Standard Operating Procedures (SOP)

for

Institutional Ethics Committee (IEC)

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Version- 02,

Date: 08/12/2021

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1. **Introduction:** The first International statement on the ethics in medical research using human subjects, the Nuremberg Code was formulated in 1947 and it laid emphasis on consent and voluntariness. In 1964, the eighteenth World Medical Assembly at Helsinki, Finland adopted a code of ethics for the guidance of doctors involved in clinical research. This is popularly known as the "Declaration of Helsinki."

   In 1980, the Indian Council of Medical Research released a 'Policy Statement on Ethical Considerations involved in Research in Human Subjects' for the benefit of all those involved in clinical research in India.

   In 1996, the International Conference on Harmonization (ICH) published a tripartite guideline for Good Clinical Practice (GCP) to harmonise technical requirements for registration of pharmaceutical products. Today, the ICH GCP guideline is followed globally for clinical research. This guideline elaborates the composition and functioning of an Institutional Ethics Committee to review clinical research proposals.

   The Institutional Ethics Committee presently functions according to the requirements laid down in Schedule Y of Drugs & Cosmetic Act and is guided by the ICH GCP guidelines for Good Clinical Practice, ethical principles set forth in the Declaration of Helsinki and the Ethical Guidelines for Biomedical Research on Human Subjects laid down by the Indian Council of Medical Research.

   The IEC of SLN Medical College & Hospital, Koraput is formed in accordance with the principles laid down by IEC functions as per the ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participant-2017 (ICMR National Ethical Guidelines), New Drugs and Clinical Trial Rules 2019, published in Gazette notification of 19th March 2019 by Ministry of Health and Family Welfare, G.S.R 227 (E) and the GCP Guidelines of CDSCO amended from time to time. This is the 2.0 Version of SOP of IEC-SLN MCH, prepared on 09.12.2021 taking into consideration New Drugs and Clinical Trial Rules 2019 & ICMR National Ethical Guidelines. Different guidelines were laid down by IEC, SLN Medical College & Hospital, Koraput (IEC-SLN MCH) for submission research projects for ethics committee approval.

2. **Authority under which IEC is constituted:** IEC-SLN MCH is an Institutional standing ethics committee which functions independently. The Dean & Principal, SLN MCH will appoint the Chairperson, Member Secretary and all the committee members, based on their qualifications, competence and experience in reviewing and evaluating the scientific and ethical aspects of biomedical research proposals. The tenure/ period of IEC members will be for 3 years or till further orders.

3. **Composition:** The number of members in an IEC may range from 8 to 10. The IEC will be multidisciplinary in composition and independent. As per the ICMR National Ethical Guidelines2017, IEC-SLN MCH should have the following categories of members

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

4. **Objectives:** The objective of this SOP is to maintain effective functioning of the IEC-SLN MCH and to ensure quality and technical excellence and consistent ethical review of all submitted biomedical research proposals and ongoing approved research studies involving human participants in accordance with the ICMR National Ethical Guidelines and New Drugs and Clinical Trials Rules 2019.
5. **Responsibilities of IEC-SLN MCH:** The main responsibility of IEC is to review all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellbeing of research participants before approving the research proposals. It should ascertain that all the ethical principles of research such as ***Autonomy, Beneficence, Non – maleficence, Respect for Free and Informed Consent. Respect for Human Dignity, Respect for Vulnerable Persons, Respect for Privacy and Confidentiality and Justice*** is taken care of in planning, conducting and reporting of the proposed research. IEC will review each study proposal for its both scientific and ethical review. Members of IEC are expected to attend all IEC meetings and prior information should be provided if a member is unable to attend meeting. Responsibilities of each member is mentioned below

- **Chairperson**
  - Conduct EC meetings and ensure active participation of all members during meeting
  - Ratify minutes of the previous meetings
  - 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**
  - Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review.
  - Schedule EC meetings, prepare the agenda and minutes.
  - Organize EC documentation, communication and archiving.
  - Ensure training of EC secretariat and EC members.
  - Ensure SOPs are updated as and when required & adherence of EC functioning to the SOPs .
  - Prepare for and respond to audits and inspections .
  - Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review.

- Assess the need for expedited review/ exemption from review or full review. Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives.
- Ensure quorum during the meeting and record discussions and decisions.

- **Basic scientist Scientific and ethical review** - emphasis on intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report, drug safety and pharmacodynamics in case of clinical trials.
- **Clinician Scientific:** review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) Review medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation. Thorough review of protocol, investigators brochure & all other protocol details
- **Legal expert:** 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 (NAC-SCRT, HMSC etc) compliance with guidelines etc.
- **Social scientist/ philosopher/ ethicist/theologian:** Ethical review of the proposal, ICD along with the translations. Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.
- **Lay person:** Ethical review of the proposal, ICD along with translation(s). Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. Serve as a patient/participant/ community representative and bring in ethical and social concerns.

6 **Condition of appointment / fixation of terms of reference/ resignation/ replacement/ removal.**

a) The members are drawn from different specialties to give a multi-sectorial, multidimensional structure.
b) Members are expected to show their full commitment, responsibility, respect for divergent opinions, maintain confidentiality review proposals from bias and without any external influences
c) All IEC members must be familiarized with guidelines related to research and ethics such as ICMR National Ethical Guidelines2017, New Drugs and Clinical Trials Rules 2019, ICH-GCP guidelines.
d) When there is any change in SOP the same will be communicated to the members and necessary training will be imparted. Record will be maintained regarding the training of members and change in the SOP/guidelines.

e) Members are expected to declare conflicts of interest, if any, before commencement of the meeting. IEC members should not take part in discussion or decision making on research proposals in which they are PI or Co –investigators or if there are any other conflicts of interest.

f) The members are appointed by the Dean & Principal SLN Medical College & Hospital, Koraput, Odisha.

g) The duration of appointment is initially for a period of 3 years.

h) At the end of 3 years, the term of appointment of members could be extended for another term or the committee may be reconstituted. A defined percentage (35 to 50%) of members could be changed on regular basis.

i) A member can be replaced in the event of transfer to other Medical College, retirement, death or long-term assignments outside the country or for any misconduct deemed unfit for a member.

j) A member can tender resignation from the committee with proper reasons to do so, which should be acceptable to the Dean & Principal SLN Medical College & Hospital, Koraput, Odisha.

k) All members should maintain absolute confidentiality of all discussions during the meeting.

l) Requirements for IEC Membership: Every EC member must provide

- Updated CV with signature
- Consent letter
- Submit training certificates on human research participant protection and good clinical practice (GCP) guidelines
- Be willing to undergo training or update their skills/knowledge during their tenure
- Declare Conflict of Interest (COI) in accordance with the policy of the IEC-SLN MCH, if applicable
- Be willing to place her/his full name, profession and affiliation to the EC in the public domain.

m) **Policy regarding training**: All IEC members must be familiarized with guidelines related to research and ethics such as ICMR National Ethical Guidelines 2017, New Drugs and Clinical Trials Rules 2019, ICH-GCP guidelines & GCP. The IEC-SLN MCH members shall be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted body(ies), so that they become aware of their role and responsibilities. Members shall be encouraged to attend National and International training programs in research ethics for maintaining quality in ethical review and to be aware of the latest developments in this area. For review of drug trials members shall have their trainings in good clinical practice.

7. **Quorum requirement** :
   a. A minimum of five members must be present in the meeting room.
   b. The quorum should include medical, non-medical or technical or/and non-technical members.
   c. Minimum two non-affiliated member should be part of the quorum.
   d. Preferably the lay person should be part of the quorum.
   e. The quorum for reviewing regulatory clinical trials should be in accordance with current New Drugs and Clinical Trials Rules 2019 requirements.
   f. No decision is valid without fulfilment of the quorum.
8. **Conflicts of interest:** In conducting human subject research, a conflict of interest is defined as a situation in which an individual (or someone in his/her immediate family) has a significant financial, professional, interest in the approval or outcome of a study and the interest could affect decisions related to either the design, conduct or reporting of the research or adversely affect the rights and welfare of research subjects, such conflicts must be identified and managed appropriately.

   Any conflict of interest of an IEC-SLN MCH member in any research project that is submitted for consideration to the IEC must be declared by the concerned member. These interests may include any personal involvement or participation in the research, any financial interest in the outcome of the research or any involvement in competing research. In event of such a conflict of interest the concerned member will refrain from voting during the IEC-SLNMCH meeting. E.g. an IEC member himself/herself is an investigator for a trial under review with IEC-SLN MCH.
9. **Offices:** The Chairperson will conduct all meetings of the IEC. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairman before communicating to the researchers.

   The location and business address of the committee is as follows:

   Institutional Ethics Committee (IEC),
   Department of Pharmacology,
   SLN Medical College & Hospital, Koraput
10. **Convention and Conduct of IEC meetings :** The meeting of the IEC will be held at least twice in a year, unless otherwise specified by the member secretary. Additional review meetings can also be held with short notice as and when required. Meetings will be planned in accordance with the need of the work load. The Chairperson will conduct all meetings of the IEC-SLNMCH. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. Member Secretary will prepare the minutes of the meetings and get it approved by the Chairperson and all the members. All proposals will be received at least 3 weeks before the meeting and after initial scrutiny by Member Secretary the proposals will be

circulated to the IEC members. The recommendations by the IEC will be communicated to all the PIs and guides/HODs in case of student's proposals If required additional review meetings can also be conducted with a short notice period.

11. **Application procedures:** All proposals should be submitted to IEC on any working day 2 weeks in advance of scheduled meeting in the prescribed application form along with relevant documents. Eight (8) hard Copies soft copy of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators/ Collaborators / should be submitted to IEC SLN MCH. Principle Investigators shall be forwarded their application to the Chairperson IEC, through Member Secretary and the receipt of the application will be acknowledged by the IEC office. Every application will be allotted an IEC registration number to be used for all future correspondence and reference. The date of IEC meeting will be intimated to the PI to attend the meeting and to make a brief presentation of the proposal and to clarify the points raised by the members. IEC-SLN MCH can suggest for online meetings and virtual presentations of the investigators in special situations such as COVID-19 pandemic, etc. If revision is to be made, the revised proposal in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

12. **Details of documents to be submitted for EC review**

a) Cover letter to the Member Secretary.

b) Type of review requested.

c) Application form for initial review.

d) Permission of using copyrighted proforma/ questionnaire.

e) A complete protocol.

f) Approval of the project for Institute Scientific Committee.

g) The correct version of the informed consent document (ICD) in English and the local language(s).

h) Case record form/questionnaire.

i) Recruitment procedures: advertisement, notices (if applicable).

j) Patient instruction card, diary, etc. (if applicable).

k) Investigator's brochure (as applicable for drug/biologicals/device trials).

l) Details of funding agency/sponsor and fund allocation (if applicable).

m) Brief curriculum vitae of all the study researchers.

n) GCP training certificate (preferably within 5 years) of investigators (Sponsored clinical trials).

p) Any other research ethics/other training evidence, if applicable as per EC SOP.

q) List of ongoing research studies undertaken by the principal investigator (if applicable).

r) Undertaking with signatures of investigators.

s) Regulatory permissions (as applicable).

t) Relevant administrative approvals (such as HMSC approval for International trials).

u) Institutional Committee for Stem Cell Research (IC-SCR) approval (if applicable).

v) MoU in case of studies involving collaboration with other institutions (if applicable).

w) Clinical trial agreement between the sponsors, investigator and the head of the institution(s) (if applicable)) Insurance policy (if applicable).

13. **Details of documents to be included in the protocol:** The protocol should include the following:

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

B. Brief summary/ lay summary of the protocol;

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

D. Justification of inclusion/exclusion of vulnerable populations.

E. Clear research objectives and end points/ outcome.

F. Eligibility criteria and participant recruitment procedures.

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

H. Duration of the study;

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

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

K. Plan for statistical analysis of the study.

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

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

N. Provision of ancillary care for unrelated illness during the duration of research.

O. An account of storage and maintenance of all data collected during the trial.

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

Q. Ethical considerations and safeguards for protection of participants.

14. **Review procedures**

- The proposals should be sent to the IEC at least 3 weeks in advance of scheduled meeting. The Member-Secretary with the support of the secretarial staff shall screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely,
    a) Exemption from review
    b) Expedited review and

c) Full committee review

- Decisions will be taken by consensus after discussion, and whenever needed voting will be done.
- The PI / Research Scholar will then present the proposal in person in the meeting. When the PI is not available due to unavoidable reasons the Co-PI will be allowed to present the proposal. Researchers will be invited to offer clarifications on case to case basis ,if needed
- The review discussions/ decisions will be charted down and the final minutes will be approved by the Chairperson.
- After the IEC meeting, the decision of the IEC members regarding the discussed proposals to obtained on the same day of the meeting.
- The type of EC review based on risk involved in the research, is categorized as follows.

Type of risk Definition/description

– **Less than minimal risk** Probability of harm or discomfort anticipated in the research is nil or not expected. Research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc

– **Minimal risk** Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely. Research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc.

– **Minor increase over minimal risk** or Low risk Increment in probability of harm or discomfort is only a little more than the minimal risk threshold.

- Routine research on children and adolescents;
- Research on persons• incapable of giving consent
- Delaying or withholding a proven intervention or standard of care in a• control or placebo group during randomized trials;
- Use of minimally invasive procedures that might cause no more than• brief pain or tenderness, small bruises or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing;
- Trying a new diagnostic technique in pregnant and breastfeeding• women etc.
- Research should have a social value. Use of personal identifiable data• in research also imposes indirect risks.
- Social risks, psychological harm and discomfort may also fall in this• category.

– **More than minimal risk or High risk Probability of harm** or discomfort anticipated in the research is invasive and greater than minimal risk. Examples include research involving any interventional study using a drug, device or invasive procedure such as

lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures

15. Types of reviews
    a. **Exemption from review**: Proposals which present "less than minimal risk" fall under this category. Following situations may come under this "less than minimal risk" category: Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. Exceptions: 1. When research on use of educational tests, survey or interview procedures, or observation of public behaviour 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. 2. When interviews involve direct approach or access to private papers
    b. **Expedited Review:** The proposals presenting "no more than minimal risk" to research participants may be subjected to expedited review. The Member-Secretary and the Chairperson of the IEC may do expedited review only if the protocols involve
        - Minor deviations from originally approved research protocol during the period of approval.
        - Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.
        - Research activities that involve only procedures listed in one or more of the following categories •
            i. Clinical studies of drugs and medical devices only when – Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.
            ii. Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.
            iii. When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and the same participants should not be included in the clinical trial that may be initiated later based on the findings of the pilot study.

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

a) Research involving vulnerable populations, even if the risk is minimal;

b) Research with minor increase over minimal risk

c) Studies involving deception of participants;

d) Research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee;

e) Amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, case record forms etc.) involving an altered risk;

f) Major deviations and violations in the protocol;

g) Any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment;

h) Research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need;

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

16. **Informed Consent**.–

(a) In all trials, a freely given, informed, written consent is required to be obtained from each study subject. The Investigator must provide information about the study verbally as well as using a patient information sheet, in a language that is nontechnical and understandable by the study subject.

(b) The subject's consent must be obtained in writing using an " Informed Consent Form". Both the patient information sheet as well as the informed consent form should have been approved by the ethics committee and furnished to the Central Licencing Authority. Any changes in the informed consent documents should be approved by the ethics committee and submitted to the Central Licencing Authority before such changes are implemented.

(c) Where a subject is not able to give informed consent (e.g. an unconscious person or a minor or those suffering from severe mental illness or disability), the same may be obtained from a legally acceptable representative a legally acceptable representative is a person who is able to give consent for or authorise and intervention in the patient as provided by the law of India).

(d) If the trial subject his or her legally acceptable representative is unable to read or write an impartial witness should be present during the entire informed consent process who must append his or her signature to the consent form.

(e) In case of clinical trials on paediatrics, the subjects are legally unable to provide written informed consent, and are dependent on their parent or legal guardian to assume responsibility for their participation in clinical studies. In such case,- (i) Written informed consent should be obtained from the parent or legal guardian. However, all paediatric participants should be informed to the fullest extent possible about the study in a language and in terms that they are able to understand. (ii) Where appropriate, paediatric participants should additionally assent to enrol in the study. Mature minors and adolescents should personally sign and date a separately designed written assent form. (iii)Although a participant's wish to withdraw from a study must be respected, there may be circumstances in therapeutic studies for serious or life-threatening diseases in which, in the opinion of the Investigator and parent or legal guardian, the welfare of a paediatric patient would be jeopardized by his or her failing to participate in the study. In this situation, continued parental or legal guardian consent should be sufficient to allow participation in the study.

(f) A checklist of essential elements to be included in the study subject's informed consent document as well as a format for the informed consent form for trial subject is given in Annexure 3.

(g) An audio-video recording of the informed consent process in case of vulnerable subjects in clinical trials of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record: Provided that in case of clinical trial of anti-HIV and anti-leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing

(i) Review of Informed consent documents will be carried out by the members of IEC-SLN MCH prior to the meeting and at the time of meeting of Ethics Committee. If it is not in accordance to guidelines mentioned in point no 16, a,b,c,d,e,f,g of SOP revised Informed consent documents will be resubmitted by applicant.

17. **Principle of research among vulnerable population:** Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests and providing valid informed consent. Include economically and socially disadvantaged; children (up to 18 years); women in special situations; tribals and marginalized communities; refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations; afflicted with mental illness and cognitively impaired individuals, differently abled –mentally and physically disabled; terminally ill or are in search of new interventions having exhausted all therapies; suffering from stigmatizing or rare diseases; or have diminished autonomy due to dependency or being under a hierarchical system and unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent. The

(12)

list of vulnerable population or groups as per ICMR 2017 guidelines Box 6.2 page-57 and NDCT Rule 2019 will be considered. IEC-SLN MCH should carefully determine the benefits and risks of the study and examine the justification provided and risk minimization strategies. Additional safety measures should be strictly reviewed and approved by the IEC . IEC must ensure that the informed consent process should be well documented and recording of assent in case of research studies involving children aged 7 to 18 years and reconsent, when applicable. Informed consent from vulnerable populations may be obtained from LAR (Legally authorized representative)in presence of impartial witness after through explanation of risks and benefits.

18. **Registration with Clinical Trials Regestry - India**: All Clinical Trials involving new drugs, procedures will be registered in CTRI.
19. **Review of Subject recruitment procedures**: IEC-SLN MCH will review Subject recruitment procedures with special emphasis to vulnerable population. It should ascertain that all the ethical principles of research such as Autonomy, Beneficence, Non – maleficence, Respect for Free and Informed Consent. Respect for Human Dignity, Respect for Vulnerable Persons, Respect for Privacy and Confidentiality and Justice is taken care of.
20. **Review of multicentric research**: Multicentre research is conducted at more than one centre by different researchers usually following a common protocol.
    - All sites are required to obtain approval from their respective ECs, which would consider the local needs and requirements of the populations being researched and safeguard the dignity, rights, safety and well-being of the participants. The ECs/Secretariats of all participating sites should establish communication with one another
    - If any EC does not grant approval for a study at a site the reasons must be shared with other ECs and deliberated upon. The EC can suggest site-specific protocols and informed consent modifications as per local needs. Separate review may be requested for studies with a higher degree of risk, clinical trials or intervention studies where conduct may vary depending on the site or any other reason which requires closer review and attention. Common review for all participating sites in multicentric research - in order to save time, prevent duplication of effort and streamline the review process, the ECs can decide to have one designated main EC, the decisions of which may be acceptable to other ECs.
    - Common review process may be applied to research involving low or minimal risk, survey or multicentre studies using anonymized samples or data or those that are public health research studies determined to have low or minimal risk.

21 . IEC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities; patient groups or special interest groups e.g. Cancer patients, HIV/AIDS positive persons or

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

22. **Ethics Committee for Clinical Trial, Bioavailability and Bioequivalence Study:**

Institute Ethics Committee (IEC-SLN MCH) shall perform the following functions for Clinical Trial, Bioavailability and Bioequivalence Study; namely:—

(i) Review and accord approval to a clinical trial, bioavailability or bioequivalence study protocol and other related documents, as the case may be, in the format specified in clause (B) of Table 1 of the Third Schedule and oversee the conduct of clinical trial to safeguard the rights, safety and wellbeing of trial subjects in accordance with these rules, Good Clinical Practices Guidelines and other applicable regulations;

(ii) Make at appropriate intervals, an ongoing review of the clinical trials for which it has accorded approval and such review may be based on periodic study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or by visiting the study sites;

(iii) Indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing and a copy of such reasons shall also be made available to the Central Licencing Authority;

(iv) Where any serious adverse event occurs to a trial subject or to study subject during clinical trial or bioavailability or bioequivalence study, the Ethics Committee shall analyse the relevant documents pertaining to such event and forward its report to the Central Licencing Authority and comply with the provisions of Chapter VI;

(v) Where at any stage of a clinical trial, it comes to a conclusion that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the committee may order discontinuation or suspension of the clinical trial and the same shall be intimated to the head of the institution conducting clinical trial and the Central Licencing Authority;

(vi) Allow any officer authorised by the Central Licencing Authority to enter, with or without prior notice, to inspect the premises, any record, or any documents related to clinical trial, furnish information to any query raised by such authorised person, in relation to the conduct of clinical trial and to verify compliance with the requirements of these rules, Good Clinical Practices Guidelines and other applicable regulations for safeguarding the rights, safety and well-being of trial subjects;

(vii) Comply with the requirements or conditions in addition to the requirements specified under the Act and these rules as may be specified by the Central Licencing Authority with the approval of the Central Government, to safeguard the rights of clinical trial subject or bioavailability or bioequivalence study subject.

23. **Proceedings of Ethics Committee for clinical trial.—**

(a) No clinical trial or bioavailability or bioequivalence protocol and related documents shall be reviewed by an Ethics Committee unless at least five of its members as detailed below are present, namely:—

(i) Medical scientist (preferably a pharmacologist);

(ii) Clinician;

(iii) Legal expert;

(iv) Social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person;

(v) Lay person.

(b) The Ethics Committee may constitute one or more sub-committees of its members to assist in the functions assigned to it.

(c) The Ethics Committee may associate such experts who are not its members, in its deliberations but such experts shall not have voting rights, if any.

(d) Any change in the membership or the constitution of the registered Ethics Committee shall be intimated in writing to the Central Licencing Authority within thirty working days.

24. Decision-making& Communication of decision

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

b. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and the same should be conveyed to the Chairperson prior to the review of the application and recorded in the minutes.

c. Decision will be made only in meetings where quorum is complete.

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

e. Decision may be to approve, reject, or revise the proposals. Specific suggestions for modifications and reasons for modifications and reasons for rejection will be given.

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

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

h. Decision taken on the proposals will be communicated by the Member Secretary/secretariat in writing to the PI / Research Scholar within two weeks after the meeting at which the decision was taken in the specified format

i. IEC approval will be valid for one year or for the duration of the project whichever is less. Investigator has to get his or her project re- approved after one year, where required.

j. The communication of the decision will include:

I. Name and address of IEC.

II. The date, place and time of decision.

III. The name and designation of the applicant.

IV. Title of the research proposal reviewed.

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

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

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

VIII. A clear statement of decision reached.

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

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

XI. Signature of the member secretary with date.

k. The IEC has the rights to revoke its approval accorded to scientific study/clinical study protocol, and further, it has to record the reasons for doing so and communicate the same to the Investigator as well as to the Licensing Authority/ other relevant stakeholders. IEC may review progress of the approved studies periodically till the completion of the study through periodic study progress report /internal audit reports. The investigator is responsible for reporting all SAEs including hospitalization or prolongation of hospitalization, clinical trial related injury or death, regardless of causal relationship to the EC within 24 hours of knowledge. Reporting of SAE may be done through email or fax communication (including on non-working days). A report on how the SAE was related to the research must also be submitted within 14 days. SAEs must be reported for all trials and if applicable timelines as specified by regulators to be followed (within 24 hours to the sponsor, EC and regulator, if applicable, followed by a due analysis report in 14 days). The IEC shall forward the report on any SAE (including, death), after due analysis, along with its opinion on the financial compensation, if any, to be paid by the sponsor or his representative, to the Chairman of the Expert Committee. The copy of the report has to be submitted the Licensing Authority within twenty one calendar days of the occurrence of the SAE.

25. **Record keeping and archiving of documents:** All Research proposals (8 hard copies along with soft copy) along with the information and documents submitted will be dated and filed. The documents will be archived for a minimum period of 3 years and for sponsored clinical trials for 5 years after completion/termination of the study. IEC members should not retain any documents with them after the meeting is over.

List of documents to be filed and archived

1. Constitution of IEC
2. SOP
3. CV & consent of IEC members
4. IEC Registration
5. Honorarium details, Income and expenses
6. Agenda & minutes of the meetings
7. One copy of proposal
8. Copy of recommendations/decision communicated to applicant
9. Review reports, documents received during the follow up period and final reports of the study

26. **Maintenance of records by Ethics Committee for clinical trial.—**

(a) The Ethics Committee shall maintain data, record, registers and other documents related to the functioning and review of clinical trial or bioavailability study or bioequivalence study, as the case may be, for a period of five years after completion of such clinical trial.

(b) In particular and without prejudice to the generality of the sub-rule (1), the Ethics Committee shall maintain the following records for a period of five years after completion of every clinical trial or bioavailability study or bioequivalence study, namely:- (i) the constitution and composition of the Ethics Committee;

(ii) The curriculum vitae of all members of the Ethics Committee;

(iii) Standard operating procedures followed by the Ethics Committee;

(iv) National and international guidelines followed by the Ethics Committee;

(v) Copies of the protocol, data collection formats, case report forms, investigators brochures, etc., submitted for review;

(vi) All correspondence with committee members and investigators regarding application, decision and follow up;

(vii) Agenda of all Ethics Committee meetings and minutes of all Ethics Committee meetings with signature of the Chairperson;

(viii) Copies of decisions communicated to applicants;

(ix) Records relating to any order issued for premature termination of study with a summary of the reasons thereof;

(x) Final report of the study including microfilms, compact disks or video recordings;

(xi) Recommendation given by Ethics Committee for determination of compensation;

(xii) Records relating to the serious adverse event, medical management of trial subjects and compensation paid.

27. **Compensation:** Compensation in case of injury or death in clinical trial or bioavailability or bioequivalence study of new drug or investigational new drug.—

(a) Where any death of a trial subject occurs during a clinical trial or bioavailability or bioequivalence study, the legal heir of the trial subject shall be provided financial compensation by the sponsor or its representative, who has obtained permission to conduct the clinical trial or bioavailability or bioequivalence study, in accordance with the procedure specified in rule 42 of New Drugs and Clinical Trial Rules, 2019.

(b) Where permanent disability or any other injury occurs to a trial subject during a clinical trial or bioavailability or bioequivalence study, the trial subject shall be provided financial compensation by the sponsor or its representative, who has obtained permission to conduct the clinical trial or bioavailability or bioequivalence study, in accordance with the procedure specified in rule 42 of New Drugs and Clinical Trial Rules, 2019.

(c) The financial compensation shall be in addition to any expenses incurred on medical management of the trial subject.

(d) In the event of an injury, not being permanent in nature, the quantum of compensation shall be commensurate with the loss of wages of the subject as provided in the Seventh Schedule. 162 THE GAZETTE OF INDIA : EXTRAORDINARY [PART II—SEC. 3(i)]

(e) The sponsor or its representative shall give an undertaking along with the application for clinical trial permission to the Central Licensing Authority to provide compensation in the case of clinical trial related injury or death for which subjects are entitled to compensation.

(f) Where the sponsor or its representative, who has obtained permission to conduct clinical trial or bioavailability or bioequivalence study, fails to provide financial compensation, the Central Licencing Authority shall, after affording an opportunity of being heard, by an order in writing, suspend or cancel the clinical trial or bioavailability or bioequivalence study or restrict the sponsor including its representative, who has obtained permission to conduct clinical trial or bioavailability or bioequivalence study, to conduct any further clinical trial or bioavailability or bioequivalence study or take any other action for such period as considered appropriate in the light of the facts and circumstances of the case.

28. **Determine the Quantum of Compensation in the Cases of Clinical Trial Related Injury or Death**

I. Formula in case of clinical trial related death:

Compensation = (B x F x R) / 99.37 Where,

B = Base amount (i.e. 8 lacs)

F = Factor depending on the age of the trial subject as per Annexure 1 (based on Workmen Compensation Act)

R = Risk Factor depending on the seriousness and severity of the disease, presence of co-morbidity and duration of disease of the trial subject at the time of enrolment in the clinical trial between a scale of 0.5 to 4 as under:

(1) 0.5 terminally ill patient (expected survival not more than (NMT) 6 months)

(2) 1.0 Patient with high risk (expected survival between 6 to 24months)

(3) 2.0 Patient with moderate risk

(4) 3.0 Patient with mild risk

(5) 4.0 Healthy Volunteers or trial subject of no risk.

However, in case of patients whose expected mortality is 90% or more within 30 days, a fixed amount of Rs. 2 lacs should be given.

II. Formula in case of clinical trial related injury (other than death): For calculation of quantum of compensation related to injury (other than death), the compensation shall be linked to the criteria considered for calculation of compensation in cases of death of the trial subject as referred to in section of this Schedule. The quantum of compensation in case of Clinical Trial related SAE should not exceed the quantum of compensation which would have been due for payment in Case of death of the trial subject since the loss of life is the maximum injury possible.

As per the definition of SAE, the following sequelae other than death are possible in a clinical trial subject, in which the trial subject shall be entitled for compensation in case the SAE is related to clinical trial.

(i) A permanent disability: In case of SAE causing permanent disability to the trial subject, the quantum of compensation in case of 100% disability shall be 90% of the compensation which would have been due for payment to the nominee (s) in case of death of the trial subject.

The quantum for less than 100% disability will be proportional to the actual percentage disability the trial subject has suffered. Accordingly, following formula shall be applicable for determination of compensation:

Compensation = (C x D x 90) / (100 x 100) Where :

D = Percentage disability the trial subject has suffered.

C = Quantum of Compensation which would have been due for payment to the trial subject's nominees) in case of death of the trial subject.

(ii) Congenital anomaly or birth defect: The congenital anomaly or birth defect in a baby may occur due to participation of anyone or both the parent in clinical trial. Following situations may arise due to congenital anomaly or birth defect. (a) Still birth; (b) Early death due to anomaly; (c) No death but deformity which can be fully corrected through appropriate intervention; (d) Permanent disability (mental or physical).

The compensation in such cases would be a lump sum amount such that if that amount is kept by way of fixed deposit or alike, it shall bring a monthly interest amount which is approximately equivalent to half of minimum wage of the unskilled worker (in Delhi).

The quantum of compensation in such cases of SAE shall be half of the base amount as per formula for determining the compensation for SAE resulting into death. In case of birth defect leading to sub-clause (c) and (d) of this clause to any child, the medical management as long as required shall be provided by the Sponsor or his representative which will be over and above the financial compensation.

(iii) Chronic life-threatening disease; and

(iv) Reversible SAE in case it is resolved.

In case of clinical trial related SAE causing life-threatening disease and reversible SAE in case it is resolved, the quantum of compensation would be linked to the number of days of hospitalisation of the trial subject. The compensation per day of hospitalization shall be equal to the wage loss. The wage loss per day shall be calculated based upon the minimum wage of the unskilled worker (in Delhi). Since, in case of hospitalisation of any patient not only the patient loses his/her wage, there will be direct or indirect losses of various kind including inconvenience, wage loss of attendant, etc. The compensation per day of hospitalisation in such case shall be double the minimum wage. Accordingly, following formula shall be applicable for determination of compensation:

Compensation = 2 X W X N. Where,

W = Minimum wage per day of the unskilled worker (in Delhi)

N = Number of days of hospitalization

29. **Policies regarding clinical trial site visit and GCP compliance monitoring by IEC-SLN MCH:** IEC-SLN MCH members will review ongoing clinical trials at appropriate intervals for which it has accorded approval and will inspect any documents related to conduct of clinical trial and to verify compliance with the requirements of rules, Good Clinical Practices Guidelines and other applicable regulations for safeguarding the rights, safety and well-being of trial subjects. Based in the findings of such a visit, IEC-SLN MCH may recommend changes and/or actions, if any, to be taken by the investigator and his/her team to comply with regulatory and ethical guideline.

30. **Administration and management:** should have an office for the IEC-SLN MCH which have adequate space, infrastructure and staff to the EC for maintaining full-time secretariat, safe archival of records and conduct of meeting. A reasonable fee for review may be charged by the IEC to cover the expenses related to optimal functioning in accordance to Institutional policies for Industry sponsored projects/ funded projects. All research proposals/clinical trials funded/sponsored by Pharmaceutical companies, Agencies, Multinationals etc. will be charged an administrative fee/ processing fee of 5% of their sanctioned budget. Waiver of these fees is permissible for non-funded studies, departmental studies, and studies funded by organizations like ICMR, UGC, DST Government of India, State Science & Technology Department, UNICEF,WHO, USAID, Non Profitable Organizations etc. There should be provision for allocating reasonable amount of funds for smooth functioning of the IEC-SLN MCH.

31. **Web page for IEC-SLN MCH:** Details of composition, SOP, registration details, circulars/notifications related to IEC meetings and status of submitted proposals and ongoing projects, submission forms, guidelines and contact details will be displayed on Institute Web page of SLN MCH, Koraput.

32. **Addressing subject's requests:** The IEC will provide timely and appropriate information in response to any requests arising from the subject. A provision must be made to provide contact details of an IEC member to every participating subject so that subject can contact the IEC to know about his/her rights as a trial subject or for any other matter relevant to the IEC.

33. **Site inspection by IEC members :**

The IEC members will perform periodically on-site inspection of relevant projects it has received for review or approved.

a. Such a visit will include but not limited to the review of study documents, study conduct and the measures taken by study team to ensure that subjects rights and well-being are protected.
b. Based in the findings of such a visit, IEC may recommend changes and/or actions, if any, to be taken by the investigator and his/her team to comply with regulatory and ethical guideline.

34. **Amendments to the Standard Operating Procedures**

a. Amendments to the Standard Operating Procedures of the Institutional Ethics Committee shall be proposed in writing.
b. The proposal for amendment shall be submitted to the Member Secretary.
c. The proposal for amendment shall be presented to the regular members at a scheduled committee meeting.
d. Only regular members shall vote to accept or reject the proposed amendment.
e. A proposed amendment shall be approved by a vote of three-fourths of the members present in a quorum at a scheduled committee meeting, rounded to the next whole number.

Approved by:

Prof. Krushna Chandra Biswal,
Dean & Principal, SLN MCH

Institutional Ethics Committee of Saheed Laxman Nayak Medical College & Hospital, Koraput, Odisha

Name, address, qualifications & designation of new members of the Ethics Committee:

Sl. No.	Name of Member	Qualification with Specialization	Current Organisation	Telephone number, fax number, e-mail.ID and mailing address	Designation/ Role of member in Ethics Committee	Affiliation of member with institute that has constituted the Ethics Committee
1	Sri Sachidananda Sahu	B.A L.L.B	Retired Judge	Sri Sachidananda Sahu, Soura Street, Jeypore, Koraput, Odisha 764001	Chairperson	No
2	Dr. Satyajit Samal	Pharmacology	SLN MCH, Koraput	SLN MCH Koraput Janiguda, Koraput-764020 dr_satyajitsamal@yahoo.com	Member Secretary	Yes
3	Prof. Krushna Chandra Biswal.	M.D. Radiodiagnosis	SLN MCH, Koraput	SLN MCH Koraput Janiguda, Koraput-764020	Member	Yes
4	Prof. Susanta Kumar Sahu	M.D. Microbiology	SLN MCH, Koraput	SLN MCH Koraput Janiguda, Koraput-764020	Member (Basic Medical Scientist)	Yes
5	Prof. Sujata Swain	M.D. O&G	SLN MCH, Koraput	SLN MCH Koraput Janiguda, Koraput-764020	Member (Clinician)	Yes
6	Sri. Ashok Kumar Shadangi	M.A (Econ.) M. Phil, LLB Advocate	Notary	Sri. Ashok Kumar Shadangi, Advocate, Housing board Colony, Koraput, Odisha 764020	Member (Legal Expert)	No
7	Sri. Radha Krishna Patnaik	Masters in Social Work, PGDRD	Private	Sri. Radha Krishna Patnaik, Jeypore Koraput, Odisha 764020	Member (Social Scientist)	No
8	Sri Gajendra Sethy	10th	Private	Forest Colony, Koraput, Odisha 764020	Member (Lay person)	No

Member Secretary, IEC Sln Mch Koraput	Chairman Iec, Sln Mch Koraput
Date: 8.12.2021	Date: 8.12.2021

MEMBER SECRETARY
Institutional Ethics Committee
SLN, MCH, KORAPUT

CHAIRMAN
Institutional Ethics Committee
SLN, MCH, KORAPUT

Annexure 1

Factor (F) for calculating the amount of compensation

Age	Factor
Not more than...	
16	228.54
17	227.49
18	226.38
19	225.22
20	224.00
21	222.71
22	221.37
23	219.95
24	218.47
25	216.91
26	215.28
27	213.57
28	211.79
29	209.92
30	207.98
31	205.95
32	203.85
33	201.66
34	199.40
35	197.06
36	194.64
37	192.14
38	189.56
39	186.90
40	184.17
41	181.37
42	178.49
43	175.54
44	172.52
45	169.44
46	166.29
47	163.07
48	159.80
49	156.47
50	153.09
51	149.67
52	146.20
53	142.68
54	139.13
55	135.56
56	131.95
57	128.33
58	124.70
59	121.05
60	117.41
61	113.77
62	110.14
63	106.52
64	102.93
65 or more	99.37

IEC SLN MCH

Annexure 2

Format for according approval to clinical trial protocol by the ethics committee

To

Dr.

Dear Dr._____

The Institutional ethics committee or independent ethics committee (state name of the committee, as appropriate) reviewed and discussed your application to conduct the clinical trial entitled
"……
"on……(date).

The following documents were reviewed:

(a) Trial protocol (including protocol amendments), dated……version No.(s) ……

(b) Patient information sheet and informed consent form (including updates, if any) in English or vernacular language.

(c) Investigator's brochure, dated …… , Version no…… Proposed methods for patient accrual including advertisements etc. proposed to be used for the purpose. (

d) Principal investigator's current Curriculum Vitae.

(e) Insurance policy or compensation for participation and for serious adverse events occurring during the study participation.

(f) Investigator's agreement with the sponsor.

(g) Investigator's undertaking (Table 4).

The following members of the ethics committee were present at the meeting held on (date, time, place)

. ……Chairperson of the ethics committee;

……Member-Secretary of the ethics committee;

……Name of each member with designation;

We approve the trial to be conducted in its presented form.

The ethics committee to be informed about the progress of the study, any Serious Adverse Events (SAE) occurring in the course of the study, any changes in the protocol and patient information or informed consent and to be provided with a copy of the final report.

Yours sincerely,

Member Secretary, Ethics Committee

INFORMED CONSENT

1. Checklist of informed consent documents for clinical trial subject,–

1.1 Essential elements:

(i) Statement that the study involves research and explanation of the purpose of the research.

(ii) Expected duration of the participation of subject.

(iii) Description of the procedures to be followed, including all invasive procedures.

(iv) Description of any reasonably foreseeable risks or discomforts to the Subject.

(v) Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.

(vi) Disclosure of specific appropriate alternative procedures or therapies available to the Subject.

(vii) Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject's medical records.

(viii) Trial treatment schedule and the probability for random assignment to each treatment (for randomized trials).

(ix) Statement describing the financial compensation and the medical management as under:

(a) In case of an injury occurring to the subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

(b) In the event of a trial related injury or death, the sponsor or his representative or the investigator or centre, as the case may be, in accordance with the rule 39, as the case may be, shall provide financial compensation for the injury or death.

(x)An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury.

(xi) The anticipated prorated payment, if any, to the subject for participating in the trial.

(xii) Responsibilities of subject on participation in the trial.

(xiii) Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled.

(xiv) Statement that there is a possibility of failure of investigational product to provide intended therapeutic effect.

(xv) Statement that in the case of placebo controlled trial, the placebo administered to the subjects shall not have any therapeutic effect.

(xvi) Any other pertinent information.

1.2 Additional elements, which may be required:

(a)Statement of foreseeable circumstances under which the participation of the subject may be terminated by the Investigator without his or her consent.

(b)Additional costs to the subject that may result from participation in the study.

(c)The consequences of a Subject's decision to withdraw from the research and procedures for orderly termination of participation by Subject.

(d) Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided.

(e). A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or foetus, if the Subject is or may become pregnant), which are currently unforeseeable.

(f) Approximate number of Subjects enrolled in the study

Format of informed consent form for Subjects participating in a clinical trial –

Informed Consent form to participate in a clinical trial

Study Title:

Study Number:

Subject's Initials: _____

Subject's Name: _____

Date of Birth/Age: _____

Address of the Subject ___

Qualification _____

Occupation: Student or Self-Employed or Service or Housewife or Others (Please click as appropriate) .

Annual Income of the subject:

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

Place Initial box (Subject)

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

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

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

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

(v) I agree to take part in the above study. ( )

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:

Date: _____/ ____ /

Signatory's Name: _____

Signature of the Investigator: _____ Date: ____ / ____ /

Study Investigator's Name: ___ _____

Signature of the Witness _____ Date: ____ / ____ /

Name of the Witness:_____

Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the subject his or her attendant.

UNDERTAKING BY THE INVESTIGATOR

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

2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted:

Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, or any other statements of qualifications)

3. Name and address of all clinical laboratory facilities to be used in the study.

4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.

5. Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigations.

6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.

7. Commitments:

(i) I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained.

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

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

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

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

IC

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

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

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

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

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

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

(xii) I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data. (xiii) I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

8. Signature of Investigator with date.

DATA ELEMENTS FOR REPORTING SERIOUS ADVERSE EVENTS OCCURRING IN A CLINICAL TRIAL OR BIOAVAILABILITY OR BIOEQUIVALENCE STUDY

1. Patient Details:
   Initials and other relevant identifier (hospital or out-patient department (OPD) record number etc)*
   Gender Age or date of birth
   Weight Height
2. Suspected Drug(s) :
   Generic name of the drug*
   Indication(s) for which suspect drug was prescribed or tested.
   Dosage form and strength. Daily dose and regimen (specify units - e.g., mg, ml, mg/kg).
   Route of administration.
   Starting date and time of day.
   Stopping date and time, or duration of treatment

3. Other Treatment(s): Provide the same information for concomitant drugs (including non-prescription or Over the Counter OTC drugs) and non-drug therapies, as for the suspected drug(s).

4. Details of Serious Adverse Event :
   Full description of the event including body site and severity, as well as the criterion (or criteria) for considering the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the event*
   Start date (and time) of onset of event.
   Stop date (and time) or duration of event.
   Dechallenge and rechallenge information.
   Setting (e.g., hospital, out-patient clinic, home, nursing home).

5. Outcome
   Information on recovery and any sequelae; results of specific tests or treatment that may have been conducted.
   For a fatal outcome, cause of death and a comment on its possible relationship to the suspected event;
   Any post-mortem findings.
   Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.

6. Details about the Investigator*

Name and Address

Telephone number Profession (specialty)

Date of reporting the event to Central Licencing Authority:

Date of reporting the event to ethics committee overseeing the site:

Signature of the Investigator or Sponsor

Note: Information marked * must be provided.

IEC APPLICATION FORM FOR INITIAL REVIEW

To

The Member Secretary,

IEC, SLN MCH, KORAPUT

(for IEC office use only)

Date of Receipt by IEC: _____ Sl. No.: _____

Date of Amendments suggested by IEC: _____

Depts.: _____

Date of resubmission to IEC: _____

Date of approved by IEC: _____ Approval No.: _____

A. BASIC INFORMATION

(a) Title of the study:

(b) Name of Principal Investigator:

(c) Department:

(d) Date of submission:

(e) Designation:

(f) Email id:

(g)Type of review requested:

- Exemption from review
- Expedited review
- Full committee review

(h) Protocol number (If any): Version number:

(i) Details of Investigators:

	Name	Designation	Dept. & Inst.
Principal Investigator (in Capital Letter)			
Co-Investigator (in Capital Letter)			
Guide (in Capital Letter)			

(j) Number of previous studies approved where applicant is a:

i) Principal Investigator at time of submission
ii) Co-Investigator at time of submission:

(k) Duration of the study:

(l) Place of study:

(m) Funding details and budget

- Total estimated budget:
- Self-funding / Institutional funding / Funding agency (Specify)

SECTION B - RESEARCH RELATED INFORMATION

1. OVERVIEW OF RESEARCH

(a) Summary (within 300 words):

(b) Objective of the study:

(c) Type of study:

- Basic Sciences / Clinical / Cross Sectional / Retrospective / Epidemiological/ CaseControl / Prospective / Public Health / Cohort / Qualitative / Socio-behavioural / Systematic Review / Quantitative / Biological samples/Data/ Mixed Method / Any others(Specify)

(d) Justification for conduct of this study:

2. METHODOLOGY

(a) Sample size/ number of participants: total sample size Control group / Study group
Justification for the sample size chosen (100 words):
(In case of qualitative study, mention the criteria used for saturation)

(b) Inclusion criteria:

(c) Exclusion criteria:

(d) Study design:

(e) Investigations specifically related to projects:

(f) Is there an external laboratory/outsourcing involved for investigations? Yes / No/ NA

(g) How was the scientific quality of the study assessed? Independent external review / Review by sponsor or Funder/Review within PI's institution/ Review within multi-centre research group/ No review

Date of the Review:

Research Comments of scientific committee/IRC, if any (100 words)

SECTION C: PARTICIPANT RELATED INFORMATION

3.RECRUITMENT AND RESEARCH PARTICIPANTS

(a). Type of participants in the study: Healthy volunteers / Patients / Vulnerable persons/ Special groups

Others (Specify)

- Who will do the recruitment?
- Participant recruitment methods used: Posters/ leaflets/Letters Others (Specify)

(b) Will there be vulnerable persons / special groups involved? Yes / No/ NA

- ✓ If yes, type of vulnerable persons / special groups

Children under18yrs, Pregnant or lactating women, Differently abled (Mental/Physical), Employees/Students/Nurses/Staff, Elderly, Institutionalized, Economically and socially disadvantaged, Refugees/Migrants/Homeless, Terminally ill (stigmatized or rare diseases) , Any other (Specify)

(c) Provide justification for inclusion/exclusion

(d) Are there any additional safeguards to protect research participants?

(e) Is there any reimbursement to the participants? Yes / No

If yes, Monetary / Non-monetary / Provide details

d) Are there any incentives to the participants? Yes / No

If yes, Monetary / Non-monetary / Provide details

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

If yes, Monetary/ Non-monetary / Provide details

4: BENEFITS AND RISKS

(a) Are there any anticipated physical/social/psychological discomforts/ risk to participants? Yes / No

If yes, categorize the level of risk: Less than Minimal risk / Minimal risk / Minor increase over minimal risk or low risk / More than minimal risk or high risk. Describe the risk management strategy:

What are the potential benefits from the study? For the participant

For the society/community

For improvement in science

Please describe how the benefits , justify the risks

Are adverse events expected in the study ? Yes/ No / NA

a. Are reporting procedures and management strategies described in the study? Yes/ No If Yes, Specify

5. INFORMED CONSENT

(a) Are you seeking waiver of consent? If yes, please specify reasons

(b) Version number and date of Participant Information Sheet (PIS):

(c) Version number and date of Informed Consent Form(ICF):

Type of consent planned for: Signed consent / Verbal/ Oral consent / Witnessed consent / Audio Video(AV) consent / Consent from LAR (If so, specify from whom)

(For children <7yrs parental/LAR consent, Verbal assent from minor (7-12 yrs) along with parental consent. Written assent from minor (13-18 yrs) along with parental consent)

(d) Who will obtain the informed consent?

PI/Co-I / Nurse/Counselor / Research Staff / Other (Specify) Any tools to be used

e) Participant Information Sheet (PIS) and Informed Consent Form(ICF) English & Local language / other (Specify). List the languages in which translations were done, if translation has not been done in local language, please justify.

f) Provide details of consent requirements for previously stored samples if used in the study.

(g) Elements contained in the Participant Information Sheet (PIS) and Informed Consent Form

(ICF) (Yes / No)

- ✓ Simple language/ Data/ Sample sharing
- ✓ Compensation for study related injury
- ✓ Risks and discomforts
- ✓ Need to recontact
- ✓ Statement that consent is voluntary
- ✓ Alternatives to participation
- ✓ Confidentiality
- ✓ Commercialization/ Benefit sharing
- ✓ Right to withdraw
- ✓ Storage of samples
- ✓ Statement that study involves research
- ✓ Benefits
- ✓ Return of research results
- ✓ Use of photographs/ Identifying data
- ✓ Purpose and procedure
- ✓ Payment for participation
- ✓ Contact information of PI and Member Secretary of EC
- ✓ Others(Specify)

6. PAYMENT/COMPENSATION

(a) Who will bear the costs related to participation and procedures?

PI/ Institution / Sponsor / Other agencies (specify)

(b) Is there a provision for free treatment of research related injuries ? Yes / No / N/A

If yes, then who will provide the treatment?

(c) Is there a provision for compensation of research related SAE? Yes / No / N/A. If yes, specify who will provide. (Sponsor / Institutional/Corpus fund / Project grant / Insurance)

(c) Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period ? Yes / No / N/A . If yes, specify.

(d) Is there a provision for ancillary care for unrelated illness during the study period ? Yes / No / N/A. If yes, please specify .

7. STORAGE AND CONFIDENTIALITY

(a) Identifying Information: Study Involves samples/data. Yes / No / N/A. If yes, please specify

(b) Who will be maintaining the data pertaining to the study?

(c) Where will the data be analyzed and by whom?

(d) For how long will the data be stored?

(e) Do you propose to use stored samples/data in future studies ? Yes / No / N/A. If yes, please specify how you might use stored material/data in the future?

SECTION D: OTHER ISSUES

8. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

a) Will the results of the study be reported and disseminated? Yes / No / N/A. If yes, please specify

b) Will you inform participants about the results of the study? Yes / No / N/A

c) Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished ? Yes / No / N/A. If yes, please specify

d) Is there any plan for post research benefit sharing with participants? Yes / No / N/A. If yes, please specify

e) Is there any commercial value or a plan to patent/IPR issues? Yes / No / N/A. If yes, please specify

f) Do you have any additional information to add in suppor to the application, which is not included else wherein the form? If yes, provide details.

SECTION E: DECLARATION AND CHECKLIST

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

Name of PI:

Signature with date:

Name of Co-PI:

Signature with date:

Name of Guide: Signature with date Name of HOD: Signature with date

Check List of Documents

Sl. No.	Document	Status		Page No.
		Yes	No	
1	IEC application form			
2	Brief CV of all Investigators			
3	Good Clinical Practice (GCP) training of investigators			
4	Approval of scientific committee			
5	IEC clearance of other centres			
6	Agreement between collaborating partners			
7	Insurance policy			
8	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification			
9	Copy of contract or agreement signed with the sponsor or donor agency			
10	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol			
Proposal related				
11	Copy of the detailed protocol			
12	Investigators Brochure (If applicable for drug/ biologicals/ device			

	trials)			
13	Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated)			
14	Assent form for minors (12-18 years) (English and Translated)			
15	Proforma/Questionnaire/Case Report Forms(CRF)/ Interview guides/ Guides for Focused Group Discussions(FGDs) (English and translated)			
16	Advertisement/material to recruit participants (fliers, posters etc)			
Permission from governing authorities				
17	CTRI			
18	Drugs Controller General (India) [DCG(I)] clearance			
19	Health Ministry Screening Committee (HMSC)approval			
20	Bhabha Atomic Research Centre (BARC) approval			
21	Genetic Engineering Advisory Committee (GEAC)approval			
22	Director General of Foreign Trade (DGFT) approval			
23	FDA marketing/manufacturing license for herbal drugs.			
24	others (specify)			

Comments of EC Secretariat:

Signature of Member Secretary with date:

IEC APPLICATION FORM
(Application Form for Exemption from Review)

To

The Member Secretary,

IEC, SLN MCH, KORAPUT

(for IEC office use only)

Date of Receipt by IEC: _____ Sl. No.: _____

Date of Amendments suggested by IEC: _____

Depts.: _____

Date of resubmission to IEC: _____

Date of approved by IEC: _____ Approval No.: _____

Title of the project (in Capital Letters)

_____

_____

_____

_____

	Name	Designation	Dept. & Inst.
Principal Investigator (in Capital Letter)			
Co-Investigator (in Capital Letter)			
Guide (in Capital Letter)			
Duration of Study			
Place of study			

Choose reasons why exemption from ethics review is requested?

i. Research on data in the public domain/ systematic reviews or meta-analyses

ii. Observation of public behavior/ information recorded without linked identifiers and disclosure would not harm the interests of the observed person

iii. Quality control and quality assurance audits in the institution

iv. Comparison among instructional techniques, curricula, or classroom management methods

v. Consumer acceptance studies related to taste and food quality

vi.Public health programmes by government agencies

vii. Any other (please specify in 100 words):

Check List of Documents

Sl. No.	Document	Status		Page No.
		Yes	No	
1	IEC application form			
2	Summary of protocol			
3	Protocol			
4	Amendments to protocol			
5	Informed consent document in English			
6	Informed consent documents in Regional languages			
7	Case Record Form / Questionnaire			
8	Principal investigators Current Curriculum Vitae			
9	Other Documents			

Signature of PI with date:

Comments of EC Secretariat:

Signature of Member Secretary with date:

Continuing Review / Annual report format

Title of study:

PrincipalInvestigator(Name,DesignationandAffiliation):

1. Date of IEC approval
2. Validity of approval
3. Date of start of study
4. Proposed date of study completion
5. Period of continuing report from to
6. Does the study involve recruitment of participants Yes ☐ No ☐

(a) Ifyes,Totalnumberexpected: NumberScreened: Number Enrolled:.

Number Completed: Number on follow up

(b) Enrolment status – ongoing / completed/stopped

(c) ReportofDSMBYes ☐ No ☐ NA

(d) Any other remark

(e) Haveanyparticipantswithdrawnfromthisstudysincethelastapproval? Yes ☐ No ☐ NA ☐

Ifyes,totalnumberwithdrawnandreasons:

7. Isthestudylikelytoextendbeyondthestatedperiod?Yes ☐ No

Ifyes,pleaseprovidereasonsfortheextension.

8. Havetherebeenanyamendmentsintheresearchprotocol/InformedConsentDocument(ICD)during thepast approvalperiod?

IfNo,skiptoitemno.9Yes ☐ No ☐

(i) Ifyes,dateofapprovalforprotocolandICD:

(II)In case of amendments in the research protocol/ICD, was re-consent sought from participants? Yes ☐ No ☐

Ifyes,when/how:

9. Is any new information available that changes the benefit - risk analysis of human participants involved in this study?Yes ☐ No ☐

Ifyes,discussindetail:

10. Have any ethical concerns occurred duringthisperiod?

Yes ☐ No ☐

If yes, give details

11. Have any adverse events been noted since thelast review? Yes ☐ No ☐

Describe in brief:

12. (a)Have any SAE's occurred sincelastreview?Yes No

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

(b) Is the SAE related tothe study?Yes ☐ No ☐

(c) Have you reported the SAE to EC? If no,statereasonsYes ☐ No ☐

13. Hastherebeenanyprotocoldeviations/violationsthatoccurredduringthisperiod?

If yes, number of deviations

b) Have you reported the deviations to EC? Yes ☐ No ☐

If no,statereasons

14. Incaseofmulticenterictrials, have reportsofoff-siteSAEsbeensubmittedtotheEC?Yes ☐ No ☐ NA ☐

15. Are there any publications or presentations during this period? If yesgivedetails.

Yes No

Any other comments:

Signature of PI:

Application/Notification form for Amendments

1. Title of the study

Application Form for Clinical Trials

1.Title of the study

2. PI details

3. Type of Clinical trial – Regulatory trial / Academic trial

CTRIregistrationnumber.

NABHaccreditationnumber.

ECregistrationnumber

4. Ifregulatorytrial,providestatusofCDSCOpermissionletter
Approved and letterattached/ Applied, under process/ Not applied(Statereason)

5. Tick all categories that apply to yourtrial

Phase-I	☐	PhaseII	☐
PhaseIII	☐	Phase IV or Post Marketing Surveillance	☐
Investigational medicinal products		Investigational Newdrug	
Medical devices		New innovativeprocedure	
Drug/device combination		Bioavailability/Bioequivalencestudies	☐
Non-drug intervention		Repurposing an existingintervention	☐
Indian system of	☐	Stemcells	☐
(AYUSH)medicinePhytopharmaceut	☐	Approved drug for any newindication	
ical drug	☐	ornewrouteofadministration	
Others (specify)			

6. Trial design of thestudy

i. Randomized	☐	Factorial	☐
Non randomized	☐	Stratified	☐
Parallel	☐	Adaptive	☐
Cross-over	☐	Comparisontrial	☐
Cluster		Superioritytrial	☐
Matched-pair		Non-inferioritytrial	☐
Others *(specify)*		Equivalencetrial	☐

II.If there is randomization, how will the participants be allocated to the control and study group(s)?

III. Describe the method of allocation concealment (blinding / masking), if applicable.

7. List the primary / secondary outcomes of the trial.

8. Is there a Contract Research Organization (CRO) /Site Management Organisation (SMO) / Any other agency such as public relation/human resource? Yes ☐ No ☐

If yes, Name and Contact details:

9. State how the CRO/SMO/agency will be involved in the conduct of the trial (tick all that apply)

Project management	Clinical and medicalmonitoring
Regulatory affairs	Datamanagement
Statistical support	Medicalwriting
Site management	

10. Please provide the following details about the intervention being used in the protocol

I. Drug/s, device/s and/or biologics; Yes ☐ No ☐ NA ☐

if yes, provide regulatory approval details.

II. Already approved drugs or a combination of two or more drugs with new indications / change in dosage form / route of administration. Yes ☐ No ☐ NA ☐

If yes, provide details.

III. Provide contact details of who prepared and /or is manufacturing the drug/s, device/s and biologics.

IV. Provide details of patent of the drug/s, device/s and biologics.

11. Describe in brief any preparatory work or site preparedness for the protocol?Yes ☐ No ☐ NA ☐

If yes, provide details

12. Is there an initial screening/use of existing database for participant selection?Yes ☐ No ☐ NA ☐ If Yes, provide details

13. Is there any anticipated incidence, frequency and duration of adverse events related to the intervention?Yes ☐ No ☐ NA ☐

If yes, provide details of arrangements made to address them.

14. Does the study use a placebo?Yes ☐ No ☐ NA ☐

If yes, justify the use of the placebo and risks entailed to participants.

15. Will current standard of care be provided to the control arm in the study?Yes ☐ No ☐ NA ☐

If no, please justify.

16. Are there any plans to withdraw standard therapy during the study?Yes ☐ No ☐ NA ☐

If yes, please justify

17. Are there any rules to stop the protocol in case of any adverse events?.Yes ☐ No ☐ NA ☐

If yes, please specify

18. Does the study have a Data and Safety Monitoring Plan? Yes ☐ No ☐ NA ☐

If no, please justify.

16. Participant Information Sheet(PIS) and Informed Consent Form (ICF)

English ☐ Local language ☐ Other(Specify) ☐

(certified that local version (s) is/are a true translation of the English version andcan be easily understood by the participants)

17. Involvement/consultation of statistician in the study design Yes No NA

18. Is there any insurance coverage of the trial? If yes, provide details. Yes ☐ No ☐

19. Is the PI registered with Medical Council of India (MCI) or the State Medical Council registration?Yes ☐ No ☐

Please provide details.

20. Is the PI trained in GCP in last 3 years? If yes, Please enclose certificate Yes ☐ No ☐

Signature of PI with date

INFORMED CONSENTDOCUMENT

Participant information sheet

(i) Statement that the study involves research and explanation of the purpose of the research. In simple language

(ii) Expected duration of the participation of subject.

(iii) Description of the procedures to be followed, including all invasive procedures.

(iv) Description of any reasonably foreseeable risks or discomforts to the Subject.

(v) Description of any benefits to the participant or others reasonably expected from research. If no benefit isexpected participants should be made aware of this.

(vi) Disclosure of specific appropriate alternative procedures or therapies available to the participant.

(vii) Statement describing the extent to which confidentiality of records identifying the participant will bemaintained and who will have access to participant's medical records.

(viii) Trial treatment schedule and the probability for random assignment to each treatment (for randomizedtrials).

(ix) Statement describing the financial compensation and the medical management as under:

(a) In case of an injury occurring to the subject during the clinical trial, free medical management shall begiven as long as required or till such time it is established that the injury is not related to the clinical trial,whichever is earlier.

(b) In the event of a trial related injury or death, the sponsor or his representative or the investigator orcentre, as the case may be, in accordance with the rule 39, as the case may be, shall provide financialcompensation for the injury or death.

(x)An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury.

(xi) The anticipated prorated payment, if any, to the participant for participating in the trial.

(xii) Responsibilities of subject on participation in the trial.

(xiii) Statement that participation is voluntary, that the subject can withdraw from the study at any time and thatrefusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled.

(xiv) Statement that there is a possibility of failure of investigational product to provide intended therapeuticeffect.

(xv) Statement that in the case of placebo-controlled trial, the placebo administered to the subjects shall not haveany therapeutic effect.

(xvi) Any other pertinent information.

Additional elements, which may be required:

(a)Statement of foreseeable circumstances under which the participation of the subject may be terminated by theInvestigator without his or her consent.

(b)Additional costs to the participant that may result from participation in the study.

(c)The consequences of a participant's decision to withdraw from the research and procedures for orderlytermination of participation by Subject.

(d)Statement that the Participant or participant's representative will be notified in a timely manner if significant newfindings develop during the course of the research which may affect the participant's willingness to continueparticipation will be provided.

(e). A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo orfoetus, if the participant is or may become pregnant), which are currently unforeseeable.

(f) Approximate number of participants enrolled in the study.

Premature Termination/Suspension/ Discontinuation Report Format

1. Title of the study
2. IEC ref no:
3. PI – Name, Designation and Affiliation

4. Date of EC approval
5. Date of Start of study
6. Date of last progress report submitted to EC
7. Date oftermination/suspension/discontinuation:
8. Reason for Termination/Suspension/Discontinuation
9. ActiontakenpostTermination/Suspension/Discontinuation(ifany):
10. Plansforpoststudyfollowup/withdrawal(ifany)
11. Details of study participants
    - Total number of participants to be recruited
    - Screened
    - Screen failures
    - Consent with drawn – reason
    - With drawn by PI- reason
    - Active on treatment / Completed treatment/ Participants on follow-up:
    - Participants lost to follow up
    - Number of drop outs
    - Reasons for each drop-out
    - Any other
12. Total number of SAEs reported till date in the study
13. Have any unexpected adverse events or outcomes observed in the study been reported to the EC?**Yes/No**
14. Have there been participant complaints or feedback about the study?**Yes/No**
    If yes provide details
15. Have there been any suggestions from the SAE Sub Committee?**Yes/No**
    If yes have you implemented that suggestion?Yes/No

16. Do the procedures for withdrawal of enrolled participants take into account their rights and welfare? Yes ☐ No☐ (e.g., making arrangements for medicalcare of research participants):
If Yes, provide details

Summary of results:

Signature of PI with date