NARAYANA
MEDICAL COLLEGE

Institutional Ethics Committee (IEC)

Nellore- 524003, Andhra Pradesh, India

Standard Operating Procedure (SOP); Version -2; 2021

The Genesis

The clinical research in Medical Colleges should be in par with international standards and ethics; but it is abysmal. In some institutions the researchers indulge in activities that are unethical and could be potentially harmful to the study participants. Hence, it is necessary to have an ethical committee (EC) to safeguard the health of the study participants and to conduct the study as per the national and international ethical guidelines. All clinical research should follow the Good Clinical Practices (GCP) guidelines and has to be conducted within the basic tenets of Autonomy (respect for participant's wishes), Beneficence (benefit to participant, family, society) and Justice (fair distribution of benefits risks and costs). It is the responsibility of the properly constituted IEC to ensure their incorporation in the protocol and observance during the course of the study. It is also equally important for a researcher to provide the necessary information pertaining to the proposed study including the detailed protocol prior to the EC meeting; thereby it can facilitate the decision making process.

IEC at Narayana Medical College (NMC), Nellore is borne out of the necessity and to safeguard the rights of the participants and to awaken the responsibilities of the researchers involved in the health research. This committee is owed to gradually develop sound conventions in the basic tenets mentioned above.

The present Standard Operating Procedures (SOPs) detailed in this booklet are developed with a goal to facilitate ethical review and monitoring of research projects involving human subjects and eventually improve the quality of clinical research conducted at this institute. SOPs should be revised periodically (once in 3 years).

I thank EC members and other faculty members of this institute for preparing these SOPs. I believe that this SOP is easy to understand and follow for the clinical researchers. Any suggestions to improve it are welcome.

Dr. Surya Prakasa Rao

Dean, NMC

Approval by EC - Chairperson

This EC – SOP booklet prepared by Dean Dr. SP Rao, reviewed by Member Secretary - Dr. Jyothi Conjeevaram and approved by all the IEC- members of Narayana Medical College is hereby released with effect from 17th May 2021 for the purpose of all IEC activities to be conducted henceforth.

I do hereby approve the SOP for the aforesaid purpose.

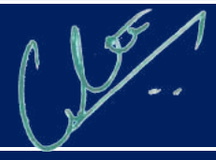
Dated: 17th May, 2021

Dr. J. N. Naidu

IEC - Chairperson, NMC

Preparation of SOP for IEC, NMC

Effective Date: 17th May 2021

	Name	Designation in IEC	Signature & Date
Prepared by	**Dr. Surya Prakasa Rao**	Member Clinician	
Reviewed by	**Dr. Jyothi Conjeevaram**	Member Secretary	
Approved by	**Dr. J. N. Naidu**	Chairperson	
Notified by	**Dr. C. Kumar**	Scientific Member	

NARAYANA MEDICAL COLLEGE

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1. Declaration:

The composition and working procedure of IEC, is based on Operational Guidelines for IEC that review Biomedical Research (WHO, 2000), International Conference on Harmonization-Good Clinical Practices (ICH-GCP) Guidelines (1996), New Drugs and Clinical Trials Rules, 2019, Indian GCP guidelines (2016) and Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2017).

2. IEC – Aim & Objectives:

Aim:

- IEC, has been constituted with an aim to provide public assurance of protection, reviewing and approving the clinical trial protocol, the suitability of the investigator(s), facilities and the methods and material to conduct clinical research at NMC under compliance of New Drugs and Clinical Trials Rules, 2019, National Ethical Guidelines for Biomedical Research on Human Participants by ICMR and its requirements.

Objectives:

- These written SOPs were adopted to ensure the protection of the rights and welfare of human participants in biomedical and behavioral research conducted at NMC.
- The objective of these SOPs of the IEC of NMC (hereinafter referred to as IEC) for research involving human subjects is to maintain effective functioning of the IEC and to ensure quality and technical excellence and consistent ethical review of all the submitted research proposals and the ongoing approved research projects involving human participants in accordance with the ICMR ethical guidelines for biomedical research on the human subjects.

3. Authority Under Which IEC Constituted:

- NMC has authorized the formation of IEC, as an independent body which functions independently and as registered body under Drugs Controller General of India (DCGI).
- With respect to decision making and it's working in order to provide public assurance of protection, reviewing and approving the clinical trials.
- Protocols, bioavailability and bioequivalence studies and Biomedical and Health Research projects, the suitability of the investigator(s), facilities and the methods

and material to conduct clinical research at NMC.

- In addition to this, the institute will provide all support to the IEC activities which includes training, resources and infrastructure at the same time.

4. Preparation of Standard Operating Procedures (SOPs) for IEC:

Purpose:

- The purpose of this SOP is to define the process for writing, reviewing, distributing and amending SOPs of IEC.
- The SOPs provide clear, unambiguous instructions so that the related activities of the Committee are conducted in accordance with: New Drugs and Clinical Trials Rules (2019), National Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2017), Indian GCP Guidelines (Access time 2003) http://cdsco.nic.in, WHO Operating Guidelines for Ethical Review Board that Review Biomedical Research (2000), The International Conference on Harmonization - Good Clinical Practices (ICH-GCP) Guidelines (1996), Declaration of Helsinki and the prevailing amendments from time to time and Amendments from CDSCO office.

Responsibility:

IEC Secretarial staff:

- Co-ordinate activities of writing, reviewing, distributing and amending SOPs
- Maintain on file all current SOPs and past SOPs
- Ensure that all the IEC members and involved staff have access to the SOPs
- Chairperson /Member Secretary appoints coordinating staff to assist IEC Functions.
- Member Secretary shall vote in IEC decisions but coordinating staff of IEC can't vote in any decision making procedure of the IEC.

SOP Team (Member Secretary and one/more members):

- Assess the requests for SOP revision in consultation with the Secretariat and Chairperson
- Propose new / modified SOPs as needed
- Select the format and coding system for SOPs

- Draft the SOP/modify SOP in consultation with the IEC members and involved staff
- Review the draft SOP
- Submit the draft for approval to Chairperson

Chairperson of IEC:

- Chairperson of IEC to appoint the SOP team to formulate the SOPs consisting of Member Secretary, one / more members of IEC and Coordinating staff
- Approve the SOPs
- Sign and date the approved SOPs

Coordinating Staff of IEC:

- Maintain on file all current SOPs and the list of SOPs
- Maintain an up-to-date distribution list for each SOP distributed
- Maintain the SOPs with a receipt to all users
- Maintain file of all past SOPs of IEC
- Assist in the formulation of SOPs
- Assist Member Secretary

IEC members:

- Sign and date the acknowledgement form when they would receive approved SOP.
- Assist in all decision-making procedures of IEC.
- Assist secretariat for any help in management

Identify the Need for New or Amending SOP:

- Any member of the IEC, Member Secretary would like a revision or notices an inconsistency/ discrepancy / has any suggestions on how to improve the existing SOPs

or requests to design an entirely new SOP can put forth his request.

- The Chairperson will inform all the IEC members about this request in a regular full-committee IEC meeting. If the IEC members agree to the request, an appropriate Member Secretary shall proceed with the revision process/ formulation process of the SOP.
- If the IEC members do not agree, the Chairperson will inform the person/ IEC member who made the request for modification of the SOP in the same meeting.
- The SOPs will be updated regularly at the interval of 3 year or if there are major changes whichever is earlier.

Appoint the SOP Team:

- The Chairperson will identify appropriate members of the IEC who have a thorough understanding of the ethical review process to constitute the SOP writing team.

List of relevant SOPs: (SOP writing team will carry out the subsequent steps)

- Write down step by step all the procedures of the IEC
- Organize, devise and name each process

New Standard Operating Procedures:

- When the need for a new SOP has been identified and agreed, a draft will be written by the Member Secretary and designated IEC members of SOP team, appointed by the Chairperson.

Review by Consultation:

- The draft SOP written by one or more members of the SOP team will be reviewed by the remaining members of the SOP team.
- After incorporating the suggestions put forth by the SOP team members, a copy of the revised draft SOP will be sent to the Member-Secretary, who will circulate it to all the IEC members to invite suggestions.

Preparation and Submission of Final Draft:

- IEC members will review the revised draft SOP in IEC meeting.

- The suggestions agreed upon unanimously, by all the IEC members will be discussed and incorporated in the revised draft SOP and the final draft SOP will be formulated.
- The SOP team would stand automatically dissolved once the IEC takes final decision regarding the SOP.

Approve a New/Revised SOP:

- The revised SOPs will be reviewed and approved in the same manner as a new SOP.
- The Chairperson signs and dates the SOP Approval page. Members Secretary shall mention final effective date on SOP, after which SOP need to be made accessible to all stakeholders for reference. Member Secretary or IEC Secretariat shall e-mail / share the approved SOP to all members.

Ensure Implementation and File all SOPs:

- The approved SOPs will be implemented from the effective date.
- When the revised version is distributed, old version is retrieved from all members and destroyed for except for one copy; this copy of the earlier version will be placed in the file entitled 'Past SOPs of IEC'.
- One complete original set of current SOPs will be filed centrally in the SOP Master file, by the Member Secretary or IEC coordinating staff, in the IEC office for review and request for a revision of existing SOPs and record the dates of review on the SOP Master file.
- Revision of approved SOPs shall occur at least once a year.

Manage Current and Archive Superseded SOPs:

- IEC office will manage current and archive old versions (superseded) of SOPs
- Superseded SOPs should be retained and clearly marked "superseded" and archived in the file entitled 'Past SOPs of IEC by the Member Secretary or IEC coordinating staff.

Glossary:

- Revision date: Date/year by which the SOP may be revised or reviewed.
- Recipients: Stakeholders who would receive a copy of SOP.
- SOP (Standard Operating Procedure): Detailed, written instructions, in a certain format, describing activities and actions undertaken by the IEC to achieve uniformity of the performance of a specific function. The aim of the SOPs and their accompanying checklists and forms is to simplify the functioning, whilst maintaining high standards of Good Clinical Practice (GCP).
- IEC: It is an independent body formally designated to review, approve and monitor clinical trials, bioavailability, bioequivalence, biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the participants. It is an independent body whose responsibility is to ensure the protection of the rights, safety and well- being of human participants involved in a clinical trial and to provide public assurance of that protection.

5. Constitution of the IEC & its Terms of References:

- The IEC is formed by the Dean, NMC in accordance with the guidelines laid down in the New Drugs and Clinical Trials Rules, 2019, National Ethical Guidelines for Biomedical Research on Human Participants by ICMR.
- Appointment / relieving / acceptance of resignation of any member of the IEC would be the prerogative of the Dean on the recommendation of IEC.
- The appointment of the IEC member will be confirmed after receipt of their consent to abide by the Good Clinical Practice (GCP) guidelines and maintenance of confidentiality.
- The Dean, IEC will appoint coordinating staff for IEC. They will be supervised by the Member Secretary.
- The IEC, will be multidisciplinary and multi-sectorial in composition and will have 7-9 members from medical, non-medical, scientific and non-scientific areas. At least 50% of members will be non-affiliated to this institute. It will have representation that is varied in terms of gender, age and social background. The members representing medical scientist and clinicians should have post graduate qualification & adequate experience in their respective fields.

The Composition Shall be as Follows:

* Chairperson (from outside the institute)
* One Member Secretary (one of the members representing the institute as designated by the Dean)
* One or more faculty members of basic medical sciences
* One or more faculty members of Dept. of Pharmacology
* One or more clinicians
* One or more legal experts
* One or more independent philosopher or ethicist or theologian
* One or more lay persons from community
* One or more woman members

- The IEC may appoint alternate members who can take part in the IEC activities in absence of regular members to maintain the quorum.
- The IEC may invite member(s) of specific patient groups or other special interest groups for an IEC meeting (if required, based on the requirement of research area, e.g. HIV AIDS, genetic disorders, stem cell research etc.) for eliciting their views.
- Such individuals will have to sign confidentiality agreement and declare in writing, conflicts of interest, if any prior to attending the meeting. They will attend the meeting in the capacity of 'Observer' and will not have right to vote.

Membership Requirements:

✓ The Dean, IEC is responsible for appointing new committee members.

✓ The Chairperson, Member Secretary or any member can suggest names of potential members but the final decision will remain with the Dean, IEC.

✓ Members will be designated in their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience as well as their commitment and willingness to volunteer the necessary time and effort for IEC.

✓ Members must disclose their interest and involvement by providing a Consent letter and in line with, the Appointment letters will be issued to members along with the Confidentiality agreement which will be required to sign for record of IEC.

- ✓ New members will be identified according to the requirement i.e. as per the composition specified.
- ✓ New / alternate members will be appointed if deemed necessary by Dean, IEC.

Tenure of Membership:

- The appointment of the members would be for a period of three years; after which they may be either replaced or reappointed with a fresh appointment letter prior to the end of tenure of members by the IEC secretariat.

Resignation:

- A member can resign by submitting the resignation letter addressing to IEC - Chairperson; and emailed/delivered to Member Secretary. The Member secretary will inform the appointing authority for formal acceptance and to initiate the necessary replacement/recruitment procedure for filling up the vacancy.
- The members if opts to step down due to any genuine cause may do so with prior notice and proper information to the appointing authority.

a) Disqualification:

- If Dean, IEC, Chairperson or member secretary received a communication in writing alleging misconduct by a member.
- A member can be disqualified if fails to attend more than 3 regular consecutive IEC meetings without prior intimation.
- A list of members of the IEC, their appointment letters, bio-data and consent forms would be maintained by Member Secretary of the IEC. This list and the copy of the working procedures would be made available to any investigator, for the purpose of filing of research projects, upon written request for the same to the Chairperson.

Chairperson:

- The Chairperson (EC – Head) will be appointed by the Dean, NMC
- The Chairperson will be responsible for conducting committee meetings and will lead all discussions and deliberations pertinent to the review of research proposals.
- The Chairperson will sign documents and communications related to IEC functioning.
- In case of anticipated absence, the Chairperson will nominate a committee member as acting Chairperson.

Member Secretary:

- To accept research study / project proposals.
- To prepare, maintain and distribute of study files.
- To schedule and organize IEC meetings after consultation with the Chairperson.
- To prepare and maintain meeting agenda and minutes.
- To maintain IEC record and archive them.
- To sign documents and communications related to IEC functioning.
- To communicate with the IEC members and applicants/investigators.
- To notify the Principal Investigator (PI) regarding IEC decisions related to the submitted research proposal.
- To arrange for training of personnel and IEC members.
- To organize the preparations, review, revision and distribution of SOPs and guidelines.
- To provide necessary administrative support for IEC related activities to the Chairperson.
- To provide updates on relevant and contemporary issues to ethics in health research as well as relevant contemporary literature to the committee members.
- To receive fees and issue official receipts for the same.
- To delegate various responsibilities to appropriate and authorized persons.
- To ensure adherence of IEC functioning as per SOPs.

Coordinating Staff:

- To support the Member Secretary in executing functions of the IEC.
- Correspondence with the IEC members and investigators.
- Arranging IEC meetings.
- Receiving all research proposals.

- Assisting in preparing agenda and minutes of the meetings.
- Maintaining and archiving study documents.
- To perform any other functions as instructed by Member Secretary/Chairperson.

Responsibilities of IEC members:

- To attend IEC meetings and participate in discussions and deliberations for appropriate decisions.
- To review, discuss and consider research proposals submitted for evaluation.
- To monitor Serious Adverse Event (SAE) reports and recommend appropriate action(s).
- To review the progress reports and monitor ongoing studies.
- To maintain confidentiality of the documents and deliberations of IEC meetings.
- To declare any conflict of interest, if any.
- To participate in continuing education activities in biomedical ethics and biomedical research.
- To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat.
- To provide an updated CV when requested for by the IEC secretariat.
- To carry out the work delegated by Chairperson and Member Secretary.
- To assist the Chairperson and Member Secretary in carrying out IEC work as per SOP.

However, following members should be held responsible for specific activities:

Clinician:

- To provide medical inputs on protocol: Informed consent forms and other aspects like standard of care, Placebo use, Sample size, dosing, Concomitant medications, Prohibited medications, risk & benefit to patients, Age group, and Inclusion / exclusion criteria.
- To take clinical judgment for the trial.

Basic Medical Scientist:

- To provide scientist aspects of the study: Investigator's brochure, safety of drug, Pharmacodynamics and pharmacokinetics of drug, lab procedures, study design, sample size, use of biological samples.
- Preclinical data and whether protocol adequately addresses issue of all this matter or not, Qualification of PI and GCP training certificate, Details of SAEs and reporting time limit from PI, all ethics issues and other procedures involved in the study.

Legal Expert:

- To review Clinical Trial Agreement (CTA): Parties involved, scope of agreement, responsibilities of parties and payment details.
- To review incidence of SAE included or not, Adequacy of amount.
- To see whether any clause is violating the norm, Confidentiality, dispute resolution, updated with regulatory requirements and interpretation of the same, Insurance policy: it should cover the participants for injury due to all clauses mentioned in Rule 122DAB, Validity, Countries for which the policy provides cover and Liability limit – per person and total.
- Indemnity: it should Covers the liability of investigator and sponsor and Could be part of CTA or separate document.
- To see informed consent document.

Social Scientist / NGO representative / Philosopher / Ethicist:

- To see Community perspective, Informed consent process, Compensation, Design of trial whether it is discomfort to subjects, Number of blood samples, Post-trial access to involved community, Confidentiality, Vulnerable population, Recruitment process.

Layperson:

- To see Informed Consent Process, Trial procedures, Post-trial access, Compensation, Confidentiality, Think from the subject's perspective, No exploitation of subject, Subject diary simple or not.

6. Quorum Requirements:

For clinical trial, the five members of quorum must be from Medical scientist (preferably a pharmacologist), Clinician, Legal expert, Social scientist or representative of a nongovernmental voluntary agency or a philosopher or an ethicist or a theologian or a similar person and one Layperson from the community as per New Drugs and Clinical Trials Rules, 2019.

7. Responsibilities of IEC:

- The IEC is to ensure that the research projects carried out or supported by IEC are sound in scientific design, have statistical validity and are carried according to the standard guidelines as prescribed by Good Clinical Practice (GCP), Indian council of Medical Research (ICMR) guidelines and New Drugs and Clinical Trials Rules, 2019.
- To protect the safety, dignity, rights and wellbeing of the potential research participants.
- To include solely those patients who have given informed consent for participation in the research.
- To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
- To ensure equitable recruitment of subjects in the study.
- To ensure that the research is conducted under the supervision of the medical persons or scientists with required experience and expertise.
- To assist in the development and the education of a research community responsive to local health care requirements.
- The IEC would review all new research projects and if approval is given it would be for a maximum period of one year (for projects > 1 year).
- After completion of a year, the progress of the project would be reviewed and further extension may be provided. Status of any project can be retrieved by tracking the record document.
- The IEC would maintain a list of all projects submitted, approved, disapproved and outcome of each project with confidentiality.
- The IEC should ensure that patients' rights are not compromised regarding any payments proposed to be made in the study to the patients towards reimbursement of incidental expenses.

8. IEC Members list

Table – Twelve IEC Members details

Role in EC	Name & Educational Qualification	Current Residential Address, Telephone/Mobile No. & e-mail ID	Affiliated to NMC – Yes/No; if no - affiliated organization
Chair Person	**Dr. J. N. Naidu** MD (Biochemistry)	15-54/1D, Padmavathi Nagar, MR Palli, Tirupathi (urban), Chitoor 517502, Andhra Pradesh (AP). **+919885675591;** drjnnaidu@gmail.com	Not affiliated to any organization
Member Secretary	**Dr. C. Jyothi** MD (Community Medicine)	305, B-block, Pavani Prestige Apts. Magunta Layout, Nellore 524003, A.P. **+919866723127;** drjyothi@narayanamedicalcollege.com	Yes
Scientific Member	**Dr. C. Kumar** MD (Community Medicine)	No 76 Staff Quarters, Narayana Medical College, Nellore – 524003, A.P., India. **+91 9849106293;** chintakumar1974@gmail.com	Yes
Basic Medical Scientist	**Dr. K. Jithendra** MD (Microbiology)	103, Sai Balaji Enclave, 4th line Harnadhapuram, Nellore -524003, A.P., India. **+919885576221;** jithendra3@gmail.com	Yes
Member Clinician	**Dr. V. Surya Prakasa Rao** MD (Community Medicine)	No F – 63, Staff Quarters, Narayana Medical College, Nellore – 524003, A.P., India. **+919422193852;** dean@narayanamedicalcollege.com	Yes
Member Clinician	**Dr. G. Kiran Kumar** MS (Ophthalmology)	Door No 24-7-147, Flat No 402, Lotus Apartment, Magunta Layout, Nellore 524003, A.P. India. **+91 9440573467;** drkiran9459@gmail.com	Yes
Member	**Dr. K. Ramalingam** PhD (Biochemistry)	No 306, Serene Woods Apartments, ISKON city, Nellore 524004, A.P. India. **+919490166078;** ramclinbio@gmail.com	Yes
Member	**Dr. S.C. Thasleema** PhD (Statistics)	No. 28/3/426, Aravinda Nagar, Mypadu Road, Nellore 524002, A.P. India. **+91 9393045706;** sethasleema@gmail.com	Not affiliated to any organization
Legal Expert	**Mr. P. Vijaya Kumara Reddy** BA., BL	16-2-583; Srinivasa Agraharam Minibypass Road, Nellore 524002; A.P. India. **+919849527270;** Pvkreddy20@yahoo.in	Advocate – Private practitioner
Lay Person	**Mr. Prabhakar Rao** BSc (Agriculture)	401, Dream homes apartment 5th lane, Ramji Nagar, Nellore, A.P. **+91 9849878168;** rprao1943@gmail.com	Madduluri Veera Raghavaiah, Kalyana mandapam Nellore
Social Scientist	**Mrs. P. R. Nalini** MA (Psychology)	203, A block, Pavani Majestic, Near Childrens park, Nellore 524002, AP. **+91 7893086770;** nalinipelluru.psychologist@gmail.com	Nalinipelluru Psychology Center Nellore, AP
Member	**Mrs. J. Jeyashri,** MCom	No. 2, Gangai Amman Koil street, Big Natham, Chengalpet, Tamil Nadu. **+919677287528;** jeyashri24@gmail.com	Not affiliated to any organization

9. Policy for Updating/Training of IEC Members:

- Member Secretary will notify - all relevant information on ethics to the IEC – members
- All IEC members shall be required to undergo refresher course in Good clinical practice (GCP) annually.
- The Chairperson, Member Secretary and members will be encouraged by the appointing authority to attend national and international training programs/conferences/workshops/seminars/courses at least once in a year in the field of research ethics (over and above his own discipline) to help in improving the quality of review of research protocols/ethics committee submissions and other related activities.

Evaluation of IEC:

The committee will conduct periodic self-assessment annually through internal meeting of the members using the Self-Assessment Tool. The individual feedback will be provided to all members by Member Secretary.

10. Selection and Responsibilities of Subject Expert:

Purpose:

To invite a subject expert either affiliated or non-affiliated to IEC, NMC to review the proposed study protocol; if the complexity of the issue(s) are not within the collective expertise of all IEC members.

Responsibility:

Upon the advice or recommendation of the secretary or any IEC member, it is the responsibility of the IEC to nominate the name of one or more special subject experts and be endorsed by the Chairperson for the given project.

Recommendation:

The IEC will designate subject experts from the different specialties and the Chairperson / Member Secretary on behalf of the IEC will invite subject expert selected by the IEC in writing to assist in the review of the project and provide his/ her independent opinion.

Selection:

IEC Chairperson approves the invited subject expert and review the research project.

Co-ordination with Subject Expert:

Subjects experts will participate after they agree to the confidentiality clause and abide by the rules & regulations of IEC whose opinion would be valuable but they would not be involved in the decision making process of the EC. The expert opinion should be obtained in writing within 30 working days' post EC meeting.

The Member Secretary will provide explanations/ clarifications (telephonically or in writing) to the subject experts if any doubts or questions are raised. The Chairperson / Legal expert / IEC members can provide any further explanations. If deemed necessary, subject expert may be reimbursed for expenses on travel, time spent, documents referred to in library/ internet, incidental expenses, etc.

11. Research Proposal Submission Procedure:

All research proposals are to be submitted to the EC- Member Secretary in the prescribed Application format along with check list in the prescribed format and detailed study protocol at least 1 to 2 weeks in advance, especially for all clinical trials. Covering letter addressed to the IEC - Chairperson / Member Secretary

The protocol would include the following:

I. Title; Name and contact details of a) Principal Investigator (PI); b) Study Sponsor.
II. Protocol - Summary; research objectives and rationale for the study involving human subjects.
III. Recent curriculum vitae (CV) of the investigators indicating qualification and experience; GCP certificate (< 3 years) of PI and his team members.
IV. Details of Funding agency / Sponsors and fund allocation for the proposed work. *;
V. Investigator's Brochure. *
VI. Undertaking by the Investigator. *
VII. Subject recruitment procedures or proposed methods / advertisement /notices.
VIII. Study subjects - Inclusion and exclusion criteria.
IX. Precise description of methodology of the proposed research, including intended dosages of drugs, planned duration of treatment and details of invasive procedures if any.
X. Statistical analysis in detail.
XI. Procedure for seeking and obtaining informed consent; with sample of patient information sheet and information consent forms in English and vernacular languages

and the validity of the translation

XII. and back translation (certificate).

XIII. Safety of proposed intervention and any drug or vaccine to be tested, including results of relevant laboratory and animal research. *

XIV. For research carrying more than minimal risk, an account of plans to provide medical therapy for such risk or injury or toxicity due to over-dosage should be included.

XV. Case Record Form (CRF) / Proforma /Questionnaire.

XVI. Proposed compensation for participation and reimbursement of incidental expenses/ serious adverse events occurring during the study participation. *

XVII. Plans - a) for storage and maintenance of all data collected during the trial; b) publication of results – positive/negative while maintaining the privacy & confidentiality of the study participants.

XVIII. Activity plan /Timeline; Amendments to protocol (if any).

XIX. Protocol signature page; signed by the study PI and all other relevant documents related to the study protocol including a) regulatory clearances; b) insurance documents as applicable.

XX. Investigator's agreement with the sponsor / Clinical Trial Agreement (CTA) / Agreement to comply with national and international GCP protocols for clinical trials.

XXI. Memorandum of Understanding (MOU) between collaborative institutions.

XXII. CTRI registration* and DCGI Approval letter.

XXIII. FDA marketing/manufacturing license for herbal drugs.

XXIV. Ethics Committee clearance of other centers (if applicable).

XXV. Any additional document(s), as required by IEC.

Note: Three copies of the research proposals for clinical trial and checklist filled in by the PI along with soft copy on CD need to be submitted, one for the records of the IEC, may constraint the need for hard-copy based submission of research projects to practice eco-friendly paperless system of operation.

12.Consent Review Process:

Informed Consent:

- The PI must obtain subject's consent in writing using Informed Consent Form (ICF).
- Patient information sheet (PIS) and ICF should be approved before initiation of study.
- Any changes in ICF should be approved before study Implementation.
- As per the new requirements, Table 3 of Third Schedule in New Drugs and Clinical Trials Rules, 2019, the ICD should clearly state that the subject is entitled to free medical management as long as required in case of injury, and financial compensation in case of clinical trial related injury or death.
- The investigator will have to clearly inform the subject about his/her right to claim compensation in case of trial related injury or death and to contact the sponsor / representative directly for any claim related queries.
- The contact details of sponsor representative should be provided in the ICF. In order to aid the calculation of compensation amount, the ICF now should have further details about the subject like qualification, occupation, annual income, address and contact details of the nominee and his/her relation with the subject.
- A copy of ICF should be provided to subject and same should be mentioned in the ICF document.
- The investigator shall provide information about the study verbally as well as using a PIS, in a language that is nontechnical and understandable by the subject.
- The PI shall describe procedures for obtaining informed consent including the procedure of Audio-Video recording from the research participant prior to enrolling into a research study, especially vulnerable subjects.
- If the subject is unable to give consent (unconscious or minor or suffering from severe mental illness or disability), the same should be obtained from a legally acceptable representative a Legally Acceptable Representative (LAR) who is able to give consent for or authorize and intervention in the patient as provided by law of India.
- If the LAR is unable to read or write, an impartial witness should be included in the consent process who will sign in the consent on behalf of his /her.
- If subject is from pediatrics age group, 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: a) Written informed consent should be obtained from the parent or legal guardian. However, all pediatric participants should be informed to the fullest extent possible about the study in a language and in terms that they are able to understand.

Where appropriate, pediatric participants should additionally assent to enroll in the study. Mature minors and adolescents should personally sign and date a separately designed written assent form.

- 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 pediatric 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.
- Assurance that the research participants shall receive information that becomes available during the course of the research relevant to their participation including their rights, safety and wellbeing is documented.
- The provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project.
- Any payments proposed to be made to subjects/patients has to be documented and notified to IEC and included on the ICD (Informed Consent Document)/ICF (Informed Consent Form).

Audio Visual (AV) Recording of Informed Consent process done as follows

- According to ICMR guidelines, when a participant is willing to participate but not willing to sign or give a thumb impression or cannot do so, then verbal/oral consent may be taken on approval by the EC, in the presence of an impartial witness who should sign and date the consent document.
- This process can be documented through audio or video recording of the participant, the PI and the impartial witness, all of whom should be seen in the frame. However, verbal/oral consent should only be taken in exceptional circumstances and for specific, justifiable reasons with the approval of the EC. It should not to be practiced routinely.
- In case of vulnerable subjects in clinical trials of New Chemical Entity (NCE) or New Molecular Entity (NME) including procedure of providing information to the subject and his understanding on such consent, should be maintained by investigator for record.
- 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 information to the subject and his understanding on such consent should be maintained by the investigator for record.

13. Conduction of IEC Meetings:

- The committee would meet once in every month or whenever it is necessary. If needed where the situation is justified the meeting may be called more than once in a month.
- The meetings would be called by the Member Secretary and the notice for the meetings would be sent usually 7 working days prior to the scheduled date. For expedited review meetings the notice can be sent within 3 working days.
- The member-secretary will record the minutes of the meeting and circulate the same to the members within a month of the meeting.

14. Proposed study review procedure:

- The IEC should review every research proposal involving human subjects as per checklist. It would ensure that a scientific evaluation has been completed before ethics review is taken up.
- The ethics review of a new project would be done through formal meetings and would not resort to decisions on them through circulation of proposals. The following decisions may be provisionally taken by the Member Secretary in communication with the Chairperson, without a formal meeting, subject to the approval of the IEC- at the next scheduled meeting:
  a) Extension of the study beyond the approved period.
  b) Amendment to the study related document not involving the study design*.
  c) Restarting a previously discontinued research project.
  d) All notifications related to adverse events.

Reviewing of Academic Research proposals submitted by Post graduate and undergraduate students:

- A separate EC with identified members may be constituted by the Chairperson, IEC for reviewing the proposals of academic research submitted by Postgraduate students as part of their thesis work & UG students.
- The IEC will not allow the use of trainees/employees working within the organization to be used as trial participants unless students and staff have the same rights as any other potential subject to participate in the research project, irrespective of the degree of risk, provided all of the following conditions exist.

- The research must not bestow upon participating Institutional subjects any competitive academic or occupational advantage over other Institutional students or staff who does not volunteer and the researchers must not impose any academic or occupational penalty on those Institutional trainees or staff who does not volunteer.
- Institutional students and staff must not be systematically treated differently from non-Institutional subjects as part of the project.
- Due to the potential for perceived or real coercion to participate, Institutional students and staff who desire to participate in the research (especially those under the direct supervision of the PI or listed research collaborators) must be reviewed by Dean of the Institution.
- Where the protocol indicates that the prior consent of the trial subject or the subject's legally acceptable representative is not possible, the IEC will determine that the proposed protocol and/or other document (s) adequately address the relevant ethical concerns and meet applicable regulatory requirements for such trials (i.e., in emergency situations). This shall be communicated to the investigator in writing while approving the protocol.
- It will also take note of the adverse events of the ongoing projects from the concerned investigators time to time and if considered may take up on site monitoring with the help of the suitable sub-committee (formed with the formal permission from the Dean, IEC) who will submit report to the IEC for reviewing. It will also report the same to DCGI within the specified time.
- The committee will also take up the issue of compensation following standard guidelines in case of any adverse events deemed to be caused by the direct association of the concerned clinical trial (guidelines for determining quantum of financial compensation to be paid in a case of clinical trial related injury or death; as per scope and provisions made in the New Drugs and Clinical Trials Rules, 2019 and ICMR guidelines.

The following types of research are considered to involve more than minimal risk and require ethical approval:

- Research involving those who lack normal physical / mental capacity. All research involving those who lack normal capacity, or those who during the research project has become lacking in capacity.
- Research involving sensitive topics – for example participants' sexual behavior, their illegal or political behavior, their experience of violence, their abuse or exploitation, their mental health, or their gender or ethnic status.
- Research involving groups where permission of a guardian is normally required for initial access to members. This includes research involving guardians such as adult professionals (e.g. those working with children or the elderly), or research in where access to research participants is not possible without the permission of another

adult, such as another family member (e.g. the parent or husband of the participant) or a community.

- Research involving access to records of personal or confidential information, including genetic or other biological information, concerning identifiable individuals.
- Research which could induce psychological stress, anxiety or humiliation or cause more than minimal pain.
- Research involving intrusive interventions or data collection methods – for example, the administration of substances, vigorous physical exercise, or techniques such as hypnotism. In particular, where participants are persuaded to reveal information which they would not otherwise disclose in the course of everyday life.
- The Committee would evaluate the possible risks to the subjects, the expected benefits and adequacy of documentation for ensuring privacy, confidentiality and justice issues.

Research Involving Potentially Vulnerable Groups:

- It describes the requirements concerning review of research that involves groups that could be potentially vulnerable to coercion in regard to autonomy and present conditions that may affect risk/benefit determinations or bearing unequal burden in research.
- IEC members are responsible for receiving, verifying, and reviewing the research protocols pertaining to vulnerable populations using the Risk benefit assessment tool. Such protocols should be reviewed keeping in mind the following points when it concerns research that involves groups that could be potentially vulnerable to coercion:
  - Measure to protect autonomy,
  - Risk/benefit determinations with respect to the vulnerability
  - Bearing unequal burden in research.
- Member of the IEC who would be reviewing such protocols should be well versed with the potential harm or risk of such population participating in the study.
- For example, children and young people, those with a learning disability or cognitive impairment, or individuals in a dependent or unequal relationship. Committee will review the safety and the rights of justice issues involving vulnerable population if applicable for any particular study involving such populace.
- A vulnerable category of subjects is those who are relatively (or absolutely) incapable of protecting their own interests which includes children, prisoners, pregnant women, handicapped or mentally disabled persons, refugees, displaced persons and economically or educationally disadvantaged persons, who are likely to be

vulnerable to coercion or undue influence.

- When a trial is to be carried out in the vulnerable populations like the pediatric, geriatric population, pregnant women, etc., the consent of the trial subject and subject's Legally Acceptable Representative (LAR) is to be mandatorily taken and the IEC will determine that the proposed protocol and/or other document(s) adequately address the relevant ethical concerns and meet applicable regulatory requirements for such trials. Where required assent of the participant will also be taken and this will be ensured during review and approval of the ICF.

Protocol deviation/Non-compliance/Violation:

IEC will be responsible to review deviation / non-compliance/ violation. The member secretary / Chairperson will categorize the protocol deviation as minor and major or may designate members (one/more) to review and take a decision depending on the seriousness of the deviation/non-compliance/violation. The decision will be taken to ensure that the safety and rights of the research participants are safeguarded. Following the procedures mentioned in this protocol in accordance with statutory provisions, National/ International ethical guidelines and procedures mandated by IEC, protocol deviation/non-compliance/violation will be detected accordingly.

Protocol Deviation(s):

Minor deviation - Any change, divergence or departure from the study design or procedures of protocol which does not have a major impact on the subject's rights, safety or well-being or completeness, accuracy, study outcome and reliability of study data is considered as minor deviation.

Major deviation - On the content of a deviation, the protocol has approved by IEC that may affect the subject's rights, safety or well-being and/or the completeness accuracy, study outcome and reliability of study data will be considered major deviation.

The PI should submit the protocol deviation report as per the format.

Protocol Violation/s:

A protocol violation is a deviation from the IEC approved protocol that may affect the subject's rights, safety, or well-being and/or the completeness, accuracy, study outcome and reliability of the study data will be considered a protocol violation. The PI should submit the protocol violation report as per the format.

***Review of Protocol Amendments:**

In any occasion of amendments to the already approved protocol by the IEC, the said amendment is reviewed by the IEC in the next meeting following the submission. The content of amendment is critically reviewed with justification in ethics point of view following GCP guidelines. The consensus approval from the committee members regarding this is recorded and communicated to the PI.

15. Conflict Resolution Policy:

The IEC, NMC, would refer to the GCP guidelines, ICMR guidelines and New Drugs and Clinical Trials Rules, 2019 and their modifications in case of any conflict as mentioned below for which the following format will be used to take undertaking from the concerned member of IEC.

No members having a conflict of interest will be involved in the oversight of the clinical trial or bioavailability or bioequivalence or biomedical or any health research study being reviewed by his/her and it is responsibility of each member to withdraw voluntarily, by expressing to the Chairperson in writing that there is no conflict of interest with a sign. The details in respect of the conflict of interest of the members will be recorded in the minutes of the meetings.

16. Decision Making Process:

a) Only IEC members who are independent of the investigator and the sponsor of the proposal would vote/provide opinion on the proposal. If a member is also an investigator for a proposal, he would not be involved in the decision making process when the said proposal is being discussed, and would not chair the session. Such a member must voluntarily withdraw from the IEC meetings, while making a decision on an application which evokes such a conflict of interest, which should be indicated in writing in the above mentioned format for undertaking and should be recorded so in the minutes.

b) The study team member (Investigator / Co-investigator / Study coordinator's) non- participation in the decision making process would be recorded in the minutes and also in the opinion letter issued for the project.

c)The decision of the IEC would be by consensus after the quorum requirements are fulfilled to recommend / reject /suggest modifications for a repeat review. If any experts are invited, they would not participate in decision making on a proposal.

The decision of the IEC would be one of the following ways:

- Approved: The study is approved in its present form. When committee approves the study, the certificate will be issued within a period of 15days.
- Conditional Approval: Revisions required; if revised protocol found satisfactory, approval will be granted.
- Resubmit: Major revisions needed. The revised project will then be reviewed in the next meeting.
- Not approved: The study is not approved in its current form. The required modifications will be suggested during the meeting with reasons. If the investigator wishes to appeal to the decision, he/she may do so by contacting the IEC Secretary. The IEC may decide to accept or deny the appeal. If the appeal is denied, the IEC decision is final and the study may not be approved or resumed.
- Defer: The decision cannot be arrived at present and therefore postponed to the next meeting. Grounds for this: lack of quorum, lack of expertise etc.

Communicating the Decision:

The IEC would issue an opinion letter to communicate the decision taken on any project following prescribed format of approval letter as per recommendation of New Drugs and Clinical Trials Rules, 2019.

This opinion letter would be issued by the Member Secretary to convey the decision of the IEC to the PI and must include the following information mentioned with turnaround time of 15 days:

- The name of the Project (Same as the Project title).
- List of documents reviewed by the IEC including the revised version of documents if any.
- List of members present at the meeting.
- Members who did not participate in the decision making process.
- The date and time of meeting.

The decision of the IEC

- GCP and latest regulatory requirements plus submission progress updates/deviations as and when it occurs while implementing the sanctioned project.
- IEC may decide to reverse its positive decision on a study in the event of receiving information that may adversely affect the benefit / risk ratio.
- The discontinuation of a research should be ordered if the IEC finds that the goals of the trial have already been achieved midway or unequivocal results are obtained.

- In case of premature termination of study, notification should include the reasons for termination along with the summary of results conducted till date.
- IEC may also ratify the provisional decision of the Member Secretary, taken in situations mentioned in clause 14.2, and such ratification if any would be recorded in the minutes of the meeting.
- All correspondence between the IEC and the Investigator/ Co-investigator/ Study coordinator and all other relevant records (Proposal, opinion letter, minutes of the meeting etc.) would be retained by the IEC for a minimum period of five years after the completion of the research.

17. Expedited Review Policy:

Purpose:

To determine if a study protocol qualifies for expedited review and provide instructions on management, review and approval of a project through the expedited review.

Responsibility:

It is responsibility of the Chairperson / Member Secretary to determine if a project / protocol qualifies for an expedited review. They may appoint a separate EC of identified members or designate one / more primary reviewers to expedite the review of proposals that require expedited decision.

Determine protocols for expedited review & designate the primary reviewers:

- The proposal submitted for initial review or where investigator should be requested for the expedited review stating the reasons in the covering letter to the IEC.
- The ICMR ethical guidelines will be followed in deciding on the need of such review. Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review. The IEC Chairperson / Member Secretary will take the final decision regarding whether a study with 'not more than minimal risk' qualifies for an expedited review.

IEC may do expedited review only if the protocols involve:

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

- Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and leftover clinical samples.
- Research involving clinical documentation materials that are non- identifiable (data, documents, records).
- Modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s).
- Revised proposals previously approved through expedited review, full review or continuing review of approved proposals.
- Minor deviations from originally approved research causing no risk or minimal risk.
- Progress reports where there is no additional risk, for example activity limited to data analysis. Expert committee will conduct expedited review of SAEs.

Review protocol & give comments and recommendations:

The designated members / primary reviewers will review the protocol and give their comments and recommendations to the member secretary within seven days from date of receipt of the protocol.

Decision of IEC:

- The Member Secretary will discuss about the comments with the Chairperson and decision will be taken in consultation with Chairperson.
- The decision will be ratified in the regular meeting of IEC.
- If deemed necessary, the proposal will be discussed in the forthcoming meeting.
- The expedited review process should be completed within 7 working days and the decision will be conveyed to the PI.

18. Policy for Fees Related to Ethics Committee Activities:

As a policy of the appointing authority IEC does not charge any fees for processing any project proposals, review of SAE and inviting subject expert as well as for any other of its activities. However, reasonable processing fees for clinical trial may be charged in consultation with the institute authority.

Fee structure:

Regular EC meeting - Rs. 25,000 and Expedited EC meeting Rs. 35,000 will be charged per study.

Bank details to pay the EC fees; Mode of payment – online.	
Payee Name	Advanced Research Centre
PAN No	AAATN1672R
Bank Account Number	116211100000405
Bank Name	Union Bank of India
Branch Name	Harnathapuram Branch
Bank Address	G Ratnam Junior College Harnathapuram, Nellore 524003, AP
Bank Swift Code / IFSC Code	UBIN0811629
GST No	Not Applicable
Address of Account holder	Narayana Medical College, Nellore, Andhra Pradesh , 524003

Budget Preparation:

The committee review fee should be incorporated in budgets or payment of funded research studies.

Expenditure:

The expenditure will be made for the following

- Paying honorarium to external members (Rs. 1000 to Chairperson and Rs. 500 to other members) for each meeting attended and invited experts per study.
- GCP training programme organized by IEC.
- IEC members who present papers on research ethics and representing institute IEC in national/international conference.

19. Responsibilities of Investigators:

- The investigators need to be submitted all proposals of funded and non-funded studies i.e. Clinical research, research projects involving human subjects, PG dissertation or research, UG research, ICMR STS, MUHS STRG and any other research studies to IEC for the review before commencing the study.
- Investigators should follow documented procedure i.e. Standard Operating Procedures (SOPs) of IEC in compliance with the regulation and the approved protocol or informed consent, safety reporting management, delegation of responsibilities and training, investigational product, clinical trial documentation, record retention,

archival and destruction.

The investigator should ensure the ethical concerns in the protocol in compliance with regulatory rules and regulations, wherein following aspects can be included in the section of ethical consideration

a) It should declare that the study will be conducted in adherence to relevant national / international guidelines.

b) Policy regarding autonomy (right to withdraw)

c) Confidentiality

d) Selection of participants should be equitable as per the format.

e) Process of obtaining informed consent

f) Protection of vulnerable subjects

g) Policy regarding treatment of study related injury, compensation for study related injury and participation.

h) Dissemination of data and Publication

i) An investigator may be invited telephonically/ through written communication in the IEC meeting to discuss for amended protocol, SAEs, serious deviations/violations or any study related issues.

It is mandatory for the investigators to submit the following documents to the IEC.

j) A report on the performance of the research on an annual basis and a copy of final report.

k) Each serious adverse event in IEC and in other centers, where the study is being implemented along with a Data and Safety Monitoring Board (DSMB) report and also if there is report received from CRO/ Audit reports from concerned authorities in case so as to ensure the reporting of the same to DCGI within stipulated time frame prescribed in the notification (vide Indian Gazette).

l) All amendments or revisions in the study protocol.

m) Protocol deviation / non-compliance/ violation.

n) Study completion or discontinuation reports.

o) Justification to restart a study discontinued earlier.

Periodic update report by the PI:

- Progress of all the research proposals will be followed (via periodic reports from PI) at regular intervals of 6 months for long duration studies i.e. studies more than 1 year and at regular intervals of 3 months for short duration studies i.e. studies less than 1 year as per format. But, in special situations IEC will ask for follow up report from PI at shorter intervals based on the need, nature and events of research project.
- Approval, therefore for long term studies will be valid for 1 year. Renewed approval will be issued on yearly basis after the progress of the study is submitted to IEC by the PI.
- The final closure report should be received by the PI as per format.

20. Review of serious adverse events (SAE) and unexpected adverse events (UAE) reports:

IEC reviews the SAEs the following the standard protocol – As per format mentioned in the New Drugs and Clinical Trials Rules, 2019 (Third Schedule Table 5)

Responsibility for review of SAE & UAE:

- The primary responsibility of the IEC is to review and address SAE and unexpected events involving risks to research participants. In addition, the committee is authorized to offer mediation under appropriate circumstances.
- IEC should also make sure that researchers are made aware of the policies and procedures concerning reporting and continuing review requirements.
- The Member Secretary is responsible for receiving the complete SAE / unexpected events reports and directing them to the members/designated expert reviewers for detailed review. The expert reviewers will prepare their report using Annexure and based on the report from expert committee (reviewers) IEC will send the same with its opinion on the financial compensation (if any, determined in accordance with the formula specified) to the DCGI expert committee for review of SAEs and ratification in the IEC meeting.
- Notifying the IEC does not relieve the PI from his/her responsibility to notify the sponsor, head of institute and regulatory authorities.

Detailed instructions about on site SAEs: SAE related activities before IEC meeting:

- The Member Secretary/ Secretariat will verify that the SAE reports in the prescribed format are complete, signed and dated by the PI. In case he/she notes that the report is incomplete, it will be forwarded to PI, to revert with adequate data.
- The IEC office should receive the initial reports of SAEs occurred for IEC approved studies within 24 hrs. of the occurrence of the SAE. If the investigator fails to report any serious adverse event within the stipulated period, he/she will have to furnish the reasons for delay to the satisfaction of the regulatory authority along with the report of the serious adverse event. Follow up reports shall be received within 14 calendar days.
- If the PI has not adhered to the above stipulated time period, the IEC office will notify the discrepancies in the reporting time and time of occurrence of SAE to the PI.

Actions to be taken by Member Secretary:

- The Member Secretary after receipt of the SAE Report will forward it to the designated reviewer within 1 working day for review.
- Designated reviewer will review the SAE and communicated the opinion by e-mail or telephone/written report to inform the Chairperson / Member Secretary, IEC.
- The Member Secretary will ratify the designated reviewer's report along with relevant documents from PI at the next IEC meeting.
- The final review opinion of IEC will be communicated to DCGI within 30 days from the SAE report.
- Compensation if applicable will be calculated as per formula specified in the New Drugs and Clinical Trial Rules, 2019 and ICMR guidelines.

Appropriate compensation will be given to the subject according to New Drugs and Clinical Trials Rules,2019.

21. Policy of Monitoring and Oversight:

The Chairperson /Member Secretary will identify and designate one or more IEC members/independent monitor from IEC to conduct site monitoring of the study. The Secretariat will inform the PI in writing about the date/time of monitoring visit and request for confirmation from the PI or Co- I to be available for the monitoring visit. The report should be submitted by them to IEC by 5 days in the specified visit report format

The monitoring will be done either as routine process (annually) during the ongoing approved project or for specific causes as follows –

- Serious deviations reported
- Repeated SAEs
- Non-compliance of progress report by the investigator

- Higher than the proposed recruitment of subjects in the study
- Complaints received from participants
- Any other cause as decided by IEC

Especially, the monitoring for vulnerable subjects will carry out twice a year.

Inspection of Site:

IEC, will inspect the study site at any time with prior intimation to site & to Investigator about the same. Key focus areas during oversight are listed below:

- Delegation log of responsibilities of study team.
- Protocol understanding of the site team.
- Approved protocols, Informed consent and Audio-Visual recording of consent and make sure that the site is using the most recent version.
- Drug accountability.
- Laboratory and other facilities necessary for the study at the site
- Source documents
- Investigator's oversight adequacy
- Availability of study specific logs and forms
- Protocol deviation/violation (if any)
- SAE reporting

Outcome of the visit will be shared by the Member Secretary with the concerned investigator in form of a report within 14 working days.

Actions to be taken by Chairperson:

The Chairperson, IEC on basis of the information and comments received from the Member Secretary, IEC and applying his/ her judgment will direct the IEC to any one or more actions listed below, but are not limited to.

- Suspending enrolment of new research participants till further review by the IEC

- Suspending all trial related procedures (except those intended for safety and wellbeing of the participant) till further review by the IEC
- Suspend some trial-related procedures.
- Call a meeting for emergency review. (This review should be initiated within 48 working hours (2 working days) of receipt of information.) This review could be done through a meeting, teleconference, email or telephonic conversation. The Member secretary will take appropriate steps to ensure that IEC members are informed about this full board meeting.
- Depending upon the complexity of the issue(s) are not within the collective expertise of all members, the Chairperson / Member Secretary on behalf of IEC will invite one or more experts. These experts could participate after they agree to the confidentiality clause and abide by the rules and regulations of IEC whose opinion would be valuable but they would not be involved in the decision making process of the Ethics committee. The expert would be requested to provide an opinioninwritingwithin30workingdays, depending upon the gravity and seriousness of the matter. The following would be designated as Subject expert during the meetings of the IEC.

22. Policy for Waiver of Written Informed Consent:

- The IEC may grant waiver for requirement of obtaining written informed consent for requesting waiver of consent by the investigators.
- The Chairperson / Member Secretary / IEC members will review the request taking into consideration the types of studies for which waiver of consent may be granted.
- The IEC will ensure that there are adequate mechanisms described in the protocol for protection of the identity of the research participants and maintaining confidentiality of the study data.
- This is necessary, as the participant cannot be assured directly about confidentiality of health data through a formal informed consent process, when consent waiver is granted.

23. Management of Premature Termination/Suspension /Discontinuation of the Study /Withdrawal of Study:

Purpose:

- To proceeds and manages the premature termination/ suspension / discontinuation of the study / withdrawal of study before site initiation of a research study.
- Protocols may be terminated at the recommendation of the IEC, Principal Investigator, sponsor, Regulator or other authorized bodies wherein subject enrolment and

subject follow-up are discontinued before the scheduled end of the study.

Responsibility:

It is the responsibility of the Chairperson to terminate any study that the IEC has previously approved when the safety or benefit of the study participants is doubtful or at risk, also to review the termination suggested by IEC members, PI, Sponsor or other authorized bodies.

The secretariat is responsible for management of the premature termination/suspension/discontinuation documents/Withdrawal of study.

Procedure:

Receive premature termination/ Suspension / Discontinuation of the study / Withdrawal of study before site initiation of a research study:

- The member secretary / Chairperson shall review the results, reasons and accrual data and discuss the report at the regular Full Board meeting.
- If the Premature termination/ suspension/discontinuation Report is unclear or more information is required from the PI, the Chairperson shall instruct the Secretariat to seek clarifications/ additional information from the Principal Investigator.
- The Chairperson /Member Secretary / IEC members will review the information available and take a decision depending on the seriousness of the termination.
- The decision will be taken to ensure that the safety and rights of the research participants are safeguarded. The decision will be taken by consensus /voting.

Record and communication:

- The decision will be communicated to the PI within 14 days and Secretariat will record of the Premature Termination / Suspension / Discontinuation of the study / Withdrawal of study in the minutes of the meeting.
- In case of termination of any such study prematurely, the detailed reasons for such termination shall be communicated immediately by the PI.
- In case of termination of any clinical trial the detailed reasons for such termination shall be communicated within thirty working days of such termination by the PI.

24. Policy for Complaint of Negligence by Research Participants: Dealing with Participants' Requests and/or Complaints to IEC

Purpose:

The purpose of this SOP is to describe procedures for dealing with requests for information by research participants regarding their rights as a participant or to resolve their complaint/s that is/are related to their participation in research approved by the Institutional Ethics Committee (IEC).

Scope:

This SOP applies to handling of requests for information/ complaints made by participants concerning the rights and wellbeing of the research participants participating in research studies by the IEC.

Responsibility:

It is the responsibility of the IEC - Chairperson / Member Secretary to initiate the process of giving information asked by research participants or to address any injustice that has occurred, if any complaints are received.

Detailed instructions:

A request, complaint or query from a research participant will be forwarded by the member secretary to the IEC after entering into the request record form. **Request/ Complaint Form**

- The Member Secretary may receive a request, complaint or query directly from the participant. He/she will record it in the request record form and notify the EC.
- The Member Secretary will additionally ascertain details of the request/ complaint by examining any relevant documents and by interviewing the participant if necessary. If required, the Member Secretary will call for additional relevant information and documents from the PI.
- The member secretary will inform the Chairperson about the request, query or complaint received from the research participant.
- In case of a request for additional information or clarification, the Member Secretary in consultation with the Chairperson will provide the information himself / herself or will designate one or more IEC member(s) to provide such information.

a) In receiving and responding to complaints, the following guiding rights and responsibilities will shape the participants' actions:

Rights of Research Participant:

- Right to voluntary participation in research study.
- Right to have enough time to decide whether or not to be in the research study, and to make that decision without any pressure from the people who are conducting the research.
- To ask any questions you may have.

- Right to know about IEC and its responsibilities towards protecting patients' rights, safety and well-being involved in a research project and to provide public assurance of that protection.
- Right to information about research study in an understandable language.
- Right to informed consent and if necessary audio-video consenting before participation in any research study.
- Right to refusal of participation or withdrawal of participation at any point in the study without disclosing any reason.
- Right to receive quality healthcare in a safe, clean environment without discrimination because of race, age, color, religion, nationality, culture, ethnicity, language, disability, sex or manner of payment.
- Right to be treated with dignity, respect and courtesy in a non-judgmental and non-threatening manner.
- Right to information regarding investigational product, duration of study, treatment option available as per standard of care, anticipated expenditure, information on medical management of any injury and compensation in case of any study related injury or death or any compensation provided for participation in an understandable language.
- Right to be informed of the risks, benefits and alternatives of proposed treatment.
- Right to privacy and confidentiality.
- Right to be informed on how to voice a complaint to express concerns, violation of your rights and/or grievance and seek re-dressal.
- Right to participation in research and innovative therapies.
- Right to consent for diagnostic and therapeutic procedures.
- Right to access clinical records.
- Right to get 24 hours' emergency contact details of research doctor.
- Right to get contact details of Chairperson and member secretary of IEC.

Responsibilities of Research Participant:

- To provide correct and complete demographic information including full name, age, address, telephone number and e-mail ID.
- To be compliant with research protocol and procedures.

- To ask question when he/she does not understand what the doctors, research study team, or other healthcare team members tells about diagnosis or treatment.
- Carefully weigh the risks and benefits when deciding whether to participate in the study.
- To inform your research study doctor and research study team, immediately in case of any injury or development of any new medical conditions.
- Not to take any medications without the knowledge of research doctor and research study team.
- To disclose to doctors and research study team if currently part of any other Clinical Trial or had participated in any other Clinical Trial in last one year.
- Provide complete and accurate information about your health including your previous medical history, and all the medications that you are presently taking including alternative treatments like Ayurveda, Homoeopathy, Unani or herbal medications, all records of previous investigations and treatment and of allergic reactions, especially sensitivity to any drug.
- To follow instructions, advice and restrictions regarding treatment plan and visit schedules.
- To treat hospital staff and study team with courtesy.

In case of a complaint received from a research participant:

The Member Secretary, in consultation with the Chairperson will initiate a process to address any injustice that may have occurred. Depending on the seriousness of the matter, the Chairperson will direct the Member Secretary to -

- Appoint a subcommittee of two or more IEC members for enquiry in order to resolve the matter.
- Call an emergency meeting of two or more IEC members for discussion or consider the matter for discussion at the next full board meeting.
- The Chairperson / Member Secretary/ designated IEC members will assess the situation and mediate a dialogue between the research participant and PI in an attempt to resolve the matter.
- The IEC will insist on factual details to determine gap, if any, between truth and individual perception.
- The final decision will be taken by the Member Secretary in consultation with the Chairperson based on the recommendation of any one of the above and it will be informed to the research participant and the PI by the member secretary.
- The information including any action taken or follow-up and final decision will be recorded in the form and the form is signed and dated.

- The IEC members will be informed about the action taken and the outcomes in the forthcoming IEC meeting (in case of requests/ complaints not discussed in full board meeting).
- The member secretary will place all documents in the relevant study file.

25. Policy of Communications with Different Stake Holders:

Purpose:

This SOP defines IEC communication with different stakeholder as per regulatory mandate and specifications.

IEC communicates with following mentioned stakeholders as per regulatory mandate and specifications:

- PI /study team designee; DCGI; Dean of the institute; Sponsor; Study participants

Letters received from and sent to different stake holders

IEC receives letters from different stakeholder submitted or sent to IEC Secretariat and maintain them in record. IEC may mention outward number for letters sent to all concerned stakeholders and records of the same also are kept.

PI: *IEC writes or e-mails to PI regarding following mentioned communications but not limited to, whenever deemed necessary.*

- Study Project Initial Dossier and Amendments, Approval/Dis-Approval letter*/ Query Letters
- Reply to Serious Adverse Event notification
- Opinion on EC analysis and compensation of Study injury/Death
- Response to Protocol deviation/Violation/Waiver
- Response to Continue review/study completion report
- Study termination letter.

****Communicating the decision:***

The IEC would issue an opinion letter to communicate the decision taken on any project following prescribed format of approval letter as per recommendation of New Drugs and Clinical Trials Rules, 2019. This opinion letter would be issued by the Member Secretary to convey the decision of the IEC to the PI and must include the

following information mention turnaround time 21days:

- Name of the Project.
- List of documents reviewed by the IEC including the revised version of documents if any.
- List of members present at the meeting.
- Members who did not participate in the decision making process.
- The date and time of meeting.
- The decision of the IEC.
- A note to PI to strictly adhere to SOP of IEC, Version 01/2020, GCP and latest regulatory requirements plus submission progress updates/deviations as and when it occurs while implementing the sanctioned project.
- An IEC may decide to reverse its positive decision on a study in the event of receiving information that may adversely affect the benefit / risk ratio.

DCGI:

IEC writes to DCGI or emails regarding following mentioned communications but not limited to, whenever deemed necessary

- Opinion on SAE Analysis and Compensation of Study injury/death if applicable.
- Study Termination letter.
- Issues with Investigators or different stake holders involved.
- Recommendations on DCGI Approved and other studies (If necessary).
- Ethics Committee Registration Communications.

Dean of the Institute:

IEC writes to Dean or emails regarding following mentioned communications but not limited to, whenever deemed necessary.

- Annual reports of IEC.
- Sharing amended SOP for final acceptance.

- Any issues in IEC functioning.
- IEC Requirements.

Sponsor:

IEC writes to Sponsor or emails regarding following mentioned communications but not limited to, whenever deemed necessary.

- Response to any queries raised.
- Confirmation of free medical management and compensation in applicable cases (If deemed necessary).

Study Participants:

IEC writes to study participants or emails regarding following mentioned communications but not limited to, whenever deemed necessary.

- Reply for complaints.
- Reply if any information requested to IEC Office.

26. Procedure for Meeting Procedures and Recording of Minutes:

Agenda:

It is responsibility of the member secretary to prepare the agenda for IEC meeting and to ensure proper recording and dissemination of minutes after the meeting is over. No limit is placed on the number of items on the agenda. The number of items is based on available expertise (members and consultants), urgency, order of submission to the IEC and its workload. In agenda the date, venue, time and list of programme/issues will be discussed.

Meeting venue:

Venue is reserved for IEC meeting, unless otherwise specified. It is responsibility of coordinator to ensure the meeting room, equipment and facilities are available in good working conditions.

List of proposals/notifications:

It is responsibility of IEC members to prepare list of proposals/notifications for disbursement along with the study documents/protocols among the members.

Conduct of Meeting:

The members should gather in IEC meeting room on scheduled time. The Member Secretary should discuss the minutes of the previous meeting of IEC as well as major issues/policies discussed in minutes of the other IEC and present the agenda for the current meeting. If an IEC member has conflict of interest involving a project then he/she should declare the same, before the meeting commences and leave the meeting room before the discussion on the same. This should be recorded in the minutes.

Decision Making Process:

IEC member will withdraw from the meeting for the decision procedure concerning the study where conflict of interest exists. If any IEC member has his/her own proposal for IEC review he/she will not participate in the IEC discussion or vote on that particular project. Decisions will only be made at meetings where a quorum is present. Neither PI nor any of proposed study team members participated during the decision making of the IEC. Only IEC members who attend the meeting will participate in the decision.

Types of Decision:

- ***Approved:*** The study is approved in its present form. When committee approves the study, the certificate will be issued within a period of 15 days.
- ***Conditional Approval:*** The major/minor revisions are required. If revisions are found satisfactory, approval will be granted.
- ***Resubmit:*** Extensive revisions are necessary. PI has to comply with the changes suggested by IEC during the meeting. The revised project will then be reviewed in the next meeting.
- ***Not approved:*** The study is not approved in its current form. The required modifications will be suggested during the meeting with reasons. If the investigator wishes to appeal to the decision, he/she may do so by contacting the IEC member secretary. The IEC may decide to accept or deny the appeal. If the appeal is denied, the IEC decision is final and the study may not be approved or resumed.
- ***Defer:*** The decision cannot be arrived at present and therefore postpone to next meeting. Grounds for this: lack of quorum, lack of expertise etc.

Preparing and Recording the Minutes:

- The member secretary, will record the minutes of the meeting and disseminate the same to the members within 15 days of the meeting for their signed approval.

- The minutes of the IEC meeting will be ratified in the subsequent IEC meeting.
- The coordinating staff will file the meeting minutes in the record section for a minimum period of five years both as soft- and hard- copies.
- The records will be maintained in such a way that it can be retrieved by tracking the records maintained in the tracking records of the minutes of the meeting.

27. Policy for Archiving and Retrieving:

Purpose of this SOP is to define the process for storage/archival / disposal of closed files and retrieval of documents in a secure manner while maintaining access for review by auditors, inspectors or any authorized persons.

Responsibility:

- It is the responsibility of the IEC to maintain closed study files and administrative documents.
- All correspondence between the IEC and the PI/ Co-I/ Study coordinator and all other relevant records (Proposals, opinion letter, minutes of the meeting etc.) would be retained by the IEC for a minimum period of five years after the completion of the research so that the records will be accessible to the authorized persons.
- The coordinating staff will maintain the confidentiality for control and archiving of the records by signing the Confidentiality agreement.
- The written request for retrieval can only be made request by IEC members, auditors or any authorized person.
- IEC Secretariat will maintain a movement register with following information related to retrieval: File number, Name and designation of individual making a request for retrieval with his/her signature, Date of approval of request by IEC Chairperson, Date and time of retrieval, Name and signature of IEC staff/ Secretariat retrieving the file, Date and time of returning the file.
- After completion of the archival period the closed files will be shredded and disposed. However, all copies of the research projects and documents submitted to IEC review will be shredded by the authorized personnel of IEC after the IEC meeting without any notification to the Principal Investigator.

28. References:

1. New Drugs and Clinical Trials Rules, 2019 – CDSCO [Internet] 2019 June. [Updated 2019 March; cited 2019 June 5] - https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdfdocuments/NewDrugs_CTRules_2019.pdf.
2. Indian Council of Medical Research. *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.* NewDelhi;2017. https://icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf. Accessed 19July 2019.

3. Good Clinical Practices for Clinical Research in India, CDSCO, http://cdsco.nic.in
4. International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), INTEGRATED ADDENDUM TO ICH E6 (R1): GUIDELINE FOR GOOD CLINICAL PRACTICE E6 (R2) [updated 2016 Nov 9; cited 2019 June5] Available from https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2Step_4_2016_1109.pdf.
5. New Drugs and Clinical Trials Rules 2019: Changes in responsibilities of the ethics committee http://www.picronline.org Accessed on Saturday, December 28, 2020, IP: 14.139.127.194)
6. WHO Operating Guidelines for Ethical Review Board that Review Biomedical Research (2000),https://www.who.int/tdr/publications/documents/ethics.pdf
7. Declaration of Helsinki and the prevailing amendments from time to time (https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/)
8. Amendments from CDSCO officehttps://cdsco.gov.in/opencms/opencms/en/Clinical- Trial/clinical-trials/

Format for Approval of Ethics Committee

To

Dear Dr.

The Institutional Ethics Committee (IEC) reviewed and discussed your application to conduct the clinical trial entitled “ ” on _____ date

The following documents were reviewed:

a. Trial protocol (including protocol amendments), and Investigators brochure - dated, version no
b. Patient Information Sheet and Informed Consent Form (including updated if any) in English and/or vernacular language.
c. Proposed methods for the patient accrual including advertisement(s) etc. proposed o be used for the purpose.
d. Principal Investigator’s current CV and Good Clinical Practice Certificate.
e. Insurance Policy/Compensation for participation and for serious adverse events occurring during the study participation.
f. Investigator’s Agreement with the Sponsor.
g. Investigator’s Undertaking

The following members of the ethics committee were present at the meeting held on_____ (date, time, place) IEC - Chairperson, Member secretary; name and designation of EC members

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

The IEC to be informed about the progress of the study, any serious adverse events occurring in the course of the study, any changes in the protocol and patient information/informed consent and to provide a copy of the final report on completion.

Yours sincerely
IEC – Members secretary

Form IA - Proforma to be submitted to the IEC

(for projects other than those mentioned in form IB)

Kindly submit 5 copies of proforma and consent forms in English & Telugu to the member Secretary, IEC, NMC Nellore

a) Project Title; PI /Co-I name, designation, medical degree registration-, GCP -certificate; clinical research experience.

b) Sponsor's details; include site monitor details also.

c) Date of approval by NMC Nellore (if any).

d) Study - Rationale and Objectives.

e) Informed Consent Form (ICF) – sample copy in both English and Telugu/vernacular language. If waiver needed – should be justified.

f) Investigator brochure – should include the details about the therapeutic –agent, side effects/ risks involved to the study subjects.

g) Methodology: It should provide details of sample size, the number of patients, inclusion criteria, exclusion criteria, control(s), study design, dosages of drug, duration of treatment, investigations to be done etc.; potential side effects of the therapeutic agent, adverse events and the plans to manage it.

h) Conflict of interest for any other investigator(s) (if yes, please explain in brief)

i) Permission from Drug Controller General of India (DCGI) if applicable

j) Any additional information regarding the study can be furnished.

k) We, the undersigned, have read and understood this protocol and hereby agree to conduct the study in accordance with this protocol and to comply with all requirement of the ICMR guidelines.

Signature of the Investigators:

Signature of the Head of the Department

(Note: The proforma must be accompanied by consent forms I & II in English and Telugu. consent form I is equivalent to patient Information Sheet. The investigators must provide information to the subjects in a simple language, and it should address the subjects, in a dialogue format)

Form IB - Proforma to be submitted to the NMC Ethics Committee (Human studies)

(for MD/MS/DM/M. Ch/Ph.D/ (for Thesis or Dissertation/Medical student projects)

Kindly submit 3 copies of proforma and consent forms in English & Telugu to the member Secretary, Institute Ethics Committee (Human Studies), NMC Nellore

1. Project Title; Name and designation of a) investigators; b) Project Guide/Co-guide; Funding source
2. Date of approval by Institute Research Council/ Scientific Advisory if any:
3. Study Rationale and Objectives:
4. Informed Consent Form (ICF) – sample copy in both English and Telugu/vernacular language. If waiver needed – should be justified.
5. Methodology: It should provide details of sample size, the number of patients, inclusion criteria, exclusion criteria, control(s), study design, dosages of drug, duration of treatment, investigations to be done etc.; potential side effects of the therapeutic agent, adverse events and the plans to manage it.
6. Permission from Drug Controller General of India (DCGI) if applicable:
7. Conflict of interest for any other investigator(s) (if yes, please explain in brief):

We, the undersigned, have read and understood this protocol and hereby agree to conduct the study in accordance with this protocol and to comply with all requirement of the ICMR guidelines (2006)

Signature of the Investigators:

Signature of the Head of the Department

Form II - Preparation of clinical study protocol

1. *Title Page*

a) Study title

b) Protocol version number and date

c) Name of the investigational drug/agent.

d) Complete name & address of the Sponsor and contract research organization (CRO) if any

e) Investigators details – name and affiliation; study site – details – name and address.

f) Name (s) of clinical laboratories and other departments and /or facilities participating in the study.

2. *Table of Contents*

A complete table of contents including a list of all Appendices.

Background and Introduction – a) Preclinical experience; b) Clinical experience

Previous clinical work with the new drug should be reviewed here and a description of how the current protocol adds knowledge to the existing data should be mentioned. If this is an entirely new indication, rationale should be given for consideration of the drug. Relevant information regarding pharmacological, toxicological and other biological properties of the therapeutic agent / medical device and previous efficacy and safety experience should be described.

3. *Study Rationale*

The reasons for conducting the proposed study should be clearly defined. Review of the literature, indicating the existing knowledge in the given topic and to identify the missing information or gaps or open questions in the chosen topic and mention the need to address those gaps involving human subjects in the study. The rationale should be followed by the hypothesis and objectives (primary and secondary)

4. *Study Design*

a. Overview of the study Design: Study type - i.e. double- blind, multi-center, placebo controlled, open labeled etc., study groups – treatment and controls; number of subjects; study site; randomization method; statistical analysis; and study time line

b. Flow chart of the study

c. A brief description of the methods and procedures to be used during the study.

d. Discussion of study design: This discussion details the rationale for the design chosen for this study.

e. Study population: Age, gender, number of subjects and the statistics used to derive the number; if it is a multicenter study, then number of subjects in each center should be mentioned.

f. Subject Eligibility – a) Inclusion Criteria; b) Exclusion Criteria

g. Undesired side effects of the intervention and comparator and the plans to monitor the adverse events to be mentioned.

5. ***Study Assessments****–plan procedures and methods to be described in detail*

6. ***Study Conduct***

stating the types of study activities that would be included in this section would be: medical history, type of physical examination, blood or urine testing electrocardiogram (ECG), diagnostic testing such as pulmonary function tests, symptom measurement, dispensation and retrieval of medication, Subject cohort assignment, adverse event review etc. Each visit should be described separately as visit I, Visit 2, etc. Mentioned can be tabulated for ease of reviewing and follow during the study period.

Discontinued Subjects: Describes the circumstances for subject withdrawal, dropouts, or other reasons for discontinuation of subjects. State how drop outs would be managed if they would be replaced.

Describe the method of handling of protocol waivers, if any. The person(s) who approves all such waivers should be identified and the criteria used for specific waivers should be provided.

7. *Describe how protocol violations will be treated, including conditions where the study will be terminated for non-compliance with the protocol. Study treatment*

a) Clearly mention the dose and frequency of both the intervention and comparators (controls/placebos)

b) Therapeutic agent supply, storage and dispensing – manufacturer, supplier, details including product stability, storage and dispensing requirements should be mentioned.

c) Dose alteration/modification: dose/frequency change due to undue side effects or stopping the medication should be anticipated and mentioned in the protocol; alternative therapeutic regimen in such case should also be clearly mentioned.

d) Possible drug interactions with the concomitant medications should be mentioned. Also, if any modifications in the diet should also be indicated.

e) Concomitant therapy: the drugs that are permitted during the study and conditions under which they may be used are detailed here. Describe the drugs that a subject is not allowed to use during parts of or the entire study. If any washout period for prohibited medication is needed prior to enrolment, should be described here.

f) Blinding procedures: A detailed description of the blinding procedure if the study employs a blind on the investigator and / or the subject

g) Un-blinding procedures: If the study is blinded, the circumstances in which un-blinding may be done and the mechanism to be used for un-blinding should be given.

8. ***Adverse Events:*** Description of expected adverse events should be given. Procedures used to evaluate an adverse event should be described.
9. ***Ethical Considerations:*** Give the Summary of: Risk/benefit assessment: EC review and communications; Informed consent process; Statement of subject confidentially
10. ***Study Monitoring and Supervision:*** A description of study monitoring policies and procedures should be provided along with the proposed frequency of site monitoring visits and the particulars of study monitor should be provided.
11. ***Case Report Form(CRF):*** Template specific for the study, any specifics in filling out the forms; if any errors, correction requirements, including who is authorized to make corrections on the CRF. The person of contact for query on the data. Investigator study files storage post study completion should be described.
12. ***Investigational Product Management:***
    a. Give Investigational product description and packaging (stating all Ingredients and the formulations of the investigational drug and any placebos used in the study)
    b. The precise dosing required during the study
    c. Method of assigning treatments to subjects and the Subject identification code numbering system
    d. Storage conditions for study substances
13. ***Investigational product accountability:*** Describe instructions for the receipt, storage, dispensation, and return of the investigational products to ensure a complete

accounting of all investigational products received, dispensed, and returned /destroyed. As well policy and procedure for handling unused investigational products

14. ***Data Analysis:***

Provide details of the statistical approach to be followed including sample size, how the sample was determined, including assumptions made in making this determination, efficacy endpoints (primary as well as secondary) and safety endpoints.

Statistical analysis:

Give complete details of how the results will be analyzed and reported along with the description of statistical tests to be used to analyze the primary and secondary endpoints defined above. Describe the level of significance, statistical tests to be used and the methods used for missing data: method of evaluation of data for treatment failures, noncompliance, and Subject withdrawals: Describe statistical considerations for Pharmacokinetic (PK) analysis, if applicable

15. ***Undertaking by the investigators***

16. ***Appendices:*** Provide a study synopsis, copies of the informed consent documents (patient's information sheet, informed consent form etc.): CRF and other data collection forms; a summary of relevant pre-clinical safety information and any other documents in the clinical protocol.

Study Investigator's Name	Signatures with date -
Witness – 1; Name, Signature and date	Witness -2; Name, Signature and date

Form III - Undertaking by the Investigator

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

Commitments:

- I reviewed the study protocol; it contains all the required information; no revisions will be made to it. I agree, to personally conduct the study in our site following the protocol approved by EC and regulatory agencies. No amendments to the protocol will be made without prior approval from sponsor and IEC. Except where necessary to eliminate an immediate hazard(s) to the trial subjects or when the changes(s) involved are only logistical or administrative in nature.
- As per the GCP guidelines, the informed consent will be obtained from the study subjects; I ensure that they understand the study protocol clearly, including the interventions given and diagnostic tests performed; and I will report all adverse events that occur during the study to both EC and sponsor.
- I have read and understood the information in the Investigator' brochure, including the potential risks and side effects of the drugs.
- 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 obligations in meeting their commitments in the trial.
- I agree to maintain adequate and accurate records and to make those records available for audit/inspection by the sponsor, EC, Licensing authority or their authorized representative, in accordance with regulatory and GCP provisions. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the sponsor.
- I agree to promptly report to the EC and sponsor about all changes in the clinical trial activities and all unanticipated adverse events within 7 days.
- I will maintain confidentially of the identification of all participating study patients and assure security and confidentially of study data.
- I agree to comply with all other requirement, guidelines and statutory obligations as applicable to clinical Investigator participating in clinical trials.

PI signature & date

Form IV - ONE PAGE CV

First Name	Last Name	Middle Initial
Date of Birth (dd/mm/yy):		Sex
Study Site Affiliation (e.g. Principal Investigator, Co-Investigator, Coordinator)		
Professional Mailing Address (Include institution name)		Study Sited Address (Include institution name)
Telephone (Office):		Mobile Number:
Telephone (Residence):		E-Mail:
Academic Qualifications (Most current qualification first)		
Degree/Certificate	Year	Institution, Country
Current and Previous 4 Relevant Positions Including Academic Appointments (Most current position first)		
Month and Year	Title	Institution/Company, Country
Brief Summary of Relevant Clinical Research Experience:		
Principal Investigator Signature:		Date:

ANNEXURES (ANX)

ANX - 01/V2 – IEC SOP revision – request form

Title of SOP	
Revision required in SOP -	
Identified by:	Date (DD/MM/YYYY):
Signature of person requesting revision:	
To be filled by IEC Member Secretary	
Discussed with SOP writing committee by (Name) and date	
SOP revision required: Yes if No Justify	
Signature of Member secretary & date:	
If SOP revision is required	
Date SOP re-finalized:	
Date SOP approved:	
Date SOP becomes effective:	
Signature of Member secretary and date:	

ANX - 02/V2 - SOP Recipients – Log

S. No	Name of the recipient	IEC member Yes/No	SOP version & date	No. of copies	Signature & date

ANX - 03/V2 - Offer letter to be the IEC - Chairperson/Member Secretary/ Member, from head of the institution

To be printed in the Letter head of Narayana Medical College

Ref: Date:

To

Dr.

Dear Dr/Mr/Ms/Mrs. ..... We are happy to invite you to be a Chairperson/Member Secretary/Member of the Institutional Ethics committee (IEC), Narayana Medical College (NMC), effective from *Day, month, year* for a period of three years. As an IEC member, your name will be featured in the website of the Institution and IEC related documents. You are requested to send your acceptance to the office of the undersigned. On receipt; you will receive a communication from the office spelling out the terms of reference.

Your willingness to serve will be appreciated.

Thanking you,

Dean, NMC & CC to IEC Member Secretary and Dean office

ANX - 04/V2 - Terms of reference letter from the head of the institution for constitution of IEC (to the selected member)

To be printed on NMC letter head

Ref: Date:

To

Dear Dr/Mr/Ms/Mrs.,

We are happy to note that you have accepted to be the Chairperson / Member secretary /a member of IEC, NMC. Your appointment is effective from Day, month, and year for a period of three years.

Terms of reference:
Before joining as a member, you need to

- Submit a letter of acceptance, one-page CV, copy of medical degree registration, GCP training certificate
- Sign a confidentiality agreement at the start of the term. The confidentiality agreement protects the privacy & confidentiality of all parties whose information may be disclosed to the IEC in the course of its work and sign a form for declaration of conflict of interest.

Your role and responsibility as a _____in the committee will be:

Kindly note that your absence for three consecutive meetings without prior approval will beconsidered as your inability to continue as an IEC member henceforth.

Your willingness to serve is well appreciated.

Thanking you,

Dean

CC: IEC member secretary and Dean office

ANX - 05/V2 - Template for preparing the annual report

IEC annual report will be prepared by member secretary and submitted to the head of the institute

Organizational Aspect:

Period of report: From (DD/MMM (letters)/YYYY) to (DD/MMM (letters)/YYYY)
Institutional Ethics Committee, Narayana Medical College, Nellore 524003, Andhra Pradesh.
CDSCO registration number; IEC members list with designation.

Table 1 – IEC meeting details

S. No	Date of Meeting	New proposals		Proposals re-submitted	
		Title	Decision	Title	Decision

Table 2 - Details of Serious Adverse Events (SAE) - subcommittee meetings

IEC No with subject ID	SAE				Compliance	Reasons for delay, if any
	Date of occurrence	Reported by PI on	Date of IEC meeting	Reported to DCGI by IEC, on		

Number and type of proposals (Pharma/ Government - sponsored/ investigator initiated) reviewed in a year, status of each study proposal whether completed / ongoing / terminated

Table 3 - Site visits

Date of visit	Team members	IEC No.	PI Name

Table 4 - Training of IEC members

Date - Continuing Medical Education	Topics Covered	Speaker

IEC resources & any other matter

NARAYANA MEDICAL COLLEGE

ANX - 06/V2 - IEC member Training Record Form

Name:	Tick one of the following		
Membership since	Chairperson	Member secretary	Member

Ethics related Training Experience

S. No	Courses / Workshops / Conferences / Meetings	Title	Organizer	Date and duration
1				
2				

Signature of IEC member & date:

ANX - 07/V2 – Documents to be submitted to IEC for reviewing the proposed study

S. No	Documents to be submitted	Version	Date
1.	Brief CV of PI and study team members; as well their Medical registration and GCP certificate		
2.	Protocol summary (500 words), Full protocol, Investigator brochure, Case report form, Insurance policy and certificate		
3.	Investigator undertaking to DCGI		
4.	Draft / Final Clinical Trial Agreement (CTA)		
5.	If DCGI approval letter is awaited, upload the application letter submitted to DCGI		
6.	Patient Information Sheet (PIS) & Informed consent forms (ICF) in English and vernacular languages (Telugu); Translation and Back translation certificates. Prescription information.		
7.	Letter to Member Secretary/ Chairperson seeking review and approval of study protocol. Filled and duly signed application form to review the protocol		
8.	Study participant recruitment procedures, advertisement, notices (If applicable)		
9.	**OTHER DOCUMENTS AS APPLICABLE:**		
10.	Administrative sanction from the Head of the Institution for: a) samples to be sent to outside host institution (one copy); b) collaborative studies with other institutions/foreign agencies (one copy).		

11.	Audio Visual Consent Form in English/regional languages (vulnerable group)		
12.	Bhabha Atomic Research Centre (BARC) approval for studies that use of radioisotopes/ ionizing radiations		
13.	Clinical Trial Agreement for drug trial / Memorandum of Understanding, as applicable, for Collaborator & Govt. sponsored trials (draft if final not ready)		
14.	Current Status of Ongoing Studies approved by IEC and conducted by PI (information may be submitted separately)		
15.	Documentation of CTRI registration/any other WHO platform registry (whenever applicable)		
16.	Ethics Committee clearance of other centers (Total No.)		
17.	FDA marketing/manufacturing license for herbal formulations/ nutraceutics		
18.	Genetic Engineering Advisory Committee (GEAC) approval for gene therapy studies		
19.	Patient instruction card, identity card, diary etc.		
20.	Research participants Questionnaire/s (If applicable)		
21.	Research involving vulnerable participants - a) Children; b) Cognitively impaired adults; c) Pregnant women and fetuses; d) Students, employees or residents.		

ANX - 08/V2 - Initial Review Submission Form for Research Proposal

1. Proposal Title; Principal Investigator (PI) and study team members; name, qualification and designation.
2. Name of the Institute/Hospital/Field area where research will be conducted.
3. Forwarding letter from the Head of the Department/Institution/Guide. (if applicable)
4. Mandatory – Consent from HOD, of the concerned department, where the proposed study will be conducted.
5. Protocol of the proposed research.
6. Proposal should be submitted with all relevant enclosures like protocol, case report forms, questionnaires, follow-up cards etc.
7. Informed consent process, including patient information sheet, informed consent form and assent form (if applicable) in English and local language(s).
8. Does the study involve vulnerable population as defined in ICMR guidelines 2017 (if yes specify)?

9. Consent for audio-video recording (If applicable)
10. For any drug / device trial, all relevant pre-clinical animal data and clinical Trial data from other centers within the country/other countries, if available. (Investigator brochure)
11. Ethical issues in the study and plans to address these issues.
12. Usefulness of the project/trial
13. Expected 'benefits' to volunteers/community
14. 'Benefits' to other categories if any
15. Explain all anticipated 'risks' (adverse events, injury, discomfort) of the project.
16. Efforts taken to minimize the 'risks'
17. Any regulatory clearance such as Research proposal approval by Scientific Advisory Committee, Drug Controller General of India, Health Ministry screening committee, NOC etc. required.
18. Source of funding and financial requirements for the project.
19. Other financial issues including those related to insurance.
20. Agreement to report all Serious Adverse Events (SAE) to IEC NMC (Investigator Undertaking).
21. Statement of conflicts of interest, if any.
22. Agreement to comply with the relevant national and applicable International guidelines.
23. Clinical Trial Agreement (If applicable) signed by sponsor, Principal Investigator and Institution.
24. Statement describing any compensation given to study participation as per the latest DCGI guidelines (including expenses and access to medical care) in the protocol and Patient Information Sheet
25. Description of the arrangements for indemnity, if applicable in study-related injuries and description of the arrangements for insurance coverage for research participants, if applicable.
26. All significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study

(whether in the same location or elsewhere) and an indication of the modification (s) to the protocol made on that account. The reasons for negative decisions should be provided.

27. Brief Curriculum Vitae of all the investigators with relevant publications in the last 3 years
28. Plans for publication of results/positive or negative/while maintaining the privacy and confidentiality of the study participants.
29. Proposal registry with www.ctri.in and submit the confirmation number provided by CTRI.
30. Any other information relevant to the study.

Signature of the Principal Investigator with date.

ANX - 09/V2 - Template of documents missing in the submission

To

The Principal Investigator

Dear sir/madam,

Thank you for submitting the proposal titled _____ for IEC review. The secretariat on perusal has found that the following document(s) are missing in the submitted documents. You are requested to include these document(s) and sent the proposal again to the IEC so that the same can be taken up for review in the forthcoming meeting.

Thanking you Regards

ANX - 10/V2 - Study Assessment Form to be used at the IEC meeting

IEC No: **Date (DD/MM/YY):**

Protocol title and number	
Principal Investigator details	
Co-Investigator / Guide:	
Total No. of Participants	
No. of Study site/s	
Study duration	

Status	New / Resubmission		
Type of study	Intervention Documents based Social survey Other specify – Observational		Epidemiology Genetic
Review of status	Regular	Expedited	Emergency
Description of the study in brief: (Mark whatever applied to the study)	Randomized Open –labeled Placebo controlled Cross-over Screening Multicenter study Post marketing surveillance		Stratified randomized Double Blinded Treatment controlled Prospective Parallel Descriptive Exploratory
Sample used	Use of tissue samples / use of blood samples / use of genetic materials		
Study design and statistical method appropriate	Yes / No		
Study Objective clearly explained	Yes / No		
Documents to be verified	Protocol		
	Prescription information		
	Investigator brochure		
	Patient information form (PIS)		
	Informed consent form (ICF)		
	Assent form, if required (AF)		
	PIS, ICF and AF in regional language		
	AV Consent (if applicable)		
	Case report form		
	Forwarding letters, if required		
	Brief CV of PI		
Regulatory requirements	DCGI Approval / acknowledgement of application		
	Clinical trial agreement (CTA)		
	CTRI No.		
	Insurance certificate		
	Investigator undertaking		
	NOC from regulatory authorities (if applicable)		
	Other regulatory documents (if applicable)		

Assessment Report

IEC No;	

Protocol Number Protocol Title	
Date of Review	
Review of New Proposal / resubmission	New proposal
Date of previous review	
Decision	Approved / Approved with recommendation / resubmission / disapproved

Risk and benefit Assessment

Risk	
Benefit	

IEC Members comments:

Medical experts:
Pharmacologist:
Social scientist:
Legal person:
Lay person:

IEC Member list

S. No.	Name	Signature	Date
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			

ANX - 11/V2 - IEC decision on proposed study protocol; Decision of Full board/Expedited Review/Re-submissions/Protocol Amendment

Institutional Ethics Committee:

(Clinical Evaluation of Drugs/ Procedures/Devices/Diagnostics/ Vaccines/Herbal Remedies)

List of IEC NMC members

To

Principal Investigator,

Designation, NMC, Nellore

Date:

Subject:

Ref: No: IEC/Year/Month/Meeting No/Proposal No.

The Institutional Ethics Committee (IEC) met on _____ under the Chairperson ship of _____ and reviewed the documents submitted (listed below) for the project titled"_____" IEC No: _____ which was presented by _____.

The following IEC members were present at the meeting held in the Room, NMC, Nellore.

Table 1. List of documents reviewed:

S. No.	Documents	Version number & date

Table 2. List of members attended:

Name, designation and affiliation

The Committee reviewed the following documents to be listed with version number and date in a tabular form and after deliberations, _____the project with the following recommendations, if required:

IEC approval validity period: 18 months from the date of approval frequency of ongoing project review

Note to PI:

1. To comply with the following before which the study should not be started at this center (proof for regulatory approval to be submitted)
2. To inform the IEC the actual date of starting the study within the 10days of starting the study.
3. To obtain the IEC approval prior to implementing any change in study procedures
4. To report Serious Adverse Events (SAE) as per DCGI guidelines
5. IECs limitations of liability: This letter of approval just indicates clearance in regard to conformity of the study protocol of the sponsor/ Investigator with the prescribed ethical standards. Neither the IEC nor any of its members shall be liable for any liability what so ever under any circumstances in relation to the conduct of the clinical trial or in connection with the study drug/devices to be administered or used as per thestudy protocol.
6. Clinical Trial Agreement (CTA)/Memorandum of Understanding (MOU) (as applicable) should be processed and signed as per the guidelines for conduct of clinical trial in IEC. A copy of the CTA/MOU duly signed by the parties concerned as mentioned above should be submitted to IEC.
7. Note that the IEC has the right to monitor the study with prior intimation.
8. To apply for extension of IEC approval if required before expiry of the validity period along with appropriate justification and summary of study findings.
9. To submit the ongoing review details of the study at the frequency mentioned.
10. To quote the IEC reference number in all communications

Signature of the Chairperson/ Member Secretary

ANX - 12/V2 - Checklist - Research Involving Students, Employees or Residents

PI:

Study Title:

Subjects who are students, employees or residents require special considerations.

Does the employer or supervisor of the research subject need to be aware of the research project?	Yes	No
Is there a letter of support from the head of the dept./institution?	Yes	No
Have the subjects been assured that their status (education, employment, and/or promotion) will not be affected by any decision employment, and/or promotion) will not be affected by any decision to participate or not?	Yes	No
Have the risks to subjects been minimized?	Yes	No
Have subjects been assured that participation is voluntary (no signs of coercion)	Yes	No
Have subjects been assured that confidentiality will be protected or maintained	Yes	No

Signature of Principal Investigator:_____**Date** _____

ANX - 13/V2 - Informed Consent Form for Audio-Video Recording

Subject's Initials:_____ Screening No.:

Study Title: Protocol No: Sponsor:

Principal Investigator: _____, the undersigned, am interested in receiving information regarding the above mentioned clinical trial for my child's participation.

I understand that prior to my child's participation in the above mentioned clinical trial, I need to undergo a detailed Informed Consent process including the AV (audio-visual) recording thereof (as mandated by the DCGI Office Order — F. No. GCT/20/SC/Clin./2013 DCGI, dated 19" November 2013).

Accordingly, I hereby give my voluntary consent for an audio-visual recording of the Informed Consent process as mandated by the regulatory authorities, subject to the condition that strict confidentiality will be maintained in this regard by the Investigator(s) / Institution and that such AV recording maintained in any form will be

accessible only to the Investigator(s) and his/her Site Staff, EC, and the Regulatory Authorities.

Name in block letters	Signature/Thumb Impression	Date
Subject	Subject's parent sign & thumb impression -	
Subject's Parent		
Witness		
PI / Designee		

The subject's parent(s) has been given a copy of this completed Informed Consent Form for AV Recording.
The original copy of Informed Consent Form (ICF) for AV Recording will remain in the Investigator Site File/ Subject file at site.

ANX - 14/V2 - Participant request/complaint form

Date	
Received by	
Request received through	Fax Letter/datee-mail/date walk in/date/time other (specify)
Participant's name	
Contact address	
Phone	
Title of the study	
Starting date of participation	
Information requested	

Signature of the participant & Date

ANX - 15/V2 - Action taken by the IEC on participant request/complaint form

Date	
Received by	
Date of receipt	
Participant's name	
Contact address	
Phone	
Title of the participating study	
Starting date of participation	
Information requested /complaint/query	
Action taken	
Outcome	
Date of reply to the participant	

Signature of the IEC Chairperson & Date

ANX - 16/V2 - Patient Information Sheet

Checklist for study Subject's informed consent form Essential Elements:

1. Statement that the study involves research and explanation of the purpose of the research
2. Expected duration of the Subject's participation
3. Description of the procedures to be followed, including all invasive /noninvasive procedures
4. Description of any reasonably fore-seeable risks or discomforts to the Subject
5. 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.
6. Disclosure of specific appropriate alternative procedures or therapies available to the Subject.
7. 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

8. Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials)
9. Compensation and/or treatment(s) available to the Subject in the event of a trial- related injury.
10. An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury
11. The anticipated prorated payment, if any, to the Subject for participating in the trial
12. Subject's responsibilities on participation in the trial
13. 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
14. Any other pertinent information

Additional elements, which may be required

15. Statement of foreseeable circumstances under which the Subject's participation may be terminated by the investigator without the Subject's consent.
16. Additional costs to the Subject that may result from participation in the study.
17. The consequences of a Subject's decision to withdraw from the research and procedures for orderly termination of participation by Subject.
18. 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.
19. A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or fetus, if the Subject is or may become pregnant), which are currently unforeseeable
20. Approximate number of Subjects enrolled in the study

ANX - 17/V2 - Informed consent form for Subjects participating in a clinical trial (Model format)

Informed Consent form to participate in a clinical trial
Study Title and Number:
Subject Name & Initials:_____; Date of Birth & Age:_____

a) I confirm that I have read and understood the information sheet dated ___for the above study and have had the opportunity to ask questions.

b) 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.

c) 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.

d) 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 purpose(s)

e) I agree to take part in the above study. A copy of this form has been given to me.

Name & signature of the following with date

1. Name & Signature (or Thumb impression) of the Subject/Legally Acceptable Representative
2. Name & Signature of the Investigator
3. Name & Signature of the Witnesses

Contact Address with phone number of the above mentioned signatories.

PI Name	Collaborator (if any) outside NMC	IEC
		Chairperson name and contact details

(A copy of the participant/patient information sheet should be given to the participant for her/ his record. In case of illiterate participant, the information is explained and thumb impression is obtained, in the presence of an unrelated witness. Thumb impression for Male – left hand; Female – right hand.

Certification of Informed Consent

I certify that I have explained the nature and purpose of this study to the above-named individual, and I have discussed the potential benefits of this study participation. The questions the individual had about this study have been answered, and we will always be available to address future questions.

Date: **Signature of person obtaining consent Name:**

Signature of PI

ANX - 18/V2 - Assent to Participate in a Research Study (form for oral assent 7-12 year olds)

Title of Study

[If applicable, designate sub-group after study title, e.g., "11–17 Year Olds"]

My name is_____, from the Department of_____at the Narayana Medical College, Nellore, Andhra Pradesh. I am doing a research study. I'd like to tell you about this study and ask if you will take part (be a "subject") in it.

What is a research study?

A research study is when people like me collect a lot of information about a certain thing to find out more about it. Before you decide if you want to be in this study, it's important for you to understand why we're doing the research and what's involved.

Please read this form carefully. You can discuss it with your parents or anyone else. If you have questions about this research, just ask me.

Why are we doing this study?

[*Explain study purpose in brief, simple terms. Note that it is different from school work.* We are doing this study to find out *[e.g., if a drug A will be better than drug B for treating a particular disease.]*

Why are we talking to you about this study?

[*Give brief explanation of why the individual is being asked to participate in study, e.g.*:] *We're asking about____adolescents if they would like to participate*. We're

inviting you to - take part because *[e.g., you are this age]*.

What will happen if you are in this study?

[*List all study procedures/activities in chronological order, using bulleted format. Indicate location where procedures will take place and amount of time needed for each procedure. Also note* total *amount of time required for study participation. See examples below.*]

- If you agree to be in the study and your parents give permission, we will ask you to: Answer a questionnaire
- *You will be asked to complete a questionnaire about your quality of life].* This part willtake about *[minutes/hours]*.
- *You can take a short break before the next part if you want to* be interviewed (maybe)

Based on the criteria we have laid out; we will decide whether you would participate in the study. We have treatment arms, and the treatment you would receive will decided by a random method. (Randomization is like pulling numbers out of a hat or flipping a coin to decide.) *If you are chosen and want to be part of this study, one of the study team members will meet with you.*

if you give your permission. If you say it's okay about the taping we will explain you about the way the study will be conducted, and audio-videotape. If you feel uncomfortable or change your mind, we can turn off the recorder at any time. Just let us know.

This procedure will take about_____[*minutes/hours]*.

If you don't want to be in the study, what can you do instead?

If you don't want to be in the study, your doctor will treat you with the standard medications available.

Are there any benefits to being in the study?

[Explain possible benefits of the study, both direct/individual (if there are no direct benefits,make this clear), and indirect/general benefits to society or scientific knowledge, e.g.:]. There is no benefit to you personally for taking part in this study. But we hope that the results of the research will (help improve ways of treatment for children in the future).

Are there any risks or discomforts to being in the study?

[*List possible risks/discomforts, using bulleted format. See examples below.*]

- If you have any discomfort at any time, please do not hesitate to report to us.
- You might get --. If so, just tell us that you want to stop.
- A possible risk for any research is that people outside the study might get hold of confidential study information. We will do everything we can to make sure that doesn't happen.

Who will know about your study participation?

Besides you and your parents [*insert others, if applicable*], the researchers are the only ones who will know the details of your study participation. If we publish reports or give talks about this research, we will only discuss group results. We will not use your name or any other personal information that would identify you.

To help protect confidentiality [*explain security measures to be taken in simple terms, e.g.:*] we will give your study data a code number, and keep it in a file with a password that only the researchers know. The file will be on a computer that only the researchers are allowed to use.

[*If data/records will be destroyed, state when; if they will be retained, explain for how long and why, e.g.:*] We plan to keep this information for years, in case we or otherresearchers want to use it later for other studies. But we will follow the same steps we just described to keep it as confidential as possible.

Will you get paid for being in the study?

[*If no payment*:] You will not be paid for being in this study. [*Or if payment*:] Your parents [*or, depending on the arrangements*, you will receive [*e.g., amount of money*] for travel and the time spent to take part in this study. [*Briefly explain how/ when compensation will be dispersed, etc.*]

Do you have to be in the study?

No, you don’t. Research is something you do only if you want to. No one will get mad at you if you don’t want to be in the study. And whether you decide to participate or not, either way will have no effect on your treatment.

Do you have any questions?

You can contact us if you have questions about the study, or if you decide you don't want to be in the study any more. You can talk to me, or your parents, or someone else at any time during the study. My phone number is *[PI/CoPI Investigator's name]*: ------, or you cancall *[other research team/lab member's name]* --

Assent of Adolescent (11–17 years old)

If you decide to participate, and your parents agree, we'll give you a copy of this form to keep for future reference.

If you would like to be in this research study, please sign your name on the line below.

_____ _____

Child's Name/Signature (*printed or written by child*) * Date

_____ _____

Signature of Investigator/Person Obtaining Assent Date

**If verbal assent only is being obtained:* Investigator or Person Conducting Assent Discussion: Initial here if child cannot sign, to document that child received this information and gave assent verbally: _____

ANX - 19/V2 - Application form for requesting waiver of consent, when applicable

1. **Principal Investigator's name and contact details**
2. **Study title**
3. **Request for waiver of informed consent:**

Please give the reason(s) for requesting waiver

a. Emergency situations as described in ICMR Guidelines (ICMR 2006 Guidelines http://www.icmr.nic.in/ethical_guidelines.pdf)

b. Any other (please specify)

- Statement assuring that the rights of the participants are not violated
- State the measures described in the Protocol for protecting confidentiality of data and privacy of research participant

Principal Investigator's signature with date:

ANX - 20/V2 - Format for Scheduled/Unscheduled meeting agenda

Agenda for the meeting to be held on_____(date) at (time) in the _____ (Venue)

1. **IEC Chairperson's Remarks**
2. **Review of activities – Member Secretary**
   a. Approval of the minutes of the meeting held in previous meeting
   b. Declaration of Conflict of Interest
   c. Date of forthcoming scheduled IEC meeting
   d. Any Other events as applicable
3. **Review of Protocol amendments IEC** No._____ "**Title of study"** Name of PI, Designation andAffiliation
4. **Ratification of protocol amendments approved by expedited process** IEC No._____ "**Title of study"** Name of PI, Designation and Affiliation
5. **Review of Protocol violations/Deviations** IEC No._____ "**Title of study"** Name of PI, Designation andAffiliation
6. **Review of Ongoing protocols (Initiated studies)** IEC No._____"**Title of study"** Name of PI, Designation and Affiliation
7. **Review of SAE** IEC No._____ "**Title of study"** Name of PI, Designation and Affiliation
8. **Review of New Protocols** IEC No._____"**Title of study"** Name of PI, Designation and Affiliation
9. **Review of Re-submissions** IEC No._____"**Title of study"** Name of PI, Designation and Affiliation
10. **Review of Clarifications/Notifications/Submissions (Yet to be initiated studies)** IEC No._____ "**Title of study"** Name of PI, Designation and Affiliation
11. Any other, as decided by the Chair, Member Secretary

ANX - 21/V2 - Format for Scheduled/Unscheduled IEC meeting

IEC meeting No:

Minutes of the Committee Meeting

Venue: Ethics Office, NMC

Date & Time:

Chairperson
Member SecretaryMembers:

At the Scheduled meeting of date, the following members were present:

List of Members present

S. No	Name	Qualification	Primary scientific or non-scientific specialty	Sex	Affiliationwith Institution (s)

Remarks by the chair:

- The meeting was called to order at time. Chair, Member-Secretary and other's remarks
- Approval of the minutes of the previous meeting held on
- Declaration of conflict of interest
- Date of forthcoming scheduled IEC meeting was tentatively fixed on
- Other events
- Review of Protocol amendments
- Name of PI who presented the amendments for the project and the IEC comment & decisions

Ratification of protocol amendments approved by expedited process:

The Member Secretary informed the committee that the above mentioned protocol and associated documents were submitted to the Chair for expedited review and was approved. The Member Secretary briefed the committee members on the amendments. The committee approved/added comments on the decision of expedited approval.

Review of Protocol violations/Deviations:

Protocol deviations /violations were briefed to the members.

Review of Ongoing protocols (Initiated studies)

IEC comments and suggestions

Review of SAE:

Name of SRC member, presented the SAE details & the IEC comments and suggestions

Review of New Protocols:

PI presented the project details, the protocol was reviewed along with the associated documents. The IEC assessed the need for the study, Risk/Benefit ratio, unmet medical needs and following a consensus opinion, the protocol and all the submissions were approved / requested to be re-submitted with the following recommendations. If approved, IEC approval validity period, frequency of ongoing reviews to be conducted

Review of Re-submissions:

PI presented the project details, the protocol was re-reviewed along with the associated documents. The IEC assessed whether the queries raised in the earlier meeting have been addressed and following a consensus opinion, the protocol and all the submissions were approved / rejected with the following recommendations. If approved, IEC approval validity period, frequency of ongoing Reviews to be conducted

Review of Clarifications/Notifications/Submissions (Yet to be initiated studies)

IEC comments

Any other, as decided by the Chair, Member Secretary

The meeting was adjourned at Time.

Signature of Chair

Date:

Copy to: All the IEC members and the Institution head

ANX - 22/V2 - Format for Protocol Amendment / Revision to be submitted to IEC

IEC No:
PI Name & Study Title
Date of submission of amendment to IEC
Covering letter to IEC Chair person should accompany.

S. No.	Section in which amendment was made	Original statement page no; para; line-	Amended statement page,para, line no;	Justification

ANX - 23/V2 - Format for Reply to IEC queries / Clarifications

IEC No: PI: Study Title:

Date of IEC query letter / conditional Approval letter / decision letter

IEC Remark	Reply

Attach covering letter to the chair person.

ANX - 24/V2 - Letter to PI for submission of status reports for ongoing review

Ref: IEC No Date: ……

To

The Principal Investigator

Sir / Madam,

Subject: Ongoing review of projects – forthcoming IEC meeting (date:) – reg.

This is to bring to your notice that the protocol titled "……" was approved by IEC on…….

IEC ID: ……

This project needs to undergo an interim ethical review. Kindly make the necessary arrangements to submit the filled-in status report form, along with their appropriate attachments, to the undersigned not later than_____days**,** so as to enable including this in the agenda for review during the forthcoming IEC meeting. IEC may require that you to present the status report at the meeting.

Thanking you.

Yours truly,

IEC - Chairperson/Member Secretary

ANX - 25/V2 - Ongoing / Completed / Terminated protocol review submission form

1.	IEC approval number and Project title
2.	PI contact details
3.	Project initiation date? If no, give reasons
4.	Project duration

5.	Number of subjects – a) Total to be recruited; b) Screened; c) Recruited; d) Continuing; e) Drop outs
6.	No. of SAE reported? Give details (subject ID & SAE)
7.	Unanticipated study related problems? If yes, give details
8.	Number of protocol violations with subject ID and details
9.	Amendment in protocol and informed consent after IEC review? If yes, did IEC approved?
10.	Is there any new risk or benefit information? Ifyes, give details
11.	Is there any new scientific knowledge relevant to the conduct of the study?
12.	Remarks, if any

ANX - 26/V2 - Letter to PI – IEC Review of status report

Ref No: **Date:_____**

To

The Principal Investigator

Sir / Madam,

Subject: IEC, NMC No:_____ “Title:_____” reg.

Ref: Your letter dated

The IEC, NMC under the Chairperson ship of _____ met on _____and reviewed the above referenced project based on the status report submitted by you.

The Committee hereby acknowledges the submission.

Recommendations if any

Thanking you.

Yours truly,

IEC - Chairperson/Member secretary

ANX - 27/V2 - Check list for site visit

IEC No.:	Date of the Visit:
Study Title:	
Principal Investigators :	Phone:
Institute : NMC	Address:
Sponsor:	Address:
Total number of expected subjects:	Total subjects enrolled:
Are site facilities appropriate? Yes/ No	Comment:
Are Informed Consents recent? Yes/ No	Comment:
Any Serious adverse events found? Yes/ No	Comment:
Any protocol non-compliance /violation? Yes/ No	Comment:
Are all Case Record Forms up to date? Yes/ No	Comment:
Are storage of data and investigating products locked? Yes/ No	Comment:
How well are participants protected? Yes/ No	Comment:
Any outstanding tasks or results of visit? Yes/ No	Give details:
Duration of visit: …….hours	Starting from: Finish:
Name of IEC/IRB member/ representatives	
Completed by:	Date:

ANX - 28/V2 – Clinical Trial Site Audit Form

Add additional columns; if needed.

Study Title
Trial site
Name of PI and Co-PI
Date and time of audit
Visiting IEC member
Name of the members present at the time of audit

Details of Audit: Template used by member for site visit

A. ***Observation of the study site setting:*** *Patient reception; receptionist and the protocol*

1. How patients are – received at reception, receptionist details, identified as study subjects.
2. Patient waiting areas?
3. Informed consent – satisfactory?

B. ***Observation of procedure of drug administration / device: Person administering the drug, level of competence of the person, training on the procedure and protocol of the study during patient visit.***

1. Who brings the medicine to the clinical site and the protocol followed for the same?
2. Who examines the study participants and administers the drug?
3. Who collects the blood samples?
4. Patient stay – duration in each visit?
5. Patient monitored post drug administration? If, so mention by whom & where?
6. Does the study warrant any special training like anaphylaxis preparedness, follow-up for acute complications, important patient/attender education after

administration of therapeutic agent(s)?

7. Details of training given to the medical and para-medical staff involved in the particular study and proof for the same.

C. Preparedness for adverse events (AE) at the time of intervention:

1. Protocol for AE in the site? Subject attended by? Availability of appropriate drugs? Hospitalization requirement, if needed?
2. Does the trial involve device implant? If so where is the implant done? Who does the implant procedure? How is follow-up care done? What is the in-hospital duration of patient stay for device implant procedure?

D. Record management – Study documents including ICF storage – by whom and where?

ANX - 29/V2 - Format for Site visit report

Date; **IEC No:**

- Name and details of the visiting team; date and time.
- PI name and affiliation, Study title
- Sponsor details
- Details of the site visit as per the checklist:
- Remarks of the site visit team:

Signature of the team members

ANX - 30/V2 - Form for reporting Serious Adverse Event

- IEC No.
- Study title and PI name and contact
- Date of this report: (dd/mm/yyyy)
- Event Details:

Table 1 - Patient Details	
Patient ID and initials	

Hospital OP/IP number:	
Age, Gender and Date of Birth	
Height, weight and BMI	

Table 2 - Suspected Drug(s)			
Generic name -			
Indication(s) for which the drug used			
Dosage – schedule and frequency			
Route of administration:			
Starting date and time of the day:			
Stopping date and time, or duration of treatment:			

Table 3 - Other Treatment(s)

S. No	Generic name of the drug	Indication(s)	Dosage form & strength (units)	Daily dose & regimen (units)	Route	Start Date	End Date
1.							

Table – 4 Details of Suspected Adverse Drug Reaction(s)	
SAE Term:	
Severity:	
Seriousness Criteria:	
Start date (and time) of onset of reaction:	
Stop date (and time) or duration of reaction:	
De–challenge information:	
Re–challenge information:	
Setting	
SAE description	
Study drug – PI's interest/ conflict of interest.	

Table 5 - Outcome
Results of specific tests:

Name of investigation	Date on investigation	Investigation Result

Table 6 - Treatment drug(s) details						
Generic Name of the drug	Indication(s)	Dosage form strength (units)	Daily dose & regimen (units)	Route	Start Date	Stop Date

Table 7 - Additional details for Fatal SAE report:	
Cause of death:	
Possible relationship to the suspected reaction	
Any post-mortem finding	
Autopsy (or any other) report details:	
• **Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings fromspecial investigations etc.**	

*Table – 8 Details about the Investigator**	
Name:	
Address:	
Telephone number:	
Profession (specialty):	
Date of reporting the event to Licensing Authority:	
Date of reporting the event to Ethics Committee overseeing the site:	
Signature of the Investigator	

ANX - 31/V2 - Justification letter from PI for delayed submission of SAE report

To
The Chairperson
Institutional Ethics Committee
Narayana Medical College, Nellore, AP

From
Dr_____
Principal Investigator,
Contact details

Subject: Details for delayed SAE reporting – Regarding IEC

- Protocol no.
- Study Title: Department:
- Reasons for delayed SAE reporting:
- Signature by PI:

ANX - 32/V2 - Intimation letter for IEC /Serious Adverse Event Committee meeting

Ref No:

From

Member Secretary

To

SAE subcommittee member

Dear SAE Subcommittee Member,

Dr_____ reported SAE in the study titled _____; to review the same, kindly convene a EC meeting on ___ at ___.

Regards

Member Secretary

ANX - 33/V2 - Minutes of the SAE subcommittee meeting

Members attended:

Ref: IEC/year/month/meeting no./serial no.

Study title:

Subject ID SAE DESCRIPTION:

The committee recommends the following:

Signature with date:

EC - Member Secretary

ANX - 34/V2 - Serious Adverse Event; Decision Letter to PI

Date:

1. **Study title:**
2. **IEC No.:**
3. **CTRI – No.:**
4 **Date of IEC approval:**
5. **Date of study initiation:**
6. **Patient ID, Age & Gender;**
7. **Treatment start date:**
8 **Type of Serious Adverse Event (SAE):**
9. **Date of SAE:**

The details with reference to the above SAE and the attached information provided by the Principal Investigator has been discussed in detail.

The consensus decision on the causality and the requirement for compensations is as follows:

- Causality: Related / Not related Compensation required: Yes / No
- Type of compensation: Free medical treatment as long as required
- Financial compensation
- Compensation amount recommended by the NMC & approved by IEC

Signature of EC- Chairperson / Member secretary with seal and date.

ANX - 35/V2 – SAE decision letter to Drug controller general of India.

This should be accompanied with a covering letter to DCGI with copy marked to the Head of the institution

Covering letter to DCGI

From

The Chairperson, IEC, NMC.

To
The Drugs Controller General-India,
Ministry of Health and Family Welfare, Government of India,
FDA Bhavan, ITO, Kotla Road, New Delhi -110 002

Subject: SAE report submission – regarding

Respected Sir/Madam

Ref: CTRI No. / PI Name

Study title:

Subject ID:

SAE description:

The institutional ethics committee recommends the following:

1. Hospitalization charges to be borne by the sponsor
2. Compensation for loss of wages = 2 x (Number of day of hospitalization (N) x Minimum wage (W)/day of the unskilled worker in Delhi; N x W)
3. Total no of days of hospitalization – Compensation =

ANX - 36/V2 - Log of Requests for Copies of IEC Documents

Date of request	Documents requested (including file number, if relevant)	No. of copies requested	Reasons for the request	Receiving individuals name, contact details and signature	Documents given by – Name, details and signature of the IEC member

ANX - 37/V2 - Log of Copies of Original Documents

Title of the Document: _____

S. No	Recipient Name	Copies	Reasons for the Request	Signature of Recipient and date	Member secretary Name, signature and date

Note: *This log should be attached to the original documents.*

ANX - 38/V2 - Log for disposal of IEC Documents

S. No.	IEC No.	Study Tile	PI Name	Study Status

ANX - 39/V2 – Payment Received from the sponsor for reviewing the proposals

S. No.	IEC No.	Sponsor	Amount Received	Date of Receipt

ANX - 40/V2 - Disbursement of the honorarium (sitting fee)

S. No.	Date of Meeting	Members Name	Amount Paid	Signature

ANX - 41/V2 - Payment for Refreshments

S. No.	Date of Meeting	Refreshment Bills	Date of Bill transferred to Accounts	Signature

ANX - 42/V2 - Payments made to the Participants; to be filled by Clinical Research Coordinator & copies sent to IEC

S. No.	IEC No.	Patient ID	Amount Paid & Date	Reason for Payments	Date of Receipt at IEC	Signature

ANX - 43/V2 - Audit and Inspection Checklist

1. Audit/inspection – letter of communication with date.
2. Date(s) on which the audit/inspection has been agreed on:
3. To ensure the IEC members and staff have been informed about the date/s and time.

4. To ensure availability of IEC related information – mandate, terms of reference,organization chart (in the print form) in the IEC office.
5. To make sure of availability of latest copy /copies of signed SOPs in print form in theoffice and/ or in electronic form on the IEC computer/s.
6. To review the SOPs and note details of any omissions or deviations, with reasons.
7. To ascertain availability of all national and international ethics guidelines and regulations in print form and / or in electronic form in the IEC office.
8. To check the files of ongoing and complete research study files for the presence of all signed documents as stated below and to note any missing/incomplete documentationand actions taken.
   - Records regarding applications of research studies for review including protocols & related documents
   - Protocol Assessment Records – Comments of IEC members, Meeting Agenda, Minutes (documented in individual study file or separately in meeting records file)
   - Communication records with investigator (documented in individual study file)
   - Amendment Approvals (documented in individual study file)
   - SAE reports and SAE related communications with investigator and regulators
   - Protocol deviation/violation/exception reports (documented in individual studyfile)
   - Continuing and final completion/termination reports (documented in individualstudy file)
9. To ensure availability of documents regarding list of members, tenure, appointmentdetails, CVs, baseline and periodic training of IEC members.
10. To ensure availability of documents regarding appointment, CVs and training of staff of the IEC.
11. To ensure measures for maintaining security of electronic database and office records.
12. To make sure that maintenance, retrieval, storage, archival and tracking of the study files are done as per the respective SOPs.
13. To ascertain proper labeling and indexing of study files and storage cabinets.
14. To make other arrangements (meeting venue for review of documents, catering, accommodation, travel) for the visit, as applicable.

ANX - 44/V2 - Template for Standard Operating Procedures

Logo of institution

Title of the SOP - IEC, NMC **SOP Code**: SOP xx/vy

Title: Title which is self-explanatory and easily understood
SOP Code: SOP xx/vy

Effective date: aa/bb/cccc

Prepared by :	xxxxxxxxx	**Signature with date ----------**
Reviewed by:	xxxxxxxx	**Signature with date ----------**
Approved by:	xxxxxxxxx	**Signature with date ----------**
Notified by:	xxxxxxxxxx	**Signature with date ----------**

Table of Contents:

1. Purpose: Summarizes and explain the objectives of the SOP.
2. Scope: States the range of activities that the SOP applies to.
3. Responsibility: Refers to person(s) assigned to perform the activities involved in the SOP
4. Detailed instructions: Describes procedures step by step in short and clear sentences in numbered bullets
5. Annexure: Forms to capture information pertaining to the SOP instructions
6. Flow chart: Simplifies the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity

ANX - 45/V2 - Documentation of History of the SOPs

Details of superseded SOP

Name of the sub- committee Convenor	Version	Effective date (dd-mm-yyyy)	Describe the main change(s)

Details of current SOP

Name of the SOP sub-committee Convenor	Version	Effective date (dd-mm-yyyy)	Describe the main change(s)

ANX - 46/V2 - Log of the IEC, NMC members receiving SOPs

S. No.	Recipients Name	Designation	SOP code number	Hard/soft copy	Signature	Date
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						

NARAYANA MEDICAL COLLEGE

ANX - 47/V2 - Terms of reference for the members at the time of appointment

All members	Appointment to IEC with designation, Training in Research Ethics, GCP, Submit updated Curriculum Vitae and training certificates, Conduct scientific and ethical review of protocols, adhere to timelines, adhere to SOPs, Follow the current regulatory guidelines, Attend the meetings regularly, Contribute actively to the deliberations and discussions in the meetings, Participate in the subcommittees, whenever required, Participate in the post-approval activities, whenever required & abide by the confidentiality agreement, Abide by the conflict of interest declaration agreement, Maintain good conduct and integrity as a member.
External members	Encourage and guide IEC to take an independent and free decision Provide details of bank account and PAN for the purpose of remuneration and reimbursement of travel expenses
Internal members	Assist the IEC in its smooth functioning
Chairperson	Head of IEC Lead the discussions and deliberation Preside over the administrative matters of the IEC & ensures adherence to SOPS and guidelines Ensures a timely ethical review process
Member-Secretary	Receive, categorize, allocate and sign the approval of the protocols Prepare and maintain the agenda and minutes of the meeting Plan training activities Schedule and conduct post-approval activities Prepare and respond to audits and inspections of the IEC & maintain the archival of files Coordinate the IEC activities with its members
Legal expert	Ethical review of protocol Emphasis on legal issues, compensation, agreements, MoUs, Insurance, Indemnity, permissions and other documents in the protocol
Social scientist/ theologist/bioethicist	Ethical review (emphasis on social, cultural & religious issues)

Layperson	Ethical review of protocol (emphasis on informed consent document)
Clinician	Ethical review of protocol (emphasis on clinical aspects, complications, management of complications issues in the protocol)
Basic scientist	Ethical review of protocol (emphasis on basic scientific issues, IND details, clinical trial phases, genomic/laboratory research, etc)

ANX - 48/V2 - Membership Agreement Form for Institutional Ethics Committee (IEC), Narayana Medical College

I, Dr/Mr/Ms (Member's name, his/her position in EC and affiliation) herein referred to as the "undersigned" have been appointed as a member of and have been asked to carry out ethical review of research studies involving human participants in order to ensure that such studies are conducted in a humane and ethical manner, adhering to the highest standards of care as per the International, National and Local regulations/guidelines and Institutional policies. I understand that my appointment as member of EC is based on individual merits and not as advocate or representative of a territory, or community, nor as a delegate of any organization. I am aware that EC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of participants and that as a member of EC; I will meet the standards of ethical behavior to carry-out its mandate. I agree to sign the confidentiality agreement and abide by it. I agree to the Conflict of interest declaration policy of EC and abide by it. I have been given the current SOP manual (Soft copy). I agree to take part in the training programs organized by the EC for the members. I agree to take part in the review process and adhere to the timelines.

Signature of the member with date **Chairperson's Signature with date**

[The original (signed and dated agreement) will be kept on file in the custody of the IEC; A copy will be given to the Undersigned.]

I acknowledge that I have received a copy of the signed Membership Agreement Signature with date

ANX - 49/V2 - Conflict of Interest (CoI) Form/ Declaration for IEC Members/ Independent consultants

To

The EC - Chairperson,

Sir/ Madam,

I am aware of the policy of the IEC regarding conflict of interest and that no member/reviewer may participate in the review, comment or participate in decision-making of any activity in which he/she has actual/potential CoI, except to provide information as requested by the IEC.

I declare actual/potential CoI (strike out whichever is not applicable) in relation to the following protocol

Protocol Number:	
Protocol Title:	
Principal Investigator:	
Funding agency:	

I declare CoI for the following reason (s): Tick whichever applicable

I am a member of the research team	
My immediate family member is a part of the research team	
I have a direct/indirect financial interest	
Any other: (Specify	

To manage the CoI (Tick after agreeing to the following points), I declare that:

I will return the protocol document package	
I will refrain from the review process	
I will not be present in the IEC meeting room during the discussion and decision-making on this protocol	

I will not participate in any of the post-approval activities like ongoing review/ site monitoring/ audit/ SAE review/ and others pertaining to this protocol.	

Date:

Signature of the IEC member/ Independent consultant Name and date
Signature of the Chairperson/Member-Secretary with date

ANX - 50/V2 - Confidentiality Agreement Form for IEC members

I, Dr/Mr/Ms_____(*Member's name, his/her position on IEC and affiliation) herein* referred to as the "undersigned" has been appointed as a member of IEC and I understand the Confidentiality policy of the IEC and I agree that

1. All the confidential information (and any copies and notes thereof) shall remain the sole property of IEC
2. All the confidential information is shared with me in trust or confidence as a IEC member
3. I shall use the documents/ information shared with only for the contemplated purposes
4. I shall not share the documents with the PI or sponsor or any third unconcerned person/party
5. I shall not photocopy/ photograph any of the documents accessed by me from the archival
6. I shall delete all the documents from my email/computer/ mobile/ electronic storage/cloud/prints after the decision on the protocol is completed.
7. I shall ensure that all e-documents are deleted annually/ at the end of my term in IEC, whichever earlier.
8. This agreement encompasses any information deemed confidential, provided to me in conjunction with my duties as a member of IEC and may include:
   a. The protocol/ protocol-related documents sent to me for review by email:
   b. The agenda and minutes of the meeting sent to me by email
   c. Proceedings of the IEC meetings including any information pertaining to the discussions, opinions, decisions, voting or any other component of the IEC meeting:
   d. The protocol/ protocol-related documents/ IEC files accessed from the archival room:
   e. Research files and data accessed during the post-approval activities like site monitoring/ audits/ deviations/ violations/ continuing review
   f. Any other, if applicable

I, Dr/Mr/Ms (Member name, IEC designation) have read and accept the aforementioned conditions as explained in this agreement. I am liable to being removed from the

EC and/or liable to legal actions from NMC, if confidentiality is willfully breached by me.

Signature **Date**

Chairperson's Signature **Date**

[The original (signed and dated Agreement) will be kept on file in the custody of the Secretariat IEC. A copy will be given to the Undersigned.]

I acknowledge that I have received a copy of this Agreement signed by the IEC Chairperson and me

Signature & Date

ANX - 51/V2 - Confidentiality Agreement Form for the Independent Consultant

I, Dr/Mr/Ms/Mrs._____ (Member's name and affiliation) herein referred to as the "undersigned" has been appointed as a, Independent Consultant (IC) of IEC, NMC and I understand the Confidentiality policy of the EC and I agree that

1. All the confidential information (and any copies and notes thereof) shall remain the sole property of IEC
2. All the confidential information is shared with me in trust or confidence as an IC to IEC
3. I shall use the documents/ information shared with only for the contemplated purposes
4. I shall not share the documents with the PI or sponsor or any third unconcerned person/party
5. I shall delete all the documents from my email/computer/ mobile/ electronic storage/cloud/prints after the decision on the protocol is completed.
6. This agreement encompasses any information deemed confidential, provided to me in conjunction with my duties as an IC of IEC and may include:
   a. The protocol/ protocol-related documents sent to me for review by email:
   b. Proceedings of the IEC meetings including any information pertaining to the discussions, opinions, decisions, voting or any other component of the IEC meeting, when applicable
   c. The protocol/ protocol-related documents/ IEC files accessed from the archival room, if applicable:
   d. Any other, if applicable

I, Dr/Mr/Ms/Mrs._(IC name) have read and accept the aforementioned conditions as explained in this agreement. I am liable to being removed from the EC and/or liable

to legal actions from Narayana Medical College, if confidentiality is willfully breached by me.

Signature **Date**

Chairperson's Signature **Date**

[The original (signed and dated Agreement) will be kept on file in the custody of the EC -member secretary. A copy will be given to the Undersigned.]

I acknowledge that I have received a copy of this agreement signed by the EC - Chairperson and me

Signature & Date

ANX - 52/V2 - Confidentiality Agreement Form for IEC's Guest Observer

I, Dr/Mr/Ms (*Member's name and affiliation) herein* referred to as the "undersigned" has been appointed permitted to visit the IEC office/ attend a IEC meeting as a Guest observer.

I understand the Confidentiality policy of the IEC and I agree that

1. All the confidential information (and any copies and notes thereof) shall remain the sole property of IEC
2. All the confidential information is shared with me in trust or confidence as a guest observer to IEC office/meeting
3. I shall use the documents/ information shared with only for the contemplated purposes
4. I shall not share the documents with the PI or sponsor or any third unconcerned person/party
5. I shall delete all the documents from my email/computer/ mobile/ electronic storage/cloud/prints after the purpose of the visit is completed, if shared with me.
6. This agreement encompasses any information deemed confidential, provided to me in conjunction with my visit to IEC and may include:
   a. The protocol/ protocol-related documents:
   b. Proceedings of the IEC meetings including any information pertaining to the discussions, opinions, decisions, voting or any other component of the IEC meeting, when applicable

c. The protocol/ protocol-related documents/ IEC files accessed from the archival room, if applicable:

d. Research files and data accessed during the post-approval activities like site monitoring/ audits/ deviations/ violations/ continuing review, if accessed by me/shared with me

e. Any other, if applicable

I, Dr/Mr/Ms/Mrs. _____(Guest observer name) have read and accept the aforementioned conditions as explained in this agreement. I am liable to legal actions from Narayana Medical College, if confidentiality is willfully breached by me.

Signature **Date**

Chairperson's Signature **Date**

[The original (signed and dated Agreement) will be kept on file in the custody of the Secretariat IEC. A copy will be given to the Undersigned.]

I acknowledge that I have received a copy of this Agreement signed by the IEC Chairperson and me

Signature **Date**

ANX - 53/V2 - Confidentiality Agreement Form for Secretarial Staff

I,___(Staff name & designation) herein referred to as the "undersigned", have been appointed as a staff of the IEC. This agreement encompasses any information deemed confidential provided to the undersigned in conjunction with the duties as a staff of the IEC. All confidential information (and any copies and notes thereof) shall remain the sole property of the IEC.

The undersigned hereby agrees not to disclose or utilize, directly or indirectly all confidential information known to him/her during the tenure of his/her service and beyond if necessary.

I,___(Staff name & designation) have read and accept the conditions as explained in this agreement.

Signature **Date**
Chairperson's signature **Date**
[The original (signed and dated agreement) will be kept on file in the custody of the IEC, NMC. A copy will be given to the undersigned.]

ANX - 54/V2 - Invitation to review the protocol as Independent consultant (IC)

To
Name of the Reviewer:

Dear Sir/Madam,

You have been assigned to review the given protocol as an IC and you are requested to -

1. Read, understand and sign the a) confidentiality agreement b) conflict of interest and declare the same
2. Review the protocol provided to you and send the duly filled and signed "study assessment form" to the EC within at least 7 calendar days from the date of receipt.
3. Be available to provide additional clarification/comments when the IEC requests.
4. Be available to attend the IEC meeting in case your services are required. However, you will not take part in the decision making of the protocol. Your travel and other expenses will be reimbursed by the IEC
5. Note – After the protocol approved in the EC meeting; your tenure as IC is terminated for the given protocol.

Details of the protocols:

1	Protocol No.	
2	Title of the study	
3	Date of IEC meeting in which tabled for discussion	
4	Due date for sending the assessment form:	

Signature of the Member-Secretary: **Date:**

ANX - 55/V2 - Assessment Form for an Independent Consultant (IC) to IEC

IEC protocol number:			
Protocol Title:			
IC responses:			
S. No.	**IEC Query**	**IC response**	**Justification/ Remarks/ Reference**
Any other comments (on Participant Information Sheet and Informed Consent Form)			
Remarks:			
Independent consultant name, signature with date.			

Signature of the Chairperson/Member-Secretary

ANX - 56/V2 - Appreciation letter to the Independent Consultant

Date: To

Name and other details of the IC

Dear Sir or Madam,

NMC Ethics Committee – 1 acknowledges and appreciates your role as independent consultant and assisting the IEC, in carrying out the ethical review of protocol no. "_____" titled "_____". The matter was discussed in the recently concluded IEC meeting and appropriate decision was taken. Your contribution to the review process of the protocol was invaluable and IEC expresses its sincere gratitude to you, for your help and assistance. Your services as IC end with this letter, however, we look forward to continued support from you, as and when we ask for it.

Signature of the Member-Secretary Date

ANX - 57/V2 - Request letter to be IEC Guest/Observer

To
The Member-Secretary/Chairperson IEC, NMC
Sir/Madam,
I request you to permit me to visit IEC office, attend its meeting and interview with EC members.

My name and contact details with phone and email ID are as follows -

Desired date and time of visit: Purpose of visit: (Provide specific details)

1. As an Inspector/ Assessor/Auditor/Trainee/Student observer:
2. As a patient representative/special interest group:
3. As a prospective IEC member/ Other EC member:
4. As a Principal Investigator:
5. Any other:

I do hereby solemnly affirm that I have no active, on-going or pending protocols in IEC –either as PI, or Co-PI or research team member. I understand that IEC reserves right to not permit me to attend its meeting and that such decision will be binding. I will sign Confidentiality agreement form and abide by the same. I have read and understood the responsibilities of the Guest/ observer and will abide by the same.

Thanking you,

Signature with Name and date

For office use only: Verified that the guest/observer has no protocols tabled on the agenda for this IEC meeting.

Date: **IEC Member Secretary**

ANX - 58/V2 - Responsibilities of the Guest/Observer Attending the IEC meeting

The guest/observer will sign the attendance sheet for the IEC meeting and take part only during the discussion of the concerned protocol and will not involve in decision making or voting. Their presence will be documented in the meeting minutes.

IEC office visit: Guest observer accompanied by member secretary or other members of IEC are allowed to visit the IEC office and permitted to access any documents only after entering into the log book. The guest observer can talk to any IEC member about the IEC functioning in general; will not be encouraged to discuss about any individual protocol or IEC decision on protocols reviewed.

ANX - 59/V2 - Application form for initial review for Regulatory (Industry and Government sponsored studies) & Non-Regulatory Clinical Trial protocols

(incomplete files will not be accepted)

Instructions to fill:

- Details to be filled in the soft copy, print and duly signed, wherever applicable
- Tick (√) in the box for the appropriate answer
- Write Not Applicable (NA) if question is not applicable this study
- Do not leave any questions unanswered
- Write the annexure numbers whenever documents are referred to in the application form

Part A: Investigator Details					
IEC Protocol No. (to be filled in by the Secretariat when a protocol number is assigned):					
Protocol Title					
	Name	**Designation & qualification**	**Department & Institution**	**Roles & Responsibility***	**Signature**
PI					

Co-PI's					
Coordinators					

* Roles and responsibilities of investigators: choose the appropriate codes (A to T) below and write them against their name in the appropriate column above.

• Concept • Design • Screening of patients • Selection and recruitment of study participants • Informed consent • Selection & Recruitment of patients • Laboratory investigations • Laboratory report interpretation • Treatment decision • Patient evaluation • SAE evaluation and reporting	• Examination of patients on follow-up • Data collection and monitoring of data • Interpretation of data • Statistical analysis & Interpretation • Maintaining patients file and master file of project • Drafting final report • Submission of final report to funding agency and

(If additional collaborators attach details and letter of Consent by collaborator(s) on a separate page); Please attach brief CV of the study team members (principal investigator, co- investigator, study coordinator);
Attached; Non-sponsored (Investigator Initiated) study / Sponsored study

Does any research team member have any **conflict of interest** in the present study? (financial/non-financial) If Yes, specify	Yes	No	NA
Whether the PI is handling other research protocols at present? If yes, Number of ongoing protocols approved by IEC to the PI and status of the protocols in brief.	Yes	No	NA
Brief CV of PI, Co-PI's, study coordinators (Information required: age, designation and department, educational qualification, previous research experience in last five years; GCP training certificates)	Yes	No	NA
Training certificates of PI and study his study team (mandatory for drug and device trials not for observational studies**)**	Yes	No	NA

Part B: Sponsor details

1	**Indian**	State Govt.	Central Govt.	Private
2	**International**	Govt.	Private	UN Agency
3	**Industry**	National	Multinational	
4	**Narayana Medical College**	Seed Grant	Institutional support	
5	**Contact address**			
6	**Indian contact address (For international sponsors)**			

Budget information	
1	**Total in Indian National Rupees (INR) -**
2	**Budget allocation under different heads -**
3	**Bank account details to deposit the research fund -**

Part C: Study Details

Details of the study (Tick whichever applicable)

Study type	Epidemiological survey/ Interventional study	Observational study
	Basic science (Proteomic/metabolic/biomarker/biochemical/histopathological)	Genetic/ genomic study
	Clinical trial	Interventional study
	Surgical intervention	Interview/ study/ Questionnaire based
	Medical device	Retrospective study
	In vitro studies	Data in public domain
	Any other: Specify	
Number of centres	Single centre	Multi-centre:
If multicentre	Number of centres In India/Global:	Names and countries of centres

Part D: Clinical Trial Details

1	**Nature of trial**	Medicine	Devices

		Vaccine	Indian system of Medicine
		Any other: Specify:	Not applicable
2	**Approved (Attach proof)**	Yes	No
		If Approved:	
		In India	In UK/Europe
		In USA	NA
		Other countries: Specify:	
3	**Route**	Does it involve change in route of administration	Yes/No/ NA
		If Yes #, whether DCGI/other regulatory authority's permission obtained.	Yes/No/ NA
		If yes * Date of Permission	
		If No **, Whether applied of permission	Yes/No/ NA
4	**New investigational drug**	Yes, No; Not applicable	If yes, IND No.
		a) Investigator's Brochure submitted	Yes/No/ NA
		b) *In vitro* studies data	Yes/No/ NA
		c) Preclinical Studies done	Yes/No/ NA
		Clinical Study Phase	I II III IV
		To submit package insert in case test drug is already marketed in India	Attached Not attached
		Are you aware if this study/similar study is being done elsewhere? If yes give details	Yes; No
		Whether DCGI's permission for testing IND obtained? If yes, Date of Permission.	Yes; No
		Whether DCGI's permission for testing IND is applied for?	Yes; No
		For Ayurvedic or herbal formulations, is a copy of the marketing/manufacturing license issued by the FDA to the company submitted?	Yes/No/ NA
	Is the trial registered with Clinical Trial Registry? (mandatory only for drug trials) Clinical Trial Registry of India (CTRI)/ any other WHO platform registry Registration number: if not registered, state the reason		Yes/No/ NA
Part E: Protocol Details			

Study protocol: (Submit as attachment) - PI to note that all the protocol and related documents must bear the title of the document, version number, page number, date and signatures wherever applicable

1. Title; Background, Rationale, Objectives; 2. Methodology (The methodology must be in great detail): 3. Sample/data collection details; 4. Study tool; 5. Statistical tests; 6. Budget and funding details; 7. Utilization of the results whether it is of national significance with rationale.

Part F: Participant Details

Provide details about research participants

Sample Size: Number of research participants at this center: Number of research participants at other sites in India
Total number of research participants at all sites (globally):

Duration of study - No. of visits for the purpose of screening and research :

Will research participants from both genders be recruited	Yes	No	NA
Inclusion / exclusion criteria given	Yes	No	NA

Type of research participants:
(*If vulnerable population is included, the PI must submit the appropriate checklist for involvement of vulnerable population in research available in and provide attachment number)

Volunteers	Yes	No	NA
Patients	Yes	No	NA
Vulnerable participants	Yes	No	NA
Pregnant women*	Yes	No	NA
Elderly	Yes	No	NA
Mentally challenged*	Yes	No	NA
Fetus*	Yes	No	NA
Illiterate	Yes	No	NA
Handicapped	Yes	No	NA
Children*	Yes	No	NA
Captives	Yes	No	NA
Terminally ill	Yes	No	NA
Seriously ill	Yes	No	NA
Economically or socially backward	Yes	No	NA

Dependent staff *	Yes	No	NA
Institutionalized students*	Yes	No	NA
Employees *	Yes	No	NA
HIV	Yes	No	NA
Any other	Yes	No	NA
Will any advertising be done for recruitment of research participants? (posters, flyers, brochures, websites, notices, letters – if so kindly attach a copy)	Yes	No	NA
Is there compensation plan for participation If Yes, (tick appropriate); Monetary in kind Specify amount and type:	Yes	No	NA
Is there compensation plan for injury? If Yes, (tick appropriate) by Sponsor by Investigator by insurance; by any other company	Yes	No	NA
Part G: Privacy & Confidentiality			
Direct identifiers (Name, address, phone numbers, photographs, videographs)	Yes	No	NA
Indirect identifiers (coded)	Yes	No	NA
Completely anonymized (delinked)	Yes	No	NA
Part H: Use of biological/hazardous materials (Tick)			
Fetal tissue or abortus	Yes	No	NA
Human organs or body fluids	Yes	No	NA
Recombinant /gene therapy; If yes: DBT approval obtained	Yes	No	NA
Pre-existing/stored/left-over samples	Yes	No	NA
Collection from banking/future research	Yes	No	NA
Collection for banking/future research	Yes	No	NA
Use of ionizing radiation/radioisotopes If yes, has Bhabha Atomic Research Centre (BARC) approval for radioactive isotopes been obtained?	Yes	No	NA
Use of Infectious/ bio hazardous specimens	Yes	No	NA
Proper disposal of material	Yes	No	NA
Will any sample collected from the patients be sent abroad?	Yes	No	NA
If yes Sample will be sent abroad because (Tick appropriate option): Facility not available in India Facility in India inaccessible Facility available but not being accessed If so, reasons_____			

Lab. Address:			
If no, Test on samples will be carried out (tick appropriate option): In institution/Outside institution If outside institution, Address: Specify with details of collaborators			
Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration? (required in case of studies involving collaborations with foreign Laboratory/ Clinic/Institution)	Yes	No	NA
In case of studies involving collaborations with other Indian or foreign Laboratory/ Clinic/Institution has administrative sanction from the Dean obtained/ applied for? If yes, details:	Yes	No	NA
Memorandum of Understanding: If yes, details	Yes	No	NA
Material Transfer Agreement; If yes, details	Yes	No	NA
Part I: Informed Consent Process			
Consent form & participation information sheet	Yes	No	NA
Tick which elements are included: Simple language Regional language understood by the participant Alternatives to participation Statement that this consent is for research and not therapy Sponsor of study Contact information Purpose and procedures in detail Risks & Discomforts Benefits Statement that consent is voluntary Right to withdraw Confidentiality of records Compensation for study related injuries Compensation for participation Benefits, if any, on future commercialization Consent for future use of biological material Consent for photographs, if applicable Consent for publication/ conference presentation			
Who will obtain the consent? PI/Co-PI/Nurse/Counselor trained in ICH-GCP guidelines Research team member Any other, specify	Yes	No	NA
Where will the consent be taken? Specify the room	Yes	No	NA
Whether audio-visual recording of consent will be done?	Yes	No	NA
Whether audio recording of consent will be done?	Yes	No	NA
Whether surrogate consent will be obtained?	Yes	No	NA

Whether written or oral assent will be obtained?	Yes	No	NA
Whether electronic consents will be obtained?	Yes	No	NA
If written consent will not be obtained, give reasons:	Yes	No	NA
Whether applied for waiver of Consent:	Yes	No	NA
Part J: Risks & Benefits			
Is the risk reasonable compared to the anticipated benefits to research participants / community / country?	Yes	No	NA
Is there physical / social / psychological risk / discomfort? If Yes, a) Minimal or no risk; b) More than minimum risk; c) High risk	Yes	No	NA
Is there a benefit to the research participants? a) Direct; b) Indirect	Yes	No	NA
Benefit to the society	Yes	No	NA
Part K - Data Monitoring			
Is there a data & safety monitoring committee/ Board (DSMB)?	Yes	No	NA
Is there a plan for reporting of adverse events?	Yes	No	NA
If Yes, reporting is done to: Sponsor a) IEC; b) DSMB	Yes	No	NA
Is there a plan for interim analysis of data?	Yes	No	NA
Are there plans for storage and maintenance of all trial database? If Yes, for how long?			

Statement of Compliance:

We hereby declare that the information given above is true and that we will comply with the guidelines mentioned in the New Drugs and Clinical Trials Rules 2019 and the current ICMR guidelines and any other recent notification/s from CDSCO (updated as applicable)], and the Indian GCP Guidelines while conducting the research study. We also ensure that Principal Investigator / Institution will pay for the expenses for the treatment and / or compensation if research related injury.

- Signature with date of the following – a) PI; b) Co-PI; c) Study Coordinators
- Forwarded by Heads of Department(s):
- Signature/s with date of Heads of Department(s):
- Stamp/Seal of the Department(s)

NARAYANA MEDICAL COLLEGE

ANX - 60/V2 - Delegation of Responsibilities of Study team

IEC Protocol No.		
Study title:		
Name	**Role**	**No.**
	Principal Investigator	1
	Co-Investigator's	2
	Study coordinators	7
	Laboratory Technicians	9
Please fill if more members on the team		

(Please place tick marks against assigned duties for each member in the following table)

S. No	Tasks	Role played by each study team member				
		1	2	3	4	5
1.	All relevant documents pertaining to protect blinding					
2.	Research participants selection/ screening					
3.	Obtain informed consent					
4.	Evaluate inclusion/exclusion criteria					
5.	Conduct the visit assessments					
6.	Physical examination					
7.	Complete the source documents					
8.	Complete Case Record Form					
9.	Final review and sign Case Report Form					
10.	Collect laboratory safety test samples					
11.	Processing of blood samples					
12.	Preparing aliquots & keeping a track of the samples sent					
13.	Review & sign of the lab reports					
14.	Receive the study drug, document drug dispensing, storage & accountability					
15.	Person to whom research participants should contact in case of adverse event					
16.	Report all serious adverse events					

17.	Follow up of Serious Adverse Event					
18.	Maintaining study site master file					
19.	In-charge of inventory & supplies					
20.	Archiving of study documents					
21.	Resolution of queries					
22.	Overall coordination & supervision					

ANX - 61/V2 - Receipt for submitted protocol

Protocol No.		
Received date:		
Submitted date:		
Protocol title		
Principal Investigator Name, Designation & Affiliation		
Communication with IEC, NMC	E-mail address: Phone: Fax:	
For office use only		
Protocol submitted	Date:	
The following documents was not submitted by PI	Name of the document	Received date
	Final signed clinical trial agreement	
	Informed consent form (English + Telugu)	
	Study budget	
	DCGI	
	CTRI	
	GCP training certificate	
	Other sites EC permission (if available)	
	Other documents (if any)	
Received by (Name, signature with date)		
Date on which documents received:		

Please note that the review process for your protocol will be initiated only when the complete protocol submission is received.

ANX - 62/V2 – Invite to be a reviewer for the proposed study protocol submitted to IEC

Part A

To

Reviewer Name

Dear Sir/Madam,

We request you to serve as expert reviewer and assess the merits and demerits of the clinical study protocol submitted to IEC of Narayana Medical College.

As a reviewer you are requested to -

1	Review the protocol and related documents as per the guidelines and our SOPs.	
2	Inform the IEC; if you have a Conflict of interest for the protocol and unable to review it within the given time on or before _ date	
4	Inform the IEC if any of the protocol or related documents are incorrect/ missing on or before _____date	
5	Fill and sign the assessment form and return the same to IEC on or before	

Details of the protocols for Expedited review:

1	Protocol No.	
2	Title of the study:	
3	Principal investigator:	
4	Co-PI (All names)	
5	Department:	
6	Date of receipt of protocol	

Signature of the Member-Secretary with Date:

Part B

Return of protocol and related documents due to inability to review the protocol

I hereby declare that I will not be able to review the protocol for the following reason: (Please tick the applicable reason)

1	**I have a conflict of interest**	
2	**I am unable to review the protocol within the time given**	

Signature of the IEC member **Date**

Signature of Member-Secretary/Chairperson with date

ANX - 63/V2 - Decision form for expedited review

IEC Protocol Number:	Date of receipt:	
Project Title:		
Name of the Principal Investigator	Department:	Contact number:
Reviewer 1: Recommendation:		
Reviewer 2: Recommendation:		

Final Decision: tick the appropriate box

- ☐ Approved
- ☐ Resubmission
- ☐ Full Review

Reason for Resubmission/ Full review:

Signature

Name of the Member-secretary/ Chairperson:

ANX - 64/V2 - Application for resubmission of the study protocol

Protocol title and number **PI name and contact details** **Date of communication of IEC comments: Resubmission Number:**
Type of Resubmission: **Resubmission for full review: Resubmission for expedited review:** **Reviewers:**
Documents submitted and the updated version numbers: Protocol Version: **Case record form version: PIS version:** **ICF version: Questionnaire version:** **Any other: (Specify with version)**
Note to the PI: It is the responsibility of the PI to Respond to every clarification sought /recommendation made by the IEC point by point; at least one week prior to the next IEC meeting Highlight all the changes made in the protocol documents, update the version number, insert page numbers and reflect these changes in the table given above. If the PI does not wish to/ is unable to make a particular change, then the PI may provide a justification/ explanation for the same. Declare any changes made in the protocol which are not recommended by IEC.

Inform the guide and other members of the research team about all the changes made in the documents and seek their approval before submitting to IEC. Respond to the IEC comments within a maximum of 180 calendar days, failing which, the protocol will be considered as closed.

Response of the PI

S. No	IEC comment (add rows as needed)	PI response	Page #	Reviewer's assessment Acceptable/not acceptable
1				
	Any other changes made in the protocol			

Signature of the PI:
Date
Signature of the Guide: Date

ANX - 65/V2 - Assessment of resubmitted protocol

Protocol Title and Number:
PI name and contact details

Assessment of the resubmission:
All the clarifications/ recommendations have been appropriately responded:
The following points have not been appropriately responded:
Following are the additional queries/ recommendations:

The justification/ explanation is not acceptable:

Provisional decision:
Approved:
Resubmission:
To be reviewed by the initial reviewer:
To be reviewed by the Member-Secretary:
For discussion in the IEC meeting:

Signature of the Reviewer: Date:

ANX - 66/V2 - Calendar for Periodic and Continuing review schedule

S. No	Protocol #	Study title	PI name	Date of IEC Approval	Frequency of continuing review	Submitted on	Date of first continuing review	Reminder sent on	Submitted on

ANX - 67/V2 – Reminder to the Principal Investigator to submit periodic & continuing review application form

Date:
Name of the Principal Investigator:
Department:
Reference:
Protocol Number:
Protocol title:
Date of IEC approval:
Date of IEC approval validity:
Frequency of Periodic review:

Subject: Reminder to submit periodic / continuing review application form Dear Dr./Mr./Ms.

You are requested to submit the duly filled and signed periodic/ continuing review application form to IEC on or before .

Any lapse or delay in submission of the periodic or continuing review application form will be considered as protocol deviation/violation.

If you are submitting the continuing review application form and requesting for extension of the EC clearance validity, then delay will result in a lapse of ethics committee approval.

Please note that data collected in the interim period where the ethics committee approval is not renewed, cannot be included in your final analysis. and if done, will constitute a protocol violation.

Thank you,

ANX - 68/V2 - Second reminder to the Principal Investigator to submit periodic / continuing review application form

Date:
PI name and contact details:
IEC reference number:
Protocol number and title:
IEC approval date:
IEC approval validity (date):
Frequency of Periodic/ Continuing review:

Subject: Second reminder to submit Periodic / Continuing review application form; first remainder sent on ____ via mail.

Dear Dr./Mr./Ms._____

Second reminder to send the periodic/continuing review application form. You are requested to submit the filled and duly signed periodic / continuing review application form to IEC within 7 calendar days; failing to send will be considered as protocol deviation/violation. Request for extension of EC approval may result in delayed EC approval. Please note that data collected in the interim period where the EC approval is not renewed, cannot be included in your final analysis, if done so, will be considered as a protocol violation.

Thanks

IEC – Chairperson/ Member-Secretary

ANX - 69/V2 - Periodic/ Continuing Review Application Form

A. Protocol details

a. Protocol No. _____

b. Title: _____

c. Principal Investigator Name: _____

d. Name of the guide (wherever applicable):

e. Department:

B. Timelines of the protocol:

a. Approved by IEC on Valid until:

b. Extension of EC clearance if any: From Valid until:

c. Amendment approved by IEC if any on Valid until:

d. Date of initiation of the study:

e. Date of the last recruitment:

f. Due date for periodic/ continuing review:

C. Version followed

a. Protocol version followed

b. PIS version followed

c. ICF version followed

d. Case record form version followed

D. Sample size details

a. Sample size approved at this site

b. Number of participants screened so far

c. Number of participants recruited so far

d. Number of participants who are ongoing

e. Number of participants who have completed the study

E. Withdrawal and discontinuation details

a. Number of participants who withdrew the consent

b. Reasons for withdrawal of each participant in detail

c. Number of participants who were discontinued from the study by the PI/Sponsor

d. Reasons for discontinuation of each participant from the study with detail

F. Adverse events details

a. Number of participants with adverse events

b. Description of each adverse event in detail

c. Any SAEs reported:

d. If yes, provide details of the reports

G. Changes in the protocol/ risk to participants:

a. Any changes made in the selection criteria of participants

b. Any changes made in the protocol

c. Any changes made in the study team; any change in guide

d. Any changes in the sample size

e. Any changes in the funding status

f. Any increase in the risk to the participants based on the findings of the current study/new information in literature:

H. Monitoring/ data analysis

a. Has interim data analysis been done? If yes, provide the report.

b. Has the data safety and monitoring board reported? If yes, provide the report?

c. Has IEC/ regulatory authorities conducted a site monitoring/ audit? If yes, provide the report

I. Any other:

a. Any investigator(s) have developed a conflict of interest during the conduct of the study

b. Any difficulties/ events faced during the study

ANX - 70/V2 - Assessment form for Periodic / Continuing Review Application

Periodic/ Continuing review application form:

Protocol number and title:

Principal investigator:

Full review:

Expedited review:

Assignment of reviewers with dates of communication

Name of the reviewer 1;

Name of the reviewer 2:

Signature with date: Chairperson/ Member-Secretary

Reviewer's assessment:

Protocol No:
Title:
PI name and contact details:

1. Any clarifications required? If yes, provide details
2. Assessment by the reviewer; any ethical issues noted? If yes provide details
3. Any scientific queries? If yes mention it.
4. Any protocol deviations noted? If yes, give the details
5. Any unreported serious adverse events? If yes, provide details

Recommendation of the reviewer:

a. The study can continue in its current form.
b. The PI has to provide more details/ provide clarifications within 30 calendar days.
c. Decision in the full review meeting.

Signature of the reviewers

Date:

ANX - 71/V2 - Final Decision form for Periodic/ Continuing review

Protocol Number:
Protocol Title
Principal Investigator name and contact details
Validity of EC clearance: From _____ to _____
Extended validity: From: _____ to _____ Final decision:

a) The study can continue without any changes
b) The PI has to provide more details/ provide clarifications within 30 calendar days.
c) The study can continue but IEC audit or site monitoring of the protocol is warranted.
d) Post incorporating the suggested amendments and approval by IEC, the study can be continued.
e) The study is suspended until audit report/ site-monitoring report/ other clarification/communications are made satisfactorily
f) The study is terminated.

Signature of Chairperson/Member-Secretary with date

ANX - 72/V2 - Application for extension of the study

PI name and contact details:
IEC Reference- and study protocol- number:
Protocol title:
Subject: Request for extension of the IEC clearance
Protocol timelines:

1. IEC approval date
2. Dates of Approval of amendments, if any:
3. Dates of previous extension of EC clearance, if any
4. Date of submission of the last continuing review application form:
5. Any lapse in IEC clearance validity:

Sample size details:

1. Sample size approved for this site:
2. Number of participants – screened; recruited; ongoing trial, completed the study, so far

Study duration details:

1. Projected duration of study at the time of first IEC approval:
2. Duration of study completed so far:
3. Expected duration in months to complete the study:

Signature of the PI
Date:

ANX - 73/V2 – Protocol Deviation / Violation Initial Report

1.	**IEC Protocol no.**	
2.	**Study Title:**	
3.	**Principal Investigator:**	
4.	**Department:**	
5.	☐ **Protocol Deviation** ☐ **Protocol Violation**	
6.	**Detected/identified by:**	
7.	**Identified/ detected on:**	
8.	**Description of deviation (s)/violation(s):** **(Please use separate form for each deviation/violation and attach supporting documents, if available)**	
9.	**Name of the person reporting the deviation/violation:** **(IEC may keep this confidential if so requested by the reporting person as described in 5.2.5)**	

10.	Signature with date:	
11.	Signature of the Member Secretary with date	

ANX - 74/V2 - Protocol Deviation / Violation Detailed Report (To be filled by the Principal Investigator)

1.	IEC Protocol no.:	
2.	Protocol deviation/ violation No: (please fill one form for each deviation/violation)	
3.	Study Title:	
4.	Principal Investigator:	
5.	Department:	
6.	☐Protocol Deviation ☐Protocol Violation	
7.	Initial report by:	
8.	Date of initial report:	
9.	Reported to IEC by:	
10.	Description of deviation (s)/violation(s):	
11.	Reason (s) for the protocol deviation/violation:	
12.	Number of participants/samples affected:	
13.	Corrective action already taken:	
14.	Corrective action planned:	
15.	Number of deviations/violations previously reported with dates	
16.	Whether corrective action taken for the same	
17.	Signature with date:	

ANX - 75/V2 - Review and decision making on the Protocol deviation/ violation report

1.	IEC Protocol no.:	
2.	Protocol deviation Number:	
3.	Study Title:	

4.	**Principal Investigator:**	
5.	**Department:**	
6.	**☐Protocol Deviation** **☐Protocol Violation**	
7.	**Name of the reviewer:**	
8.	**Reviewer's comments**	
9.	**Whether there has been an increase in the risk of harm to the participants/ participant rights have been affected**	Yes/No: Description:
10.	**Whether there is a possible impact on the scientific integrity of the study**	Yes/No: Description:
11.	**Provisional Decision by the Reviewer**	
12.	**Final decision by the IEC;** • **At the emergency meeting on** • **At the IEC meeting on**	
13.	**Final decision:** **Any recommendation:** **Signature of the** **Member-Secretary/Chair person** **Date:**	

ANX - 76/V2 - Checklist for Onsite Adverse Events/SAE Submission

S. No.	Details				
1.	Country				
2.	SAE report of death or other than death; Please tick (✓)	Death		Other than death	
		Yes	No	Yes	No
3.	If any injury to the participant due to SAE; Please tick yes/no in the adjacent column	Yes/No			
4.	Protocol Title				

5.	Protocol Study No./ ID /Code	
6.	Copy of clinical trial permission obtained from CDSCO	
7.	CTRI Registration number	
8.	Sponsor's contact details	
9.	Clinical Research Organization contact details	
10.	Subject follow-up from the study initiation till date	
11.	In case of follow-up: patient diary no. and date of recently submitted report information	
12.	**Participant Details:** Initials & other relevant identifier (hospital/OPD, record number etc.) gender, age and/or date of birth Weight, Height	
13.	**Nature of the intervention:** Drug – generic name. 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 b. Any other intervention (specify) Provide the same information for concomitant drugs (including nonprescription/ OTC drugs) and non-drug therapies, as for the suspected drug(s).	
14.	Details of clinical findings: Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, assign a specific diagnosis for the reaction. Onset and duration of adverse reaction – date and time De-challenge and re-challenge information (if any) Setting (e.g. hospital, out-patient clinic, home, nursing home).	
15.	Outcome: Required hospitalization: Yes/No Number of days in admission: Please provide results of specific tests and other laboratory reports (if any) that were carried out in relation to the adverse event:	

	Details of the treatment provided (including any procedures or surgeries or any other interventions done in relation to the adverse event): Details on the recovery or other sequelae: If discharge summary is available, please provide a copy: Is there a permanent disability or functional loss? Is the adverse event associated with a congenital anomaly? For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction (include post mortem findings - if any):	
16.	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	
17.	Details about the Investigator Clinical trial Site number (if any), Name, Address, Telephone/Mobile Number & Email Profession (specialty) Date of reporting the event to Licensing Authority Date of reporting the event to Narayana Medical College Ethics Committee	
18.	Details about Narayana Medical College Ethics Committee Name and address	
19.	Name of Chairperson & Address Telephone/Mobile Number Email; Whether EC is recognized by DCGI	Yes/No
20.	Causality assessment by investigator	Related/Unrelated
21.	Causality Assessment by sponsor/CRO	Related/Unrelated
22.	Details of compensation provided for injury or death. *In case no compensation has been paid, reason for the same*	
23.	Other related documents: Duly filled SAE Form as per current regulations. Post-mortem report (if applicable). Any additional documents	
24.	Details of payment for medical management of SAE? (please give information who paid, how much was paid, to whom and evidence of the same	
25.	What is the investigator's assessment for the amount of compensation to be paid?	
26.	What is the sponsor's assessment for the amount of compensation to be paid?	
27.	Has the participant made a claim?	Yes/No - Comment
28.	If yes for 27, then, for how much amount?	
29.	If no, please ensure that the participant/nominee have been made aware of his/her rights regarding compensation.	

	Please submit documentation regarding the same.	
30.	Signature of the Principal Investigator with date	

Note: Information not relevant to a particular SAE should be marked with NA

ANX - 77/V2 - Checklist for Offsite Adverse Event/Adverse Drug Reaction/SAE Submission

S. No.	Details		
1.	**Country** (Name of the country should be specified)		
2.	**SAE report of death or other than death -** Please tick (✓)	**Death**	**Other than death**
		Yes/No	Yes/No
3.	**In case of Serious Adverse Event (SAE), please specify if there is any injury to the participant -** (Please specify Yes/No) in the box	Yes/No	
4.	If not SAE, then reporting as AE/ADR?	Yes/No	
5.	Protocol Title		
6.	Protocol Study No./ID/Code		
7.	Copy of IEC registered with CDSCO		
8.	CTRI Registration No.		
9.	Sponsor's details with contact		
10.	Clinical research organization details with contact		
11.	Initial assessment of participant/ Follow-up (FU)		
12.	In case of follow-up: Date & Diary no. of recently submitted report information		
13.	**Participant Details:** Initials & other relevant identifier (hospital/OPD record number etc.)/gender, age and/ or date of birth Weight, Height		
14.	**Nature of the intervention:** • 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 Any other intervention (specify) *Provide the same information for concomitant drugs (including non-prescription/ OTC drugs) and non-drug therapies, as for the suspected drug(s).*	
15.	**Details of clinical findings:** • Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. • In addition to a description of the reported signs and symptoms, whenever possible, assign a specific diagnosis for the reaction. • Adverse reaction onset and duration (Date and Time) • De-challenge and re-challenge information (if any) • Setting (e.g. hospital, out-patient clinic, home, nursing home).	
16.	**Outcome:** • Required hospitalization: Yes/No • Number of admission days: • Please provide results of specific tests and other laboratory reports (if any) that were carried out in relation to the adverse event: • Details of the treatment provided (including any procedures or surgeries or any other interventions done in relation to the adverse event): • Details on the recovery or other sequelae: • If discharge summary is available, please provide a copy: • Is there a permanent disability or functional loss? • Is the adverse event associated with a congenital anomaly? • For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction (include post mortem findings - if any):	
17.	**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*	
18.	***Details about the Investigator*** **-** CT Site number, if any Name, Address, Telephone/Mobile Number & Email Profession (specialty)	

19.	Event reporting date to - Licensing Authority, - IEC, Committee overseeing the site Signature of the Investigator	
20.	• **Details about the Ethics Committee** • Name and address • Name of Chairperson & Address Telephone/Mobile Number Email • Whether EC is recognized by DCGI	Yes/No
21.	Causality assessment by investigator	Related / Unrelated
22.	Causality assessment by sponsor/CRO	Related / Unrelated
23.	Details of compensation provided for in case of injury or death. *In case no compensation has been paid, reason for the same*	
24.	**Other related documents:** a) Duly filled SAE form as per current regulations; b) Post-mortem report (if applicable); c) Any additional documents	

Note: Information not relevant to a particular SAE should be marked with NA

ANX - 78/V2 - Periodic/Study Completion Report Form

Part A: To be filled by the Principal Investigator

S. No	Details	Response
1.	IEC Protocol No.	
2.	Study title	
3.	Name and affiliation of the Principal Investigator:	
4.	Total number of study participants recruited	
5.	Total number of study participants approved by IEC at start of study	
6.	Study duration	
7.	Brief summary report with the following headings: Title: Background: Objectives: Brief methodology Results: Analysis Discussion Conclusion: Note: If the final report is not available from the Sponsor it may be submitted to the IEC as soon as possible.	

8.	Number of serious adverse events (SAE) at the study site related to the ethical clearance provided by IEC	
9.	Whether all SAEs were reported on time to IEC	Yes/No - Comments
10.	Number of participants withdrawn	
11.	Reasons for withdrawal	
12.	Name and signature of the PI with date	

Part B: To be filled in by the IEC – Member Secretary		
S. No	**Details**	**Response**
1.	Action taken	Noted/Approved/Require more information/action (please specify):
2.	Signature of the Member-Secretary and date	
3.	IEC meeting date in which ratified	
4.	Extract of the resolution from the minutes	
5.	Signature of Chairperson/ Member-Secretary with date	

ANX - 79/V2 - Site Monitoring Visit Report

1.	**IEC Protocol No.**	Date of visit:
2.	**Title:**	
3.	**PI - Name and affiliation**	
4.	**Type of Study:** Investigator initiated Sponsored/funded	
5.	IEC approval date:	
6.	Study start date:	
7.	Study duration:	
8.	Reason for monitoring: Routine/ for a cause	
9.	Protocol violations/deviations	
10.	SAE reporting; Recruitment rate Others	
11.	Last site monitoring:	1. Date:
		2. Decision:
12.	Study status	1. Ongoing

		2. Completed 3. Recruitment completed 4. Follow up/Extension 5. Suspended 6. Terminated
13.	Recruitment details	• Recruited (so far): • Screened • Screen failures • Enrolled Withdrawn • Reasons for withdrawing • Discontinued • Reasons for discontinuing • Completed • Active
14.	Does the study team members were approved by IEC?	Yes/No - Comment
15.	Does the site facilities are equipped for the study?	Yes/No - Comment
16.	Did IEC approved the informed consent documentation?	Yes/No - Comment
17.	Whether patient consent was obtained in a language that they can read and understand (English/Vernacular language)?	Yes/No - Comment
18.	Any other findings noted about the ICDs?	Yes/No - Comment
19.	Was the IEC approved protocol version is used in the study?	Yes/No - Comment
20.	Was the stated inclusion, exclusion criteria is strictly followed?	Yes/No - Comment
21.	Any adverse/ serious adverse – events (AE/SAE) found?	Yes/No - Comment
22.	Were the SAEs informed to IEC within timelines specified by CDSCO?	Yes/No - Comment
23.	Number of deaths reported; Deaths unrelated to trial participation; Deaths possibly related to trial participation; Deaths due to trial participation; Any other non-death study-related injury	Comments (if any):
24.	Compensation paid for study related injury or death	Yes/No - Comment
25.	Any protocol non-compliance deviations/violations noted? If so, was it informed to EC?	Yes/No - Comment

26.	Are all Case Record Forms are up to date	Yes/No - Comment
27.	Are storage of data and investigating products locked?	Yes/No - Comment
28.	If participant recruitment has been observed/ monitored, was the recruitment process fair and free?	Yes/No/ Not observed Comments:
29.	Is informed consent process was observed/ monitored during the visit?	Yes/ No/ Not observed
	Was the informed consent appropriately obtained in terms of providing information, testing comprehension, ensuring voluntariness & agreement?	Comments:
30.	How well are the participants protected?	Good/Fair/Not good Comment
31.	Any other remarks	Yes/No - Comment
32.	Duration of visit: hours	Start & End time:
33.	Study team member(s) – name & signature with date	
34.	IEC members present during the visit – name and signature with date	
35.	Provisional decision	Discussion in the next IEC meeting
36.	Completed by:	Signature with date:

Extract of resolution of minutes	
IEC meeting number and date	
Discussion in the IEC meeting:	
Final decision at the meeting	
1. Noted the report and recommended continuation of the project without changes	
2. Recommended continuation of the project with one or more of the following changes a. Restrict further enrollment of participants b. Recommended additional training of the PI or trial staff c. Recruit additional members in the study team d. Cause the PI to amend the methodology such that the risks are mitigated.	
3. Temporary suspension of the study until further decision at the IEC	
4. Termination of the study	
Signature of the Chairperson with date:	

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ANX - 80/V2 - Monitoring of informed consent process

Elements	Yes/ No	Remarks
A designated study team member taken the informed consent from patients		
The informed consent was taken in privacy in a room		
Informed consent document was the same version as approved by IEC		
The informed consent was obtained in a language that the participant is conversant with		
The participant was made to feel at ease and no coercion was applied by the PI or the research team		
PI's demeanor was open and friendly		
Inviting participant to ask questions		
The PI reconfirmed whether the participant had understood the nuances of the research and that this was different from therapy		
PI described (in simple language) the choice to enroll or not; right to refuse; possible alternative; risks and benefits		
The PI made it clear about reimbursement for time spent; compensation in the event of adverse event; and the role of nominee in case of SAE (including death)		
PI provided a copy of the participant information sheet to the participant and encouraged him/her to read it		
The PI gave ample time to the participant to consider the risks and benefits before signing informed consent document		
PI gave a copy of the informed consent form to the participant		
In the case of a minor, parent/legally authorized representative was present & included in the discussion.		
In case of a minor (between 12 and 18 years) assent form was explained and signature of the participant taken		
The overall time taken for the PI to complete the IC process (in minutes)		

Name of IEC member: Sign: Date:

ANX - 81/V2 - Monitoring of Audio-visual (AV) Recording of AV Consent Process

S. No	Checklist item	Response
1.	Is the facility is well lit, noise-free & privacy-ensured to obtain informed consent from study participants/ legally authorized representative (LAR)/ witness (as applicable)?	Yes/No - Comment
2.	Is the consent form prepared in a language readable and understandable by the participants/ LAR?	Yes/No - Comment
3.	Was the study member introduced themselves to the participant/LAR / impartial witness, during informed consent process?	Yes/No - Comment
4.	Was the participant/LAR/witness informed that this process is being recorded for documentation purposes as required by the Government rules?	Yes/No - Comment
5.	Was information provided to the participant/ LAR/ witness (as applicable) that the confidentiality of information and privacy of participants is assured?	Yes/No - Comment
6.	Was the information provided to the participant/ LAR/ witness (as applicable) that the recording may be shown to government agencies or members from the IEC	Yes/No - Comment
7.	Was explanation or narration provided by the person conducting the informed consent discussion?	Yes/No - Comment
8.	Were the questions asked by the potential participant/LAR answered satisfactorily?	Yes/No - Comment
9.	Did the PI allow ample time and opportunity to read/understand the information in the informed consent document or discuss the same with family members?	Yes/No - Comment
10.	Did the PI or his team member- encouraged the participant/LAR (or having read out by impartial witness) to carefully read the informed consent document and give consent at their will.	Yes/No - Comment
11.	Was there appropriate documentation of signatures of all those involved in the informed consent process?	Yes/No
12.	Was there adequate clarity and completeness of the audio-video recording of the informed consent process?	Yes/No - Comment
13.	Was the recording stored in password protected laptop/desktop computer and/or hard drive and/or labeled CD with access allowed only to the principal investigator and designated members of study team?	Yes/No - Comment

Name(s) of the study team members carrying out the informed consent process with signature and date:

Name(s) of the IEC monitor(s) observing the informed consent process with signature and date:

Final decision at the IEC meeting held on (date)	Extract of resolution of minutes:
Signature of Chairperson/member secretary with date:	

ANX - 82/V2 - Document Request Form

Protocol Number & Title -	
PI name and contact details	
Requested by	
List of documents requested	
Purpose of the request	
Signature of requesting person with date	
Date and signature of Member Secretary/Chairperson	

ANX - 83/V2 - Form for confirming deletion of softcopies related to IEC protocols

I,_____, Member of IEC, hereby confirm that I have deleted the soft copies of all the protocols and protocol related documents, the review forms and communications related to the IEC functioning including meeting details and subcommittee reports received so far, from my laptop/other electronic devices and my email id. I confirm that I have maintained strict confidentiality and have not shared these documents with any unauthorized third party.

Name of the IEC member **Signature** **Date**

Signature of the Chairperson/ Member-Secretary **Date**

ANX - 84/V2 - Checklist: Research Involving Children < 18 years

Children (minors) have reduced capacity to understand and give informed consent. Such participants have decreased autonomy, and increased exploitative potential and are considered as vulnerable participants. Current regulations and guidelines require EC to ensure that researchers provide ample safeguards in the research protocol for the protection of vulnerable populations. Filling out this checklist will help researchers in strengthening the research protocol, and EC in reviewing this study more systematically. Principal Investigators are requested to provide their responses in this checklist in an honest and forthright manner.

Study Title:

S. No	**Checklist - for the PI; prior to submission to EC** (information should be clearly & unambiguously mentioned in the methodology, participant information sheet and informed consent form)	Y	N	NA
1	Does the research pose greater than minimal risk to children?			
2	If yes: Are there convincing scientific and ethical justifications to carry out the research as designed?			
3	If yes: Are adequate safeguards in place (and described in the protocol) to minimize these risks?			
4	Is there an alternate study design that can achieve the same objectives? without involving such vulnerable participants?			
5	Does the study involve healthy children?			
5A. If yes:				
5Ai	Is the inclusion of healthy children justified?			
5Aii	Have scientifically appropriate preclinical studies, including studies on animals, and clinical studies, including studies on children and/or adults, been conducted and do these provide data for assessing potential risks to children/minors?			
5Aiii	Do the results of those studies justify this study?			
5B. If no:				
5Bi	Is the lack of studies conducted on animals and/or adults justified?			
5Bii	Would this study still be justified despite the lack of animal studies?			
6	Will older children be enrolled before younger ones?			
7	Is permission of both parents necessary?			
If yes:				
7A	Are conditions under which one of the parents may be considered: “not reasonably available” described?			
7B	Are the conditions acceptable?			
8	Will efforts be made to ensure that parents’ permission to involve their children in research studies is free from coercion, exploitation, and/or unrealistic promises?			

9	Are provisions made to obtain the written assent of children over 12 years, and oral assent of children between 7 and 12 years, and where appropriate, honor their dissent?			
10	Are provisions made to protect participants' privacy and the confidentiality of information gathered in the course of the research?			
11	Are there special problems that call for the presence of an external monitor during consent procedures?			
12	Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?			
13	Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?			
14	Does the research involve possibility of findings which may have implications for other family members? (for eg. genetic risk, HIV infection, Hepatitis C)			
If yes:				
14Ai	Are there adequate mechanisms in place to deal with other members of the family, should there be a risk to such bystanders?			
14Aii	Are parents required to be present during the conduct of the research?			

For the Principal Investigator *(tick whichever is applicable in the risk-benefit columns)*	**For the IEC Member Secretary** *(this column for IEC; circle whatever is applicable)*	
Risk determination	**Benefit assessment**	**IEC Action**
Minimal risk*	Direct benefit	Approvable
	No direct benefit	Approvable
Greater than minimal risk	Potential benefit to participant	Approvable
	No direct benefit; or offers new knowledge about the condition being investigated	Case-based approval on merits

*Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life. ** Consent of both parents (and assent) may be needed as applicable*

Signature of the Principal Investigator:

Date:

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Comments of Primary Reviewer:	
Primary Reviewer Signature and Date:	

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ANX - 85/V2 - Checklist: Requirements for Research Involving Pregnant Women, Neonates & Fetuses

Pregnant women and their unborn or just born fetuses are considered as vulnerable participants in research and therefore subject to increased harm. Current regulations and guidelines require ethics committees to ensure that researchers provide ample safeguards in the research protocol for the protection of vulnerable populations. Filling out this checklist will help researchers in strengthening the research protocol, and ethics committees in reviewing this study more systematically. Principal Investigators are requested to provide their responses in this checklist in an honest and forthright manner.

Study Title:
Name of the Principal Investigator:
If the research involves pregnant women and/or their fetuses, please fill this form and submit along with the research protocol:

S. No.	Check list	Yes	No	NA
1	Have scientifically appropriate preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, been conducted and do these provide data for assessing potential risks to pregnant women and fetuses?			
2	Is the risk to the pregnant woman or the fetus “not greater than minimal”, or, any risk to the woman or the fetus, which is greater than minimal, is caused solely by the research intervention/procedure and this holds out the prospect of direct benefit for the woman or the fetus?			
3	Is any risk that is likely to occur, the least possible for achieving the objectives of this study?			
4	Is the woman’s consent or the consent of her legally authorized representative (if the participant herself is unable to give consent) obtained in accordance with the informed consent provisions (as described in the ICMR National Ethical Guidelines for Biomedical Research involving Human Participants - 2017)?			
5	Is the woman or her legally authorized representative (as appropriate)? Fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child?			
6	Do individuals engaged in the research have a part in determining the viability of the fetus?			
7	Do individuals engaged in the research have a part in any decisions as to the timing, method, or procedures used to terminate the pregnancy?			
8	Will any inducements, monetary or otherwise, be offered to terminate the pregnancy?			

If the response to items 1-7 is **NO**, the research should not be approved by IEC. Response to item no. 8 will be assessed on a case-to-case basis.

Please fill this section of the checklist if the research involves neonates:

S. No	Checklist item	Y	N	NA
1	Can this research be performed in any other non-vulnerable participants?			
2	Is there adequate justification for involvement of vulnerable population in the research?			
3	Are scientifically appropriate, preclinical and clinical studies, conducted and provide data for assessing potential risks to neonates?			
4	Is the individual providing consent, fully informed regarding the reasonably foreseeable impact of the research on neonate?			
5	Will any inducements, monetary or otherwise, be offered to terminate the pregnancy?			
6	Do individuals engaged in the research have a part in any decisions as to the timing, method or procedures used to terminate pregnancy?			
7	Do individuals engaged in the research have a part in determining the viability of a fetus?			

If the response to item no. 1 is **YES** and to item no. 2-7 is **NO**, the research should not be approved by IEC.

Fetus of uncertain viability:

S. No	Check list	Y	N	NA
1	Is the purpose of the research the development of important biomedical knowledge which cannot be obtained by other means?			
2	Is any risk the fetus is exposed to, the least possible for achieving the objectives of the research?			
3	Does the research hold out the prospect of enhancing the probability of survival of the enrolled fetus to the point of viability?			
4	Will the legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence or temporary incapacity, then informed consent of either parent's legally authorized representative be obtained.			

If the response for any of the items no. 1-4 is **NO**, then IEC should not approve the research

S. No	Check list	Y	N	NA
1	Will vital functions of the neonate be artificially maintained in the course of the research, despite clinically being pronounced “non-viable”?			
2	Will the research-related risk to the neonate be less than minimal?			
3	Can the knowledge acquired out of this research; be obtained by any other means?			
4	Will the legally effective informed consent of both parents of the neonate be obtained? Please note: If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable fetus will suffice to meet the requirements of this paragraph. (The consent of a legally authorized representative of either or both of the parents of a nonviable fetus will not suffice to meet the requirements of this paragraph.)			

Non-viable fetus:

If the response to any of above is **NO,** the research should not be approved by the IEC.

This type of research can be conducted only after IEC determines that

a) The research presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of pregnant women and/or fetuses**.**
b) The research will be conducted in accordance with applicable regulatory and ethical guidelines.

Signature of the Principal Investigator: **Date:**

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Comments of Primary Reviewer:	
Primary Reviewer’s Signature and Date:	

ANX - 86/V2 - Checklist: Research Involving Cognitively Impaired Adults

Cognitively impaired adults have reduced capacity to understand and give informed consent. Such participants have decreased autonomy, and increased exploitative potential and are considered as vulnerable participants. Current regulations and guidelines require ethics committees to ensure that researchers provide ample safeguards in the research protocol for the protection of vulnerable populations. Filling out this checklist will help researchers in strengthening the research protocol, and ethics committees to review this study more systematically. Principal Investigators are requested to provide their responses in this checklist in an honest and forthright manner.

Study title:

Name of the Principal Investigator:

1. Research Involving Cognitively Impaired Adults in which there is anticipated direct benefit to the participant

S. No	Checklist - *All items should be answered and the substantiation for the same should be evident in the protocol (methodology) as well as in the participant information sheet and informed consent form)*	Y	N	NA
1	Is recruitment of participants justified considering the rationale & objectives of the study?			
2	Is the risk justified by the anticipated benefit?			
3	Is the relation of the anticipated benefit to the risk at least as favorable to the participants as that presented by available alternative approaches?			
4	Will the participants be withdrawn if they appear to be unduly distressed?			
5	Is the proposed plan for the assessment of the capacity to consent adequate?			
6	Will consent be taken from participants capable of being consulted?			
7	Does the consent document include provision for a legally authorized representative in case participants are not capable of being consulted?			

*2. **Research Involving Cognitively Impaired Adults in which there is no anticipated direct benefit to the participant***

S. No	Check list	Y	N	NA
1	Is the recruitment of participants justified considering the rationale & objectives of the study?			
2	Are the foreseeable risks to the participants low?			
3	Is the negative impact on the participant's well-being minimized and low?			
4	Will the participants be closely monitored?			
5	Will the participants be withdrawn if they appear to be unduly distressed?			
6	Is the proposed plan for the assessment of the capacity to consent adequate?			
7	Will consent be taken from participants who are capable of being consulted?			
8	Does the consent document include provision for a legally authorized representative in case participants are not capable of being consulted?			

Signature of the Principal Investigator: **Date:**

IEC Office use only	
Comments of Primary Reviewer	
Primary Reviewer Signature and Date	

ANX - 87/V2 - Checklist: Genetic research study

Genetic research is still poorly understood and there is much to be learned by the scientific community, for a fuller and more comprehensive understanding of the genetic functions of the human body. Potential participants may have difficulty in understanding the research details and thus give informed consent on less-than-optimal understanding. Such participants have decreased autonomy, and increased exploitative potential and are considered as vulnerable participants. Current regulations and guidelines require ethics committees to ensure that researchers provide ample safeguards in the research protocol for the protection of vulnerable populations. Filling out this checklist will help researchers in strengthening the research protocol, and ethics committees to review this study more systematically. Principal Investigators are requested to provide their responses in this checklist in an honest and forthright manner.

Name of the Principal Investigator

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Study Title:

S. No	Check list	Y	N	NA
1	Will the samples be made anonymous to maintain confidentiality?			
2	Will the results be disclosed to the participant or legally authorized representative? If yes, has the investigator established clear guideline for disclosure of the information, including interim or inconclusive research results? Will the results be used in management of current condition of the patient?			
3	Has the appropriateness of the various strategies for recruiting participants and their family members been considered?			
4	Does the proposed study population comprise family members?			
5	Will family members be implicated in the studies without consent?			
6	Will the samples be destroyed in the future?			
7	Will the samples be used for future research?			
8	Will the human biological sample or the data associated with it, be shared with other researchers?			
9	Will genetic counseling be offered?			

Signature of the Principal Investigator: Date:

IEC Office use only	
Comments of Primary Reviewer	
Primary Reviewer Signature and Date	

ANX - 88/V2 - Self-assessment form for IEC members

IEC member name: **Role in IEC:** **Date of joining in IEC:**

Period of assessment: From **to**

S. No	Self-assessment item	Response

1	Current tenure	
2	Terms served	
3	Type of training received: Initial; Continuous:	
4	Number of meetings attended in the current year	
5	Number of protocols reviewed per meeting as lead discussant	
6	Number of protocols reviewed per meeting as primary reviewer	
7	Number of protocols reviewed per meeting as secondary reviewer	
8	Level of participation in the ethical discussions in the meetings (your perception as an approximate percentage)	25% 26-50 % 51-75% >75%
8	Participation in SAE report review process	Yes/No
9	Participation in site monitoring visits	Yes/No
10	Other contribution to the field of research ethics	
11	How satisfied are you with your work in the IEC	25% 26-50 % 51-75% >75%

Signature of IEC member and date:

Assessment observations of the Chairperson:

Signature of the Chairperson and date:

ANX - 89/V2 - Self-assessment form for IEC Member-Secretary

Name of the IEC Member-Secretary: **Date of joining IEC:**
Period of assessment from to

S. No	Self-assessment	Response
1	Current tenure	
2	Terms served	
3	Training received	

4	Type of training received		
5	Number of meetings attended in the current year		
6	Number of protocols reviewed per meeting as lead discussant		
6	Number of protocols reviewed per meeting as primary reviewer		
7	Number of protocols reviewed per meeting as secondary reviewer		
8	Level of participation in the ethical discussions in the meetings	25% 26-50 % 51-75% >75%	
8	Participation in SAE report review process	Yes/No	
9	Participation in site monitoring visits	Yes/No	
10	Number and type of continuing training workshops organized for IEC members		
11	Number and type of continuing training workshops organized for staff of IEC		
12	Any other contribution to research ethics		
11	How satisfied are you with your work in the IEC	25%	26-50 %
		51 -75%	>75%

Signature of IEC Member-Secretary and date:

Assessment observations of the Chairperson:

Signature of the Chairperson and date:

ANX - 90/V2 - Self-assessment form for IEC Chairperson

Name of the IEC Chairperson:

Date of joining IEC:

S. No	Self-assessment	Response
1.	Current tenure; Terms served;	
2.	Type of training received	
3.	Number of meetings attended in the current year	
4.	Number of protocols reviewed per meeting as lead discussant	

5.	Number of protocols reviewed per meeting as - primary reviewer & - secondary reviewer.	
6.	Level of participation in the ethical discussions in the meetings	25%, 26-50 % 51-75%, >75%
7.	Participation in SAE report review process	Yes/No
8.	Participation in site monitoring visits	Yes/No
9.	Whether considerations related to conflict of interest considered	Yes/No
10.	Any other significant contribution to the field of research ethics	
11.	Whether quorum requirement fulfillment ensured as per current guidelines in IEC meetings	
12.	Whether considerations related to conflict of interest explored	
13.	Any other contribution to research ethics	
14.	How satisfied are you with your work in the IEC	25%, 26-50 %, 51-75%, >75%

Signature of Chairperson and date:

ANX - 91/V2 - Self-assessment form for IEC Secretarial Staff

Name of the IEC Secretarial Staff:
Date of joining IEC:
Role in IEC:
Period of assessment: From to

S. No	Self-assessment item	Response
1.	Years of service	
2.	Status of service	
3.	Type of training received: Initial: Continuous:	
4.	Number of meetings assisted member-Secretary in the current year	
5.	Number of days attended work:	
6.	Number of protocols handled in the assessment period	
7.	Whether Member-Secretary or Chairperson made corrections in the protocol works	

8.	Number of SAE report review assisted in:	Yes/No
9.	Number of site monitoring visits assisted in:	Yes/No
10.	Any other significant contribution to the work in the IEC	
11.	How satisfied are you with your work in the IEC	25%; 26-50 %; 51-75%; >75%

Signature of IEC Secretarial staff and date:

Assessment observations of the Chairperson:

Signature of the Chairperson and date:

ANX - 92/V2 - Feedback form of the IEC members on the IEC functioning

S. No.	Feature	Yes	No	Remarks
1.	Adequate time is allotted to review the expedited protocols			
2.	The time allotted for review of full-review protocols is adequate			
3.	The checklist provided for review of protocols is appropriate			
4.	Reminders are sent by the secretarial staff if timeline for review is missed			
5.	The SOPs, guidelines and regulations are provided by IEC for reference			
6.	Confidentiality of the documents is adequately maintained			
7.	Training programs are conducted regularly			
8.	Training programs conducted by IEC are useful			
9.	In decision making on proposals; members are free to express their dissent.			
10.	IEC meetings are conducted as per SOP (time, quorum, discussion, decision making)			
11.	The IEC manages conflict of interest as per the SOP			
12.	The EC meeting duration is adequate for reviewing the submitted protocols			
13.	The functioning and decision making of the IEC is independent			
14.	The meeting- agenda and notes are circulated well ahead of the meeting			
15.	The meeting minutes are circulated within 1 week for EC members approval			
16.	The review process includes both scientific and ethical issues in the protocols			

17.	Every member is able to freely contribute to discussion and deliberation of protocols in the meeting			
18.	The SOPs are clear and practical			
19.	The venue and arrangement of the meetings is adequate			
20.	What according to you is the strength of the IEC?			
21.	What according to you needs improvement?			