary shall update the minutes to the member(s) who lost connection in between.

APPLICATION REVIEW FEE

SOP Number: SNHRCEC/IEC/SOP/19 Version: 02

Effective Date : 19.02.2024
Effective Upto : 19.02.2029

SOP prepared by	Dr. Ramprasad Srinivasan Senior Scientist, SNHRC.	
Reviewed by	Dr. N. Balaji Director, SNHRC.	
Approved by	Dr. R. Magesh Babu Member Secretary, SNHRCEC.	

26. HONORARIUM, FEES AND IEC OFFICE EXPENSES

SNHRCEC/IEC/SOP/19/Version:02

The members of the IEC, Sri Narayani Hospital and Research Centre Ethics Committee, SNHRC shall be paid Rs 1000/- for reviewing internal and external proposals and Rs 2000/- for reviewing clinical trial proposals as honorarium for attending the IEC meetings and reviewing the proposals.

26.1. COMPENSATION AND REIMBURSEMENTS TO EXTERNAL MEMBERS

All external members, and experts invited (if any) will be paid an honorarium of Rs. 1000/- for each meeting attended and transport facilities would be either provided by the institution or reimbursement will be done for travel costs incurred towards contributing to the workings of the IEC according to the Institution‘s norms.
Appropriate bills shall have to be submitted together to the Member Secretary.

26.2.EC REVIEW FEE

The Ethics Committee (EC) shall charge an application fee for sponsored research projects. All research proposals/clinical trials funded/sponsored by pharmaceutical companies, Agencies, Multinationals etc. will be charged an administrative fee/ processing fee.

All applications need to be mandatorily accompanied by application fee before it can be processed.

26.3. INITIAL REVIEW FEE

The EC shall charge a non-refundable, initial one-time review fee as administrative charges given below:
Pharmaceutical Industry and Contract Research Organisation (CRO) Funded Clinical Trials … …… Rs. 50,000/- .
Internal proposal ……..……..…….... Rs. 2,000/-
External proposal ……...…….... Rs. 5,000/-

26.4. STUDY RENEWAL FEE

The EC shall charge a yearly fee (Rs. 500/) for ongoing review of the study from the second year. The study renewal review fee funds the costs of the Committee renewal review of the ongoing review of adverse events, protocol variances and site visits. The committee examines each Investigator’s progress reports and activities for the previous year.

26.5. AMENDMENT FEE

The EC shall charge an amendment fee of Rs.5,000/- for any amendment(s) in the ongoing study.

26.6. OFFICE EXPENSES

For the maintenance of the office, a sum of Rs 1000/- per month shall be given to the secretariat.