I. Introduction

Vision:

To be a Centre of Excellence in ethical review, fostering a culture of responsible and high-quality biomedical and health research that upholds the dignity, rights, safety, and well-being of all human participants and contributes to societal welfare.

Mission:

To provide an independent, competent, and timely ethical review of all research proposals involving human participants, ensuring strict adherence to national (ICMR, other regulatory bodies) and international ethical standards.

To safeguard the dignity, rights, safety, and well-being of all actual and potential research participants, with special attention to vulnerable populations, in line with the core principles of Autonomy, Beneficence, Non-maleficence, and Justice.

To educate and guide researchers on the ethical conduct of research and continuously build the capacity of IEC members and staff in bioethics and regulatory requirements.

Objectives:

A. <u>Protection of Participants</u>

1. To review the scientific design, ethical justification, and methodology of all research protocols to ensure that the risks to participants are minimized and outweighed by potential benefits, and that the rights and welfare of subjects are protected throughout the study.
2. To provide additional safeguards and protections for research involving vulnerable populations (e.g., children, economically or educationally disadvantaged persons) as per ICMR guidelines.
3. To ensure adequate provisions are in place to protect the privacy and confidentiality of participants' data and biological materials.

B. Competent and Consistent Review

4. To establish, document, and implement Standard Operating Procedures (SOPs) that comply with ICMR Guidelines, relevant regulatory requirements (e.g., New Drugs and Clinical Trials Rules), and Good Clinical Practice (GCP) guidelines.
5. To conduct competent, objective, and timely ethical review (Exempt, Expedited, or Full Committee) and provide clear, reasoned decisions (Approval, Modification, or Disapproval) to the Principal Investigator (PI).
6. To undertake periodic review and monitoring of approved research projects, including reviewing progress reports, amendments, and reports of Serious Adverse Events (SAEs), until study completion.

C. Capacity Building

7. To ensure that all IEC members and the secretariat receive mandatory, initial, and continuous training in bioethics, research regulations, and SOPs.

II. Structure of Institutional Ethics Committee of S. Nijalingappa Medical College & Hanagal Shri Kumareshwar Hospital & Research Centre, Bagalkote

Establishing, Constituting and Apellate Authority: Dean, S. Nijalingappa Medical College & Hanagal Shri Kumareshwar Hospital & Research Centre, Bagalkote

The ICMR Ethical Guidelines, 2017 and the New Drugs and Clinical Trial Act & Rules, 2019 has been followed while constituting the IECSNMC. The composition of IECSNMC is as below

S. No	Name of the Member	Designation	Role in Ethics Committee	Affiliation to the Institution
1	Dr. S. L. Hoti	Former ICMR Emeritus Scientist 'G', ICR Vector Control Research Centre, Puducherry	Chairperson	Non-Affiliated
2	Dr. Anand Bhimaray Janagond	Professor of Microbiology S. Nijalingappa Medical College, Bagalkote	Member Secretary	Affiliated
3	Dr. Ashwini Mutalik	Professor of Anatomy S. Nijalingappa Medical College, Bagalkote	Basic Medical Scientist	Affiliated
4	Dr. Shambhavi Kulkarni	Associate Professor of Pharmacology S. Nijalingappa Medical College, Bagalkote	Basic Medical Scientist	Affiliated
5	Shri. Prakash G. Yaragatti	Pharmacy Officer Govt District Hospital, Bagalkote	Basic Medical Scientist	Non-Affiliated
6	Dr. Narayan Mutalik	Professor & Head, Dept of Psychiatry, S. Nijalingappa Medical College, Bagalkote	Clinician	Affiliated
7	Dr. Anilkumar Ganeshnavar	Professor of Anaesthesiology S. Nijalingappa Medical College, Bagalkote	Clinician	Affiliated
8	Dr. Jayaraj Mhetri	Associate Professor of Community Medicine S. Nijalingappa Medical College, Bagalkote	Clinician	Affiliated
9	Shri. T. B. Korishetti	Former Principal,	Lay Person	Non-Affiliated

		BVVS Independent College, Bagalkote		
10	Smt. Shreelatha Rao	Former Professor & Head Dept of Management Studies Basaveshwar Engineering College, Bagalkote	Lay Person	Non-Affiliated
11	Shri. Laxminarayan Kasat	NGO Member, Bagalkote	Social Scientist	Non-Affiliated
12	Shri. S. M. Tavali	Advocate, Bagalkote	Legal Expert	Non-Affiliated

III. Terms of reference of IEC

A. Purpose

This Standard Operating Procedure (SOP) describes the Terms of References (TOR), which provide the framework for constitution, responsibilities, and activities of the Institutional Ethics Committee (IEC).

B. Scope of SOP

The SOP applies to all activities performed by the Institutional Ethics Committee.

C. Responsibility

It is the responsibility of the Institutional Ethics Committee members and the Secretariat to read, understand, follow and respect the SOP set by the Institutional Ethics Committee.

No.	Activity	Responsibility
1	Composition of the Institutional Ethics Committee	Head of the Institute, Chairperson, IEC Members and Secretariat
2	Selection and appointment of Chairperson	Head of the Institute
3	Membership requirements	Head of the Institute, Chairperson
4	Appointment of new members and relieving of members	Head of the Institute
5	Tenure of Membership	Chairperson, IEC Members and Secretariat
6	Conduct of meetings and maintenance of records	Secretariat
7	Quorum requirements	IEC Members and Secretariat
8	Appeal	Head of the Institute

The committee has the following general responsibilities to review and approve when deemed fit, all research involving human participants conducted at SNMC, Bagalkote:

1. To protect and safeguard the dignity, rights, safety and well-being of all actual or potential research participants, and vulnerable population.
2. To consider the principle of justice, that the benefits and burdens of research be distributed fairly among all groups and classes in society taking into account age, gender, economic status, culture and ethnic consideration.
3. To advice the researchers on all aspects of the welfare and safety of research participants after ensuring the scientific soundness of the proposed research.
4. To ensure that trials are sound in scientific design, have statistical validity and are conducted according to the established national guidelines as well as local regulatory requirements.
5. To ensure that no participants are admitted into the study without Committee's written approval for the conduct of the study.

D. Scope of IECSNMC

1. The institutional Ethics committee of S. Nijalingappa Medical College reviews both academic and investigator-initiated studies conducted in the medical college and Hospital and/or by the students/faculty/staff affiliated to the institution.
2. If there is any proposal from outside the institution such proposals will be accepted provided the trial site is within 50km radius of S. Nijalingappa Medical College, Bagalkot and there shall be a MOU between hospital/institute intending to do the research and Dean of SNMC.
3. Fees charged: Institutional Ethics committee of S. Nijalingappa Medical College, Bagalkot does not charge fee for the review of research proposals submitted to it.

IV. Membership requirements

1. In the interest of the Institute's research program, the IECSNMC members including the Chairperson, Member Secretary will be selected by the Dean, SNMC, taking into consideration of their eligibility and capacity to function as a member of the IECSNMC.
2. IECSNMC members will be selected on the basis that they are willing to publicize full name, profession and affiliation. Their Curriculum vitae shall be submitted to the IECSNMC secretariat for records.
3. Selected members shall possess the necessary research experience- scientific knowledge and expertise; knowledge of ethics, and their commitment and willingness to volunteer the necessary time and effort for the IECSNMC work.
4. The Chairperson and the IECSNMC members shall be informed of the potential members by the Member Secretary in the meeting and their concurrence shall be obtained.
5. The duration of appointment initially shall be for a period of 3 years.
6. Tenure of the members including the Chairperson, and the Member Secretary shall be for maximum 3 consecutive terms of 3 years each.
7. The appointments of members may be renewed by the Dean, SNMC for up to three consecutive terms or as required at the discretion of the Dean, SNMC.
8. Members will be required to sign a confidentiality agreement at the start of their tenure. One copy of agreement will be kept with EC Office and another copy will be provided to the members.
9. Freshly appointed members will act as observers for at least three meetings prior to their induction into the EC.
10. Members must disclose in writing any conflicts of interest or involvement – financial, professional or otherwise – in a project or proposal under consideration. The IECSNMC will decide the extent to which members who might have a conflict of interest may participate in bringing out an advice/decision.
11. An investigator can be a member of the IEC; however, the investigator-as-member cannot participate in the review and approval process for any project in which he or she has presence as a PI, Co-PI or CI or potential conflict of interest.
12. **Procedure for resignation, replacement or removal of members:** A member can be replaced in the event of death or long-term non-availability or for any action not commensurate with

the responsibilities laid down in the guidelines deemed unfit for a member. Members may resign before completing their term by writing their intention to the chairperson with one-month notice. Once a member resigns, chairperson and appointing authority shall appoint a person to replace him as per norms. Chairperson and appointing authority have the power to remove a person if the member remains absent for 3 consecutive meetings without any justifiable reasons.

13. Members will be conversant with the provisions of clinical trials under the provisions of Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and wellbeing of trial subjects.

V. Composition of IECSNMC

The IECSNMC will be formed in accordance with the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, ICMR. It will comply with the following

1. The number of members in the IECSNMC will be between seven and 15 and a minimum of five members will be present to meet the quorum requirements.
2. Ethics Committee will be multi-disciplinary and multi-sectoral with adequate representation of age and gender.
3. The EC will have a balance between medical and non-medical members/technical and non-technical members, depending upon the needs of the institution.
4. Preferably, 50% of the members will be non-affiliated or from outside the institution. So as to maintain independence, the head of the institution will not be part of the EC but will act as an appellate authority to appoint the committee or to handle disputes.
5. The Chairperson and Member Secretary could have dual roles in the ethics committee. They could fulfil a role based on their qualifications (such as that of clinician, legal expert, basic scientist, social scientist, lay person, etc.) in addition to taking on the role of Chairperson or Member Secretary.
6. The EC may also have a set of alternate members who can be invited as members with decision-making powers to meet the quorum requirements. These members have the same TORs as regular members and can attend meetings in the absence of regular members. The EC can maintain a panel of subject experts who are consulted for their

subject expertise, for instance, a paediatrician for research in children, a cardiologist for research on heart disorders, etc. They may be invited to attend the meeting to give an expert opinion on a specific proposal but will not have decision making power/voting rights. The EC may invite subject experts as independent consultants or include a representative from a specific patient group as a member of the EC or special invitee, for opinion on a specific proposal, for example HIV, genetic disorders, or cancer, with appropriate decision-making power.

7. EC may raise scientific queries besides ethical ones as both good science and ethics are important to ensure quality of research and participant protection.

VI. Eligibility and roles of members of IECSNMC

1. **Chairperson**/ Vice Chairperson (optional)

Eligibility:

a. Non-affiliated (External member)
b. Qualifications - A well-respected person from any background with prior experience of having served/ serving in an EC

Role in IECSNMC:

a. Conduct EC meetings and be accountable for independent and efficient functioning of the committee
b. The chairperson shall preside over all administrative matters pertinent to the committee's functions.
c. Ensure active participation of all members (particularly non-affiliated, non-medical/ non- technical) in all discussions and deliberations
d. Ratify minutes of the previous meetings
e. In case of anticipated absence of both Chairperson and Vice Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting.
f. Seek COI declaration from members and ensure quorum and fair decision making.

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

2. **Member Secretary**/ Alternate Member Secretary (optional)

Eligibility:

a. Affiliated (Institutional member)

b. Qualifications –

- should be a staff member of the institution
- should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills.
- Should be able to devote adequate time to this activity which should be protected by the institution

Role in EC:

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

b. Schedule EC meetings, prepare the agenda and minutes

c. Receive all research proposals. Forward all materials for review to the committee members. Establish time limits for receipt of reviewer's comments from EC Members

d. Organize EC documentation, communication and archiving

e. Ensure training of EC secretariat and EC members

f. Ensure SOPs are updated as and when required

g. Ensure adherence of EC functioning to the SOPs

h. Prepare for and respond to audits and inspections

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

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

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

l. Ensure quorum during the meeting and record discussions and decisions.

3. Basic Medical Scientist(s)

Eligibility

a. Affiliated/ non-affiliated
b. Qualifications
   - Non-medical or medical person with qualifications in basic medical sciences
   - In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist.

Role in EC:

a. Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report
b. For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.

4. Clinician(s)

Eligibility

a. Affiliated/ non-affiliated
b. Qualifications: Should be individual/s with recognized medical qualification, expertise and training

Role in EC:

a. Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics
b. Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report)
c. Review medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation.
d. Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents

5. Legal expert/s

Eligibility

a. Affiliated/ non-affiliated
b. Qualifications
    - Should have a basic degree in Law from a recognized university, with experience
    - Desirable: Training in medical law.

Role in EC:

a. Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc.
b. Interpret and inform EC members about new regulations if any

6. Social scientist/ philosopher/ ethicist/theologian

Eligibility

a. Affiliated/ non-affiliated
b. Qualifications
    - Should be an individual with social/ behavioral science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values.
    - Can be from an NGO involved in health-related activities

Role in EC:

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

7. Lay person(s)

Eligibility

a. Non-affiliated
b. Qualifications
    - Literate person from the public or community
    - Has not pursued a medical science/ health related career in the last 5 years
    - May be a representative of the community from which the participants are to be drawn
    - Is aware of the local language, cultural and moral values of the community
    - Desirable: involved in social and community welfare activities

Role in EC:

a. Ethical review of the proposal, ICD along with translation(s).
b. Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks.
c. Serve as a patient/participant/ community representative and bring in ethical and societal concerns.
d. Assess on societal aspects if any.

VII. Quorum requirement

Meetings will be held as scheduled, provided there is a quorum. In accordance with the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, ICMR the quorum requirements for ethics committee are

1. A minimum of five members present in the meeting room.

2. The quorum should include both medical, non-medical and technical or/and non-technical members.

3. Minimum one non-affiliated member should be part of the quorum.

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

5. The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements.

6. No decision is valid without fulfilment of the quorum

VIII. Conduct of meeting

1. The Chairperson conducts all meetings of the IECSNMC. If for reasons beyond control, the Chairperson is not available; Vice-chairperson conducts the meeting.
2. The Member Secretary is responsible for organizing the meetings, maintaining the records, and communicating with all concerned. He/she prepares the minutes of the meetings and gets it approved by the Chairman before communicating to the researchers. If for reasons beyond control, the Member-Secretary is not available, Alternate member Secretary conducts the meeting.
3. All the meetings will be held once in 2 months (Preferably on Thursday of the last week). Dates will be announced and notified in advance to all members. Additional review meetings may also be held with a short notice as and when required and deemed necessary.
4. Members will be given at least a week's time in advance to review study proposals and the relevant documents.
5. Committee meetings will be recorded and all the proceedings and deliberations will be documented and approved by the Chairperson.
6. Independent expert will be invited to the meeting or to provide written comment whenever necessary. The invited experts will be required to sign a confidentiality / conflict of interest agreement form prior to accessing the EC documents.
7. The meetings can be held on virtual platform also. The records are archived for a period of 5 years from the end of the project.
8. E-archiving is being done in view of the space and cost constraints. Where indicated, archiving may be done for a longer time and in hardd-copy.

IX. Procedure for submission of application

1. The Principal Investigator has to submit an application along with study protocol for review by the committee.
2. Application should be prepared in the format prescribed by the committee.
3. All the proposals received at least 10 working days in advance from the scheduled meeting will be included for review; otherwise, they will be deferred to the next meeting.
4. Five (5) copies of study proposal (with all other essential documents) along with soft copy of the proposal must be submitted along with application form duly signed and dated by the investigator(s). One copy in paper-form and/or scanned digital version will be preserved at the office of the Ethics Committee after the meeting.
5. On receipt, the applications will be allotted a registration number for all future correspondence and reference.

X. Review procedure

1. The Committee will review all research proposals /studies.
2. The Committee will evaluate the possible risks to the participants with proper justifications, the expected benefit and adequacy of documentation for ensuring privacy, confidentiality and justice issue.
3. The PI or one of the co-investigators shall present the study protocol and ethical concerns to the committee. The review will be done through formal meetings and discussions by the members in the meeting.

Types of Review

The Committee may conduct either expedited review or full board review:

1**. Expedited Review**: For certain kinds of research involving no more than minimal risk and for minor changes in approved research, the Chairperson or a designated voting member or group of voting members shall review the proposed research rather than the entire committee.

2. Full Board Review: When full board review is necessary, the research proposal is presented and discussed at a meeting at which a quorum of committee members is present.

Note: The determination of whether a protocol requires a full board review or an expedited review shall be made by the Chairperson/Member Secretary.

XI. Procedure for decision-making

A. In making decision on an application for the ethical review of any research proposal, the committee will consider the following:

1. Decision will only be taken at meetings where a quorum is complete.
2. Decision will be taken only after reviewing a complete application with all the required documents necessary for proposal has been examined by the Committee.
3. Only members who participated in review and discussion will participate in decision-making.
4. Member having conflict of interest will indicate to the chairman prior to the review of application and same will be recorded in the minutes.
5. Whenever there is conflict of interest, member will withdraw from the decision-making procedure.
6. Decision procedure will specify, during approval, clear suggestions and review procedure.
7. Negative decision will be supported by clearly stated reasons and justifications.
8. No person, who is not a member of the Committee, will be allowed to participate in the proceedings of the meeting while making the decision.
9. Procedure for communicating the decision of the Committee to the applicant/Principal Investigator
10. A decision of the Committee will be communicated to the applicant Investigator in writing, within seven working days of the meeting at which the decision was taken.

B. Validity of approval and renewal of approval

1. Approval of the research protocol shall be valid for a period of up two years from the date of issue, or as decided by the committee.

2. In case the research project work exceeds two years, the PI shall seek renewal of approval at two-yearly intervals. The application for renewal of approval shall be submitted to the EC no later than 15 days prior to the expiry of approval.

3. In case of failure to comply with the above, the PI shall stop the trial and submit an application for approval. The research project will be treated as a fresh proposal.

C. Follow up procedure

1. Based on the periodic study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or visiting the study sites the committee will review the progress of all the studies for which a positive decision was taken, from the time of approval till the completion/termination of the research.

2. Progress of all the research proposals will be monitored at regular intervals of six months. However, in special situations, Committee will conduct follow up review at shorter intervals based on the need, nature and events of research project.

3. Following instances and events will require follow-up review:

i. Protocol amendment likely to affect, rights, safety or well-being of research participants in conduct of study.
ii. 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 Licensing Authority and same will be followed up in terms of action taken by investigator, sponsor and regulatory authority.
iii. Any event or information that may directly/indirectly affect the benefit/risk ratio of the study.

iv. A decision of a follow up review will be issued and communicated to applicant indicating modification/suspension/termination/continuation of the project.

v. In case of premature suspension/termination, the applicant must notify the reasons to the Committee for suspension/termination with a summary of results.

XII. Conflict of Interest

Conflict of Interest: A situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties.

Conflict of interest is present and interferes with ability to make an objective evaluation when ethics committee members

1. Have their own research projects under review by the Ethics Committee, when they are investigators, co-investigators, or when they are in a supervisory or mentoring relationship with a Principal Investigator.
2. A member whose spouse is a Principal Investigator, co-investigator, for any project under review is also considered to have conflict of interest.
3. Members may also be in a conflict of interest situation when they have interpersonal or financial relationships with the researchers, or personal or financial interests in a company, organization that may be the sponsor of the research project, or that may be substantially affected by the research.

To maintain the independence and integrity of research ethics review, members will identify, eliminate, minimize or otherwise manage real, potential or perceived conflicts of interest.

If a member has a personal or financial conflict of interest, the members must disclose the nature of the conflict and absence themselves from any discussion or decision regarding that research project.

In the event that a member's conflict of interest and necessary withdrawal from the meeting will threaten the maintenance of quorum, the Committee will ensure that an alternate member be in attendance to maintain quorum.

Strategies to manage Conflict of Interest:

a. Disclose conflict of interest
b. Document the conflict of interest in attendance register /minutes of the meeting
c. Refrain from taking part in any discussion/review/ debate about the proposal
d. Refrain from participating in the review process of project proposal by leaving the meeting room.

XIII. Procedure for documentation and archiving

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

2. Only the person, who is authorized by the Chairman of the Committee, will have the access to the various documents. Under special circumstances, other persons may be provided access to various documents upon executing a confidentiality/conflict of interest agreement.

3. All the documents related to research proposals will be archived for a minimum period of 5 years following the completion of the study or as deemed necessary by regulatory authorities. These will be:

i. The constitution, written standard operating procedures of the Committee, and regular (annual) reports.
ii. The curriculum vitae of all Committee members.
iii. A record of all incomes and expenses, if any, of the Committee, including allowances and reimbursements made to the secretariat and Committee members.
iv. The agenda of the Committee meetings.
v. The minutes of the Committee meetings.
vi. One copy of all material submitted by an applicant.

vii. The correspondence by Committee members with applicants or concerned parties regarding application, decision and follow-up.

viii. A copy of the decision and any advice or requirements sent to an applicant.

ix. The final summary or final report of the study.

XIV. Investigator's Responsibility

1. Investigator should promptly report to the Committee the following:
   i. Changes/amendment that increase the risk to study participants and /or those significantly affecting the conduct of the study.
   ii. All deviations from the approved protocol or changes in the protocol to eliminate immediate hazards to the study participants.
   iii. All Serious Adverse Events (SAEs) within 72 hours of their occurrence.
   iv. New Information that may affect adversely the safety of the participants or the conduct of the study.
   v. Any changes in the study documents.
   vi. Progress of the study as mentioned in the approval letter, and the final report after completion of the study.

2. Essential documents to be submitted with the proposal:

   i. Application form.
   ii. The current version of the protocol of the proposed research.
   iii. Case report forms, diary cards and other questionnaires intended for research participants.
   iv. Investigator(s) curriculum vitae (updated, signed and dated).
   v. Material to be used (including advertisements) for the recruitment of potential research participants.
   vi. A description of the process to be used to obtain and document consent.
   vii. Written and other forms of information for potential research participants (clearly identified and dated) in the language(s) understood by the potential research participants.
   viii. Informed consent form in the language understood by the potential research participants in their own language. The document should be customized for the site by including Principal Investigator's name, address & phone number and also that of Ethics Committee.
   ix. Indicate amount of compensation to be paid to study participant/parents/Guardian in informed consent form.

x. A statement describing any compensation for study participation (including expenses and access to medical care) and medical insurance (negligent and non-negligent) to be given to research participants or institutional policy of medical insurance.

xi. Documentation of submission of protocol to the concerned regulatory authorities (e.g.- Drug Controller General of India) for approval. However, final letter of approval shall be submitted to the Ethics Committee prior to commencement of enrolment of participants to the trial.

XV. SOP for Vulnerable population

1. Special considerations shall be taken while reviewing projects involving research on vulnerable population like pregnant women, children (up to 18 years), economically disadvantaged, sexual minorities, terminally ill, suffering from mental, stigmatizing, or rare diseases, tribals and marginalized communities, differently abled-mentally and physically disabled, those having diminished autonomy due to dependency, etc.
2. The IECSNMC shall examine whether inclusion/exclusion of the vulnerable population is justified.
3. Only the full Committee shall do initial and continuing review of such proposals. If possible, empowered representatives from the specific populations are included during deliberations.
4. Efforts shall be made to ensure that individuals or communities who are economically or socially disadvantaged and are invited for research are selected in such a way to ensure a balanced benefit-risk and advise risk minimization strategies wherever possible.
5. Additional safeguards, such as more frequent review and monitoring, including site visits shall be done.
6. The rights and welfare of mentally challenged and differently abled persons who are incapable of giving informed consent or those with behavioral disorders are protected. It is ensured that appropriate proxy consent from legal guardian is taken after the person is well informed about the study, need for participation, risks and benefits involved and the privacy and confidentiality procedures undertaken. It is ensured that the entire consent process is adequately documented.
7. Adequate care shall be taken while reviewing proposals involving patients such as students, subordinates, employees, service personnel, etc. who have reduced autonomy as research participants since the consent provided could be under duress or due to other compulsions.

XVI. Training of Ethics committee members

Purpose:

The purpose of this section is to inform the Ethics committee personnel and members why training is necessary and how the members should seek to occasionally attend training or workshop programs to up-date themselves on the progress of technology, information and ethics.

New IEC members are required to undergo a training program on or before joining the Committee. It is the responsibility of the IEC Secretariat to give copy of the SOPs of the IEC, ICMR guidelines to the IEC members for reference and use. The SOP applies to all personnel of the IEC.

Responsibility

It is the responsibility of the IEC members to have themselves educated and trained periodically.

Training Procedure

The members can get the information about training courses, workshops, conferences, etc. which is periodically announced on the websites. Upon selecting the one needed, member may take the approval from the Chairman IEC and register to attend the same. The member shall keep the receipt of the same to reimburse the training expenses as approved by the Dean, SNMC as per the institutional rules.

Upon getting the training the member shall keep the original record of the training programmes with himself or herself and submit the copy of the same to the office of the IECSNMC.

Trainings can be related with GCP Guidelines, EC functions and SOPs, New Drugs and Clinical trial rules and ICMR National Ethical Guidelines.

XVII. Self-Assessment of IEC

1. Self-Assessment of IEC shall be done on the basis of self-assessment checklist mentioned in Annexure - 15.

2. Self-assessment shall be conducted annually. Member Secretary and one of the members will conduct self-assessment together, and review performance of ethics committee. Chairperson may appoint other ethics committee internal/external member to conduct self-assessment if required.

3. The Member Secretary will present self-assessment reports to all members in the subsequent full Board meeting.

4. After reviewing the self-assessment, recommendation including corrective and preventive action will be finalized in full board meeting for its future implementation.

Review policy

The Standard Operating Procedures will be reviewed/revised/modified from time to time. Any member of the committee can apply for the modification of the SOP in writing, which will be taken up in the next meeting and will be amended if the committee makes an approval of the same after the deliberation with all committee members.

ANNEXURES

Annexure 1: Conflict of Interest Agreement Form for Ethics Committee Members

B.V.V. Sangha's
S. Nijalingappa Medical College & Hanagal Shri Kumareshwar Hospital & Research Centre
Navanagar, Bagalkot-587102, Karnataka State, India.
(Recognized by National Medical Commission of India and Affiliated to Rajiv Gandhi University of Health Sciences, Karnataka.)
SNMC-INSTITUTIONAL ETHICS COMMITTEE ON HUMAN SUBJECTS RESEARCH
Website: www.snmcbgk.in ☎08354-235340 Fax: 08354-235360 Email: iechsrsnmcbgk@gmail.com

Office of the Institutional Ethics Committee

Agreement on Conflict of Interest

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me towards a quorum for voting.

I, ……., have read and accept the aforementioned terms and conditions as explained in this Agreement. I shall abstain from any participation in discussions or recommendations in respect of such proposals. I shall maintain all the project related documents and information confidential and shall not share or reveal the same to anyone other than the project related personnel.

_____ _____

Undersigned Signature Date

Name:

_____ _____

Chairperson's signature Date

Name: