JSS MEDICAL COLLEGE

Sri Shivarathreeshwara Nagara,
Mysuru – 570 015, Karnataka, India
P:+91-821-2548337 / 338|F: +91-821-2548345|

INSTITUTIONAL ETHICS COMMITTEE

IEC Registration ECR/387/Inst/KA/2013/RR-19
NABH Accreditation Certificate No. EC-CT-2018-0018
E:iecjssmc@gmail.com, jssmc09@gmail.com

STANDARD OPERATING PROCEDURES (SOPs)

Version 5, 2024

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P:+91-821-2548337 / 338|F: +91-821-2548345| E:jssmc@jssuni.edu.in|www.jssuni.edu.in

JSS ACADEMY OF HIGHER EDUCATION & RESEARCH
(DEEMED TO BE UNIVERSITY) MYSURU

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STANDARD OPERATING PROCEDURE (SOPs)

Version 5

Prepared by:

Dr Prathima C Associate Professor of Pharmacology & Member Secretary- IEC, JSSMC	Member Secretary, Institutional Ethical Committee J S.S. Medical College, S.S. Nagar MYSORE-570 015

Reviewed by:

Dr Pratibha Periera Professor & Head, Dept of Geriatrics, NABH assessor & GCP training faculty & Member - IEC, JSSMC	Dr. PRATIBHA PEREIRA MBBS., MD., PGDGM (Geriatrics) Professor and HOD of Geriatric Dept. of Geriatric JSSMC & Hospital, MYSURU KMC No: 32880

Approved by:

Dr Srinivas M Senior Consultant, Physician & Chairman- IEC, JSSMC	Chairman Institutional Ethical Committee J.S.S. Medical College, S.S. Nagar MYSORE-570 015

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FORMAL APPROVAL BY THE CHAIRMAN, INSTITUTIONAL ETHICS COMMITTEE

This document- The Standard Operating Procedures (SOP), Version 5 after being prepared by the Member Secretary and duly approved by all the members of the Institutional Ethics Committee is hereby being released with effect from 7th March 2024 for the purpose of all Institutional Ethics Committee activities to be conducted henceforth. I do hereby approve the SOPs for the aforesaid purpose.

Dated:

Chairman

Dr Srinivas M
Institutional Ethics Committee
JSSMC, Mysuru

Chairman
Institutional Ethical Committee
J.S.S. Medical College, S.S. Nagar
MYSORE-570 015

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INSTITUTIONAL ETHICS COMMITTEE

JSS MEDICAL COLLEGE, MYSURU

Members List

Sl.no.	Name of the Member	Position	Affiliation
01	Dr M. Srinivasa, Senior Consultant and DNB Course coordinator, Kamakshi Hospital, Kuvempunagar, Mysuru-570001,	Chairman	Non-Affiliated
02	Dr. Prathibha Pereira, Professor of Geriatrics, JSS Medical College & Hospital, Mysore	Clinician	Affiliated
03	Dr. Srinath K.M Professor, Dept of General Medicine, JSS Medical College & Hospital, Mysore -570004	Clinician	Affiliated
04	Dr. Smitha Rani Associate Professor, Dept of Forensic Medicine & Toxicology, JSS Medical College, Mysore -570015	Basic Medical Scientists	Affiliated
05	Dr. Kalabharathi H. L Professor, Dept of Pharmacology, JSS Medical College, Mysore -570015	Basic Medical Scientists	Affiliated
06	Dr. Sathyanarayana Mamatha Assistant. Professor, Dept of Hindi, De Paul Degree College, Mysore	Lay Person	Non-Affiliated
07	Mr. Palaksha, No. 645, 1st Floor, Narayana Sastry Road Behind Seetha vilasa Choultry, Mysuru -570024	Legal Expert	Non-Affiliated
08	Mr H.N.Nithin, B.B.M.,LL.M.,CCL(Cyber Law, Advocate, Legal Expert,IEC,JSSMC,No.67,1st Cross,2nd Main,4th Stage, T.K Layout Mysore-570009,Karnataka	Legal Expert	Non-Affiliated
09	Smt. H.S. Sandhya Treasurer of Inner wheel club of Mysore Mid town, Mysore	Social Scientist	Non-Affiliated
10	Smt. Sudhaphaneesh, Secretary, Samarpana Trust ®, Mysore	Social Scientist	Non-Affiliated

11	Sri. R.S. Nagaraj, Secretary, Shree Vanamali Charitable Trust ®, No. 1737, First Floor, 4th Cross North, Kuvempunagar, Mysore-570023	Lay Person	Non-Affiliated
12	Dr. Sri Harsha Chalasani Assistant Professor, Dept of Pharmacy Practice, JSS College of Pharmacy, Mysore -570015	Scientific Member	Affiliated
13	Dr. Prathima.C, Associate. Professor. of Pharmacology, JSS Medical College, Mysore.	Member Secretary (Clinical Trials)	Affiliated
14	Dr Shivaprakash S, Associate. Professor of Anatomy, JSS Medical College, Mysore	Member Secretary (Academic studies)	Affiliated

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TABLE OF CONTENTS

APPENDICES

ABBREVIATIONS

Term	Expansion
IEC	Institutional Ethics Committee
ICF	Informed Consent Form
COI	Conflict of Interest
LAR	Legally Acceptable Representative
IW	Impartial witness
CTA	Clinical Trial Agreement
IB	Investigator's Brochure
CRF	Case Report Form
DCGI	Drug Controller General of India
ICMR	Indian Council of Medical Research
SOP	Standard Operating Procedures
CIOMS	Council for International Organizations of Medical Sciences
SUSAR	Suspected Unexpected Serious Adverse Reports
PI	Principal Investigator
AE	Adverse Event
SAE	Serious Adverse Event
ICH	International Council for Harmonization
GCP	Good Clinical Practice
BARC	Baba Atomic Research Centre

DEFINITIONS

- **Ethics Committee:** An independent review board or committee comprising of medical / scientific and non– medical / non– scientific members, whose responsibility is to verify the protection of the rights, safety and well – being of the human subjects involved in the study.
- **Good Clinical Practice:** It is a standard for clinical trials that encompasses the design, conduct, monitoring, termination, audit, analysis, reporting and documentation of the studies. It ensures that the studies are implemented and reported in such a manner that there is assurance that the data are credible, accurate and that the rights, integrity and confidentiality of the subjects are protected.
- **Informed Consent:** Voluntary written assent of a subject's willingness to participate in a particular study and in its documentation. The confirmation is sought only after information about the trial including an explanation of its status as research, its objectives, potential benefits, risks and inconveniences, alternative treatment that may be available and of the subject's rights and responsibilities has been provided to the potential subject.
- **Assent:** To agree or approve after thoughtful consideration an idea or suggestion to participate in research by a young person below the age of 18 years who is old enough to understand the implications of any proposed research but not legally eligible to give consent. The assent has to be corroborated with informed consent of parent/LAR.
- **Informed consent document (ICD):** Written signed and dated paper confirming a participant's willingness to voluntarily participate in a particular research, after having been informed of all aspects of the research that are relevant for the participant's decision to participate.

- **Investigator:** Investigator is a person responsible for the conduct of the clinical trial / research study at a study site. If a trial or study is conducted by a team of individuals at a trial or study site, the investigator is the responsible leader of the team and may be called the Principal Investigator.
- **Co-investigator(s):** Co-investigator(s) is/are a person(s) legally qualified to be an investigator, to whom the Investigator delegates a part of his responsibilities.
- **Serious Adverse Event (SAE):** An adverse event is serious when the research outcome for the participant is death, life threatening injury requiring hospitalization, prolongation of hospitalization, significant disability/incapacity, congenital anomaly, or requirement of intervention to prevent permanent impairment or damage.
- **Compensation:** Provision of financial payment to the research participants or their legal heirs when temporary or permanent injury or death occurs due to participation in biomedical and health research.
- **Confidentiality:** Keeping information confidential which an individual has disclosed in a relationship of trust and with the expectation that it shall not be divulged to others without permission.
- **Legally acceptable representative (LAR):** A person who will give consent on behalf of a prospective participant who, for either legal or medical reasons, is unable to give consent herself/himself to participate in research or to undergo a diagnostic, therapeutic or preventive procedure as per research protocol, duly approved by the EC.

- **Sponsor:** Sponsor is an individual or a company or an institution that takes the responsibility for the initiation, management and / or financing of a Clinical / research Study. An Investigator who independently initiates and takes full responsibility for a trial or study automatically assumes the role of a Sponsor.
- **Suspension of a trial:** Recruiting or enrolling participants has halted prematurely but potentially will resume.
- **Termination of a trial:** Recruiting or enrolling participants has halted prematurely and will not resume; participants are no longer being examined or treated.

1. VERSION HISTORY

Sl. No.	Description	Date of effect	Valid till Date	Approved by Date
01	Version –2	Dec 2011	Dec 2015	IEC, JSSMC Mysore
02	Version –3	30th Jan 2016	31st Dec 2016	
03	Version -4	1st Jan 2017	31st July 2017	
04	Version – 4.1	1st Aug 2017	8th July 2019	
05	Version – 4.1 addendum	9th July 2019	30th May 2021	
06	Version 4.2	31st May 2021	30th May 2024	
07	Version 5	7th Mar 2024	6th Mar 2029	

2. 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 and its amendments, Indian GCP guidelines (2016) and Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2017).

3. AIMS AND OBJECTIVES OF IEC, JSSMC

AIMS :

Institutional Ethical Committee (IEC) of JSS Medical College and Hospital, JSS Academy of Higher Education and Research, Mysore 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 under compliance of New Drugs and Clinical Trials Rules, 2019, National Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2017) and its requirements.

OBJECTIVES:

- These written Standard operating procedures (SOPs) were adopted to ensure the protection of the rights, safety and welfare of human participants in clinical, biomedical and health research.
- The objective of these SOPs of the IEC of JSS Medical College (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 subject conducted within the institution or Institutions / center's which have MOU with JSSMC/ JSS AHER, under the condition that PI/ one of the Co PI must be from JSSMC and hospital.
- Assist in the development and the education of a research community responsive to local health care requirements.

4. ROLE OF IEC

- The Institutional Ethical Committee is intended to ensure a competent review of scientific and ethical aspects of the project proposals received. The IEC is entrusted not only with the initial review of the proposed research protocols prior to initiation of the projects but also have a continuing responsibility of regular monitoring to ensure ethical compliance of the approved proposals till the same are completed.
- IEC ensures that the Principles of Ethics- Autonomy, Beneficence, Non -

maleficence and Justice are taken care of in planning, conduct and reporting of the proposed research, it will also look into the aspects of informed consent process, risk benefit ratio, distribution of burden, benefit and provisions for appropriate compensations wherever required.

- The committee also examines compliance of the research with all regulatory requirements, applicable guidelines and laws. It will review all research projects involving human subjects to be conducted at the Institute, irrespective of the funding agency.
- IEC has the authority to take final decision on approval and may approve or suggest the require modifications for approval or disapprove the submitted research proposal.

5. EC AUTHORITY:

IEC, JSS Medical College has been authorized to be established and to function under- The Principal, JSS Medical College, Mysuru (Appendix-I). IEC, JSSMC is as an independent body which functions independently at the site as registered body under Drugs Controller General of India (DCGI) and function according to rules and regulations envisaged in the International Conference of Harmonization- Good Clinical Practice (ICH-GCP) guidelines, New Drugs and Clinical Trials Rules, 2019 and ICMR National Ethical Guidelines for Biomedical Research on Human Participants, 2017 with respect to decision making and its working in order to:

i. To approve, require modifications to secure approval, or disapproval of all research activities overseen and conducted at JSS Medical College & Hospital / Organizations/ Hospitals which have MOU/ Clinical Trial Agreement JSS Medical College or JSS AHER, Mysore (Appendix I)

ii. To suspend or terminate approval of research not being conducted in accordance with IEC, Indian GCP requirements or that has been associated

with unexpected serious harm to participants. This is done by reviewing regular reports from CIOMS, SUSAR reports, and reports of SAEs.

iii. To review the suitability of the investigator(s), facilities and the methods and material to conduct clinical research at our site. In addition to this, the institute will provide all support to the ethics committee activities which includes training, resources and infrastructure at the same time.

6. PREPARATION OF STANDARD OPERATING PROCEDURES (SOPs) FOR IEC:

6.1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to define the process for writing, reviewing, distributing and amending SOPs of IEC, JSSMC, Mysore. The SOPs provide clear, unambiguous instructions on the related activities of the Committee being 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, 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.

6.2. Responsibility:

IEC Member secretary:

- Assess the requirements/ reasons for SOP revision in consultation with the Chairman
- Propose new / modified SOPs as needed
- Draft the SOP/modify SOP in consultation with the IEC members
- To get the draft SOP reviewed by another EC member
- Submit the draft for approval to Chairman

Chairman of IEC:

- Chairman of IEC to appoint the SOP team to formulate the SOPs consisting of Member Secretary and the Coordinating staff, and reviewed by another IEC member.
- Assist in all decision-making procedure of IEC.
- Assist secretariat for any help in management

IEC Coordinator:

- Co-ordinate the activities of writing, reviewing, distributing and amending SOPs.
- Maintain on file all current SOP and past SOPs.
- Ensure that all the IEC members and involved staff have access to the SOPs
- Maintain an up-to-date distribution list for each SOP distributed
- Assist Member Secretary in the formulation of SOPs

6.3. 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 Chairman will inform all the IEC members about this request in a regular full-Committee IEC meeting. If the IEC members agree to the request, the Member Secretary shall proceed with the revision process/ formulation process of the SOP. If the IEC members do not agree, the Chairman 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 5 years or if there are major changes whichever is earlier.

The Chairman will instruct the IEC Member secretary who have a thorough understanding of the ethical review process to amend the SOP as per the requirements and discussions.

6.4. Design a SOP format:

The revised SOP will have a new version, continuation of the previous version, effective date and the validity period. Each page of SOP will bear the header which will have effective date i.e. date of approval and validity of the SOPs. The SOP number will be on the cover page while the bottom of page will bear the page numbers. The first page of SOP document will be signed and dated by the Member secretary, the IEC member/s who has reviewed the SOPs and the IEC Chairman and subsequently the SOP will be implemented from that date.

6.5. New Standard Operating Procedures:

When the need for a new SOP has been identified and agreed on, a draft will be written by Member Secretary and reviewed by the designated IEC member, appointed by the Chairman.

6.6. Review by Consultation:

The draft SOP will be reviewed by the other member/s of the IEC. After incorporating the suggestions put forth by the SOP team members, a copy of the revised draft SOP will be circulated to all the IEC members to invite suggestions.

6.7. 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.
- Approve the SOPs
- Sign and date the approved SOPs

6.8. Approve a new/ revised SOP:

- The revised SOPs will be reviewed and approved in the same manner as a new SOP.
- The Chairman 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.

6.9. Ensure implementation and filing of previous 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 Institutional Ethics Committee'.
- Revision of approved SOPs shall occur when necessary.

6.10. Manage current and archive superseded SOPs:

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

6.11. 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.

- Institutional Ethics Committee (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 wellbeing of human participants involved in a clinical trial and to provide public assurance of that protection.

7. TERMS OF REFERENCES (TOR):

- The IEC is formed by the Principal, JSSMC 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 principal 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 declaration of conflict of interest and confidentiality.
- The IEC, will be multidisciplinary and multi-sectorial in composition and will have 7-15 members from medical, non-medical, scientific and non-scientific areas. At least 50% of members will be non-affiliated to this institute.
- A list of members, their qualifications, affiliation and contact details will be maintained by the Institutional Ethical Committee. A copy of the Institutional Ethical Committee composition and operating procedures are to be made available to any member of the Hospital/Institute for filing of research projects, upon written request for the same to the EC

- The EC members must make themselves available for training, review process, SAE reporting and compensation requirements. They should be aware of their roles and responsibilities and the Ethical guidelines and regulations.
- The Chairperson will conduct all meetings of the IEC. If for any reasons beyond control, the Chairperson is not available, the Deputy Chairperson or an alternate Chairperson will be selected from those members who are external members of the IEC, who is going to be intimated in writing in advance and taken his permission and conduct the meeting in presence of alternate Chairman.
- The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairman
- The non-member Subject experts are invited to obtain their suggestions on specific indications with clinical trial projects of Pediatrics/ HIV related/ Cancer/ Cardiology/ Psychiatry etc., by sending a written invitation 15 days prior to the IEC Meeting. However, Non-member subject experts will not be allowed to vote in the decision-making procedure.

8. LOCATION, TENURE AND APPROVED TRIAL SITES OF IEC, JSSMC

IEC Office: The office of the IEC is Located at II floor, JSS Medical College, Sri Shivarathreeshwara Nagar, Mysore –570015, Karnataka.

Tenure: The tenure of IEC, JSSMC is for a period of 5 years (Appendix-II)

Approved Trial Sites:

1. JSS Hospital, Mysore

2. All those sites which have an MOU with JSS Medical College & Hospital/JSSAHER, under the condition that the PI or one of the Co PI must be

from JSS Medical College & Hospital.

The staff members of JSS Medical College & Hospital are approved as PI / Co PI for conduct of clinical trials at JSS Medical College & Hospital site under the condition that, they should submit GCP training certificate and experience as co-investigator before taking up any clinical trial.

9. COMPOSITION OF IEC

The IEC constitutes the members based on their competencies and integrity (Appendix III).

i. The IEC is multidisciplinary and multispectral in composition. Independent and competent in its functioning.

ii. There should be adequate representation of age and gender.

iii. Preferably 50% of the members should be non-affiliated or from outside the institution. The external members could be drawn from many public or private institute anywhere in the country.

iv. The number of members in an EC should preferably be between 7 and 15 and a minimum of five members should be present to meet the quorum requirements.

v. The EC should have a balance between medical and non-medical members/technical and non-technical members.

The number of persons in the ethics committee is kept fairly small (7- 15 members). The Institutional head shall appoint a chairperson who is competent, experienced and not affiliated to the institute. The Member secretary also appointed by the Institutional head should be from the same institution. Other members should be a mix of medical/non- medical, basic science, scientific and non-scientific persons including lay person/s to represent the differed points of view. The ethics committee (EC) can have as its members, individuals from other

institutions or communities with adequate representation of age and gender to safeguard the interests and welfare of all sections of the community /society.

If required, subject experts from external institute will be invited to offer their views, for instance, a pediatrician for pediatric conditions, cardiologists for cardiac disorders etc. Similarly, based on the requirement of research area, such as HIV, genetic disorders etc, it is desirable to include a member from specific patient groups in the committee.

10. QUORUM REQUIREMENTS:

The requisite quorum of five members consisting at least one 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 besides the Chairman and member Secretary are must for discussion on any research proposal. (Appendix-IV)

- For clinical trial, the five members of quorum is a must be as follows- as per New Drugs and Clinical Trials Rules, 2019 and 2022 (Amendments)

- A Medical scientist (preferably a pharmacologist),

- A Clinician,

- A Legal expert,

- A social scientist or representative of a nongovernmental voluntary agency or a philosopher or an ethicist or a theologian or a similar person and

- A Layperson from the community

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

11. IEC MEMBERS- AFFILIATIONS, QUALIFICATIONS, ROLES AND RESPONSIBILITIES

11.1 Chairperson:

- Non-affiliated

- Qualification- A well respected person from any background with prior experience of having served/ serving in an EC capable of managing IEC, and the matters brought before it with fairness and impartiality.

-Responsibilities:

- To conduct EC meetings and be accountable for independent and efficient functioning of the committee
- Ensure active participation of all members (particularly non-affiliated, non-medical/ non- technical) in all discussions and deliberations. Any EC member not complaint with policies and procedures, has an undue number of absences or not fulfilling the responsibilities will be replaced
- Ratify minutes of the previous meetings
- In case of anticipated absence of Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting.
- Seek COI declaration from members and ensure quorum and fair decision making.
- Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.
- The Chairperson will be primarily responsible for ensuring that IEC is

perceived as fair, impartial and immune to pressure by the institution's administration, the investigators whose protocols are brought before it, and other professional and non-professional sources.

11.2 Member Secretary

- Affiliated

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

-Responsibilities:

- Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review
- Schedule EC meetings, prepare the agenda and minutes of the meeting
- He/she is signatory to all the documents of the EC to the PI and also Minutes of meeting. In his/her absence, he/she will delegate this work to the alternate member secretary who is also the signatory to the minutes of meeting & in absence of the member secretary for the meeting, the designee will take the responsibilities of the member secretary who will also be one of the IEC members.
- Organize EC documentation, communication and archiving
- Ensure training of EC secretariat and EC members
- Ensure SOPs are updated as and when required and adherence of EC functioning to the SOPs
- Prepare for and respond to audits and inspections
- Ensure completeness of documentation at the time of receipt and timely

inclusion in agenda for EC review. He/she communicates with the staff of JSS Medical College & Hospital, PIs, and research staff in the matters related to the requirements of the EC with respect to the research protocol and other documents.

- He/she also follows up the PI in matters related to clarification of SAE reports received and also any complaints received with respect to coercion, conflict of interest or informed consent process.
- Assess the need for expedited review/ exemption from review or full review.
- Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives.
- Ensure quorum during the meeting and record discussions and decisions.

11.3 Basic Medical Scientist (s)

- Affiliated

- Qualifications- Non-medical or medical person with qualifications in basic medical sciences

- In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist

-Responsibilities:

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

11.4 Clinician(s) Member

-Affiliated

-Qualification: Should be individual/s with recognized medical qualification, expertise and training.

- Responsibilities:

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

11.5 Legal expert/s

-Non-affiliated

-Qualification: Is a qualified advocate / Judge with Bachelor or Master degree in Law. A legal person can be a retired expert in law (judge) or medico-legal expert.

-Responsibilities:

- The clear articulation of law by legal person improves the ethical analysis of study.
- Should review Clinical Trial Agreements (CTA), insurance document in clinical trials, MoU, regulatory approval, other site approvals, researcher's undertaking, etc.

11.6 Social scientist/ philosopher/ ethicist/ theologian

-Non-affiliated

-Qualification:

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

-Responsibilities:

- Ethical review of the proposal, Informed Consent form (ICD) along with the translations.
- Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any
- Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.
- The Social Scientist will visit the site along with other members and witness the informed consent process and interview the subjects enrolled in the study. This procedure is followed and the same will be documented in the concurrent IEC meeting.

11.7 Lay person(s)

- Non-affiliated

-Qualification:

- Literate person from the public or community
- Has not pursued a medical science/ health related career in the last 5 years
- May be a representative of the community from which the participants are to be drawn

- Is aware of the local language, cultural and moral values of the community
- Desirable: involved in social and community welfare activities

-Responsibilities:

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

11.8 Ethical Obligations and Expectations of EC members:

Confidentiality disclosure agreement will be signed by all the EC members on appointment (Appendix-V). Abide by the decision of EC, follow the SOP's for EC action, and completion of work within timelines.

All members should maintain absolute confidentiality of all discussions during the meeting. Conflict of interest should be declared by members of the EC.

All the members sign the conflict of interest (COI) for each clinical trial separately on the day of IEC meeting (Appendix-VII). Any member who has conflict of interest will not sign the proforma and He/ She will inform the IEC before the meeting either by telephone / inwriting.

11.9 Expert Member/ Independent Consultants/ Subject Expert:

- Subject matter experts may be invited to offer their views on review of research protocols, therapeutic area and causality assessment for SAE, however the expert members or independent consultants will not be voting members.
- Their inputs shall be maintained on record and considered when reaching a decision. This is to ensure that scientific review is appropriate, approval of the

trial meets regulatory requirements and vulnerable participants are protected from undue risk. i.e. a cardiologist for cardiac disorders and a pediatrician for review of pediatric studies, psychiatrists for psychiatry Studies. Similarly based on requirements of research areas like HIV, genetic disorders, etc., it is desirable to invite an expert from specific patient groups to the committee meeting, like a social worker who has experience in working with HIV patients can be invited.

- Subject expert will sign the confidentiality agreement on appointment and the Conflict of Interest will be declared before the meeting (Appendix-VI). They will give their opinion after a detailed assessment of the clinical trial document and its scientific validation (through checklist) and give their opinion accordingly. This will be recorded in the minutes of the meeting. The CV of the subject experts will be collected and made available in the IEC office.

12. PROCEDURE FOR SELECTION, APPOINTMENTS, RECONSTITUTION OF EC MEMBERS

12.1 Ethics Committee Members Selection

i. EC members are selected based on appropriate diversity, including consideration of race, gender, cultural backgrounds, specific community concerns in addition to representation by multiple, diverse professions, knowledge and experience with vulnerable subjects, and inclusion of both scientific and non-scientific members.

ii. The appointments are made by the Principal, JSSMC, authority to the IEC based on the EC requirement and the, members are selected after their Curriculum Vitae is reviewed to confirm the qualification. The acceptance is communicated to the appointed EC members. The members are then appraised about the responsibilities of the EC and their role in EC functioning.

iii. Once the member agrees to be a part of EC, this is informed to the office of institution, Chairman and other members of the committee. It is recorded in the minutes of the meeting and updated in the SOP. The members are then formally introduced in the EC meeting by the institution designee/ Member secretary.

iv. The structure and composition of EC must be appropriate to the amount and nature of the research that is reviewed and also to meet the ICMR guidelines.

12.2 Appointments, Resignation and Reconstitution Procedures

12.2.1 Criteria for Selection of Members

Members shall be selected in their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience in the domain field and profile and availability of time for spending to review and monitor the progress of the studies. Listed below are some criteria that are applied when assessing candidates for becoming a member of the IEC:

- The head of the Institute (JSS Medical College & Hospital) will appoint an EC chairperson, to serve the IEC. Any change in appointment, including reappointment or removal, requires written notification.
- Have a strong personal commitment to the interests of research participants who take part (or are asked to) in health care research.
- Have a strong personal commitment to ensuring the highest standards for health care research. Be a good communicator with a practical approach and confidence to voice his/her opinions.
- Be able to discuss issues with people who may not agree with the member including being able to influence others from a range of backgrounds.
- Be able to demonstrate an ability to contribute to the work of the IEC.

- Understand the requirement for confidentiality in issues faced by an IEC.
- Be willing to undertake training to equip to carry out his/her role.
- Need to be confident about expressing and supporting their own opinions.
- Live in, or close to, the geographical area of the institution and IEC.

12.2.2. Procedure for Selection of IEC Members

- Selection of members is by invitation by the Head of the Institution. Individual with prior training or experience in ethical review is preferred though it is not mandatory eligibility criterion for invitation. Acceptance of the chairperson / membership shall be purely voluntary and member's consent should be in written format.
- The head of the Institute (JSS Medical College & Hospital) will appoint an EC chairperson, to serve the IEC. Any change in appointment, including reappointment or removal, requires written notification.
- EC Member Secretary is appointed by the head of the Institute (JSS Medical College & Hospital) in consultation with the Chairman who will be from outside the institution.
- The members of IEC will be appointed for a period of 5 years and the Chairperson of the IEC will be elected from this group by the Head of the Institution in consultation with all the IEC Members.
- At the end of 5 years the committee is reconstituted, and 50% of the members will be replaced by a defined procedure.
- If any member is absent for three consecutive meeting, he/she will be disqualified from the membership of the committee.
- If a member resigns for whatsoever reason or in case of death, new member will be appointed within one month of resignation/ disqualification/death.

- The members have to inform the IEC at least one month in advance before resigning for the membership of IEC.
- The members will be intimated by IEC, at least one month in advance about disqualifying the members from the membership of IEC with justification for the action taken.
- The specific & corresponding member will be replaced within one month by after identifying the resource person.
- IEC will inform in writing and by mail to DCGI in case of any change in the IEC membership or Constitution.

12.2.3 Appointment of Alternate Members:

IEC alternate members are selected based on appropriate diversity, including consideration of race, gender, cultural backgrounds, specific community concerns in addition to representation by multiple, diverse professions, knowledge and experience with vulnerable subjects, and inclusion of both scientific and non-scientific members. The appointments are made based on the IEC requirement and the members are selected after their Curriculum Vitae is reviewed to confirm the qualification. The acceptance is communicated to the appointed IEC members, the members are then appraised about the responsibilities of the IEC and their role in IEC functioning. Once the member agrees to be a part of IEC, this is informed to the office of IEC. It is recorded in the minutes of the meeting and updated in the SOP. The members are then formally introduced in the IEC meeting.

Functions of Alternate Members: The alternate members substitute the primary members in the event the primary members are unable to attend the scheduled EC meeting. The functions, roles and responsibilities of the alternate members are similar to that of the primary members they are representing for & during the meeting they are voting member

12.2.4 Membership Tenure

The duration of appointment is for a period of 5 years. At the end of 5 years the committee will be reconstituted. If need arises, the Institutional may dissolve the EC at any given time and reconstitute a new EC.

12.2.5 EC Members Resignation/ Removal Process

i. EC Members Resignation Process

- A member can be replaced in the event of death or long-term non-availability for any action, not commensurate with the responsibilities laid down in the regulatory guidelines or deemed unfit for a member will be replaced suitably within two months.
- The sitting member of the EC can tender his resignation from the committee. The following is mandatory for the smooth running of the EC so that the quorum is not affected.
- Adequate reasons to be provided for resignation.
- IEC Members to continue in the position till the next member with similar qualification and position is replaced with adequate reasons from the committee with proper reasons to do so.

ii. EC Members Removal Process

The IEC members are regularly evaluated for their participation and attendance for EC deliberation. If conduct of the EC member is not as per the regulations and guidelines this will be brought to the notice of the institution head by the EC chairperson

iii. Individuals who are responsible for business developments are prohibited from:

- Serving as member or ex-officio members on the EC
- Carrying out day-to-day operations of the review process

12.3 Attendance Requirements

Members should attend all scheduled meetings. If a member is unable to attend a scheduled meeting, they should inform the EC as soon as possible. If the inability to attend will be prolonged, a request to replace him/her is submitted to the chair or EC Member secretary.

Minimum requirement of attendance should be more than 80% of the specific category to be present in every meeting

If an EC member is to be absent for an extended period of time, such as for a sabbatical, he/she must notify EC at least 30 days in advance so that an appropriate replacement can be obtained by sending the details of new replaced member to DCGI.

12.4 Process of evaluation of EC members

The performance of the EC will be reviewed & evaluated on annual basis provided with the questionnaire and interviews. Members will also be audited for their knowledge evaluation. Their attendance is also evaluated annually. The EC members have to have a **more than of 80 percent attendance as mandatory requirement.** Attendance is evaluated by the number of meetings attended. EC members are also evaluated for their participation in the EC deliberation this will be evaluated by the assessment of draft minutes based on the above criteria. The data will be recorded in the EC member secretary evaluation checklist and the same will be reviewed by the EC Chairman. If the EC members are not acting in accordance with its mission, following the laid down policies and procedures, has an undue number of absences or not fulfilling the responsibilities of the committee, the organization will decide whether to continue the service or to terminate the member. Institution has the right to remove any IEC member if Conflict of Interest (COI) is reported by the EC Member secretary.

13. ROLES AND RESPONSIBILITIES OF IEC:

All the members of IEC are responsible for review and according approval to safeguard the rights, safety and well-being of human subjects. Ethics committee shall decide on the form/type of consent to be taken or its waiver based on the degree of risk that may be involved. All non- exempt human subjects research conducted must be reviewed and approved by the IEC prior to the initiation of the research.

i. IEC will review and approve different types of study protocols and relevant documents involving human participants in order to safeguard the dignity, rights, safety and well- being of all actual and potential research participants.

ii. The goals of research are never permitted to override the health, safety and well-being of the research subjects. The basic responsibility of the Institutional Ethical Committee is to ensure a competent review of all scientific and ethical aspects of the project proposals received and execute the same free from any bias and influence that could affect their objectivity.

iii. The IEC members are required to follow the SOP, regulations and guidelines. If the EC members wants any change in the SOP, it will be documented and changes will be made once in five years OR addendum is permitted as and when required to update the SOP and this will be communicated to all the PI in writing and the same SOP addendum is trained to all IEC members.

iv. The EC will ensure that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non-maleficence and Justice are taken care of while execution of the proposed research. For this purpose, it will look into the aspects of informed consent process, risk- benefit ratio, distribution of burden, benefit and provisions for appropriate compensations wherever required.

v. It will review the proposals before start of the study as well as monitor the research throughout and after completion of the study through appropriate

documented procedures. For example, continued annual reviews, site visits, final reports, Audit report of IEC members and study close out reports etc.

vi. It will also examine compliance with regulatory requirements, applicable guidelines and laws. The mandate of the EC will be to review all study protocols involving human subjects to be conducted at the hospital, irrespective of the funding agency.

vii. EC takes responsibility to protect the privacy and confidentiality of all the research participant especially when it's related to studies involving disease areas like HIV.

viii. EC will not review or approve studies in which the sponsor / CRO is affiliated with the institution.

IEC is responsible to:

a) To safeguard the dignity, rights, safety and well-being of all trial subjects.

b) To ensure that universal Ethical values and international scientific standards are expressed in terms of local community values and customs.

c) To assist in the development and the education of a research community responsive to local health care requirements

d) The committee will review the projects which are associated with pharmaceuticals, biomedical devices, epidemiological studies, retrospective studies, nutraceuticals, isolated components of herbal products.

e) To ensure the following in Clinical trial projects:

i. Are sound in design and are conducted in accordance with ICH-GCP/ Indian GCP and other regulatory requirements as appropriate.

ii. Do not compromise safety of study patients.

iii. Are conducted under the responsible investigator qualified by education, training and experience in the respective research field.

iv. Patients enrolled in the study must have given voluntary informed consent.

v. IEC insist on reconsenting of ICF as per ICMR guidelines & SOP of IEC, JSSMC. To assist in the development and the education of a research community responsive to local health care requirements.

f) Revision of SOP will be done once in 5 years / earlier if required, prepared by Member Secretary and approved by Chairman and reviewed by the external member or internal members and all other members with effective date and termination date and the same will be trained to all the IEC members.

g) IEC will review the proposals before start of the study and monitor till the completion of the study once in 6 months.

h) The IEC will monitor the projects every year / end of the project whichever occurs earlier.

i) IEC will review any non-compliance or protocol violation submitted by the PI in the concomitant meeting.

j) The stake holders are communicated through the PI as and when the situation arises (viz., SAE review, & submission of SAE report to DCGI)

k) IEC will inform the Principal, JSS Medical College or Director, JSS Hospital, Mysore in case of PI violating the guidelines of SOP in spite of repeated reminders.

14. EC PROPOSAL SUBMISSION AND MEETINGS

14.1 Procedure for submission of proposal.

The proposals shall be addressed to the chairperson/ Member Secretary of the Ethics Committee and shall be submitted to the IEC office at least 2 weeks prior to the IEC meeting.

The IEC office will communicate with the applicant and will acknowledge receipt of the application with supporting annexes.

The Member Secretary shall screen the proposals for their completeness as well as with regard to any clarifications or additional documentation that may be required as per checklist along with his / her remarks.

Appropriate number of copies of each document should be submitted.

Investigators shall be notified via telephone / email to present the protocol during the IEC meeting. IEC will review all clinical trials under the following headings which serves as checklist for submission of various documents.

14.2 Clinical trial Protocol Review procedure: -

For a thorough and complete review, all research proposals (5 hardcopies & a Softcopy) should be submitted in the following manner:

- Study Submission Form with DCGI / CTRI registration number.
- Patient Information Sheet & Informed Consent Forms (ICFs) -in atleast 3 languages [English, Kannada, and Hindi are mandatory] and understandable by the subject along with certificates of translations and back translations.
- Study Protocol
- Investigator's Brochure
- Case Record Form (CRF) or paper copy of electronic CRF

- A recent, signed and dated curriculum vitae of the Investigators indicating qualifications and relevant experience.
- Investigator's Undertaking (Appendix XII)
- Agreement to comply with national regulations and guidelines and study protocol.
- Regulatory clearance from appropriate regulatory authorities i.e. CDSCO approval/ DCGI/ ICMR/ Health Ministry Screening Committee (HMSC) (if applicable)
- For international collaborative study Memorandum of Understanding between the collaborating institutes
- Clinical Trial Agreement (if applicable)
- Insurance/ Indemnity policies, indicating who are covered (if applicable)
- Participant recruitment and enrollment procedures.
- A statement describing any reimbursement and compensation for study participation (including expenses and access to medical care) to be given to research participants.
- Any other important information relevant to the study
- Decision of other Ethics Committees (If required/ asked for)

14.3 IEC Meeting:

i. **Frequency of Ethics Committee Meetings:** Ethics Committee meeting will be held regularly once in 6-8 weeks either offline or online.

However, additional meeting/s may be called if required; meeting could be cancelled if the quorum (as per NDCT 2019 guidelines) fails to meet. This will be communicated to the staff and the PI over telephone or through letter and the next date is also confirmed.

ii. Venue of the meeting will be in the JSS Medical College, Mysore.

iii. All proposals to EC for initial full review should be submitted at least 2 weeks prior to meeting to EC office. However, the documents for continuing review to be submitted 1 month prior to the expiry of approval date deadline given by the EC. DCGI approval, contract and CTRI number may be submitted 3 days prior to the proposed EC meeting date.

If not submitted 3 days prior to IEC meeting, Final approval will be given only after submission of the remaining documents as per checklist like, DCGI approval/Application to DCGI, Signed copy of Clinical trial agreement, CTRI Registration, etc.

iv. The Principal investigator designated for a given research project should submit the protocol and study related documents with a covering letter for review by the Institutional Ethical Committee. The documents required for the submission by Principal investigator for consideration and review is mentioned in details in Appendix VIII & Appendix IX of the SOP.

v. A copy of (EC copy) all the documents as per the check list should be submitted duly signed by the PI to the EC for consideration. A proforma/ synopsis/ summary of the Protocol/ IB/ ICF/ COI/ undertaking by the PI/scientific committee approval are mandatory. The ethical committee review charges for the new drug trial / project are Rs. 75,000/- (excluding service charges & GST) and amendment charges is Rs. 20,000/- (excluding service charges & GST).

vi. ICF in English needs to be submitted initially by the PI for the meeting, once English gets approved the PI can go for the translation of the same in other languages & needs to provide the translation certificates for the translated documents. Back translations need not be submitted to EC for approval.

vii. A copy of the documents like, protocol, ICF, CTA are to be sent to the external EC members by the EC.

viii. In case of any amendment(s) to the study protocols requiring approval from

the DCGI the EC will give letter of approval on receiving the DCGI approval letter or acknowledgement of submission to DCGI. A copy of the amendment along with the summary of changes needs to be submitted to IEC.

ix. All study protocols should be submitted in the prescribed application form, the details of which are given under documentation.

x. The date of meeting will be intimated to the PI or Co PI through mail/ hard copy communication/telephonic communication by the EC staff outlining the agenda of the EC meeting. PI needs to make power point presentation of his/her study in the EC meeting.

xi. The decision will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

14.4 Documentation Requirements:

- For a thorough and complete review, all research proposals should be submitted in the prescribed application form with a covering letter from the PI (5 hard copies of all the relevant documents & CD containing all the relevant documents) ICD should include the amount and schedule of all payments to the subjects of the trial.
- Name of the applicant with designation
- Name of the institute/ hospital / field area where research will be conducted.
- Protocol of the proposed research (for scientific rationale) / Amendments to the Protocol. Proforma/synopsis/summary of the protocol needs to be enclosed with the study documents.
- Ethical issues in the study and plans to address these issues.
- Proposal should be submitted with all relevant enclosures.

- Investigator undertaking has to been signed and dated by the PI of the trial (Appendix XII).
- Informed Consent Document, including patient information sheet and informed consent form in local languages needs to be submitted only after English gets approved from the EC, for the safety and welfare of the research subjects and to protect the rights of research subjects (Appendix XI).
- For any drug / device studies, all relevant pre-clinical animal data and clinical trial data from other centers within the country / countries, if available.
- Curriculum vitae of the principal investigators & Co investigator along with the MRC.
- Any regulatory clearances required.
- Other financial issues including those related to insurance
- Report of any SAE to EC.
- Statement of conflicts of interest if any
- Agreement to comply with the relevant national and applicable international guidelines.
- A statement describing any compensation for study participation (including medical expenses and access to medical care) to be given to research participants as per the new DCGI compensation clause which also must be added in the ICF.
- All recruitment strategy methods and advertising materials needs to be submitted for EC approval before implementing the same. Without prior approval from the EC, these methods cannot be implemented.
- Information for EC to evaluate the researcher's provisions to protect the privacy and interests of the participants.

- Information for EC to evaluate the researcher's provisions to maintain the confidentiality of the data.
- Researcher to provide a description of provisions for monitoring data to ensure the safety of Participants, when appropriate. Any other study related information.
- The EC will conduct an analysis of Risk benefit assessment as per Assessment tool and assess the risks and potential benefits.
- EC determines whether Selection of participants will be equitable such as, gender, age, etc.
- The setting in which the research will be conducted.
- Whether prospective participants will be vulnerable to coercion or undue influence. The selection (inclusion/exclusion) criteria.
- Participant recruitment and enrollment procedures.
- The amount and timing of payments to participants.

14.5 EC Review Procedures

i. The meeting of the EC will be held once in 6 to 8 weeks.

ii. The proposals for initial full review (either hard copy or soft copy) will be circulated to members at least 2 weeks prior to the scheduled EC meeting by the EC staff.

iii. Decisions will be taken by consensus after discussions and voting.

iv. Researchers will have to be present during the initial full review & has to make a power point presentation of his/her study. In absence of the PI, Co-PI can present the study. In absence of both PI & Co-PI the study will be taken up for the next EC meeting & the same will be communicated to the PI. PI may be invited to offer clarifications, if need be, for the continuing Review/ SAE/ deviation/ violations

vi. Independent consultants/experts will be invited to offer their opinion on

specific study protocols involved with recruitment of vulnerable subjects.

vii. The decisions will be minuted and Chairperson's approval taken in writing.

viii. The Member Secretary evaluates the protocol and ensures that at least one EC member is knowledgeable about or experienced in working with such subjects will be present at the meeting.

ix. If the IEC requires a major change, the study is deferred pending clarification from the research for review at the next convened IEC meeting.

14.6 IEC approves research with conditions:

- Minor or prescriptive changes or requirements may be reviewed for approval by the IEC chair or designated IEC member
- The date of approval is the date the condition was determined to be met
- If the research expires before the conditions are reviewed and approved, all research activities must stop until approval is obtained.
- Limits are not placed on the number of items on the agenda.
- All documents submitted to IEC 2 weeks prior to the IEC meeting will be taken in the agenda.
- Except for the documents pertaining to the SAE, unanticipated problems will be taken irrespective of the timelines. Other functions of the agenda include informing the IEC members of research protocols approved by the expedited process, updating the IEC members on the order's released by the Licensing authorities with respect to the clinical trials, important notifications of the trials & training programmes for IEC members.

14.7 Review Procedures Additional information.

- The Ethical Committee is to be notified of any payments proposed to be made to study patients towards reimbursement of incidental expenses.
- Advance notice of 14 days before each meeting will be sent to the IEC

members, along with the agenda and remarks of member secretary along with the protocol copy, which they will return to IEC office on the day of meeting, 2 copies will be kept in IEC office, the remaining clinical trial protocol documents are sent for shredding to JSS AHER shredding machine for document destruction within 15-20 days after the meeting.

- Meeting date will be fixed by the member secretary in consultation with the Chairman and other members.
- The requisite quorum of at least 5 members (Appendix II) is required to be present at each review meeting.
- A study team member be called to the meeting to present the study or answer specific queries. However, he/she will not participate in the decision making / voting process of that study even if he/she is a regular member of the IEC.
- The Study Team Member's non-participation in the decision making/voting process will be recorded in the response letter from the IEC.
- The decision of the committee will be taken by a majority vote after the quorum requirements are fulfilled to recommend/reject/suggest modifications for a repeat review or advise appropriate steps. If subject experts are invited to offer their views, they will not take part in the voting process.
- The member secretary, will record the Minutes of the meeting and ratify the same to the members in the next meeting.

14.8 EC Approval process

- Only those IEC members who are independent of the investigator team and the sponsor of the trial and who are present in the meeting have voting rights and this will be documented in the minutes of meeting.
- Once the majority of members present approve the project and the quorum

is met, the final approval is given.

- Committee will give its opinion on the project in one of the following ways:
  - Approval
  - Conditional Approval
  - Approval with Amendments Deferment
  - Discontinuation of a previously Approved project
  - Not Approved/ Rejected

- Members will discuss the various Scientific & ethical issues before arriving at a consensus decision along with detailed discussion of scientific validity, risk assessment, expected benefits which are documented. (Checklist, Scientific validity, risk assessment, expected benefits are enclosed as Appendix- XIII & XX)
  - All the members should declare the COI before the meeting (Appendix-VII). The member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises, and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.
  - Decisions will be made only in meetings where quorum is complete.
  - Only members can make the decision. The expert consultants will only offer their opinions.
  - Specific suggestions for modifications and reasons for rejection will be given and the same will be noted in the proceedings of the meeting.
  - In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed will be specified.
  - Modified proposals will be reviewed by the committee to arrive at a conclusion of approval/disapproval.
  - All the 3 above situations will be documented in the minutes of meeting and conveyed to PI.

- The conditional approvals are issued from the next day within a week period highlighting the pending documents to be submitted for getting the final approval, and also notifying that the recruitment of subjects into the trial must be undertaken only after receiving the Final approval.
- The Final approval is given after fulfilling the suggestions made by IEC and submitting of remaining documents as per check list of documents to be submitted & reviewed for IEC approval (Appendix X)
- The final approval is valid for one year from the date of issue.
- In all cases, the study will be unambiguously identified by protocol title and number. All documents reviewed will be listed in the response letter, which will also state the list of members present and date of the meeting at which the study was reviewed.
- The outcome of the committee's review will be recorded in writing and conveyed to the Principal Investigator within a week of IEC meeting. The response letter will include the signature and date by the Ethical Committee chairperson / Member Secretary.
- To already approved research proposals: All amendments of research proposal to be approved shall be submitted immediately to the committee for its review. No change in the protocol be initiated without prior approval of the committee except when necessary to eliminate immediate hazards to the patients or when the changes involve only logistic or administrative aspect of the trial/study.
- Review of Ongoing studies: The committee will conduct continuing review of each ongoing study by obtaining the status report from the Principal Investigator/sponsor at intervals appropriate to the degree of risk to the human subjects e.g. in pediatrics trial reports are at more frequent intervals but at least once in six months/ earlier if study closes with in one year.
- Submission of the annual report of the clinical trial is mandatory for continuation of the study.

- The IEC will monitor and audit all the Clinical Trials through Clinical trial audit & Site visit Report by IEC members to safeguard the safety and wellbeing of subjects enrolled in the trial.
- The IEC maintain the confidentiality and privacy of the subject and instruct the PI about the same.
- IEC will promptly review all serious adverse events reported to it and decide if any urgent action is warranted to be taken e.g. amendment to the protocol, continuation of study or its termination. As per Appendix XXIII of SOP (SAE Reporting)
- Correspondence between the IEC and the Principal Investigator/Study Team and other relevant records (response letter, minutes of meetings, composition etc) will be retained for a minimum period of 5 years after completion of the trial.
- The PI will inform the IEC about issues related to the Clinical Trial through notifications like submission of CIOMS, additional documents, amendments, etc. The same will be acknowledged by the IEC.
- The IEC ensures complete and effective administration of informed consent process of the subject (Appendix XIV).
- The IEC directs the PI to take care of the subject if an SAE occurs during the trial, Standard of Care must be given to the subjects as per norms during the stay at Hospital, whether the SAE is related to the drug under trial / trial procedure/ trial device or not.
- IEC insists on ICF to be signed by LAR/IW where a subject is not able to give informed consent (e.g. an unconscious person or a minor or those suffering from severe mental illness or disability) the above information should be provided to the legally acceptable representative (LAR). If the subject or his/her legally acceptable representative is unable to read/write – an Impartial witness (IW) should be present during the entire informed consent process.

- IEC imposes that, the Investigator has the duty to communicate to the subjects/ LAR/ IW, all the information necessary for informed consent. There should not be any restriction on subject's right to ask any questions related to the study as any restriction on this undermines the validity of informed consent.

- Institutional Ethics Committee undertake a Detailed verification and review of the document like undertaking by the investigator for clinical trial projects along with bio-data of the PI and GCP training certificate of the PI and assess the credentials of PI/CO-PI to carry out the clinical trials at the site before approving the Clinical Trials.
- IEC considers a feasibility study of the site and the following infrastructure facility before approval of the clinical trial:

- Clinical trial site facility for all the phases of the clinical trial (From Phase I to Phase IV) like ICCU, MICU, SICU, Emergency, Inpatient facility, outpatient facility, Infrastructure facility, Equipment facility, Lab facility, Storage facility for trial medications.
- Qualification of the personnel in each department where the study is going to be conducted
- Informed consent process facility including facility for audio visual consenting.
- Transportation facility
- Facility for communication with PI/ Co PI for emergency situations and IEC authorized personnel for any trial related grievances.

14.9. SAE review procedure:

- The discussion of the SAE reported by the PI can be done in a separate scheduled expedited meeting or during the regular meeting considering the timelines.

- The PI has to submit the initial SAE report in both hard and soft copies to IEC within 24 hours of their occurrence (Appendix XXII) & follow up report to be submitted within 14 days of reporting of SAE, if the investigator fails to report SAE within the stipulated period, he/she has to furnish the reasons for delay in reporting
- The member secretary will present the details of the SAE reported by the PI during the meeting and after detailed discussion of the same in the meeting, the opinion of the IEC will be sent to DCGI within 30 days of receiving the report of the SAE.
- The members of the IEC will visit the site for each SAE reported to collect the details of the SAE and status of the other subjects enrolled in the study.
- IEC monitors the SAE in the site through the in-house members posted exclusively at JSS Hospital and ensures the standard of care given to the subjects till their stay at JSS Hospital.
- IEC insists on free medical care for subjects with SAE till DCGI decision is received and insists the PI about this procedure of standard of care to the subjects.
- IEC suggest SAE compensation to the enrolled subject as per NDCT 2019 guidelines.
- The IEC discusses each SAE in the full board meeting before sending its opinion about the SAE to DCGI. The documents that are sent to DCGI are:
- Covering letter
- Brief report of SAE
- Causality assessment report
- Minutes of Meeting of that particular SAE

The details of the SAE are presented to the IEC by the Member Secretary

during the IEC Meeting after detailed discussion and deliberation with all the members the report will be sent to DCGI along with the above-mentioned documents. Due consideration is paid for those SAE's which are to be awarded with compensation following the guidelines of the DCGI and New drugs & Clinical trial rules 2019 for the calculation of compensation to be awarded.

14.10 Expedited review Policy

- The proposal may be submitted for expedited review where the investigator requests 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 Chairman / Member Secretary will take the final decision regarding whether a study with 'not more than minimal risk' qualifies for an expedited review & designate the primary reviewers with quorum.

IEC may do expedited review only if the protocols involve –

a) Proposals that pose no more than minimal risk, 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).

b) Modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s).

c) Revised proposals previously approved through expedited review, full review or continuing review of approved proposals.

d) 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.

14.11 Additional Elements of review considered during IEC meeting.

a. Examination of predictable risks/harms.

b. Examination of potential benefits.

c. Procedure for selection of subjects in methodology including inclusion/exclusion, withdrawal criteria and other issues like advertisement details.

d. Management of research related injuries, adverse events.

e. Compensation provisions.

f. Justification for placebo in control arm, if any.

g. Availability of products after the study, if applicable.

h. Protection of privacy and confidentiality.

i. Involvement of the community, wherever necessary.

j. Plans for data analysis and reporting

k. Adherence to all regulatory requirements and applicable guidelines

l. Competence of investigators, research and supporting staff

m. Facilities and infrastructure of study sites

n. Criteria for withdrawal of patients, suspending or terminating the study.

14.12 Decision-Making

- At each of the review meetings, it will be ensured that at least two external members not affiliated to the institution are present.

- Members will discuss the various issues and make consensus decision.
- A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.
- Decisions will be made only in meetings where quorum is complete.
- Only members can make the decision. The expert consultants will only offer their opinions.
- In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.
- Modified proposals may be reviewed by an expedited review through identified members.
- It is ascertained that the PI will not participate in the decision- making/voting process if he/she is a regular member of the EC.

14.13 Minutes Recording

- Minutes of the meeting are recorded for each meeting narrating the details of deliberations that occur in the meeting and discussion of scientific validity and opinion of lay person, social scientist, legal expert, clinician & basic medical Scientist and type of approval given by IEC as on the day of meeting.
- The minutes of the meeting also narrates the details of all the activities of the IEC from the previous date of meeting like details of conditional approval given, final approval given, protocol deviation and protocol violations submitted, safety letters and CIOMS submitted, site visit details and audit report etc.

14.14 Communicating the Decision

- All IEC Decision will be communicated in writing duly signed by the Member

Secretary within 7 days of the meeting.

- The IEC will give its views in writing, clearly identifying the study protocols, the documents reviewed and the clarifications needed in the clarification form.
- Full Approval is valid for a period of one year from the date of final approval, Renewal of approval is given from IEC only after submission of interim report after one year and Application for Renewal of approval must be submitted 1 month before the completion of validity of approval
- Suggestions for modifications required prior to its approval, if any
- Disapproval/negative opinion: The reasons for rejection will be informed to the researchers.
- Termination / suspension of any prior approval / favorable opinion.
- The date of expiry of the approval for the continue review will be mentioned in the letter. Following which the principal investigator needs to give a letter to continue the trial 1 month prior to the date of expiry of the study.

14.15 Suspensions and Termination of EC Approval

IEC will terminate or suspend the study in the following circumstances:

i. When research is not conducted in accordance with IEC requirements.

ii. When research is associated with unexpected serious harm to the participants.

iii. The terminating of the approval would be done during or after the follow up or ongoing review. When the research is terminated or suspended the IEC will review the process of the informing the participants of the termination and also the process of follow-up of the participants with AE /SAE.

iv. Other than the convened IEC the DCGI (licensing Authority) can suspend or terminate the research.

v. Organization head (Principal) can suspend the research

- If it becomes aware of the fraud or
- If the Conflict of Interest is not declared

Organization will suspend but not terminate the research and shall put across to the IEC.

1. IEC Communication of Suspending or Terminating the Trial:

In case of premature termination or suspension of the study, notification is given from the IEC to the PI, DCGI and to be reported to the sponsor. The IEC member secretary is responsible for this notification. The notification will contain reasons for termination along with the summary of results till date the suspension may be under following circumstances:

- Complaints of unethical practice
- Safety concerns- Reference to SAEs/ SUSAR
- Revoking the medical license of the PI
- Protocol violations (Major)

2. Prompt Reporting of Suspension and Termination of IEC Approval

i. In any situation the IEC will inform the enrolled subjects about the suspensions and Terminations of the Clinical trial through phone/letter within 7days

ii. IEC Will Inform the Principal Investigator about the Suspensions and Terminations of the Clinical Trial through Letter within 7days

14.16 Record Keeping and Archival

The IEC Will Archive the Following Documents:

i. Consent Forms of All IEC Members

ii. Curriculum Vitae of All Members Of IEC.

iii. Copy of all study protocols with enclosed documents, progress reports, and SAEs.

iv. Agenda and Minutes of the meetings duly signed by the Member Secretary.

v. Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.

vi. Copy of all correspondence with members, researchers and other regulatory bodies

vii. Final report of the approved projects will be archived.

viii. The correspondence between the IEC and the Principal Investigator/Study team

ix. All documents listed above will archived in the archival room for a period of five years after completion of the research. The Archival room should be near the IEC office for the easy access of documents during the inspection by the regulatory agencies/ authorities

x. All documents pertaining to complaints received with respect to coercion, non compliance, SAE reporting.

xi. IEC records are accessible for inspection and copying by authorized representatives of regulatory agencies at reasonable times and in a reasonable manner.

xii. In order to allow a reconstruction of a complete history of EC actions related to the review and approval of the protocol, the IEC records include copies of:

- Recruitment materials
- Data and safety monitoring reports if any

- Modifications to previously approved research.
- Unanticipated problems involving risks to participants or other significant new findings.

14.17 Review procedure For Bio Medical Devices: -

The committee review the following details in addition to the regular procedure of review:

- A medical device is defined as a medical tool which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means but which may be assisted in its intended function by such means. It may be an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals for one or more of the specific purposes of:
  i. detection, diagnosis, prevention, monitoring
  ii. treatment or alleviation of any physiological condition or state of health, or illness
  iii. replacement or modification or support of the anatomy or congenital deformity
  iv. supporting or sustaining life
  v. disinfection of medical devices; or
  vi. control of conception.

- Details of the device with photographs, technical details including Materials used in the manufacturing of the device, properties and safety of those materials used in the device, mechanism of operation, expected benefits of the device. Advantages and Disadvantages of new device over the existing device (Whenever applicable), earlier data about the device (If available with respect to application, usage etc.), improvisation made in the device

compared to the existing device. Any other details IEC follow DCGI guidelines for approving the Clinical trials of medical devises as: - notified medical devices are regulated as Drugs under the Drugs and Cosmetics Act 1940 and Rules made there under in 1945.

- Clinical trials should be conducted in accordance with the ethical principles described in these guidelines, Indian GCP as well as applicable regulations for medical and medicated devices, that is, GSR 78 (E) dated 31.1.2017 or as per amendments/modifications issued from time-to-time.
- Clinical trials should be conducted in accordance with the ethical principles described in these guidelines, Indian GCP as well as applicable regulations for medical and medicated devices, that is, GSR 78 (E) dated 31.1.2017 or as per amendments/modifications issued from time-to-time.
- Devices could be used internally or externally for diagnosis, treatment, mitigation or prevention of disease or disorder. Depending upon risks involved, devices (other than in vitro diagnostic devices) are classified as given
- Classification of medical devices

Class	Level of risk	Device examples
A	Low	Thermometers/ bandages /tongue depressors
B	Low–moderate	Hypodermic needles /suction equipment
C	Moderate–high	Lung ventilator /bone fixation plate
D	High	Heart valves/implantable defibrillator

Devices used for in vitro diagnosis could be a reagent, calibrator, control material, kit, instrument, apparatus, equipment, system, or specimen receptacle, whether used alone or in combination with any other such devices, that is intended by its manufacturer to be used in vitro for examination of any specimen, including

any blood or tissue donation derived from the human body solely or principally for the purpose of providing information.

The information could be related to:

(i) a physiological or pathological state

(ii) congenital deformity

(iii) determining the safety and compatibility of any blood or tissue donation with a potential recipient thereof or

(iv) monitoring of therapeutic measures.

Diagnostics devices can be notified and non-notified (Appendix XXV). Notified are in vitro diagnostic devices for testing HIV, HBsAg, HCV and blood grouping. Non-notified are those for testing malaria, TB, dengue, chikungunya, typhoid, syphilis, cancer markers, etc.

14.18. Phytopharmaceutical drugs:

The Drugs and Cosmetics Rules, 8th Amendment, 2015 defines a new class of drugs called phytopharmaceutical drug as “purified and standardized fraction with defined minimum four bio-active or phyto-chemical compounds (qualitatively and quantitatively assessed) of an extract of a medicinal plant or its part, for internal or external use of human beings or animals for diagnosis, treatment, mitigation or prevention of any disease or disorder but does not include administration by parenteral route”.

14.19 Pharmacogenomic study

- A separate Informed Consent Form consisting of the pharmacogenomic details collected or studied should be included.
- A clause can be included in the contract that the pharmacogenomic results will not be used for commercial purposes (cloning or generating immortalized cell lines) & the same to be reflected in the Informed Consent Form

- The pharmacogenomic as an end point will be accepted with clarity to the above point and it needs to reflect in the Informed Consent Form
- The subject has right to know the areas of usage of the sample and the results
- It is the responsibility of the EC to see that the quorum is met and the timelines are followed for giving the communication letters to the PI within 10 days of the EC meeting in case of clarifications or approval.

15 ELEMENTS OF REVIEW

The IEC will review the following elements listed below but not limited to;

15.1 Risks to participants

i. Risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.

ii. Risks to participants are minimized whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.

iii. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.

15.2 Selection of Participants

- Selection of participants is equitable taking into account the purposes of the research, the setting in which the research will be conducted, the special problems of research involving vulnerable populations, the selection criteria, and the recruitment procedures (Appendix XXVI).
- IEC evaluates whether the selection of research participants is equitable when determining whether to approve research, or any changes to research.

To make this assessment, IEC will consider the following:

- Whether the purpose/nature of the research requires or justifies using the proposed population.
- The setting in which the research will be conducted.
- Whether there is an intention for the population to benefit from the research.
- Whether recruitment of participants, including any advertisements or payments, will be coercive or present undue influence.
- The inclusion/exclusion criteria for participants.
- Whether potential participants are vulnerable to coercion or undue influence, and what measures are being proposed to minimize the risks to these vulnerable participants.

Additional General Consideration for Participant Selection

- When research involves vulnerable participants, the IEC considers the following to determine whether the population is suitable, and whether the burdens of research are being distributed equitably.
- Inconvenience to participants (i.e., the time required, travel involved, restrictions on diet, or other activities), and any discomfort, or potential embarrassment in addition to the risks associated with the research procedures.
- Whether it would be possible to conduct the study with other, less vulnerable participants, and whether that would entail additional expense or inconvenience.
- Whether the convenience of the researcher, or possible improvement in the quality of the research, justifies the involvement of participants who may be susceptible to pressure or who are already burdened.

- Whether it is possible to reduce pressure on certain groups of participants to participate in research (such as by consulting with a representative of the group beforehand)
- Whether recruitment materials and consent documents are appropriate for the population, and do not include exculpatory language.
- IEC generally require that someone involved in the individual's care approach the potential participant first about study participation.

Investigators are required provide the following information to allow the IEC to determine whether the selection of participants is equitable:

1. The purpose of the research and the setting in which the research would be conducted.
2. Whether prospective participants would be vulnerable to coercion or undue influence.
3. The selection (inclusion/exclusion) criteria.
4. Participant recruitment and enrollment procedures.
5. The amount and timing of payments to participants.

Additional information:

1. Equitable Selection of Subjects: The reviewer checklist will document whether the reviewer feels that the selection of participants is equitable. EC members must check whether the selection of participants is equitable.
2. Vulnerable Populations: EC members must consider whether vulnerable participants will be involved and if so, whether safeguards are in place to prevent coercion or undue influence. EC members must ensure the following:

• None of the participants are likely to be vulnerable to coercion or undue influence.

• Additional safeguards been included in the study to protect the rights and welfare

of participants likely to be vulnerable to coercion or undue influence.

• If a vulnerable population is involved, an additional checklist is required.

3. Compensation: EC members must evaluate payment for participation in the trial- to determine that it is not coercive or present undue influence. EC members must also ensure that the compensation offered to the participants is appropriate in case of any SAE related to the intervention done in the trial.
4. Recruitment: EC members must evaluate the recruitment methods and advertisements. EC members must ensure that the recruitment methods, including advertisements, support an equitable selection of participants.

15.3 Safety Monitoring

IEC consider the Safety letters, DSMB report, CIOMS, SUSAR Details submitted by PI

When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.

The types of research (i.e risk trials vulnerable population) that the IEC considers provisions for monitoring the data collected to ensure the safety of participants are:

- Paediatric trials
- Mentally challenged
- Elderly population
- Placebo controlled trials

16 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 submission. The content of amendment is critically reviewed with justification in ethics point of view following Good Clinical Practice (GCP) guidelines. The consensus approval from the committee members regarding this is recorded and communicated to the Principal Investigator.

17 PERIODIC REVIEW AND OVERSIGHT

- The IEC conducts periodic review and oversight of all the ongoing trials at the site once in 6 months and once in every 3 months for clinical trials involving vulnerable population (Appendix XXIII).
- The Chairman/Member Secretary will identify and designate one or more members from IEC to conduct site monitoring of the study. The Secretariat will inform the Principal Investigator in writing about the date/time of monitoring visit and request for confirmation from the Principal Investigator or Co-investigator to be available for the monitoring visit.
- Any other cause as decided by IEC If required interim monitoring may also be conducted by a team of IEC members during the ongoing approved project or for specific causes as follows –
    - o Serious Protocol deviations reported
    - o Protocol involving particularly high-risk research
    - o Reported AE
    - o Non-compliance of progress report by the investigator
    - o Higher than the proposed recruitment of subjects in the study
    - o Complaints received from participants

- Final report should be submitted at the end of study
- SAEs and the interventions undertaken should be intimated through SAE reporting form as per the DCGI specifications & sponsor specifications in a prescribed format approved by the ethics committee.
- All unanticipated risks and the interventions undertaken should be intimated as per the SOP.
- Protocol deviation, if any, should be informed with adequate justifications as per the prescribed reporting template on non-compliance (Appendix XXI).
- Any amendment to the protocol or informed consent should be resubmitted for renewed approval.
- All Major amendments to the protocol need DCGI approval, once DCGI approval is obtained the same needs to be approved by the IEC.
- New information related to the study protocol should be communicated to IEC.
- Premature termination of study should be notified with reasons along with summary of the data obtained so far.
- Change of investigators / sites should be informed.

Every clinical trial is monitored as per the checklist by IEC authorized personnel once in 06 months and 03 months for research on vulnerable population and submit the details to IEC which is going to be discussed in the next IEC Meeting and the monitoring of clinical trial is followed as per regulatory guidelines and the same is recorded in the next IEC meeting.

18 REVIEW OF PROTOCOL DEVIATIONS AND VIOLATIONS

18.1 Responsibilities of PI and the study team: - to submit any Protocol deviation / Protocol violation in the study protocol in the format (Appendix XXI), with due reasons for it, how it has affected the safety of subjects, and remedial

actions taken to prevent in due future.

Member secretary: - to present the report in the meeting through agenda and arrange for a training session to the Study team by designated IEC members.

IEC members: - to review such reports

Chairperson: Take a final decision on the protocol with consensus of members

18.2 Handling Protocol Deviations and Protocol Violations:

Protocol Deviation- A protocol deviation is any change, divergence, from the study design or procedures of a research protocol that is under the investigator's control and that has not been approved by the IEC.

Protocol Violation- A protocol violation is a deviation from the IEC approved protocol that may affect the subject's rights, safety, or wellbeing and/or the completeness, accuracy and reliability of the study data.

If the deviation meets any of the following criteria, it is considered a protocol violation.

Example list is not exhaustive.

i) The deviation has harmed or posed a significant or substantive risk of harm to the research subject. For example:

- A research subject received the wrong treatment or in the correct dose.
- A research subject met withdrawal criteria during the study but was not withdrawn.
- A research subject received an excluded concomitant medication.

ii) The deviation compromises the scientific integrity of the data collected for the study. For example,

- A research subject was enrolled but does not meet the protocol's eligibility criteria.
- Failure to treat research subjects as per protocol procedures that specifically relate to primary efficacy outcomes. (if it involves patient safety, it meets the

first category above)

- Changing the protocol without prior IEC approval.
- Inadvertent loss of samples or data.

iii) The deviation is a willful or knowing breach of human subject protection regulations, policies, or procedures on the part of the investigator(s). For example:

- Failure to obtain informed consent prior to initiation of study-related procedures.
- Falsifying research or medical records.
- Performing tests or procedures beyond the individual's Professional scope or privilege status(credentialing)

iv) The deviation involves a serious or continuing noncompliance with national, state, local or institutional human subject protection regulations, policies, or procedures. For example:

- Working under an expired professional license or certification
- Failure to follow national, state and/or local regulations,
- Repeated minor deviations.
- A breach of confidentiality.
- Inadequate or improper informed consent procedure.

Minor Protocol Deviation- A minor protocol deviation is any change, divergence, or departure from the study design or procedures of a research protocol that has not been approved by the IEC and which does not have a major impact on the subject's rights, safety or well-being, or the completeness, accuracy and reliability of the study data.

18.3 Detection of Protocol deviation/violation

Protocol deviation/ violation may be detected in one the following ways (but not limited to those listed below):

i) Self-reporting by Principal investigator (Appendix XXI).

ii) IEC members while performing on site monitoring.

iii) The IEC members may detect protocol deviation/ violation when scrutinizing annual/ periodic reports/ SAE reports/ any other communication received from the Investigator/ trial site/ sponsor/ study monitor/ contract research organization.

iv) Communication/ complaint/ information received from a research participant who has been enrolled or any individual who has been approached for enrolment.

v) Any report/ communication brought to the notice of Member, Secretary/ Jt. Secretary/ Chairperson of IEC by an independent person.

vi) Communication received from the Head of the Institution informing IEC about an alleged protocol violation/ protocol deviation.

18.4 Receipt of protocol deviation / violation report by the IEC office

The PI will report the protocol deviation/violation as per the format with adequate justification for non-compliance.

18.5 Actions to be taken

1. The action of the IEC will be based on:

   i) The nature and seriousness of the deviation /violation.

   ii) Frequency of deviation/ violation in the study in the past.

   iii) Frequency of deviation/ violation in previous studies conducted by the same PI/ Co-PI

2. Member Secretary will decide on the impact of the protocol deviation / violation and act accordingly. Depending upon the seriousness, the IEC shall do the following:

   i) Ask PI for written clarification as soon as the deviation is received

ii) If the impact is serious, this report will be shared with the Chairperson and all members through e-mail.

iii) If the impact of the protocol deviation is serious enough, the Member Secretary call for and schedule a full-board meeting specifically to discuss the issue within 7 working days of the initial scrutiny

iv) The Secretariat will put up the information and communication at the next full board meeting for discussion and deliberations on it.

3. The Chairperson will take a final decision depending on the seriousness of the violation. 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, and the quorum required for the meeting is same as that required for the initial approval of the protocol.

4. The decision taken by IEC could include one or more of the following:

i) Determine that no further action is required or take other actions as appropriate.

ii) Inform the PI that the IEC has noted the violation / deviation and instruct the PI to ensure that deviations/ violations do not occur in future and to follow IEC recommendations.

iii) Enlist measures that the PI would undertake to ensure that such deviations / violations do not occur in future.

iv) arrange for a training session for the Study team by designated IEC members.

v) Suggest modifications to the protocol.

vi) Alter the interval for submission of the continuing review/ annual project status.

vii) Ask for additional training of the investigator and study team

viii) Suspend the study till additional information is made available and scrutinized.

ix) Suspension or termination of the study.

x) Inform DCGI/ other relevant regulatory authorities.

xi) Keep other research proposals from the PI/ Co-PI under abeyance, review and/ or inspect other studies undertaken by PI/Co-PI.

18.6 Procedure for notifying the PI and other concerned authority

i) The Member Secretary will draft a notification letter.

ii) The signed letter by Member Secretary will be sent to the PI regarding site visit by IEC team to look into the PD details and CAPA (Corrective action and Preventive action) undertaken.

iii) After the site visit the details will be highlighted in the next EC meeting and recording in the respective Minutes of the meeting.

iv) Records and follow up to be kept by IEC secretariat. The IEC office will keep a copy of the notification letter in the respective project file.

19 VULNERABLE POPULATION:

Any research proposal that includes vulnerable population and /or special group population and presents unusual risks / high risks should undergo thorough and more detailed review by all the members of the committee. Also, if required, relevant subject experts will review the proposal.

Following are some examples of vulnerable populations or groups:

• economically and socially disadvantaged (unemployed individuals, orphans, abandoned individuals, persons below the poverty line, ethnic minorities, sexual minorities etc.

• unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent

• children (up to 18 years)

• women in special situations (pregnant or lactating women, or those who have

poor decision-making powers/poor access to healthcare)

• tribals and marginalized communities

• refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations;

• afflicted with mental illness and cognitively impaired individuals, differently abled – mentally and physically disabled

• terminally ill or are in search of new interventions having exhausted all therapies.

• suffering from stigmatizing or rare diseases or

• have diminished autonomy due to dependency or being under a hierarchical system (students, employees, subordinates, defence services personnel, healthcare workers, institutionalized individuals, under trials and prisoners).

Special concerns:

- IEC ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed.
- Persons who are economically or socially disadvantaged will not be used to benefit those who are better off than them.
- Rights and welfare of mentally challenged and mentally differently able persons who are incapable of giving informed consent or those with behavioral disorders are be protected.
- IEC expects adequate justification for the involvement of participants such as prisoners, students, subordinates, employees, service personnel etc. who have reduced autonomy as research participants.
- Individuals whose willingness to volunteer in a research study may be unduly influenced by the expectation, whether justified or not, of benefits associated

with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate may also be considered vulnerable.

19.1 Role of Principal Investigator during enrollment of vulnerable population into the study.

ii. The PI along with EC is responsible for protecting vulnerable subjects.

iii. PI is primarily responsible for following the SOP, training research staff and creating awareness in the participant and legal guardians of principle of voluntariness.

iv. The PI is responsible for identifying the potential for enrolling vulnerable subjects in the research proposal. The PI is responsible for identifying patients who are at risk for impaired decisional capacity as a consequence of psychiatric illness, and who are being asked to participate in a research study with greater than minimal risk.

v. The responsibility for ensuring that a patient has the necessary information and advice lies with the treating doctor/ or the principal investigator who performs a procedure, operation or treatment or recruits a patient into the trial

vi. The treating doctor (or delegate) obtains consent from the patient / parent / guardian/ substitute decision maker in the specific consent form which is filed in the patients' medical record.

vii. In the event of clinical trial or any research involving vulnerable subjects as per the guidelines the consent should be taken by the LAR in this situation it could be Parents, Adult siblings, Spouse, legally accepted guardians [adopted children].

vii. In the event of clinical trial, the principal investigator should obtain the consent from the eligible subject.

viii. In the event that the treating doctor asks another doctor (delegate) to obtain the consent on his/ her behalf the treating doctor remains legally responsible for ensuring that the doctor obtaining consent fully understands and

discloses the elements of consent to the patient / parent / guardian (if a child) / substitute decision –maker.

19.2 Issues addressed by IEC during review of protocols with respect to Vulnerable Population

Among the vulnerable populations three aspects are addressed;

i. Informed consent: Ethics Committee ensures that the regulatory guidelines and Plan is followed to with regards to informed consent process to avoid coercion in vulnerable subjects.

a. A non-therapeutic clinical trial (i.e. a trial in which there is no anticipated direct clinical benefit to the participant) should be conducted in participants who personally give consent and who sign and date the written consent document.

b. Non-therapeutic clinical trials may be conducted in participants with consent of a legally acceptable representative.

ii. Exploitation.

iii. Confidentiality.

- EC reviews research that involves categories of participants vulnerable to coercion or undue influence, one or more individuals who are knowledgeable about or experienced in working with such participants are present. EC takes the opinion of outside expert in the respective field and discuss about the same. Then the opinion of EC will be conveyed to the PI.

- For research that involves no more than minimal risk or more than minimal risk with the prospect of direct benefit to the individual children, the EC determines whether:

  - The permission of both parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has

legal responsibility for the care and custody of the child, or the permission of one parent is sufficient.

- For research that involves more than minimal risk without the prospect of direct benefit to the individual children, the EC determines that the permission of both parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

If the trials in children include vaccination, where the vaccine is not used in the hospital, the EC will request the hospital administration to review the protocol and to give consent to the use of vaccine for research purpose.

19.3 Research on Psychiatric / Cognitively Impaired Subjects

- Mentally differently able persons who are incapable of giving informed consent or those with behavioral disorders must be protected.
- Adequate justification is required for the involvement of research subjects (Appendix XVII).
- These principles are commonly addressed by procedures to obtain individual informed consent that ensure that respondents understand-

➢ The purpose of the research,

➢ The risks and benefits of participation,

➢ That their participation is voluntary.

- By the presence of a legal guardian in the entire process of informed consent
- Examples of studies that warrant independent monitoring include those involving schizophrenic patients who will be exposed to placebo, and/or drug wash out, and/or treatment with agents that are not approved by the (DCGI). Populations requiring independent monitoring would include individuals with schizophrenia, other psychotic disorders or conditions characterized by lack of

reality testing (i.e., psychosis).

- If they are needed to be admitted they have to be admitted in special ward with a nurse monitoring, and reporting to the PI and the study coordinator.
- For research protocols involving subjects who have fluctuating or limited decision-making capacity, EC may ensure that investigators establish and maintain ongoing communication with involved caregivers. Periodic re-consent should be considered in some cases, example: in cases of schizophrenia, bipolar disorders and Alzheimer's disease.

19.4 Research Involving Children

- IEC shall ensure the following while reviewing the research proposal involving children: Interventions intended to provide direct diagnostic, therapeutic, or preventive benefit for the individual child participants must be justified in relation to potential risks involved in the study and potential benefits to society.
- The risk presented by interventions not intended to benefit the individual child participant is low when compared to the importance of the knowledge that is to be gained (Appendix XV) .
- Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child participant as any available alternative interventions.
- A parent or legal guardian of each child has given proxy consent.
- High risk studies in relation to the children must take signature from both the parents in the ICF.

19.5 Research Involving Adults Unable to Consent

- If research involves adults unable to consent, the ethics committee must consider additional safeguards to protect their rights and welfare, for example unconscious patients, where the probable benefit of the trial procedure/ drug is

more comparable to the standard of care.

- The ICF in such situations must be signed by LAR
- The objectives of the clinical trial cannot be met by means of a trial in participants who can give consent personally.
- The foreseeable risks to the participants are low. participants, and the written opinion covers this aspect.
- Participants in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.
- When adults are unable to consent, the IEC shall ensure that an on-therapeutic clinical trial (i.e. Atrial in which there is no anticipated direct clinical benefit to the participant) should be conducted in participants who personally give consent and who sign and date the written consent document. Non-therapeutic clinical trials may be conducted in participants with consent of a legally acceptable representative.

19.6 Research Involving Pregnant Mothers, Foetuses and Neonates:

- 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 will provide their responses in this checklist in an honest and forthright manner (Appendix XVI).

19.7 Research Involving Students, Employees or Residents

- Research participants drawn from institutions with hierarchical cultures, 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 will provide their responses as checklist in an honest and forthright manner (Appendix XVIII).

19.8 Research Involving Human Genetic Studies:

- 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 shall provide their responses in this checklist promptly (Appendix XIX).

19.9 Audio Visual Consenting Process:

- IEC insist on Audio-visual recording of Informed Consent Process shall only be

mandatory for cases where vulnerable population is involved & the trial is of New Chemical Entity or New Molecular Entity

- For clinical trials of Anti-HIV and anti-Leprosy drugs, only audio recording of the informed consent process shall be mandatory.
- The Investigator must provide the subject/LAR/IW with the information described in ICF before signing the informed consent by the subject. The language of information is to be non-technical and understandable by the study subjects/LAR/ IW and the same shall be recorded through audio-visual means. Details of questions, if any, asked by the subject/LAR/IW and his/her understanding on consent are also to be recorded through the audio video recording. The process of signing/ putting thumb impression by the subject/LAR/IW are to be also video recorded.
- During the audio-visual recording of informed consent process, the identity and records of the trial subjects are kept confidential.
- The Investigator must safeguard the confidentiality of trial data, which might lead to the identification of the individual subjects.
- The trial data of subjects can be disclosed only in a court of law under the orders of the presiding judge or in some cases may be required to communicate to Drug regulatory/ Health authority.
- Only those subjects who give the consent for the AV recording shall be included in the clinical trial.
- Audio-visual recording of informed consent process and other related documents are to be preserved safely after the completion/termination of the study for a period of 5 years.
- Audio visual recording process are monitored at JSS Hospital site by the IEC members who are posted at JSS Hospital.

20. REVIEW OF INFORMED CONSENT DOCUMENT & INFORMED CONSENT PROCESS

Consent will be sought from each prospective participant or the participant's legally authorized representative (LAR) as per applicable regulations and guidelines.

20.1 Informed Consent Document:

- The informed consent document should contain all the information that the person needs to make an informed decision about taking part in the study (Appendix XI).
- Many research teams use the consent document to guide the verbal explanation of the study to potential participants.
- The participant must sign and date the informed consent document before taking part in any study procedures. Signing the consent form is NOT the final step in the informed consent process.
- The participant may withdraw consent and decline to participate in the study at any time before or after signing the consent document until their participation in the study is completed.
- All researchers must ensure that the process of obtaining informed consent from study participants not only conforms to state and local regulations but also respects each individual's right to make a voluntary, informed decision.

1. Study Purpose The consent document must state:

   That the trial involves research. The purpose of the trial.

2. Study Treatment and Randomization The consent document must state: The trial treatment(s) and the probability for random assignment to each treatment (if a randomized clinical trial).

3. Study Procedures The consent document must state:

a) The trial procedures to be followed, including all invasive procedures. The participant's responsibilities. Those aspects of the trial that are experimental. The expected duration of the participant's involvement in the trial.

b) Risks of Taking Part in the Study The consent document must state: The reasonably foreseeable risks or inconveniences to the participant and, when applicable, to an embryo, fetus, or nursing infant.

c) Benefits of Taking Part in the Study: The reasonably expected benefits. When there is no intended clinical benefit to the participant, the participant should be made aware of this.

d) Alternatives to Taking Part in the Study: The alternative procedure(s) or course(s) of treatment that may be available to the participant, and their important potential benefits and risks. the informed consent document to list other therapies available for the condition under treatment in addition to other treatment options at the facility where the study is being conducted.

e) Costs of Participation and Compensation in the Event of Injury: The compensation and/or treatment available to the participant in the event of trial-related injury. The anticipated expenses, if any, to the participant for participating in the trial. When research involves more than minimal risk to the participant, the consent document must describe the treatment and compensation that will be provided if a participant sustains a research-related injury. The language in the consent cannot appear to limit the participant's rights in seeking damages related to injury in atrial. Regulations do not limit the definition of "injury" to a physical injury. An injury may be psychological, social, financial, or of another nature.

f) Payment for Taking Part in the Study: The anticipated prorated payment, if any, to the participant for participating in the trial. Points to note: Payment to

participants for their participation in a research study must never be coercive in either amount or method of distribution.

g) Voluntary Nature of Study: That the participant's participation in the trial is voluntary and that the participant may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the participant is otherwise entitled.

The foreseeable circumstances and/or reasons under which the participant's participation in the trial may be terminated.

a. Confidentiality of Personal Information:

The consent document must state that the monitor(s), the auditor(s), the IEC, and the regulatory authority(ies) will be granted direct access to the participant's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the participant or the participant's legal representative is authorizing such access. That records identifying the participant will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the participant's identity will remain confidential.

b. New Information that may Affect Study Participation:

The consent document must state that the participant or the participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the participant's willingness to continue participation in the trial.

c. Study Contacts:

The consent document must state the person(s) to contact for further information regarding the trial and the rights of trial participants in the event of trial-related injury.

d. Duration of Participation and Number of People taking part in the Study:

The consent document must state the expected duration of the participant's participation in the trial. The approximate number of participants involved in the trial. A consent form should be written in a non-technical language that participants would understand. Also, it should be written in language consistent with the participants educational level, cultural views, and familiarity with research.

20.2 Informed consent Process: -

- Capacity to Give Informed Consent Before the informed consent process can begin, the potential participant must be deemed capable of understanding his or her actions and making a reasoned decision. If the person lacks capacity because he or she is a minor, is ill, or for any other reason, special provisions must apply (such as a life- threatening emergency), or the person may not be included in the study.
- A person who has a court-appointed legal guardian or who has been determined by a court to be legally incompetent cannot sign an Informed Consent Form

20.2.1 Disclosure of all Relevant Information: -

The research team must disclose all relevant information about the study to the potential participant. The information disclosed must be sufficient to enable the potential participant to make an informed reasoned decision about whether to participate. This information generally includes: The purpose of the study. The nature of the procedure or intervention that is being studied. Reasonable alternatives to participation in the study. The potential risks and benefits as well as the uncertainties of study participation. The participants have obligations for the duration of the study.

20.2.2 Comprehension by the Participant: -

The potential participant must understand the information disclosed to him or her about the research study, The participant is free to ask questions to the study team

as well as take additional time to make a decision regarding participation. The research team must be able to evaluate the potential participant's ability to understand what his or her participation in the study would involve. The informed consent document might include a quiz or other documented assessment to assess whether the participant truly understands the study.

20.2.3. Voluntary Agreement by the Participant: -

The participant must agree to participate in the research study and his or her agreement must be voluntary and free from coercion or undue influence.

20.2.4. Right to Withdraw: -

- The participant must be informed that he or she has a right to withdraw from the study at any time and for any reason, without penalty or loss of benefits that he or she would otherwise be entitled to receive. If a participant wishes to withdraw from a study in which an experimental drug is being tested, he or she must be informed of any procedures that are recommended to ensure safe withdrawal from the study drug. The participant must also be advised of any consequences of withdrawal, such as the inability to continue taking the study medication. No further data will be collected on the participant, but the participant will be informed that data already collected can be used for study analysis.
- Participant must be capable of understanding information about the study and giving informed consent voluntarily.
- The participant been given sufficient, accurate information about the study.
- The participant understands the information given about the study.
- ICF must be in the vernacular language of the subject to be enrolled into the study.
- When not possible an interpreter is utilized to administer the ICF, whose signature also to be taken in the ICF. If a participant is unable to read, a witness must be present throughout the informed consent discussion and must sign the consent form(s).

- The PI must ensure that the participant's decision to participate in the study entirely voluntary or has he or she been coerced or influenced in any way (e.g., by circumstances or by other people)
- Participant must understand that signing the informed consent document indicates agreement to participate in the study.
- The Participant must sign the Informed consent form before the study procedures is initiated in addition to signature of the Investigator or witness and dated accordingly.
- Whiteout / whitener should never be used on any research or medical record document.
- Consenting to be done only with present version of the Consent Form.
- If consented with previous versions of ICF- Present approved version of ICF and other documents should be used for consenting. Corrective Action: When the issue is identified, reconsent the participant using the appropriate Informed Consent Form. Attach a memo identifying the issue and the corrective action to the new consent form.
- If the Original Consent Form Has Been Lost: -

Written procedures for the handling of informed consent documentation and train all staff in the use of these procedures. Corrective Action: Report the loss of a consent form immediately to the IEC and/or the sponsor and get another signed as soon as possible.

20.3 Special Requirements Concerning Consent

The information that must be provided for informed consent should be specified in the consent document and to include the following:

- State that the study involves research.
- Briefly explain the purpose of the research, the reason(s) why the person is being invited to participate, and the expected duration of the person's participation in the study.

- Describe the procedures or interventions to be carried out, identifying which procedures are investigational and which might be provided as standard care in another setting.
- Explain the use of research methods such as randomization and placebo controls. Describe any foreseeable risks or discomforts to the participant.
- Estimate how likely it is that these risks and discomforts will occur.
- Describe the steps that will be taken to prevent or minimize risks or discomforts to the participant.
- Acknowledge that participation in the study may pose unknown and unforeseeable risks.
- Describe any benefits to the participant or to others that the research may reasonably be expected to produce.
- Estimate how likely it is that these benefits will occur.
- Disclose any appropriate alternative procedures or courses of treatment that may benefit the participant.
- Describe the extent to which records will be kept confidential and provide examples of people or organizations that may have access to research records (e.g., hospital personnel, study sponsors, etc).
- For research that involves more than minimal risk, explain and describe any compensation and any medical treatments that are available if participants are injured as a result of participation in the study, where further information can be obtained, and who should be contacted in the event of a research-related injury.
- Explain who should be contacted for answers to questions about the research and the participant's rights (including the name and phone number of the principal investigator). State that participation in the study is voluntary and that declining to participate or deciding to withdraw at any time will involve no penalty or loss of benefits to which the participant is otherwise entitled.

- State that the participant's signature will indicate that he or she has decided to participate in the study, having read and discussed the information presented to him or her about the research.

20.4 Special Requirements Concerning the Consent of Pregnant Women

When a research activity involves pregnant women as participants:

- Both mother and father must be informed about any potential impact of the research on the fetus. Both mother and father must consent to the woman's participation in the research.
- The father's consent is not required in the following circumstances:

- The purpose of the research is to meet the health needs of the mother.
- The father's identity or whereabouts cannot be determined.
- The father is not reasonably available.
- The pregnancy resulted from rape.
- If either parent is unable to consent because of availability, incompetence, or temporary incapacity.

20.5 Special Requirements Concerning the Consent of Children

- The legal age for consent in most states is 18; persons under age 18 are considered minors. Additional protections for children and minors involved as participants in research are set.
- Assent means a child's agreement to participate in research. When children or minors are involved in research, both the assent of the child or minor and the permission of his or her parent(s)are required.
- Both parents must give their permission for their child or minor's participation in research.
- There is no need to document assent for children below 7 years of age.
- For children between 7 and 12 years, verbal/oral assent must be obtained in

the presence of the parents/LAR and should be recorded.

- For children between 12 and 18 years, written assent must be obtained. This assent form also has to be signed by the parents/LAR.

20.6 Special Requirements for Psychiatric patients/ diminished autonomy:

- Mentally differently able persons who are incapable of giving informed consent or those with behavioral disorders must be protected. Adequate justification is required for the involvement of research subjects.
- These principles are commonly addressed by procedures to obtain individual informed consent that ensure that respondents understand-
  a. The purpose of the research,
  b. The risks and benefits of participation,
  c. That their participation is voluntary.
- A legal guardian should be present in the entire process of informed consent

  Examples of studies that warrant independent monitoring include those involving schizophrenic patients who will be exposed to placebo, and/or drug washout, and/or treatment with agents that are not approved by the DCGI. Populations requiring independent monitoring would include individuals with schizophrenia, other psychotic disorders or conditions characterized by lack of reality testing (i.e., psychosis).
- If they are needed to be admitted, they have to be admitted in a special ward with a nurse monitoring and reporting to the PI and the study coordinator.

  For research protocols involving subjects who have fluctuating or limited decision-making capacity, EC may ensure that investigators establish and maintain ongoing communication with involved caregivers. Periodic consent should be considered in some cases, for example: in cases of schizophrenia, bipolar disorders and Alzheimer's disease.

- Special Requirements Concerning the Consent of Prisoners because of their incarceration, prisoners may be under constraints that potentially affect their ability to make a truly voluntary decision about whether or not to participate in a study.
- Additional safeguards for the protection of prisoners involved in research include: - The IEC must approve the study as prisoner research.

  - The IEC reviews and approves the study including a prisoner.

  -The study must present no more than minimal risk to the participants.
- The proposed research must involve the study of: The possible causes, effects, and processes of incarceration and criminal behavior. Practices intended to improve the health or well-being of the participants.

21 REPORTING, ANALYSIS OF SAEs AND MAKING OPINION ON COMPENSATION

- IEC reviews the SAEs the following the standard protocol– As per format mentioned in the New Drugs and Clinical Trials Rules, 2019
- A separate session of the regular meeting is reserved for discussion of the SAE reported by the PI.
- The PI has to submit the initial SAE report to IEC within 24 hours of their occurrence & follow up report to be submitted within 14 days of reporting of SAE, if the investigator fails to report SAE within the stipulated Period, he/she has to furnish the reasons for delay in reporting.
- The member secretary will present the details of the SAE reported by the PI during the meeting and after detailed discussion of the same in the meeting, the opinion of the IEC will be uploaded in SUGAM portal or sent to DCGI within 30 days of receiving the report of the SAE.

- IEC team of 3-4 members (Chairman, Member secretary, Clinician, layperson/ social scientist) will visit the site for each SAE reported to collect the details of the SAE and status of the other subjects enrolled in the study.
- IEC also monitors the SAE in the site through the in-house members posted exclusively at JSS Hospital and ensures the standard of care given to the subjects till their stay at JSS Hospital.
- IEC insists on free medical care for subjects with SAE even if they are not related to the clinical trial. And till DCGI decision is received insist the PI about this procedure of standard of care to the subjects.
- PI should ensure that the medical expenses or surgical interventions along with his /her stay at hospital are taken care in consultation with the sponsor.
- IEC suggest the compensation to the enrolled subject as per NDCT 2019 guidelines
- The IEC discusses each SAE in the full board meeting before sending its opinion about the SAE to DCGI. The documents that are sent to DCGI are:

- Covering letter
- Brief report of SAE
- Causality assessment report,
- Decision of IEC
- Minutes of Meeting of that SAE with details of compensation (if any)

- The details of the SAE are presented to the IEC by the Member Secretary during the IEC Meeting. After detailed discussion and deliberation with all the members the report will be sent to DCGI along with the above-mentioned documents.
- Due consideration is paid for those SAE's which are to be awarded with compensation following the guidelines of the DCGI and New drugs & Clinical trial rules 2019 for the calculation of compensation to be awarded.

22 CONFLICT OF INTEREST

Conflict of interest (COI) is a set of conditions where professional judgement concerning a primary interest such as participants welfare or the validity of research tends to be unduly influenced by a secondary interest, financial or non-financial (personal, academic or political). COI can be at the level of researchers, EC members, institutions or sponsors.

- If COI is inherent in the research, it is important to declare this at the outset and establish appropriate mechanisms to manage it.
- Researchers must ensure that the COI that may affect the research is disclosed to the EC before the meeting
- EC must evaluate each study in light of any disclosed interests and ensure that appropriate means of mitigation are taken.
- No regular, alternate, or ex officio member or consultant may participate in the review (initial, continuing, or modification) of any research project in which the member or consultant has a conflict of interest (COI), except to provide information as requested.
- IEC will not review or approve studies in which the sponsor / CRO is affiliated to the Institution.
- It is the responsibility of each IEC voting member to disclose any COI in a study submitted for review and to then excuse him/herself from Voting for project approval. At convened meetings, the IEC member excuses himself from the deliberations and vote by leaving the room. Any primary, secondary, or expedited reviewer with a conflict of interest must notify the IEC staff who will re-assign the protocol.
- Committee Members and Consultants may find themselves in any of the following conflicts of interest when reviewing research:

i. Where the member or consultant is involved in the design, conduct, and reporting of their search.

ii. Where a family member of an IEC member or a consultant is involved in the design, conduct, and reporting of their search.

iii. Where the member holds significant financial interests related to the research being reviewed

iv. Any other situation where an IEC member believes that another interest conflicts with his or her ability to deliberate objectively on a protocol.

- The IEC Chairperson will poll IEC members at each convened meeting to determine if a COI exists regarding any protocols to be considered during the meeting and reminds them that they should excuse themselves by leaving the room during the discussion and vote of the specific protocol. IEC members with conflicting interests are excluded from being counted towards quorum. All refusals by members with COI are recorded in the minutes.
- All members should declare conflict of interest for all those proposals that are under review. Any IEC member who has a conflict of interest or any other relationship, either directly or indirectly with the research proposal under review, that may be inappropriate for objective review will not participate in the deliberations and voting except to provide information as requested by the committee.
- The presence of a member, who has a conflict of interest of research proposal that is under review, in the meeting will be decided by the committee as appropriate. The same will be documented in the minutes of the meeting. All the members will sign the conflict-of-interest agreement.
- IEC also keeps in mind the Institution conflict of interest which is going to be documented in the minutes of the meeting.

- The PI involved in any clinical trial with an element of Conflict of Interest must declare to the Chairman before the meeting, otherwise the declaration letter of Conflict of interest & confidentiality will be signed on the day of meeting.

23 PRIVACY AND CONFIDENTIALITY:

- When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
- Disruption of governance, infrastructure and communication networks and inflow of visitors during emergencies can lead to a breach of privacy and confidentiality. In some situations, there can be stigmatization and discrimination which should be minimized at all stages of research.
- Special efforts (culturally appropriate and scientifically valid) are required to maintain dignity, privacy and confidentiality of individuals and communities.
- Efforts should be made to protect the identifying information about individuals and communities, for example, from exploitation by the print and visual media.
- **Confidentiality agreement will be signed by all the IEC members and the invited subject expert before each IEC meeting.**

24 FINANCES RELATED TO ETHICS COMMITTEE ACTIVITIES AND FUNCTIONING.

Ethics Committee Review Fees: Institutional Ethics Committee (IEC) shall charge an application fee for review of research projects.

The IEC shall charge for initial review, amendment/ additional document review, annual review and SAE review fee for the proposals.

Following are the charges for review:

Fees structure:

- New Clinical Trial/ Project: Rs 75,000/- (excluding GST)
- Clinical Trial Amendment/ Approval of Additional documents: Rs 20,000/- (excluding GST)
- Annual Renewal: Rs 10,000/- (excluding GST)
- SAE Review: Rs 5,000/- (excluding GST)

Fees payment:

- The review fee for pharmaceutical and government sponsored study will always be accepted by cash or online or can be paid by cheque drawn in favor of “IEC JSSMC account”.
- The revised fees is applicable for prospective clinical trials. The EC fees is non-negotiable however under exceptional circumstances as decided by the Member secretary/ Chairman in consultation with the Head of the institute, reduction/ waiver of the fee may be considered.
- The EC fees has to be paid against the invoice raised before the procurement of the final approval for the study.

Online payment details:

Name of Account: JSS Medical College, Institutional Ethics Committee

Name of Bank: State Bank of India, SS Nagar Mysore-570015.

Account No. 38956283831

IFSC Code: SBIN0040547

GST Number for payee: 29AABTJ135OM1ZH

PAN No: AABTJl 350M (JSS University)

Budget Preparation:

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

Expenditure:

1. Conduct of Meeting & refreshments
2. Staff salary
3. Maintenance of IEC facility e.g. repair work, construction, renovation, fire proofing etc.
4. Making resources available for office e.g. Stationaries, purchase of computers, printers, scanners etc.
5. Paying fixed honorarium to members and subject expert for each meeting attended.
6. Training programs/ CMEs/ Conferences organized by IEC.
7. IEC members who present papers on research ethics and represent institute IEC in national/international conference.
8. Fees related to audits/registrations /accreditations /recognitions, etc

Remuneration to IEC members:

The details of remuneration for the IEC members for each meeting is as follows

Sl.No	Designation/ Position	Remuneration
01	Chairman	Rs. 2500
02	External Members	Rs. 1500
03	Inhouse members	Rs 1000
04	Subject Expert	Rs 2000

25. IEC ADMINISTRATION AND MANAGEMENT

IEC Office: The office of the IEC is situated at JSS Medical College, Sri Shivarathreeshwara Nagar, Mysore –570015, Karnataka.

The telephone Number is (0821-2548337-341, Ext 205/ 242), Fax No (0821-2548345). The Email is: iecjssmc@jssuni.edu.in / jssmc09@gmail.com

- The Principal, JSS Medical College and Hospital, Mysore has authorized the formation of IEC, JSSMC as an independent body which functions independently at the site as registered body under Drugs Controller General of India (DCGI)
- The member secretary shall be responsible for the day to day functioning of the IEC and maintaining documents, such as research protocols, notifications and other trial related documents, current list of members and their CVs, current version of SOP, reference documents used by the IEC for its functioning e.g. ICH – GCP guidelines, CDSCO guidelines, ICMR Ethical guidelines, New Drugs And clinical; trial Rules 2019, Declaration of Helsinki, Drugs and Cosmetics Act and Rules. Copies of these have been and shall continue to be made available to all the members by email or in other suitable media and shall have to be updated.
- Member secretary shall maintain a file for each proposal received, reviewed, followed, concluded, with chronological documentation. He/ she should maintain records of all the meetings, comprising the notice, attendance log and minutes of minutes.

26. TRAINING FOR COMMITTEE MEMBERS

- The IEC Members undergo training in ICMR guidelines, and GCP guidelines, New Drugs & Clinical trial rules 2019, bioethics and NABH standards at regular intervals.

- IEC trains the new members through inhouse training programme to facilitate them to work along with other members efficiently though training sessions related to the Clinical trials review procedures and other IEC working patterns within 3 months of their appointment from DCGI.
- The IEC will provide all members with an orientation about their roles and responsibilities. All the members are expected to familiarize themselves with the working procedures of the committee and their responsibilities. Also, members should have an understanding about regulatory and any other standard documents that are relevant to research ethics.
- All members will be kept abreast of the latest information pertaining to research ethics. And, if required, especially for new member an informal training will be provided within 3 months of his/her appointment and the same will be documented. The committee conduct in house training programme for the IEC members regularly to update about the recent IEC issues once in 6 months/ earlier if required the members will be deputed to participate in CME's/ workshops which appraise the ethical issues and working of IEC on regular basis.
- The experienced members of the committee are the one who have the knowledge of the regulatory guidelines and have been trained on the SOPs of the ethics committee.
- Regular training courses with a frequency of six months are essential for the IEC staff & Members to keep them abreast of the latest developments in the field of research and in particular to the context of ethics.

Updating of relevant new guidelines about clinical trials to IEC Members

i. All relevant new guidelines will be brought to the attention of the members by member secretary through written communication/ Presented by regular IEC meeting.

ii. Members are encouraged to attend national and international training and in house training programs in research ethics for updating their knowledge in ethical review and be aware of the latest developments in this area and the relevant SOP.

Self-assessment and Auditing

- Bi-annual self-assessment will be conducted to assess the TOR, qualification of the IEC. They will also be assessed for regular attendance and knowledge of the various regulations and SOP.
- A report of the same will be given to each of the member. This is done to improve the functioning of the IEC.
- An internal Audit will be conducted annually, and the report will be submitted to the chairperson. Necessary corrective action must be taken by the IEC members.

27. RESPONSIBILITIES OF INVESTIGATORS:

The Committee expects from the Principal Investigator:

a) To submit and present the study details to the Ethics committee

b) To provide report of the clinical trial on biannual basis or more frequently if so directed

c) To inform about the occurrence of SAE to the sponsor and IEC within 24 hrs and to submit a report of each serious adverse event regarding the study with due analysis to IEC within 14 days of reporting of SAE, both hard and soft copy to IEC.

d) To be kept informed of amendments / revisions to any study-related document as well as patient safety related information.

e) To be kept informed of study completion and discontinuation with reasons.

f) To submit justification for approval to restart studies discontinued earlier.

g) Report of Protocol deviation / Protocol violation

h) Details of Premature termination of Trials With details of reasons for premature termination

i) To submit CIOMS, SUSARS, safety reports of the trial.

28. POLICY OF COMMUNICATIONS WITH DIFFERENT STAKE HOLDERS:

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

- o Principal Investigator /study team designee
- o DCGI
- o Dean of the Institute
- o Sponsor
- o Study Participants

IEC receives letters from different stakeholders submitted or sent to IEC Secretariat and maintains them in record. IEC may mention an outward number for letters sent to all concerned stakeholders and records of the same also are kept. All the communications will either in the form of email or hard copy

Principal Investigator:

IEC writes or e-mails to Principal Investigator regarding the following mentioned communications but not limited to, whenever deemed necessary.

- o Study Project Initial Dossier and Amendments, Approval/Dis-Approval letter/ Query Letters
- o Reply to Serious Adverse Event notification
- o Opinion on EC analysis and compensation of Study injury/Death

o Response to Protocol deviation/Violation/Waiver

o Response to Continue review/study completion report

o 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 Principal Investigator and must include the following information:

o the name of the Project (Same as the Project title)

o List of documents reviewed by the IEC including the revised version of documents if any.

o List of members present at the meeting.

o Members who did not participate in the decision-making process.

o the date and time of the meeting.

o the decision of the IEC

o A note to PI to strictly adhere to SOP of IEC, JSSMC Ver 4.3, GCP and latest regulatory requirements plus submission progress updates/deviations as and when it occurs while implementing the sanctioned project.

o 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 the following mentioned communications but not limited to, whenever deemed necessary.

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

Dean of the Institute:

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

- o Annual reports of IEC.
- o Sharing amended SOP for final acceptance.
- o Any issues in IEC functioning
- o IEC Requirements

Sponsor:

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

- o Response to any queries raised.
- o 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.

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

29. SUBJECT GRIEVANCE REDRESSAL PROCESS

- IEC maintenance the procedure of Subject grievance redressal process at times of complaint and concerns of subjects enrolled in Clinical trial. The process is addressed by the inhouse members of IEC who are posted at JSS Hospital to begin with and the same will be discussed in IEC meeting, with their contact numbers.
- EC collects the Patient feedback forms from the PI and research team and address the grievances (Appendix XXVIII).
- Grievances or complaints received from the subjects enrolled in the clinical trial will be immediately attended by the members of IEC who are constantly available in the JSS Hospital site. (Dr. Srinath KM, Dr. Prathiba Periera & Dr Harsha Chalassani) and immediate remedial measures are suggested on the spot. It will be brought to the notice of IEC immediately and an emergency meeting is scheduled to decide the remedial measures to be adopted with respect to the particular clinical trial and the same is communicated to the PI and get his clarification about the grievances of the subject enrolled in the study.

30. POLICY FOR REVIEW OF STUDY PROPOSALS DURING THE EPIDEMICS / LOCKDOWN:

Purpose: The purpose of this SOP is to describe how the EC will function and conduct ethics review in an emergency with restrictions as imposed by social distancing requirements during the epidemics or lockdown.

Scope: It covers the procedures applied to review of all protocols submitted during the epidemics or lockdown.

Responsibility: IEC Chairman / Member Secretary is responsible to ascertain epidemics/ periods of lockdown and follow the procedure of submission, review, and decision conveying according to the conditions. It is the responsibility of the IEC Secretariat or Member Secretary to receive the submission package (hard and

soft copies), ensure complete documentation and record receipt of the package. The Member Secretary shall categorize the research into full review, expedited review or exemption from review and identify need for review by experts/ independent consultants/ patient /others, designate reviewers or in the full board meeting.

Detailed instructions: Following any announcement by college, hospital or government Authorities on restricting movements of individuals for certain duration- a virtual (online) IEC meeting can be conducted. IEC Secretariat shall manage the protocol submissions as soft email/ soft copies to the IEC and the same to be circulated to the EC members during periods of lockdown/ epidemics.

Meeting procedures:

o The IEC Secretariat and Member Secretary in consultation with Chairman will schedule a virtual meeting and decide the agenda.

o The Secretariat will intimate virtually about the date/time of meeting and invite the members and investigators / researchers for the meeting.

o The Chairman shall open the meeting and determine the quorum. The members of IEC will declare in writing a conflict of interest if any prior to discussion.

o The investigator or representative shall present the research virtually through a brief PowerPoint Presentation (PPT). The designated Subject expert (if any) would be requested to provide an opinion on the proposal.

o The IEC members and Primary reviewers (if designated) will discuss and reach consensus to decision-making.

o In case, if Chairman deemed necessary, the secretariat will share entire documents with the IEC members through email for review. The IEC members / subject experts (if appointed) will share their decision or queries (if any), on the research proposals. If any queries are raised by the members, IEC secretariat will convey the same to the investigators for rectification / revised submission. The

concerned investigator will reply with rectification / revised submission through email similarly. IEC will not come to a decision unless the reviewer ratify the revised submission. IEC Secretariat will preserve the emails for record in the files.

o The Member Secretary / Secretariat will record the decision in the minutes of the meeting.

Post meeting activities:

o The secretariat will communicate the decision to the Principal Investigator and maintain the record.

o The decision about the follow-up / Monitoring / Analysis of SAE/ handling of issues related to non-compliance, violation, complaints will be taken by the Member Secretary in consultation with Chairman.

31. POLICY FOR RECORD KEEPING, ARCHIVAL AND RETRIEVAL OF DOCUMENTS:

31.1 Maintenance of Active clinical trial files:

- It is the responsibility of the EC staff to ensure that all study files are prepared, maintained and kept securely for complete period of the study. A proper system ensures confidentiality and facilitates retrieval at anytime.
- A study file contains of all essential documents and correspondence related to the clinical trial/ protocol. A study file will be maintained from the time of initial submission in the EC office.
- One copy of all the documents submitted by the applicant like study protocols along with all enclosed documents and related notifications will be maintained along with the approval letters in cupboards for different departments and labelled with unique number as identifiers.
- All the files will be kept securely with controlled access. Only authorized

individuals like EC Member secretary, members, Chairman and EC coordinator will have access to the files.

31.2 Archival, retrieval and disposal of closed files:

- All closed study files after reviewing of the project completion or study reports by EC are archived and arranged in the cupboards with controlled access. The closed project files are clearly labelled and stored for 5 years after the closure.
- All closed study files after completion of archival period will be shredded and disposed off by the authorized EC personnel.
- The EC study files for clinical trials will be made available for EC members and relevant statutory authority upon request. These files will also be made available for inspection and copying by authorized representatives of regulatory bodies or investigator after receiving the request in writing.

32. REFERENCES

1. New Drugs and Clinical Trials Rules, 2019 – CDSCO [Internet] 2019 June. [Updated 2019 March; cited 2019 June 5] and 2022 (Amendments) Available from https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/New-Drugs
2. Indian Council of Medical Research. National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. New Delhi; 2017.
3. Good Clinical Practices for Clinical Research in India, CDSCO, http://cdsco.nic.in
4. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), INTEGRATED ADDENDUM TO ICH E6 (R1): GUIDELINE FOR GOOD CLINICAL PRACTICE E6 (R2)
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. Forum for ethical review committees in the Asian and Western Pacific Region http://www.fercap-sidcer.org/selftool.php
7. R4-RA Clinical trial - http://www.r4ra-nihr.whri.qmul.ac.uk/feedback.php
8. National Institute of Allergy and Infectious Diseases https://clinregs.niaid.nih.gov/country/india#ethics_committee
9. Clinical Trials Toolkit India https://cdsatoolkit.thsti.in/route-map-2/
10. ICMR Bioethics unit https://ethics.ncdirindia.org/Tools_and_Instruments.aspx
11. WHO Operating Guidelines for Ethical Review Board that Review Biomedical Research (2000), https://www.who.int/tdr/publications/documents/ethics.pdf
12. Declaration of Helsinki and the prevailing amendments from time to time (https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-formedical-research-involving-human-subjects/)
13. Amendments from CDSCO office https://cdsco.gov.in/opencms/opencms/en/ClinicalTrial/clinical-trials/
14. National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During Covid-19 Pandemic from https://ethics.ncdirindia.org//asset/pdf/EC_Guidance_COVID19.pdf

APPENDICES

APPENDIX-I: AUTHORIZATION LETTERS FOR ESTABLISHMENT OF IEC, JSSMC AND ITS INDEPENDENT FUNCTIONING

JSS ACADEMY OF HIGHER EDUCATION & RESEARCH
Sri Shivarathreeshwara Nagara, Mysuru – 570 015, Karnataka, India.
+91-821-2548400 / 416 +91-821-2548394 registrar@jssuni.edu.in www.jssuni.edu.in
JSS ACADEMY OF HIGHER EDUCATION & RESEARCH (DEEMED TO BE UNIVERSITY) MYSURU

Date: 04.11.2022

TO WHOM SO EVER IT MAY CONCERN

Dr. H. Basavanagowdappa, Principal, JSS Medical College, Mysuru is the **authority** under which the Institutional Ethics Committee (IEC), JSS Medical College & Hospital, Mysuru is established and functioning.

JSS Academy of Higher Education & Research Mysuru-570 015

REGISTRAR
REGISTRAR
JSS Academy of Higher Education & Research
Sri Shivarathreeshwara Nagara
Mysuru-570015, Karnataka, India

JSS MEDICAL COLLEGE
Sri Shivarathreeshwara Nagara, Mysuru – 570 015, Karnataka, India
P: +91-821-2548337 / 338 | F: +91-821-2548345 | E: jssmc@jssuni.edu.in | www.jssuni.edu.in

JSSMC / IEC / Independence of IEC / 2022-23 Date: 01.06.2022

TO WHOMESOEVER IT MAY CONCERN

I, Dr. H. Basavana Gowdappa, Principal, JSS Medical College, Mysore, issue this documented policy to ensure the Independence of Ethics Committee in its functioning and decision making without any bias.

The Institutional Ethics Committee of JSS Medical College, shall function according to the rules and regulations envisaged in the International Conference of Harmonization – Good Clinical Practice (ICH-GCP) guidelines, CDSCO- DCGI & New Drugs and Clinical Trial Rules 2019, ICMR Ethical Guidelines for Bio- Medical Research on Human Participants, and also in accordance with SOP of IEC, JSS MC, Mysore.

(Dr. H. Basavana Gowdappa)
Principal & Prof of Medicine
JSS Medical College
Dean Faculty of Medicine
JSS Academy of Higher Education & Research, Mysore
Ph: (O) 0821-2548338, (P) 2548334, (R) 2330845 Fax: 2548345
Cell Phone: 098451 15962
Email: hbgowda@gmail.com, jssmc09@gmail.com

APPENDIX II

LOCATION AND TENURE OF IEC, JSSMC

Name of the Ethics Committee	Institutional Ethics Committee
Address: Institution name	JSS Medical college, SS Nagara,
City	Mysore
State	Karnataka
Country	India
Pin code	560017

Tenure of this Ethics Committee 11-06-2022 to 10.06.2027

APPENDIX III

COMPOSITION OF INSTITUTIONAL ETHICS COMMITTEE

The Composition of Institutional Ethical Committee will be as follows:

i. One Chairperson
ii. One Member Secretary
iii. 1-2 Basic medical scientists (preferably one pharmacologist).
iv. 1-2 Clinicians
v. One Legal expert
vi. 1-2 Social scientist/ representation of non-governmental voluntary agency / philosopher/ ethicist / theologian or similar person
vii. 1-2 Lay person from the community.
viii. Minimum of one-Woman Member

APPENDIX IV

QUORUM OF INSTITUTIONAL ETHICS COMMITTEE

The Ethical Committee approving drug trials should have in the quorum at least one representative from the following groups and with at least one women representative in the group:

1. One Basic medical scientist
2. One Clinician
3. One Legal expert
4. One Social scientist/ representative of non-governmental organization / philosopher/ethicist/ theologian or a similar person
5. One Lay person from the community

APPENDIX V

INSTITUTIONAL ETHICS COMMITTEE

IEC Registration ECR/387/Inst/KA/2013/RR-19

NABH Accreditation Certificate No. EC-CT-2018-0018

CONFIDENTIALITY AGREEMENT FORM FOR ETHICS COMMITTEE MEMBERS

In recognition of the fact, we the members of Institutional Ethics Committee, JSS Medical College, Mysore herein referred to as the "Undersigned", have been appointed as a designated against their names for Clinical Studies has been asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines; Whereas, the appointment of the undersigned as a member of IEC, JSSMC, Mysore for Clinical Studies is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest; Whereas, the fundamental duty of IEC, JSSMC, Mysore. The IEC member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review; Whereas, IEC, JSSMC, Mysore for Clinical Studies 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 human subjects.

The undersigned, as a member of the IEC, JSSMC, Mysore for Clinical Studies, is expected to meet the same high standards of ethical behaviour to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the of IEC, JSSMC, Mysore. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly. As such, the undersigned agrees to hold all Confidential information/ data in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose, or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained.

All Confidential information (and any copies and notes thereof) shall remain the sole property of the of IEC, JSSMC, Mysore.

Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with the institute's policies. Confidential information includes any information submitted by the Scientists in connection with Ethics Committee review, whether written or oral, including, but not limited to technical, scientific, financial, strategic, marketing or product information. It also includes, but is not limited to, information concerning EC's computer processes, programs and codes, financial information, pending projects and proposals, standard operating procedures, legal and regulatory affairs. Confidential and proprietary information includes the above information even when it is not marked as such.

I agree to cooperate with Ethics Committee if Ethics Committee wishes to seek a protective order

I also understand that as a member I will be given copies of the study proposals/necessary documents to be evaluated. These will be duly returned by me to the of IEC, JSSMC, Mysore during the meetings/as and when requested for. I also understand that these documents are confidential, hence every effort will be taken to prevent access to any other person other than me or the office staff of IEC, JSSMC, Mysore

At times documents/proposal in soft copy format will be given/send to me. I will assure that these documents/proposals will be kept confidentially.

We have read and accept the afore mentioned terms and conditions as explained in this Agreement.

Name of Member & Role / Designation in IEC	Signature

APPENDIX VI

Conflict of Interest and Confidentiality Agreement form for Institutional Ethical Committee Subject Experts of JSS Medical College & Hospital, Mysore.

In recognition of the fact, that I, **----------,** herein referred to as the "Undersigned", have been appointed as a Subject Expert of the Ethics Committee (EC), would be asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines;

Whereas, the appointment of the undersigned as a Subject Expert of the EC is based on individual merits and not as a representative of a home province/ territory/ community nor as the delegate of any organization or private interest;

Whereas, the fundamental duty of an EC Subject Expert is to independently review research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review.

Whereas, the 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 human subjects.

The undersigned, as a Subject Expert of the EC is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a Subject Expert of the EC. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets “information” in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the EC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that my performance of this agreement is consistent with the Institute’s policies and any contractual obligations they may have to third parties.

Conflict of Interest

It has been recognized that the potential for conflict of interest will always exist but have faith in the Institutional Ethical Committee, JSS Medical College & Hospital, Mysore, and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

In accordance of the policy of the Ethics Committee, I shall not participate in the review, comment or approval of any activity in which I have a conflict of interest, except to provide information as requested by the EC.

_____ _____

Undersigned Signature Date

The Undersigned will immediately disclose to the Chairperson of the Institutional Ethical Committee, JSS Medical College & Hospital, Mysore, any actual or potential conflict of interest that I may have in relation to any particular proposal submitted for review by the committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that a Ethics Committee Subject Expert has a potential conflict, the investigator may request that the Subject Expert be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the Ethics Committee Subject Expert in question.

The committee may elect to investigate the applicant's claim of the potential conflict.

When a Subject Expert has a conflict of interest, the Subject Expert should notify the Chairperson and may not participate in the Ethics Committee review or approval except to provide information requested by the Committee.

Examples of conflict of interest cases may be any of the following:

• A Subject Expert is involved in a potentially competing research program.

• Access to funding or intellectual information may provide an unfair competitive advantage.

• A Subject Expert's personal biases may interfere with his or her impartial judgment.

Agreement on Confidentiality and Conflict of Interest:

In the course of my activities as a Subject Expert of the EC, I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the access to it, as per the right to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any

minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member.

Whenever I have a conflict of interest, I shall immediately inform the committee not to count me toward a quorum for consensus or voting.

I, **----------** have read and I accept the afore-mentioned terms and conditions as explained in this agreement.

_____ _____

Undersigned

Signature **Date**

APPENDIX VII

CONFLICT OF INTEREST AND CONFIDENTIALITY AGREEMENT FORM FOR ETHICS COMMITTEE MEMBERS BEFORE THE MEETING

Date:

Time:

The below mentioned members do not have any conflict of Interest with the projects enlisted below and all of them maintain confidentiality during the IEC review process.

Sl. No	Title of the Project	Name of PI
01		
Sl. No	**Name of Member**	**Signature**

APPENDIX VIII

A. CONTENTS OF THE PROPOSED PROTOCOL FOR CONDUCTING CLINICALTRIALS

The researcher should submit an appropriate application to the IEC in a prescribed format at least 14 days in advance to IEC meeting date along with a covering letter.

Number of Copies: 5 hard copies and 2 soft copies (CD)

Submit the documents in SPIRAL BOUND/ place in file and numbered in the following manner to the Ethical Committee:

I. Title Page

a. Full title of the clinical study

b. Protocol / Study number, and protocol version number with date

c. The IND name/number of the investigational drug

d. Complete name and address of the Sponsor and contract research organization if any

e. List of the Investigators who are conducting the study, their respective institutional affiliations and site locations

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

II. Table of Contents

A complete Table of Contents including a list of all Appendices.

1. Background and Introduction

a. Preclinical experience

b. Clinical experience

Previous clinical work with the new drug should be reviewed here. If this is an entirely new indication, how this drug was considered for this should be discussed. Relevant information regarding pharmacological, toxicological and other biological properties of the drug/ biologic/ medical device, and previous efficacy and safety experience should be described.

2. Study Rationale

This section should describe a brief summary of the background information relevant to the study design and protocol methodology. The reasons for performing this study in the particular population included by the protocol should be provided.

3. Study Objective(s) (primary as well as secondar y) and their logical relation to the study design.

4. Study Design

   a. Overview of the Study Design: Including a description of the type of study (i.e., double-blind, multicentric, placebo controlled, etc.), a detail of the specific treatment groups and number of study Subjects in each group and investigative site, Subject number assignment, and the type of enrolment, sequence and duration of study periods.
   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. Medical Management in case of Adverse Reaction,

5. Study Population: the number of Subjects required to be enrolled in the study at the investigative site and by all sites along with a brief description of the nature of the Subject population required is also mentioned.

6. Subject Eligibility:-

    a. Inclusion Criteria

    b. Exclusion Criteria

7. Study Assessments – plan, procedures and methods to be described in detail

8. 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 1, Visit 2, etc.

Discontinued Subjects: Describes the circumstances for Subject withdrawal, dropouts, or other reasons for discontinuation of Subjects. State how dropouts would be managed and 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.

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

9. Study

    a. Dosing schedule (dose, frequency, and duration of the experimental treatment) Describe the administration of placebos and/or dummy medications if they are part of the treatment plan.

    If applicable, concomitant drug(s),their doses, frequency, and duration of concomitant treatment should be stated.

    b. Study drug supplies and administration: A statement about who is going

to provide the study medication and that the investigational drug formulation has been manufactured following all regulations Details of the product stability, storage requirements and dispensing requirements should be provided.

c. Dose modification for study drug toxicity: Rules for changing the dose or stopping the study drug should be provided.

d. Possible drug interactions

e. Permissible Concomitant therapy: Details must be provided.

f. Blinding procedures: A detailed description of the blinding procedure if the study employs a blind on the Investigator and/or the Subject.

g. Unblinding procedures: If the study is blinded, the circumstances in which unblinding may be done and the mechanism to be used for unblinding should be given.

10. Adverse Events- Description of expected adverse events should be given. Procedures used to evaluate an adverse event should be described.

11. Patient Information Sheet / Consent Sheet /Informed consent Form in three languages English, Kannada & Hindi (or any vernacular language)

- Back Translation Certificates of Patient Information Sheet
- Investigator's Brochure
- Subject recruitment procedures if any, e.g. advertisement, etc
- Information about payments or compensations to subject.
    - Amount, method, schedule for payments to subjects must be set forth in the Informed Consent Form & other information provided to subject.
    - Payment to subjects should only include reimbursement of travel expenditure incurred by patient.

- Investigator's Agreement with the Sponsor. (Clinical Trial Agreement -CTA)
- Principal Investigator's [PI]undertaking
- Approval of DCGI / DGFT as appropriate
- Insurance Certificate

Any other documents related to the study protocol which requires an approval

12. Ethical Considerations: Give the summary of:
    a. Risk/benefit assessment:
    b. Ethics Committee review and communications- If available
    c. Informed consent process
    d. Statement of Subject confidentiality including ownership of data and coding procedures
13. 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 who is expected to perform monitoring.

Case Record Form (CRF) completion requirements, including who gets which copies of the forms and any specifics required in filling out the forms CRF correction requirements, including who is authorized to make corrections on the CRF and how queries about study data are handled and how errors, if any, are to be corrected should be stated.

Investigator study files, including what needs to be stored following study completion should be described.

14. Investigational Product Management
    a. Give Investigational product description and packaging (stating all Ingredients and the formulation of the investigational drug and any placebos used in the study)

b. The precise dosing required during the study

c. Method of packaging, labeling, and blinding of study substances

d. Method of assigning treatments to Subjects and the Subject identification code numbering system

e. Storage conditions for study substances

Investigational product accountability: receipt, storage, dispensation, and return of the investigational products to ensure a complete accounting of all investigational products received,

f. Describe policy and procedure for handling unused investigational products.

15. Data Analysis:

Provide details of the statistical approach to be followed including sample size, how the sample size 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 the data for treatment failures, non-compliance, and Subject withdrawals; rationale and conditions for any interim analysis if planned. Describe statistical considerations for Pharmacokinetic (PK) analysis, if applicable

16. Undertaken by Investigator

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

APPENDIX IX

DOCUMENTS OF CLINICAL TRIAL TO BE SUBMITTED & REVIEWED FOR IEC APPROVAL (CHECKLIST)

Date of Meeting ----------

New Clinical Trial /Amendment (ICF /Protocol)

Sl.No	Particulars	Remarks
01	DCGI Approval letter	
02	CTRI Registration No. & letter	
03	Title of Clinical Trial Protocol, Clinical Trial Protocol No., Name of PI & Version No., Details of sponsor.	
04	ICF – 2 Languages (Kannada & any other 1 language) in addition to English & corresponding Translation certificates, Version No.	
05	Investigator broacher, Version No. / Edition No	
06	CRF/ Patient data evaluation form / Patient data collection form	
07	CV of PI	
08	Insurance Details for Study related injuries	
09	Clinical Trial Agreement	
10	Investigator undertaking	
11	Statement describing the details of reimbursement and compensation for the study participants incorporated in the ICF	
12	GCP Trained certificate of PI/ CO PI	
13	Any other	
14	Remarks of Member Secretary	
15	The IEC review charges for the new drug trial / project (Payment Details)	

APPENDIX-X

FORMAT FOR ETHICS COMMITTEE APPROVAL OF CLINICAL TRIAL PROJECTS

To,

Dr.

Dear Dr._____

The Institutional Ethics Committee, JSS Medical College, S S Nagara, Mysore - 570015 reviewed and discussed your application to conduct the clinical trial entitled —……ll on

……. (date).

The following documents were reviewed:

a. Trial Protocol (including protocol amendments), dated____Version no(s). _____

b. Patient Information Sheet and Informed Consent Form (including updates if any) in English and/or vernacular language.

c. Investigator's Brochure, dated__, Version no.

d. Proposed methods for patient accrual including advertisement (s) etc. proposed to be used for the purpose.

e. Principal Investigator's current CV.

f. Insurance Policy / Compensation for participation and for serious adverse events occurring during the study participation.

g. Investigator's Agreement with the Sponsor.

h. Investigator's Undertaking

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

_____Chairman of the Ethics Committee

_____Member secretary of the Ethics Committee

_____Name of each member with designation

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

The Institutional Ethics Committee expects to be informed about the progress of the study at least once in 6 months, any SAE occurring in the course of the study, any changes in the protocol and patient information /informed consent and asks to be provided a copy of the final report of the trial.

Yours sincerely,

Member Secretary, Ethics Committee

APPENDIX- XI

FORMAT FOR INFORMED CONSENT FORM IN A CLINICAL TRIAL

Audio-Visual Informed consent process is enforced on every clinical trial Project associated with vulnerable subjects / new drug/ new chemical entity approved by IEC, JSS Medical College, Mysore.

1. Checklist for study Subject's informed consent documents.

1.1 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 procedures.
4. Description of any reasonably foreseeable 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

1.2 Additional elements, which may be required.

a. Statement of foreseeable circumstances under which the Subject's participation may be terminated by the Investigator without the Subject's consent.

b. Additional costs to the Subject that may result from participation in the study.

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

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

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

f. Approximate number of Subjects enrolled in the study

If the subject has any grievance or complaints, he/or she can contact

1] Chairperson Dr Srinivas Ph number: 9845035639

2] Member Secretary Dr Prathima C…Ph number: 9886100388

3] PI: - Name: ---------- Ph Number: ----------

2. Format of informed consent form for Subject participating in a clinical trial Informed Consent form to participate in a clinical trial Study

Title:

Study Number:

Subject's Initials: Subject's Name: Date of Birth /Age:

Please initial

(Subject)

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

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

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health [ ]

records both in respect of the current study and any further research

that may be conducted in relation to it, even if I withdraw from the

trial. I agree to this access. However, I understand that my identity

will not be revealed in any information released to third parties or published.

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

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

Signature (or Thumb impression) of theSubject/Legally Acceptable Representative:_____

Date: _____ /_____/___/

Signatory's Name:

Signature of the Investigator: _____

Date:_____/_____/_____

Study Investigator's Name:

Signature of the Witness_____ Date:____/ _____/____

Name of the Witness: _____

APPENDIX XII

A. UNDERTAKING BY THE INVESTIGATOR FOR CLINICAL TRIAL PROJECTS.

1. Full name, address and title of the Principal Investigator or Investigator(s)
2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the conduct of clinical trial (Attach details including Medical Council registration number, and / or any other statement(s) of qualification(s)
3. Name and address of all clinical laboratory facilities to be used in the study
4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.
5. Names of the other members of the research team (Co- or sub-Investigators) who will be assisting the Investigator in the conduct of the investigation (s).
6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.
7. Commitments:

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

ii. I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval /

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

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

iv. I agree to inform all Subjects, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the GCP guidelines are met.

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

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

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

viii. I agree to maintain adequate and accurate records and to make those records available for audit / inspection by the Sponsor, Ethics Committee, Licensing Authority or their authorized representatives, in accordance with regulatory and GCP provisions. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.

ix. I agree to promptly report to the Ethics Committee all changes in the clinical trial activities and all unanticipated problems involving risks to human Subjects or others.

x. I agree to inform all unexpected serious adverse events to IEC within 14 days of Reporting of SAE injury / knowledge of occurrence of SAE.

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

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

xiii. Submission of Reports of the project to IEC at prescribed intervals (once in 6 months at the end of study whichever is earlier) for review.

xiv. Final report submitted at the end of study.

Signature of Principal Investigator with Date

APPENDIX: XIII

TEMPLATE OF SCIENTIFIC VALIDATION OF THE CLINICAL TRIAL

(Form to be filled by Reviewer)

Date:

Proposal Title/ Protocol No:

Principal Investigator: Co-Investigators:1.

2.

3.

Supporting Agency:

Name of Agency:

Project Status: New | Revised

Review: Regular | Interim

Date of Review:

1. Research Design

i.	Scientifically sound enough to expose subjects to risk.	Yes	No
ii.	Relevant to contribute to further knowledge.	Yes	No
iii.	Of national importance.	Yes	No

2. Risks

a. Is there physical /social/ psychological risk/ discomfort? Yes No

b. Is the overall risk/benefit ratio Acceptable Unacceptable

3. Benefits

Direct: Reasonable | Undue ☐ None

Indirect: improvement in Science / Knowledge

4. Subject Selection:

i)	Inclusion / exclusion criteria addressed?	**YES**	**NO**
ii)	Vulnerable subjects (woman, child, mentally challenged, Seriously or terminally ill, fetus, economically or socially backward and healthy volunteers) adequately protected?	**YES**	**NO**
iii)	Special group subjects (captives, students, nurses & dependent staff) adequately protected	**YES**	**NO**

5.	**Privacy & Confidentiality maintained?**	Yes	No
6.	**Patient Information Sheet:**	Adequate	Inadequate
7.	**Consent Form components addressed adequately?**	Yes	No
8.	**Compensation, (if applicable) addressed adequately?**	Yes	No
9.	**Is there a Conflict of Interest?**	Yes	No
	If yes	Acceptable Appropriate	Inacceptable Inappropriate

10. Budget:

Appropriate: Inappropriate:

11. Decision of Review

Recommended

Recommended with suggestions

Revision

Rejected

Any Other Remarks/ Suggestions:

Particulars	Name & Designation of IEC member	**Signature**

APPENDIX XIV:

INFORMED CONSENT CHECKLIST (FOR IEC USE)

Details of the Trial:

Title:

Name of the PI: **Protocol Version:**

IEC Number:

Informed Consent Checklist

To fulfill requirements for informed consent, the consent document should address the elements listed below.

The Basic Elements are required of all consent forms.

Information on the Additional Elements should be included as applicable. Basic Elements

_____A statement that the study involves research.

_____An explanation of the purpose of the research.

_____The expected duration of the subject's participation.

_____A description of the procedures to be followed.

_____Identification of any procedures which are experimental.

A description of any reasonably foreseeable risks or discomforts to the subject. Note that potential risks may be physical, psychological, social, legal, or economic. Any risks that may be irreversible should be clearly labeled as such.

A description of any potential benefits to the subject or to others. Benefits may pertain to the individual subject as well as to society. Benefits may take the form of increased knowledge, improved safety, technological advances, and better health.

A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained.

An explanation of whom to contact for answers regarding the following: a) questions about the research and research subjects' rights. b) questions about subjects' rights. c) whom to contact in the event of a research-related injury to the subject.

A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.

Additional Elements As applicable, the consent also must provide the following additional elements:

_____A description of standard care for the condition under study and how the proposed investigational treatment or procedure differs from standard care.

_____A statement that the particular treatment or procedure may involve risks to the subject.

_____Anticipated circumstances under which the subject’s participation maybe terminated by the investigator without regard to the subject’s consent.

_____Additional costs to the subject that may result from participation in the research.

_____Consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject.

APPENDIX XV

CHECKLIST: RESEARCH INVOLVING CHILDREN <18 YEARS (To be filled by PI)

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 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:

No.	Checklist item for the PI to fill before submission (information provided here should also clearly and unambiguously reflect 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 counselling 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:				
	Are there adequate mechanisms in place to deal with other member of family, should there be a risk to such bystanders?			
	Are parents required to be present during the conduct of the rch?			

For the Principal Investigator *(tick whichever is applicable in the risk-benefit columns)*		**For the IEC Secretariat** *(To 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:

IEC Office use only	
Comments of IEC Member:	
IEC Member Signature and Date:	

APPENDIX: XVI

CHECKLIST: REQUIREMENTS FOR RESEARCH INVOLVING PREGNANT WOMEN, NEONATES & FETUSES (To be filled by PI)

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:

Sl.No.	**Checklist item**	**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 will 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:

	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 **IES** and to item no. 2-7 is **NO**, the research will not be approved by IEC.

Fetus of uncertain viability:

Sl No	Checklist item	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, the legally effective 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-1 should not approve the research

Non-viable fetus:

Sl No	Checklist item	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	Is the purpose of the research the development of important biomedical knowledge that cannot be obtained by 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.)			

If the response to any of above is **NO,** the research will 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:

IEC Office use only:

Comments of IEC Member:	
IEC Member Signature and Date:	

ANNEXURE: XVII

CHECKLIST: RESEARCH INVOLVING COGNITIVELY IMPAIRED ADULTS (To be filled by PI)

Study title:
Name of the Principal Investigator:

Sl No	Checklist item *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 and objectives of the study?			
2	Is the risk justified by the anticipated benefit?			
3	Will the participants be closely monitored?			
4	Is the relation of the anticipated benefit to the risk at least as favorable to the participants as that presented by available alternative approaches?			
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 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 IEC Member:	
IEC Member Signature and Date:	

APPENDIX: XVIII

CHECKLIST- RESEARCH INVOLVING STUDENTS, EMPLOYEES OR RESIDENTS

Name of the Principal Investigator:

Study title:

Sl No	Checklist item	Y	N	NA
1	Have the participants been assured that their status (education, employment and/or promotion) will not be affected by any decision to participate or not?			
2	Have the risks to participants been minimized and are such strategies described in the protocol?			
3	Have participants been assured that participation is voluntary (no signs of coercion)?			
4	Have participants been assured that privacy and confidentiality will be protected?			

All items must be marked 'yes' and the same should reflect in the

Signature of Principal Investigator Date:

IEC Office use only	
Comments of IEC Member	

APPENDIX: XIX

CHECKLIST: RESEARCH INVOLVING GENETIC RESEARCH

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

Study Title:

	Checklist item	**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 guidelines for disclosure of information, including interim or inconclusive research results? Will the results be used in management of current condition of 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 Principal Investigator Date:

IEC Office use only	
Comments of IEC Member	

APPENDIX: XX

CLINICAL TRIALS RISK BENEFIT ASSESSMENT TOOL	
HIGH RISK/LOW BENEFIT (CLASS-A)	**HIGH RISK/HIGH BENEFIT (CLASS-B)**
Risks: - Completely new drug/formulation - Highly Toxic substances - Safety/Effectiveness not established through earlier studies - High incidence of SAEs/side effects in prelim studies - Inadequate or no risk AE handling mechanisms - High data disclosure and data leakage possibilities - Affects large no. Of participants - Violation legal/statutory regulations - Inadequate project documentation - Inadequate PI/Staff expertise - New/untried procedures	**Risks:** - Completely new drug/formulation - Highly Toxic substances - Safety/Effectiveness not established through earlier studies - High incidence of SAEs/side effects in prelim studies - Inadequate or no risk AE handling mechanisms - High data disclosure and data leakage possibilities - Affects large no. Of participants - Violation legal/statutory regulations - Inadequate project documentation - Inadequate PI/Staff expertise - New/untried procedures
Benefits: - Cost of treatment/drug borne by participant - Replaces current drugs with no extra benefits either treatment wise or cost wise - Short term relief as opposed to long term action - No post-trial alternatives	**Benefits:** - Completely new cure - Preventive for life i.e. Vaccinations - Significant improvement over existing cures/treatments - Minimal side effects vis a vis existing treatment - Elimination of disease rather than temporarily curative - Significant reduction in treatment costs/mode (ex. Pill vs surgery) - Extension of benefits / availability of treatment posttrial - Benefits large no. of participants

LOW RISK/LOW BENEFIT (CLASS-D) **Risks:** - Proven/Acceptable toxicity - Proven safety and efficacy - Drug/formulation a variation of approved drug/class of drugs - SAEs indicate minor/acceptable reactions, side effects - No drug but only data analysis - Minimal data disclosure/leakage possibilities - Minimal risk to legal/statutory regulations - Standard operating / surgical procedures **Benefits:** - Cost of treatment/drug borne by participant - Replaces current drugs with no extra benefits either treatment wise or cost wise - Short term relief as opposed to long term action - No post-trial alternatives	**LOW RISK/HIGH BENEFIT (CLASS-C** **Risks:** - Proven/Acceptable toxicity - Proven safety and efficacy - Drug/formulation a variation of approved drug/class of drugs - SAEs indicate minor/acceptable reactions, side effects - No drug but only data analysis - Minimal data disclosure/leakage possibilities - Minimal risk to legal/statutory regulations **Standard operating/ surgical procedures** **Benefits:** - Completely new cure - Preventive for life i.e. Vaccinations - Significant improvement over existing cures/treatments - Minimal side effects vis a vis existing treatment - Elimination of disease rather than temporarily curative - Significant reduction in treatment costs/mode (ex. Pill vs surgery) - Extension of benefits / availability of treatment posttrial - Benefits large no. of patients

APPENDIX: XXI

CHECKLIST: PROTOCOL DEVIATION/ VIOLATION REPORTING FORMAT

Title of Study & Protocol No:

……

……

……

Principal Investigator Details:

……

……

Date of EC approval: Date of start of study:

1. Date of PD occurrence:

2. Subject ID: ……

3. Total number of deviations /violations reported till date in the study: ……

4. Is the deviation related to (Tick the appropriate box):

Consenting	☐	Source documentation	☐
Enrollment	☐	Staff	☐
Laboratory assessment	☐	Participant non-compliance	☐
Investigational Product	☐	Others (specify)	☐
Safety Reporting	☐		

5. Provide details of Deviation/Violation:

……

……

……

……

6. Corrective action and Preventive actions taken by PI/Co-I:

……

……

……

7. Any Impact of PD on the outcome of the study(if any):

Yes ☐ If Yes, Study participant …… Quality of data ……..

No ☐

Signature of PI/ CoI: ……

Date: ……

APPENDIX: XXII

SERIOUS ADVERSE EVENT REPORTING FORMAT

Institutional Ethics Committee, JSS Medical College, Mysuru – 570 015

Title of the Study:

……

……

……

Principal Investigator (Details)

:……

……

1. Participant details:

Initials and Case No./ Age at the time of event Gender Weight:……(Kgs)

Subject ID ……

Male Height: ……(cms) ☐

Female ☐

2. Report type: ☐ Initial ☐ Follow-up ☐ Final

If Follow-up report, state date of Initial report

What was the assessment of relatedness to the trial in the initial report?

By PI – ☐ Related By Sponsor – ☐ Related By EC –☐ Related

☐ Unrelated ☐ Unrelated ☐ Unrelated

3. Describe the event and specify suspected SAE Diagnosis:……

.....……

.....……

4. Date of onset of SAE:…… Date of reporting:……..

5. Onset lag time after administration of intervention:

Location of SAE (Clinic/Ward/Home/Other)…… …….

6. Details of suspected drug/device/investigational procedure causing SAE:

I. Suspect drug (include generic name) device/intervention:

……

.....……

II. Indication(s) for which suspect drug was prescribed or tested:

……

.....……

III. Route(s) of administration, daily dose and regimen, dosage form and strength

.....……

IV. Therapy start date:…….. Stop date:……..

7. Was study intervention discontinued due to event? ☐ Yes ☐ No

8. Concomitant drugs history and lab investigations:

I. Concomitant drug (s) and date of administration:

.....……

.....……

II. Relevant test/laboratory data with dates:

.....……

.....……

III. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)

……

.....……

.....……

9. Have any similar SAE occurred previously in this study? If yes, please provide details. Yes ☐ No ☐

.....……

.....……

10. Seriousness of the SAE:

Death	☐	Congenital anomaly	☐
Life threatening	☐	Required intervention to prevent	☐
Hospitalization-initial or prolonged	☐	permanent impairment / damage	☐
Disability	☐	Others (specify)	☐

.....

11. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom).

.....……

.....……

12. Outcome of SAE:

Fatal	☐	Recovered	☐
Continuing	☐	Unknown	☐
Recovering	☐	Other (specify)	☐

.....

13. Was the research participant continued on the trial? ☐ Yes ☐ No ☐ NA

14. Provide details about PI's final assessment of SAE relatedness to trial.

.....

.....

15. Has this information been communicated to sponsor/CRO/regulatory agencies? Yes ☐ No ☐

Provide details if communicated (including date)

16. Does this report require any alteration in trial protocol? Yes ☐ No ☐

17. Provide details of compensation provided / to be provided the participants (Include information on who pays, how much, and to whom)

……

……

Signature of PI:

Date:

APPENDIX: XXIII

STUDY MONITORING VISIT CHECKLIST

1) Project No/ Protocol No.:

2) Title:

3) Principal Investigator:

4) Institute: JSS Medical College & Hospital, Mysore

5) Type of study: Investigator initiated, pharmaceutical company Sponsored, Thesis,

6) a) Date of IEC approval:

   b) Is the period of IEC approval valid: Yes No

7) Start Date of study:_____/____/_____

8) Duration of study:

9) Date of monitoring visit:_____/____/_____

10) Reason for monitoring: Routine

    For Cause (State reason)

    Protocol Violations/Deviations

    SAE reporting

    Recruitment rate

    Any complaints related to the research

    Non-Compliance / Suspicious conduct

    Other _____

11) Last Monitoring done: Yes, Date of last monitoring____/____/_____

12) Project Status: Ongoing, Accrual Completed, Follow-up, Completed, Suspended, Terminated, Closed, Closed Prematurely

13) Recruitment Status:

Total participants/samples to be recruited-_____

Screened:_____

Screen failures: _____

Enrolled:_____

Withdrawn:_____Reason:_____

Discontinued:_____Reason:_____

Completed:_____

Active:_____

Follow-up:_____

14) Is the recruitment on schedule?

Yes

No If 'No' is it acceptable? Yes No

15) Protocol

a) Have there been any amendments to the Protocol? Yes No If Yes then state changes leading to amendment:

b) Is the Protocol version approved by IEC? Yes No

c) Is the latest version of the protocol being used for the study? Yes No

16) Informed Consent

a) Is Informed consent obtained from all enrolled participants? Yes No

b) Have there been any amendments to the ICF? Yes No

c) Is the Informed consent form version approved by IEC? Yes No

d) Is the latest version of the ICF being used for the study? Yes No

e) Is there source documentation of the ICF process? Yes No

f) Is ICF signed by PI /Co-Principal Investigator/Co-I? Yes No

g) Is ICF signed by Participant? Yes No

h) Is ICF signed by LAR? Yes No

j) Is ICF signed by Impartial Witness? Yes No

17) Any Protocol Deviations/Violations noted? Yes No

18) Have all the deviations/violations notified to IEC? Yes No

19) Has the eligibility, inclusion exclusion criteria been adhered to? Yes No

20) Are all the Case report forms complete? Yes, No NA

21) Have there been any AE/SAE on the study? Yes No

If Yes-

a) No. of Adverse events:_____

b) No. of Serious adverse events:_____

c) No. of deaths reported:_____

Deaths unrelated to participation in the trial:_____

Deaths possibly related to participation in the trial:_____

Deaths related to participation in the trial:_____

22) Any are there any changes to the study personnel? Yes, No

If 'Yes' kindly state the same:

Is the change notified to IEC? Yes No

23) Duration of the visit: _____

Monitoring visit conducted by IEC members:

Name of member 1._____

2._____

3._____

Signature and Date 1._____

2._____

3._____

Name of study team member present:_____

Signature and Date:_____

APPENDIX: XXIV

CHECKLIST: CLINICAL TRIAL AGREEMENT (CTA)

Institutional Ethics Committee, JSS Medical College, Mysuru – 570 015

Sl.No	Description	Yes	No
1.	**Protocol Number and Title**		
2.	**Effective date**		
3.	**Parties Involved**- (Sponsor/CRO, Principal Investigator, Institution and or SMO) **Bipartite**		
	Tripartite		
	Quadripartite		
4.	**Agreed terms**-Definition, Conduct of the study, Responsibility of the company, Principal investigator, Institution		
5.	**Study drug and Materials**		
6.	**Study and Protocol**		
7.	**The Study Schedules**		
8.	**Monitoring and audit by the company**		
9.	**Inspection by the regulatory authorities**		
10.	**Payment Details**- Budget and Payment scheduled, Payment of cost outside budget and payment schedule, Payment terms, payment recipient and address, Reimbursement, Payment for screen failure, payment for study coordinator.		
11.	**Obligations of the institution and Principal Investigator**-EC Approval, Performance of the study, Key personnel, sponsor Visit, Supplies		
12.	**Study Records, reports and Data** - Study records, Case report form, Annual reports, Final Reports, **(In case of PI is no longer associated with the institute, Institute head or authorized designee will be responsible for maintenance and retention of study records)**, Reporting of SAE (Sponsor, EC, DCGI and head of institution), 14th day PI analysis Report (Sponsor, EC, DCGI and head of institution).		

13.	**Confidentiality**		
14.	**Publications**		
15.	**Ownership of materials, data, inventions and discoveries.**		
16.	**Representations, warranties and covenant**. -Of the PI, Of the Sponsor, No other Representations or warranties, Of the Institutions		
17.	**Governing Law -This agreement and any dispute or claim out of or in connections with it or its subject matter (including non-contractual disputes or claims) shall be governed by and constructed in accordance with the laws of India without regard to the conflict of law principles thereof. The parties irrevocably agree that the courts of India shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this agreement or its subject matter (including non-contractual disputes or claims).**		
18.	**Indemnification-Sponsor Indemnification, Institution Indemnification, Notification, Claims, Representation, subject injury.**		
19.	**Insurance-Sponsor insurance**		
20.	**Compliance, Transparency, Anti-bribery, Anti-corruption and Conflict of Interest.**		
21.	**Term and Termination**		
22.	**Miscellaneous**		
23.	**Agreed by the parties-Sponsor/CRO, PI, Institution, SMO (if involved)**		
24.	**Witness details**		

Comments:

Signature of Legal Expert:

APPENDIX: XXV

List of Notified and Non-Notified Medical Devices as Per Indian Drugs & Cosmetics Act

(List of Medical Devices which require DCGI approval and the same to be reviewed by IEC)

Notified Medical Devices: -

Drugs Disposable Hypodermic Syringes Disposable Perfusion Sets

In-vitro Diagnostic Devices for HIV, HbSAg,) Cardiac Stents Drug Eluting Stents Catheters

Intra Ocular Lenses

IV cannula

Bone cements

Heart valves

Scalp vein sets

Orthopedic Implants

Internal Prosthetic Replacements Spinal needles

Non-notified Medical Devices: -

Blood Grouping Sera

Ligatures, Sutures and Staplers

Intra Uterine Devices (Cu-T)

Condoms

Tubal Rings

Surgical Dressings

Umbilical Tapes

Blood/Blood Component Bags

APPENDIX: XXVI

FORMAT FOR RECRUITMENT OF EQUITABLE SUBJECTS

Study Title:

PI:

Period of recruitment: Total no. of patient recruitment:

Sl No	Subject Initial	Gender	Age	Address	Education	Date of Consent taken	Randomized or screen failed	Details of Compensation / Travel reimbursement

APPENDIX: XXVII

SUBJECT CHARTER FOR THOSE PARTICIPATING IN THE CLINICAL TRIAL

Rights of subjects who are enrolled in the clinical trial or legal guardians who are going to sign on behalf of the subject

1. 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.
2. To refuse to be in the study at all, and to stop participating at any time after you begin the study.
3. To be told what the study is trying to find out, what will happen to you, and what you will be asked to do if you are in the study.
4. To be told about the reasonably foreseeable risks of being in the study.
5. To be told about the possible benefits of being in the study.
6. To be told whether there are any costs associated with being in the study and whether you will be compensated for participating in the study.
7. To be told who will have access to information collected about you, and how your confidentiality will be protected at any point of time during the clinical trial process.
8. To be told whom to contact with questions about the research, about research-related injury, and about your rights as a research subject. If the study involves treatment or therapy:
9. To be told about the other non-research treatment choices you have.
10. To be told where treatment is available should you have a research- related injury, and who will pay for research-related treatment.
11. To be told about the concomitant medications permissible which do not

affect the trial.

12. Ask questions and understand his/her rights.
13. Follow carefully all directions pertaining to drug dosing, tests and procedures and appear for CT visits as scheduled.
14. Report any apparent /potential adverse drug reaction to the investigator.

Responsibilities Of the Subjects who are going to be enrolled in the Clinical study:

1. Respect investigators / research staff and other participants
2. Read the consent form and other documents. Ask questions if they do not understand something about the study or their rights and responsibilities as a research participant or need more information.
3. Carefully weigh the risk and benefits when deciding whether to participate in the study.
4. Refrain from the signing the consent document until they believe that they understand its content and feel comfortable with their decision to participate.
5. Must sign the Informed Consent Form or undergo informed consent process before enrollment into the clinical trial.
6. Follow directions for proper use, dosing and storage of self-administrated study medications, providing biological samples, and preparing for test, procedures or examinations.
7. Follow directions for abstaining from non-study related medications, or other contraindicated medications or procedures.
8. Know when the study begins and ends. This is particularly important for an intervention trial that has a follow-up period after the intervention is completed.

9. Show up at scheduled appointments on time, and inform the staff within a reasonable time if they need to reschedule an appointment.
10. Provide truthful answers to questions asked during screening / enrolment and during the study.
11. Inform staff if other medical care is needed while on the study.
12. Inform the staff if there are questions, they would rather not answer.
13. Report pain, discomfort, nausea, dizziness and other problems and symptoms they experience during the study.
14. Keep information about the study confidential, if asked to do so.
15. Keep staff informed when contact information (e.g., phone number, address) changes.
16. If they decide to withdraw from the study, inform the staff and follow the procedures for withdrawal.
17. Must return the unused medications to the site without handing over to anybody.
18. The study medication must not be shared with any other person for therapeutic benefit.
19. Must declare the ongoing medications for management of other diseases already associated with participants.

Kannada version

ಅನುಬಂಧ XXVII

ವಿಷಯ ಹಕ್ಕುಪತ್ರ

ಕ್ಲಿನಿಕಲ್ ಪ್ರಯೋಗದಲ್ಲಿ ಭಾಗವಹಿಸುವವರಿಗೆ ವಿಷಯ ಹಕ್ಕುಪತ್ರ

ಕ್ಲಿನಿಕಲ್ ಪ್ರಯೋಗದಲ್ಲಿ ದಾಖಲಾದ ವಿಷಯಗಳ ಹಕ್ಕುಗಳು ಅಥವಾ ಸಹಿ ಹಾಕಲಿರುವ ಕಾನೂನು ಪಾಲಕರು

ವಿಷಯದ ಪರವಾಗಿ

1. ಸಂಶೋಧನಾ ಅಧ್ಯಯನದಲ್ಲಿ ಇರಬೇಕೆ ಅಥವಾ ಬೇಡವೇ ಎಂದು ನಿರ್ಧರಿಸಲು ಸಾಕಷ್ಟು ಸಮಯವನ್ನು ಹೊಂದಿರುವುದು ಮತ್ತು ಸಂಶೋಧನೆ ನಡೆಸುತ್ತಿರುವ ಜನರಿಂದ ಯಾವುದೇ ಒತ್ತಡವಿಲ್ಲದೆ ಆ ನಿರ್ಧಾರ ತೆಗೆದುಕೊಳ್ಳುವುದು.

2. ಅಧ್ಯಯನದಲ್ಲಿರಲು ನಿರಾಕರಿಸುವುದು, ಮತ್ತು ನೀವು ಅಧ್ಯಯನವನ್ನು ಪ್ರಾರಂಭಿಸಿದ ನಂತರ ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಭಾಗವಹಿಸುವುದನ್ನು ನಿಲ್ಲಿಸುವುದು.

3. ಅಧ್ಯಯನವು ಏನನ್ನು ಕಂಡುಹಿಡಿಯಲು ಪ್ರಯತ್ನಿಸುತ್ತಿದೆ, ನಿಮಗೆ ಏನಾಗಬಹುದು, ಮತ್ತು ನೀವು ಅಧ್ಯಯನದಲ್ಲಿದ್ದರೆ ಏನು ಮಾಡಬೇಕೆಂದು ಕೇಳಲಾಗುತ್ತದೆ.

4. ಅಧ್ಯಯನದಲ್ಲಿರುವುದರಿಂದ ಸಮಂಜಸವಾಗಿ ನಿರೀಕ್ಷಿಸಬಹುದಾದ ಅಪಾಯಗಳ ಬಗ್ಗೆ ಹೇಳುವುದು.

5. ಅಧ್ಯಯನದಲ್ಲಿರುವುದರಿಂದ ಆಗಬಹುದಾದ ಪ್ರಯೋಜನಗಳ ಬಗ್ಗೆ ತಿಳಿಸುವುದು.

6. ಅಧ್ಯಯನದಲ್ಲಿರುವುದಕ್ಕೆ ಯಾವುದೇ ವೆಚ್ಚಗಳಿವೆಯೇ ಮತ್ತು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಿದ್ದಕ್ಕಾಗಿ ನಿಮಗೆ ಪರಿಹಾರವನ್ನು ನೀಡಲಾಗುತ್ತದೆಯೇ ಎಂದು ಹೇಳಬೇಕು.

7. ನಿಮ್ಮ ಬಗ್ಗೆ ಸಂಗ್ರಹಿಸಿದ ಮಾಹಿತಿಗೆ ಯಾರು ಪ್ರವೇಶವನ್ನು ಹೊಂದಿರುತ್ತಾರೆ ಮತ್ತು ಕ್ಲಿನಿಕಲ್ ಪ್ರಯೋಗ ಪ್ರಕ್ರಿಯೆಯಲ್ಲಿ ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ನಿಮ್ಮ ಗೌಪ್ಯತೆಯನ್ನು ಹೇಗೆ ರಕ್ಷಿಸಲಾಗುತ್ತದೆ ಎಂದು ತಿಳಿಸುವುದು.

8. ಸಂಶೋಧನೆಯ ಬಗ್ಗೆ, ಸಂಶೋಧನೆಗೆ ಸಂಬಂಧಿಸಿದ ಗಾಯದ ಬಗ್ಗೆ ಮತ್ತು ನಿಮ್ಮ ಹಕ್ಕಿನ ಬಗ್ಗೆ ಯಾರನ್ನು ಸಂಪರ್ಕಿಸಬೇಕು ಎಂದು ಹೇಳಬೇಕು

9. ನೀವು ಹೊಂದಿರುವ ಇತರ ಸಂಶೋಧನಾ ೇತರ ಚಿಕಿತ್ಸಾ ಆಯ್ಕೆಗಳ ಬಗ್ಗೆ ಹೇಳಬೇಕು.

10. ಚಿಕಿತ್ಸೆ ಎಲ್ಲಿ ಲಭ್ಯವಿದೆ ಎಂದು ಹೇಳಲು ನೀವು ಸಂಶೋಧನೆ-ಸಂಬಂಧಿತ ಗಾಯವನ್ನು ಹೊಂದಿರಬೇಕು ಮತ್ತು ಸಂಶೋಧನೆ-ಸಂಬಂಧಿತ ಚಿಕಿತ್ಸೆಗೆ ಯಾರು ಪಾವತಿಸುತ್ತಾರೆ.

11. ಪ್ರಯೋಗದ ಮೇಲೆ ಪರಿಣಾಮ ಬೀರದ ಅನುಮತಿಸುವ ವೈದ್ಯಕೀಯ ಆರೈಕೆ ಬಗ್ಗೆ ಹೇಳುವುದು.

12. ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಿ ಮತ್ತು ಅವನ / ಅವಳ ಹಕ್ಕುಗಳನ್ನು ಅರ್ಥಮಾಡಿಕೊಳ್ಳಿ

13. ಔಷಧದ ಡೋಸಿಂಗ್, ಪರೀಕ್ಷೆಗಳು ಮತ್ತು ಕಾರ್ಯವಿಧಾನಗಳಿಗೆ ಸಂಬಂಧಿಸಿದ ಎಲ್ಲಾ ನಿರ್ದೇಶನಗಳನ್ನು ಎಚ್ಚರಿಕೆಯಿಂದ ಅನುಸರಿಸಿ ಮತ್ತು ಭೇಟಿಗಳಿಗೆ ನಿಗದಿಯಂತೆ ಕಾಣಿಸಿಕೊಳ್ಳಿ.

14. ಯಾವುದೇ ಸ್ಪಷ್ಟ / ಮಡಕೆ ವರದಿ ಮಾಡಿ ಕ್ಲಿನಿಕಲ್ ಅಧ್ಯಯನಕ್ಕೆ ಸೇರ್ಪಡೆಗೊಳ್ಳಲಿರುವ ವಿಷಯಗಳ ಜವಾಬ್ದಾರಿಗಳು:

ಕ್ಲಿನಿಕಲ್ ಅಧ್ಯಯನಕ್ಕೆ ಸೇರ್ಪಡೆಗೊಳ್ಳಲಿರುವ ವಿಷಯಗಳ ಜವಾಬ್ದಾರಿಗಳು:

1. ತನಿಖಾಧಿಕಾರಿಗಳು / ಸಂಶೋಧನಾ ಸಿಬ್ಬಂದಿ ಮತ್ತು ಇತರ ಭಾಗವಹಿಸುವವರನ್ನು ಗೌರವಿಸಿ
2. ಒಪ್ಪಿಗೆ ಪತ್ರ ಮತ್ತು ಇತರ ದಾಖಲೆಗಳನ್ನು ಓದಿ. ಸಂಶೋಧನಾ ಭಾಗವಹಿಸುವವರಂತೆ ಅಧ್ಯಯನದ ಬಗ್ಗೆ ಅಥವಾ ಅವರ ಹಕ್ಕುಗಳು ಮತ್ತು ಜವಾಬ್ದಾರಿಗಳ ಬಗ್ಗೆ ಅವರಿಗೆ ಏನಾದರೂ ಅರ್ಥವಾಗದಿದ್ದರೆ ಅಥವಾ ಹೆಚ್ಚಿನ ಮಾಹಿತಿ ಅಗತ್ಯವಿದ್ದರೆ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಿ.
3. ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಬೇಕೆ ಎಂದು ನಿರ್ಧರಿಸುವಾಗ ಅಪಾಯ ಮತ್ತು ಪ್ರಯೋಜನಗಳನ್ನು ಎಚ್ಚರಿಕೆಯಿಂದ ಅಳೆಯಿರಿ.
4. ಟಿ ವರೆಗೆ ಒಪ್ಪಿಗೆ ಡಾಕ್ಯುಮೆಂಟ್‌ಗೆ ಸಹಿ ಮಾಡುವುದರಿಂದ ದೂರವಿರಿ
5. ಕ್ಲಿನಿಕಲ್ ಪ್ರಯೋಗಕ್ಕೆ ದಾಖಲಾಗುವ ಮೊದಲು ತಿಳುವಳಿಕೆಯುಳ್ಳ ಒಪ್ಪಿಗೆ ಪತ್ರಕ್ಕೆ ಸಹಿ ಹಾಕಬೇಕು ಅಥವಾ ತಿಳುವಳಿಕೆಯುಳ್ಳ ಒಪ್ಪಿಗೆ ಪ್ರಕ್ರಿಯೆಗೆ ಒಳಗಾಗಬೇಕು.
6. ಸ್ವಯಂ ಆಡಳಿತದ ಅಧ್ಯಯನ ಆರೋಗ್ಯ ರಕ್ಷಿಸುವ ಮದ್ದು ಸರಿಯಾದ ಬಳಕೆ, ಡೋಸಿಂಗ್ ಮತ್ತು ಸಂಗ್ರಹಣೆ, ಜೈವಿಕ ಮಾದರಿಗಳನ್ನು ಒದಗಿಸುವುದು ಮತ್ತು ಪರೀಕ್ಷೆ, ಕಾರ್ಯವಿಧಾನಗಳು ಅಥವಾ ಪರೀಕ್ಷೆಗಳಿಗೆ ಸಿದ್ಧತೆಗಾಗಿ ನಿರ್ದೇಶನಗಳನ್ನು ಅನುಸರಿಸಿ.
7. ಅಧ್ಯಯನೇತರ ಸಂಬಂಧಿತ ಆರೋಗ್ಯ ರಕ್ಷಿಸುವ ಮದ್ದು ಅಥವಾ ಇತರ ವಿರೋಧಾಭಾಸದ ಔಷಧ ಅಥವಾ ಕಾರ್ಯವಿಧಾನಗಳನ್ನು ತ್ಯಜಿಸಲು ನಿರ್ದೇಶನಗಳನ್ನು ಅನುಸರಿಸಿ.
8. ಅಧ್ಯಯನ ಪ್ರಾರಂಭವಾದಾಗ ಮತ್ತು ಕೊನೆಗೊಂಡಾಗ ತಿಳಿಯಿರಿ. ನಾನು ವಿಶೇಷವಾಗಿ ಮುಖ್ಯವಾಗಿದೆ
9. ನಿಗದಿತ ನೇಮಕಾತಿಗಳನ್ನು ಸಮಯಕ್ಕೆ ಸರಿಯಾಗಿ ತೋರಿಸಿ, ಮತ್ತು ಅಪಾಯಿಂಟ್‌ಮೆಂಟ್ ಅನ್ನು ಮರು ನಿಗದಿಪಡಿಸುವ ಅಗತ್ಯವಿದ್ದರೆ ಸಮಂಜಸವಾದ ಸಮಯದೊಳಗೆ ಸಿಬ್ಬಂದಿಗೆ ತಿಳಿಸಿ.
10. ಸ್ಕ್ರೀನಿಂಗ್ / ದಾಖಲಾತಿ ಸಮಯದಲ್ಲಿ ಮತ್ತು ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಕೇಳಲಾದ ಪ್ರಶ್ನೆಗಳಿಗೆ ಸತ್ಯವಾದ ಉತ್ತರಗಳನ್ನು ಒದಗಿಸಿ.
11. ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಇತರ ವೈದ್ಯಕೀಯ ಆರೈಕೆ ಅಗತ್ಯವಿದ್ದರೆ ಸಿಬ್ಬಂದಿಗೆ ತಿಳಿಸಿ.
12. ಅವರು ಉತ್ತರಿಸದ ಪ್ರಶ್ನೆಗಳಿದ್ದರೆ ಸಿಬ್ಬಂದಿಗೆ ತಿಳಿಸಿ.
13. ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಅವರು ಅನುಭವಿಸುವ ನೋವು, ಅಸ್ವಸ್ಥತೆ, ವಾಕರಿಕೆ, ತಲೆತಿರುಗುವಿಕೆ ಮತ್ತು ಇತರ ಸಮಸ್ಯೆಗಳು ಮತ್ತು ರೋಗಲಕ್ಷಣಗಳನ್ನು ವರದಿ ಮಾಡಿ.
15. ಸಂಪರ್ಕ ಮಾಹಿತಿ (ಉದಾ., ಫೋನ್ ಸಂಖ್ಯೆ, ವಿಳಾಸ) ಬದಲಾದಾಗ ಸಿಬ್ಬಂದಿಗೆ ಮಾಹಿತಿ ನೀಡಿ.
16. ಅವರು ಅಧ್ಯಯನದಿಂದ ಹಿಂದೆ ಸರಿಯಲು ನಿರ್ಧರಿಸಿದರೆ, ಸಿಬ್ಬಂದಿಗೆ ತಿಳಿಸಿ ಮತ್ತು ಹಿಂತೆಗೆದುಕೊಳ್ಳುವ ವಿಧಾನಗಳನ್ನು ಅನುಸರಿಸಿ.
17. ಬಳಕೆಯಾಗದ ations ಷಧಿಗಳನ್ನು ಯಾರಿಗೂ ಹಸ್ತಾಂತರಿಸದೆ ಸೈಟ್‌ಗೆ ಹಿಂತಿರುಗಿಸಬೇಕು.
18. ಚಿಕಿತ್ಸಕ ಪ್ರಯೋಜನಕ್ಕಾಗಿ ಅಧ್ಯಯನದ ation ಷಧಿಗಳನ್ನು ಬೇರೆ ಯಾವುದೇ ವ್ಯಕ್ತಿಯೊಂದಿಗೆ ಹಂಚಿಕೊಳ್ಳಬಾರದು.
19. ಭಾಗವಹಿಸುವವರೊಂದಿಗೆ ಈಗಾಗಲೇ ಸಂಬಂಧಿಸಿರುವ ಇತರ ಕಾಯಿಲೆಗಳ ನಿರ್ವಹಣೆಗಾಗಿ ನಡೆಯುತ್ತಿರುವ ಆರೋಗ್ಯ ರಕ್ಷಿಸುವ ಮದ್ದು ಪೋಷಿಸಬೇಕು.

APPENDIX: XXVIII

CLINICAL TRIAL SUBJECTS FEEDBACK FORM

Study Title:

Patient ID:

Section 1: General Information

1. **Date of Feedback:**

2. **How long have you been participating in the clinical trial?**

3. **Overall, how satisfied are you with your experience in the trial?**
   Very Satisfied
   Satisfied
   Neutral
   Dissatisfied
   Very Dissatisfied

Section 2: Communication and Information

1. **How would you rate the clarity of information provided about the trial?**
   Excellent
   Good
   Fair
   Poor
2. **Were the trial procedures and requirements explained to you in a way you could easily understand?**
   Yes
   No
   Not Applicable

Section 3: Study Medication and Treatment

1. **Did you experience any side effects from the study medication?**
   Yes
   No
   Not Sure

2. **If yes, please describe the side effects and their impact on your daily life:**

Section 4: Staff Interaction

1. **How would you rate the professionalism and friendliness of the clinical trial staff?**
   Excellent
   Good
   Fair
   Poor

2. **Were your questions and concerns addressed promptly by the study team?**
   Yes
   No
   Not Applicable

   Section 5: Overall Experience

1. **Considering your experience, would you recommend participation in this clinical trial to others?**
   Definitely
   Maybe
   Not Sure
   Probably Not
   Definitely Not

2. **Please provide any additional comments or suggestions for improvement:**

KANNADA VERSION

ಅನುಬಂಧ: XXVIII

ಕ್ಲಿನಿಕಲ್ ಪ್ರಯೋಗದ ವಿಷಯಗಳ ಪ್ರತಿಕ್ರಿಯೆ ಪತ್ರ

ಅಧ್ಯಯನದ ಶೀರ್ಷಿಕೆ:

ರೋಗಿಯ ID:

ವಿಭಾಗ 1: ಸಾಮಾನ್ಯ ಮಾಹಿತಿ

1. **ಪ್ರತಿಕ್ರಿಯೆಯ ದಿನಾಂಕ:**
2. **ಕ್ಲಿನಿಕಲ್ ಪ್ರಯೋಗದಲ್ಲಿ ನೀವು ಎಷ್ಟು ಸಮಯದಿಂದ ಭಾಗವಹಿಸುತ್ತಿದ್ದೀರಿ?**
3. **ಒಟ್ಟಾರೆಯಾಗಿ, ಪ್ರಯೋಗದಲ್ಲಿನ ನಿಮ್ಮ ಅನುಭವದಿಂದ ನೀವು ಎಷ್ಟು ತೃಪ್ತರಾಗಿದ್ದೀರಿ?**
    - ತುಂಬ ತೃಪ್ತಿಯಾಯಿತು
    - ತೃಪ್ತಿಯಾಯಿತು
    - ತಟಸ್ಥ
    - ಅಸಮಾಧಾನ
    - ತುಂಬ ಅಸಮಾಧಾನ

ವಿಭಾಗ 2: ಸಂವಹನ ಮತ್ತು ಮಾಹಿತಿ

1. **ಪ್ರಯೋಗದ ಕುರಿತು ಒದಗಿಸಲಾದ ಮಾಹಿತಿಯ ಸ್ಪಷ್ಟತೆಯನ್ನು ನೀವು ಹೇಗೆ ರೇಟ್ ಮಾಡುತ್ತೀರಿ?**
    - ಅತ್ಯುತ್ತಮ
    - ಒಳ್ಳೆಯದು
    - ನ್ಯಾಯೋಚಿತ
    - ಬಡವ
2. **ಪ್ರಾಯೋಗಿಕ ಕಾರ್ಯವಿಧಾನಗಳು ಮತ್ತು ಅವಶ್ಯಕತೆಗಳನ್ನು ನೀವು ಸುಲಭವಾಗಿ ಅರ್ಥಮಾಡಿಕೊಳ್ಳುವ ರೀತಿಯಲ್ಲಿ ವಿವರಿಸಲಾಗಿದೆಯೇ?**
    - ಹೌದು
    - ಇಲ್ಲ
    - ಅನ್ವಯಿಸುವುದಿಲ್ಲ

ವಿಭಾಗ 3: ಅಧ್ಯಯನದ ಔಷಧಿ ಮತ್ತು ಚಿಕಿತ್ಸೆ

1. **ಅಧ್ಯಯನದ ಔಷಧಿಗಳಿಂದ ನೀವು ಯಾವುದೇ ಅಡ್ಡ ಪರಿಣಾಮಗಳನ್ನು ಅನುಭವಿಸಿದ್ದೀರಾ?**

- ಹೌದು
- ಇಲ್ಲ
- ಸರಿಯಾಗಿ ಗೊತ್ತಿಲ್ಲ

2. ಹೌದು ಎಂದಾದರೆ, ದಯವಿಟ್ಟು ನಿಮ್ಮ ದೈನಂದಿನ ಜೀವನದಲ್ಲಿ ಅಡ್ಡ ಪರಿಣಾಮಗಳು ಮತ್ತು ಅವುಗಳ ಪ್ರಭಾವವನ್ನು ವಿವರಿಸಿ:

ವಿಭಾಗ 4: ಸಿಬ್ಬಂದಿ ಸಂವಹನ

1. ಕ್ಲಿನಿಕಲ್ ಟ್ರಯಲ್ ಸಿಬ್ಬಂದಿಯ ವೃತ್ತಿಪರತೆ ಮತ್ತು ಸ್ನೇಹಪರತೆಯನ್ನು ನೀವು ಹೇಗೆ ರೇಟ್ ಮಾಡುತ್ತೀರಿ?

- ಅತ್ಯುತ್ತಮ
- ಒಳ್ಳೆಯದು
- ನ್ಯಾಯೋಚಿತ
- ಬಡವ

2. ನಿಮ್ಮ ಪ್ರಶ್ನೆಗಳು ಮತ್ತು ಕಾಳಜಿಗಳನ್ನು ಅಧ್ಯಯನ ತಂಡವು ತ್ವರಿತವಾಗಿ ಪರಿಹರಿಸಿದೆಯೇ?

- ಹೌದು
- ಇಲ್ಲ
- ಅನ್ವಯಿಸುವುದಿಲ್ಲ

ವಿಭಾಗ 5: ಒಟ್ಟಾರೆ ಅನುಭವ

1. ನಿಮ್ಮ ಅನುಭವವನ್ನು ಪರಿಗಣಿಸಿ, ಇತರರಿಗೆ ಈ ಕ್ಲಿನಿಕಲ್ ಪ್ರಯೋಗದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನೀವು ಶಿಫಾರಸು ಮಾಡುತ್ತೀರಾ?

- ಖಂಡಿತವಾಗಿ
- ಇರಬಹುದು
- ಸರಿಯಾಗಿ ಗೊತ್ತಿಲ್ಲ
- ಬಹುಷಃ ಇಲ್ಲ
- ಖಂಡಿತವಾಗಿಯೂ ಇಲ್ಲ

2. ಸುಧಾರಣೆಗಾಗಿ ದಯವಿಟ್ಟು ಯಾವುದೇ ಹೆಚ್ಚುವರಿ ಕಾಮೆಂಟ್‌ಗಳು ಅಥವಾ ಸಲಹೆಗಳನ್ನು ಒದಗಿಸಿ: