JKKN
Dental College & Hospital

J.K.K.NATTRAJA DENTAL COLLEGE & HOSPITAL
(MANAGED BY J.K.K. RANGAMMAL CHARITABLE TRUST)
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CODE OF ETHICS FOR RESEARCH AT JKKN INSTITUTION

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Introduction:

All research projects conducted in JKKN Dental college and Hospital were submitted to Institutional Review Board (IRB) and got approval from Institutional Review Board (IRB).

Upon approval from IRB, the research projects will be assessed by Institutional ethics Committee which was functional in JKKN Dental College and Hospital with effect from October 2022 and got registered in DHR portal with effect from 03.10.2023.

Research Integrity

a. Conduct research with honesty, integrity, and transparency.

b. Ensure the accuracy and reliability of research data, methodologies, and results.

c. Avoid plagiarism and give proper credit to the work of others. The Institution uses Urkund Plagiarism software, drillbit plagiarism software, Anti-plagiarism Web-Tool Turnitin or any other software given access to post graduate students by The Tamilnadu MGR Medical University on payment of subscription fees paid by the Institution during uploading of post graduate research work to the university portal.

d. Disclose conflicts of interest that may influence the research process or outcomes.

Compliance with Laws and Regulations

a. Conduct research in accordance with applicable laws, regulations, and ethical guidelines.

b. Obtain necessary approvals, permits, and informed consent from relevant parties.

c. Protect the privacy and confidentiality of research participants and their data.

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Respect for Human Subjects

a. Prioritize the welfare, rights, and dignity of research participants.

b. Obtain informed consent from participants, ensuring they are fully aware of the research purpose, procedures, and potential risks or benefits.

c. Minimize any potential harm or discomfort to participants and provide appropriate care and support.

d. Respect participants' right to withdraw from the research at any time.

Animal Welfare

a. Conduct research involving animals in accordance with relevant laws, regulations, and ethical guidelines.

b. Minimize the use of animals and ensure that their use is justified by the potential benefits to society.

c. Provide appropriate care, housing, and treatment for animals, ensuring their well-being and minimizing any harm or distress.

Data Management and Security

a. Safeguard research data and ensure its accuracy, integrity, and confidentiality.

b. Adhere to data protection and security protocols to prevent unauthorized access, use, or disclosure of research data.

c. Retain research data in accordance with legal and regulatory requirements.

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Collaboration and Authorship

a. Promote fairness, transparency, and appropriate attribution in research collaborations.

b. Clearly define roles, responsibilities, and authorship criteria to acknowledge the contributions of all individuals involved.

c. Avoid any form of research misconduct, including ghostwriting and honorary authorship.

Reporting and Dissemination

a. Communicate research findings accurately, honestly, and objectively.

b. Avoid selective reporting or manipulation of data to support predetermined conclusions.

c. Publish or share research results promptly, ensuring proper acknowledgment of funding sources and contributions.

Continuous Learning and Professional Development

a. Stay updated with the latest advancements, methodologies, and ethical standards in the field of research.

b. Seek opportunities for training, education, and professional development to enhance research skills and knowledge.

Ethical Oversight and Accountability

a. Establish mechanisms for ethical review, oversight, and accountability of research activities.

b. Address any ethical concerns or violations promptly and appropriately.

c. Cooperate with relevant authorities in investigations and inquiries related to research misconduct or ethical breaches.

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This Code of Ethics for research at JKKN Institution serves as a guideline to promote ethical conduct, integrity, and accountability in research activities. It outlines the fundamental principles and standards that researchers at the institution should adhere to, ensuring the responsible and ethical advancement of knowledge and the well-being of research participants and stakeholders.

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NORMS AND GUIDELINES FOR JKKN INSTITUTIONAL ETHICAL COMMITTEE - SOP'S FOR JKKN INSTITUTIONAL ETHICS COMMITTEE

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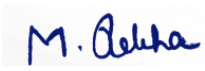
JKKN INSTITUTIONAL ETHICS COMMITTEE JKK Nattaraja Educational Institutions - Dental, Nursing, Pharmacy and AHS			
SOP -5	Title: Standard Operating Procedures to be followed by the committee in General Effective for a period of five years – 2023 to 2028		
Prepared by	Reviewed by		Approved by
Dr Dinesh Kumar, Member secretary, JKKNIEC	Dr Arun R, Basic medical scientist, JKKNIEC	Dr M. Rekha Clinician, JKKNIEC	Dr. Mahendran R, Chairperson, JKKNIEC
			

Purpose

The purpose of this Standard Operating Procedure (SOP) is to explain the process of writing, reviewing, distributing and amending SOPs of the JKKN Institutional Ethics Committee (JKKNIEC}. The SOP provides clear unambiguous instructions so that the related activities of the committee are conducted in accordance with Indian regulations and relevant, national and international ethical guidelines.

1. Scope

This SOP covers the procedures of writing, reviewing, distributing and amending the SOPs of the JKKN Institutional Ethics Committee (JKKNIEC}.

2. Responsibility

It is the responsibility of the Chairperson of the JKKN INSTITUTIONAL ETHICS COMMITTEE(JKKNIEC}. to appoint SOP team to formulate new SOP or to revise existing SOP. The SOP team shall do this by following the standard procedures, format and coding system that is used while drafting or editing any SOP of the IEC. Head of the Institute is responsible for implementing this SOP. The responsibilities of various stake holders of IEC namely secretariat, members, member secretary and chairperson are given below.

Responsibilities of Chairperson of the IEC

- appoint one or more SOP teams consisting of the member-secretary and two or more members of IEC with thorough understanding of ethical review process
- approve the SOPs, sign and date the approved SOPs

Responsibilities of SOP team

- assess the request(s) for SOP/s revision in consultation with the Secretariat, Member Secretary and Chairperson
- propose new / modified SOP/s as needed
- draft the SOP/s in consultation with the IEC members and involved administrative staff
- review the draft SOP

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- submit the draft for approval to Chairperson

Responsibilities of Secretariat of the IEC:

- assist chairperson to constitute SOP Team, co-ordinate activities of writing, reviewing, distributing and amending SOPs
- ensure that all IEC members and involved administrative staff have access to SOPs
- ensure that all IEC members and involved staff work according to current SOP version
- maintain an up-to-date distribution list for each SOP distributed to the IEC members.
- maintain a register to record the names of investigators to whom SOPs are distributed
- maintain a file of all current SOPs and the list of SOPs
- maintain a file of all past SOPs of the IEC

Responsibilities of IEC members and involved administrative staff

- sign and date the approved SOP when they receive it and maintain a file of all SOPs received

4. Detailed instructions

a. Identify the need for new or amendment of current SOP

Any member of IEC or Secretariat who would feel the requirement of 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/ her request by writing to the IEC Chairperson either as an email/ letter/ verbal request in a meeting. The chairperson will inform all the IEC members about this request at a regular full-board IEC meeting. If the IEC members agree to the request, an appropriate SOP team(s) will be appointed by the chairperson and designated the task to proceed with the revision process/ formulation process of the SOP. If the IEC members do not agree, no further action will be taken. The Chairperson will inform the member of the IEC or Secretariat who made the request for modification of the SOP.

b. List of relevant procedures to be carried out by SOP writing team

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- Write all the procedures of IEC that are to be standardized in the form of an SOP
- Organize, divide and name each process

c. Write and review a new SOP

When the need for a new SOP has been identified and agreed upon, a draft will be written by one or more designated members of the SOP team, appointed by the chairperson. Each SOP should be given a number and a title that is self-explanatory and easily understood. A unique code number (JKKNIEC/SOP xa) where " a" will be alphabet assigned specifically to each activity based SOP and "x" will be a number of the sop i.e ., SOP 01a is SOP number 01 with sub title a. The draft SOP written by one or more members of the SOP team will be reviewed by the remaining members of the SOP team. After incorporating the suggestions put forth by the SOP team members; a copy of the revised draft SOP will be sent to membersecretary to circulate it to all the IEC members.

d. Write and review a revised SOP:
If a SOP supersedes a previous version, the previous SOP version will be indicated in Document History Form (JKKNIEC/SOP01/VI) along with description of the main change/s where V1 is version 1.

e. Prepare and submit final draft

- SOP team will submit reviewed SOP to IEC Members who will review it at a meeting.
- The suggestions that are agreed upon by the IEC members present at the meeting will be discussed and incorporated in the revised draft SOP and it will be finalized.
- SOP team would stand automatically dissolved once IEC takes final decision on SOP.

f. Approve the new / revised SOP

- The final version will be presented to the Chairperson for review and approval.
- The authors, reviewers and chairperson will sign and date the SOP on the first page of the SOP document. This date of approval will be declared as the effective date from

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which the SOP will be implemented. The front page will contain signature of Dean Research and Director of the Institution as having accepted the document.

g. Implement, distribute and file SOPs

- The approved SOP will be implemented from the effective date.
- The Member Secretary will discuss the approved SOP with the administrative staff and instruct them to implement it accordingly.
- The approved SOP will be distributed to the IEC members and a log will be maintained.
- One hard copy of complete original set of current version of SOP will be filed in the SOP Master file, by IEC Secretariat in the IEC office.
- Following distribution of revised version, all IEC members will be requested to destroy their earlier version. Only one copy of earlier version will be filed in the file entitled 'Past SOPs of IEC' by IEC Secretariat in IEC office.
- The IEC members and secretariat will review SOPs at least once in every 5 years.

Note: All the standard operating procedures have been made adapting, Forum for Ethics Review Committees in India (FERCI) SOP MODEL as obtained from http://ferci.org/sops/ with few modifications to suit JKKNIEC, JKK Nattaraja Educational Institutions.

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Secretariat of the JKKN Institute Ethics Committee (JKKNIEC) manages protocol and other document submission.

2. Scope

The scope of this SOP includes:

- Submission of Research Project and related documents for initial review of the protocol
- Resubmission of Protocols or Research Projects with corrections
- Submission of Protocol Amendment
- Submissions of written communications related to continuing review of approved protocols
- Protocol completion/Termination of Protocol deviations/violation
- SAE initial/ follow up/ final reports
- Submission of Protocol deviations, Protocol violations

3. Responsibility

It is the responsibility of the IEC Secretariat to receive, record and distribute the received protocols and any other documents for review, act on the instructions given by the appropriate member of the IEC and ensure that the communication reaches the concerned recipient.

4. Detailed Instructions

A. Receive study protocols/ documents

Principal Investigator (PI) will submit a research proposal to the IEC office for review and decision under any of the following sections within the specified time period:

○ New Proposals for Initial Review ○ Re-submission of Protocols with Corrections ○ Amended Protocols and related documents ○ Submission of SAE (On-Site)

Projects should be submitted on or before 5th of a month for consideration of research proposal in that monthly meeting of IEC. All other documents for consideration at the full board meeting (except those related to participant safety, which may be submitted any time) must be submitted at least 72 hours in advance of the meeting to be considered in next meeting agenda.

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B. Initial Review Application

Check for submission items: The Secretariat will check the hard and soft copies of the following items:

a. 2 sets of research proposals (1 original and I set of Xerox copy).

b. Completely filled IEC Project Submission Application Form for Initial Review

c. The marked checklist

d. Duty Delegation Log of the Study team

e. Document Receipt Form.

C. Verification of the contents of Submitted Documents:

The Secretariat will Use the checklist to confirm whether all the ticked documents are there in the application and ensure that the application is complete in terms of required documents (if any essential document is not available an explanation must be sought in writing for the IEC to review). All the following documents must be in the file

1. Project approval by Research committee.
2. Covering letter to Member Secretary/ Chairperson
3. Protocol
4. Amendments to protocol (if any)
5. Informed consent document (ICD) in English and Tamil OR Waiver of Consent form
6. Back translations of ICDs and Back translation certificates (if applicable)
7. Amendments to the ICI) (if any)
8. Case Record Form
9. Recruitment procedures: advertisement, notices, letters to doctors (if applicable)
10. Patient instruction card, identity card, diary etc. (if applicable)
11. Investigator Brochure (if applicable)
12. Regulatory permissions (DCGI approval, FDA marketing/manufacturing license for herbal drugs, Health Ministry Screening Committee (HMSC) approval, Bhabha Atomic Research Centre (BARC) approval) (if applicable)
13. Investigator's Undertaking to DCGI
14. Administrative sanction from the head of the Institution or Memorandum of Understanding in case of studies involving collaboration with other institutions. (if applicable)

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15. A copy of Administration sanction from the head of the Institution or Memorandum of Understanding for sending the samples to laboratories outside the Institution. (if applicable)
16. Brief Curriculum Vitae of all the study team members
17. GCP training certificate (within 5 years) of principal investigator, co-investigator/s and study coordinator/s. (if applicable)
18. Research Methodology training certificate (within 5 years) of principal investigator, coinvestigator/s and study coordinator/s (if applicable)
19. List of ongoing research studies undertaken by principal investigator
20. Investigator's Brochure (as applicable for Drug/Device trials)
21. Agreement to comply with national and international ethical guidelines and GCP protocols
22. Details of Funding agency / Sponsor and fund allocation
23. Clinical Trial Agreement between sponsors, investigators and head of the institution(s)
24. Insurance policy (it is preferable to have the policy and not only the insurance certificate) for study participants indicating conditions of coverage, date of commencement and date of expiry of coverage of risk
25. Indemnity policy clearly indicating the conditions of coverage, date of commencement and date of expiry of coverage of risk
26. Memorandum of Understanding (MOU)for collaborative studies (if applicable)
27. Ethics Committee clearance of other centers (if applicable)
28. Institutional Stem cell Research Committee approval (if applicable)
29. Documentation of clinical trial registration (if available)
30. Any additional document(s), as required by IEC

D. Complete the submission process: The Secretariat will:

Complete the checklist of submission

- Stamp the receiving date on the first page/last page of the covering letter and initial it.
- Keep the copies of the submitted documents with original signatures in the protocol "Submission" file.
- Number the project file asJKK Nataraja Educational Institutions/ IEC/ SNO of proposal/year (20..)

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E. Dispatch and Store the received Documents: The Secretariat will Prepare 2 sets of a protocol package containing completed application form, protocol related documents along with checklist and send 1 set to the IEC members along with a copy of Project Assessment Form for Initial Review after the last day of submission is over, ensuring at least 5 days for review before the next meeting.

F. Store the appropriately labelled original protocol documents in the designated storage area in the IEC office.

G. If the IEC members prefer to receive and review soft copies, these are sent in a CD/pen drive/ email along with a copy of Project Assessment Form for Initial Review after the last day of submission is over, ensuring at least 5 days for review before the next meeting.

5. Resubmission of Protocols with corrections and Amendments of protocol/ related documents

For resubmitted protocol, the PI will submit one soft copy and one hard copy of the amended Protocol and related documents.

- The Secretariat will verify the completeness of the documents and confirm that the copy contains the modifications highlighted with respect to the earlier protocol submitted mentioning the justification for the amendment.
- The protocol related documents which do not require to be changed and are already submitted for the IEC office during initial review are not required to be submitted again.
- The Secretariat will present the file to the Member Secretary

The Member Secretary will decide if a resubmitted protocol

6. will follow all steps of initial review and handle it as decided in the meeting (e.g. Carry out review by one or more member(s) selected by the Chairperson. The selected members are normally those who reviewed and recommended the previous version of that protocol) or keep on full board agenda. Annual Continuing Reviews of Approved Protocols, Amended Protocols and related documents, Study completion/ termination, SAE report, Protocol deviations.

The IEC will receive one soft copy and one hard copy of the Continuing Review Report, Amended Protocols and related documents, Study completion/ termination, SAE report, protocol deviations in the prescribed format as given in the applicable SOPs.

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7. Annexures

Annexure 1: AX 01/JKKNIEC /SOP 05a- Document Receipt Form

Annexure 1: AX 01/JKKNIEC /SOP 05a- Document Receipt Form

Protocol Number:

Received number:

Submitted date:

Protocol Title:

Principal Investigator: Department

Communication with the IEC

- E-mail address
- Phone
- Fax

Documents submitted: •

Complete

- Incomplete, will submit on… . . . .

Documents to be submitted later:

- Final signed clinical trial agreement
- To verify and tick whether documents received.
- informed consent form (in vernacular language)
- final signed clinical trial agreement
- study budget

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- DCGI approval
- GCP Training certificate
- CTRI registration

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JKKNIEC Application Form

Version 1.0 for

PG students

JKKN EDUCATIONAL INSITITUTIONS

(Affiliated to The Tamilnadu Dr Mgr Medical university)

FORMAT FOR SUBMITTING PG DISSERTATION PROPOSAL

SECTION- 1

PART A - GENERAL INFORMATION

1. Title of the dissertation
2. Name of the Student Researcher with mobile numbers and email ID
3. Name of the course studying
4. Year of admission
5. Month and year of appearing for final examination
6. Month and year of submitting dissertation
7. Name (s), Designation (s) & Addresses of the guide and co-guide (s) with mobile numbers and email ID
8. A. State whether it is intradepartmental or interdepartmental
   B. If the study is interdepartmental
      I. State the names of collaborating departments ll. State whether consent has been obtained from them.
9. Total funds required for the study (in rupees)
10. Source of funding.

PART B — TECHNICAL DETAILS

1. Title of the dissertation
2. Introduction
   A. Problem statement
   B. Rationale
   C. Novelty
   D. Expected outcome and application
3. Research question(s)
4. Research hypothesis (es), if any
5. Aim and objectives: Primary objective(s) & secondary objective(s)
6. Review of literature
7. Methodology

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1. Study design
2. Study participants (human, animals or both)
    a. Inclusion criteria
    b. Exclusion criteria
    c. Withdrawal criteria, if any (trial-related therapy, follow-up and documentation are terminated prematurely as it is indicated to ensure safety of the participants)
    d. Rescue criteria, if applicable (starting symptomatic therapy either to control symptoms of disease or to overcome lack of adequate efficacy of the study drug or placebo)
    e. Number of groups to be studied, identify groups with definition
3. Sampling
    a. Sampling population
    b. Sample size calculation
    c. Sampling technique
4. Randomization details (for interventional studies)- Intervention details with standardization techniques (drugs / devices / invasive procedures / noninvasive procedures / others)
5. Study procedure
6. Data collection methods including settings and periodicity
7. If the clinical trial, whether registration with CTRI will be done
8. Are the drugs/devices to be used approved for these indications by Drug Controller General of India (DCG-I)? (Enclose the approval letter for the drug/device from DCG-I for trial on humans or give undertaking to get the approval from DCGI; For all drugs and devices submit
documents showing DCGI approval for the proposed indication of the study)

I.List of variables and their measurement methods with standardization techniques
    a. Independent variables
    b. Outcome variables
    c. Confounding and interacting variables

J. List variable wise statistical tests to be used for data analysis

8. List risks and benefits of the study
9. Relevant references for the project
(Minimum 10, Maximum 20) (in Vancouver style)
10. Enclosures
    1. Brief CV of guide and co-guides
    2. Data collection proforma
    3. Questionnaires
    4. Consent form (English version)
    5. Other relevant papers
11. Undertaking for DCGI approval
12. Declaration by guide

1.Signature of the Student Researcher
(Name & Designation)

2.Signature of Head of the Department of the

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candidate
(Name & Designation,
Department Seal and Date)

3.. Signature of the guide
(Name & Designation,
Department, Seal and Date)

4. Signature (s) of the co-guide
(Name & Designation,
Department seal and Date)

5.Signature(s) of Head(s) of the Collaborating department (s)
(Name & Designation,
Department Seal and Date)

6.Signature(s) of the Co-guide from collaborating department (s) (Name & Designation, Department, Seal and Date)

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SECTION - 2

(For Institute Ethics Committee (IEC)-Human Studies)

Proforma to be submitted to the JKKN Institutional Ethics Committee for MDS Students (for Thesis or Dissertation) l. Title of the project:

2. Name and department/address of the Student Researcher:
3. Name of Faculty (Guide/Co-guide) with designation & department:
4. Date of approval by Departmental PG monitoring committee:
5. Ethical issues involved in the study [Along with level of risk, the risks should be written in detail. If you feel there will be no risk, give justification]:

   less than minimal risk / minimal risk / minor increase over minimal risk/more than minimal risk to the study subjects (for guidance please consult "National Ethical Guidelines for Biomedical and Health Research involving Human Patticipants, 2017")

6. Do you intend to co-enroll participants from other studies where the guide or co-guide are the principal investigator or co-investigator? Yes / No

7. If co-enrollment will be done, details of the other projects should be given as following:
8. Benefit of the study:
9. Details of Informed Consent Process:

a) Who will take the informed consent?

b) When will the informed consent be taken?

c) How will the informed consent be taken?

d) Where will the informed consent be taken?

10. Do you need exemption from obtaining Informed Consent from study subjects - if so give justifications.

1 1. Whether Consent forms in English and in local language are enclosed? (if the consent form in local language is not applicable, appropriate explanations must be provided)

12. Documents attached

   a. Waiver Application Form (Annexure-I)-if applicable
   b. Review Exemption Application Form (Annexure-2)-if applicable
   c. Brief CV of Guides and Co-Guides (including no. of projects with him/her) - Needed for all Investigators for each project separately
   d. For student projects, the guide should give a signed statement on a separate sheet with details of the project proposal that "I take full responsibility and accountability for planning,

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execution and adverse events occurring during the study. The data collected and records will be retained by me for a period of three years"

e. Investigator's brochure

f. Others

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

14. We, the undersigned, have read and understood this protocol and hereby agree to conduct the study in accordance with this protocol and to comply with all requirements of the ICMR guidelines (2017)

A. Signature of the Student Researcher
(Name & Designation)

Signature of the guide
(Name & Designation, Department,
Seal and Date)

Signature (s) of the co-guide
(Name & Designation, Department,
Seal and Date)

Signature of Head of the Department of the candidate
(Name & Designation, Department,
Seal and Date)

B. Signature(s) of the Co-guide from collaborating department (s)
(Name & Designation, Department,
Seal and Date)

Signature(s) of Head(s) of the Collaborating department (s)
(Name & Designation, Department,
Seal and Date)

Note: The proforma must be accompanied by Informed Consent Document (ICD) in English and Tamil. Informed Consent Document should comprise Patient Information Sheet and the consent form. The investigator must provide information to the subjects in a simple language, and it should address the subjects, in a dialogue format. Studies involving children below 7 years should include parent / LAR consent form, while studies involving children above 7 years and below 18 years of age should also include written assent form for children 12-18 years of age and verbal assent for children 7-12 years to be mentioned in parent/LAR consent form, in addition to parent / LAR consent form

DECLARATION

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Title of the Study:

I take full responsibility and accountability for planning, execution and adverse events occurring during the study. The data collected and records will be retained by me for a period of three years.

Signature of Guide

(Name & designation of guide)

INFORMED CONSENT DOCUMENT (ICD) PART-I

PATIENT / PARTICIPANT INFORMATION SHEET

INFORMATION FOR PARTICIPANTS OF THE STUDY

Instructions - This is the patient information sheet. It should address the participant of this study. Depending upon the nature of the individual project, the details provided to the participant may vary. A separate consent form for the patient/test group and control (drug/procedure or placebo) should be provided as applicable. While formulating this sheet, the investigator must provide the following information as applicable in a simple language in English and Tamil which can be understood by the participant. (Do not copy & paste from the study protocol). Do not use technical terms in the PIS. If participants are children, the participant information sheet should address the parents/LAR of the children and should be worded accordingly.

Title of the project

- Name of the Student Researcher/Guide/Co-Guides
- Purpose of this project/study
- Procedure/methods of the study

Expected duration of the subject participation

- The benefits to be expected from the research to the participant or to others and the post trial responsibilities of the investigator
- Any risks expected from the study to the participant

Maintenance of confidentiality of records

- Provision of free treatment for research related injury
- Reimbursement for participating in the study
- Compensation to the participants for foreseeable risks and unforeseeable risks related to research study leading to disability or death.
- Freedom to withdraw from the study at any time during the study period without the loss of benefits that the participant would otherwise be entitled
- Possible current and future uses of the biological material to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, this should be mentioned

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- Possible current and future uses of the data to be generated from the research and if the data is likely to be used for secondary purposes or would be shared with others, this should be mentioned
- Address and mobile number of the Student Researcher and Guide:
- Address and Contact details of IEC office –

Signature of the participant: Signature of the investigator:
Place:
Date:

INFORMED CONSENT DOCUMENT (ICD) PART-2

INFORMED CONSENT FORM

Title of the project: Participant's name:
Address:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I confirm that I have understood about the compensation and the risks and benefits involved in this research. I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving any reason, and without my routine medical care in this hospital being affected. I understand that confidentiality of my identity will be maintained during the research period, after its completion as well as during publication of the results. Only investigator, ethics committee, institutional or regulatory authorities may have access to my information when required.

I have been given a copy of information sheet giving details of the study. I volunteer to participate in the above mentioned study.

(I also consent/ do not consent to use of my stored biological samples or related data for future scientific purposes, if applicable)

(I also consent / do not consent to be contacted over telephone for study purposes/ knowing the results — if applicable)

Name and Signature/thumb impression of the participant: Date:

Date:

Signature of the witness with date:

Name and address of the witness for illiterate participants:

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Signature of the investigator with date: ——————————Date: ——————

CONSENT FORM (for participants less than 18 years of age and for patients who cannot consent)

Parent/Legally authorized/acceptable representative (LAR)

Title of the project:

Participant's name:

Address:

Parent/LAR' s name:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I confirm that I have understood about the compensation and the risks and benefits involved in this research. I understand that my child's/ward's participation in the study is voluntary and that I am free to withdraw at any time without giving any reason, and without my child's/ward's routine medical care in this hospital being affected. I understand that confidentiality of my child's/ward's identity will be maintained during the research period, after its completion as well as during publication of the results. Only investigator, ethics committee, institutional or regulatory authorities may have access to my child's/ward's information when required.

I have been given a copy of information sheet giving details of the study. I volunteer my child/ward to participate in the above mentioned study.

Verbal assent taken for children 7-12 year of age: Yes/No

(I also consent/ do not consent to use of my child's/ward's stored biological samples or related data for future scientific purposes, if applicäble)

(I also consent / do not consent to be contacted over telephone for study purposes/ knowing the results — if applicable)

Name and Signature/thumb impression of the parent/LAR: Date:

Signature of the witness with date: Date:

Name and address of the witness for illiterate participants:

Signature of the investigator with date: Date: ASSENT FORM

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(for children above 12 years and below 18 years of age)

Assent form to participate in a clinical research

Child Participant's name: Date of birth/Age:

rent/LAR' s name: Address:

Title of the project:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I confirm that I have understood about the compensation and the risks and benefits involved in this research. 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 the medical care that will normally be provided by the hospital being affected. 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). I understand that following completion of study as well as during publication of the results, confidentiality of my identity will be maintained. I have been given an information sheet giving details of the study. I fully assent to participate in the above study.

Signature of the child participant: Date:
(If child knows to sign/Thumb impression)

Signature of the parent or guardian Date:

Name and address of the witness:

Signature of the witnessDate:

Signature of the Investigator Date:

(Assent form should be accompanied by patient / participant information sheet for children in a simple language comprehensible to a child from12-18 year; Verbal assent to be recorded in LAR consent form for children 7-12 years of age and written assent form for children from 12-18 years of age. Language used should be simpler for children in the age group 7-12 years compared to children in the age group > 12-18 years)

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Annexure-2 AXO2/JKKNIEC /SOP 05a

Application form for requesting waiver of consent

1. Student researcher's and Guide's name.
2. Department:
3. Title of project:
4. Names of co-guides and Department/s:
5. Request for waiver of informed consent:

☐ Please tick the reason(s) for requesting waiver (Please refer the back of this annexure for criteria that will be used by EC to consider waiver of consent).

1. Research involves hot more than minimal risk'
2. There is no direct contact between the researcher and participant
3. Emergency situations as described in ICMR Guidelines
4. Any other (please specify)

☐ Statement assuring that the rights of the participants are not violated:

☐ State the measures described in the Protocol for protecting confidentiality of data and privacy of research participant:

Student Researcher and Guide signature with date.

_____

Final decision at full board meeting held on:

_____

Waiver granted: Yes ...No.....

If not granted, reasons,

_____

Signature of the Chairperson with Date:

_____

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Annexure-3 AX03/JKKNIEC /SOP 05a REVIEW

EXEMPTION APPLICA TION FORM

1 Student Researcher and Guide Name:

_____

2 Department:

_____

3 Title of Project:

_____

4 Names of other participating staff and students:

_____

5 Brief description of the project:

Please give a brief summary (approx. 300 words) of the nature of the proposal, including the aims/objectives/hypotheses of the project, rationale, participants' description, and procedures/methods to be used in the project:-

6 State reasons why exemption from ethics review is requested?

☐ Audits of educational practices

☐ Research on microbes cultured in the laboratory

☐ Research on immortalized cell lines

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☐ Research on cadavers or death certificates provided such research reveals no identifying personal data

☐ Analysis of data freely available in public domain ☐

Any other

(This should include justification for exemption e.g. study does not involve human participants. If exemption is being requested on the basis of low risk involved in the study please refer to the backside of this annexure.)

Student Researcher and Guide signature with date::

_____

Forwarded by the Head of the department:
Name: _____Signature: _____
Date

Recommendations by the IEC Member Secretary:
Exemption
Cannot be exempted
Reasons
Discussion at full board

Signature of the Member Secretary: _____
Date_____

Final Decision:
Exemption
Cannot be exempted
Reasons_____

Discussion at full board
Signature of the Chairperson: _____
Date_____

Final Decision at Full Board meeting held on

_____

Signature of the Chairperson: _____
Date_____

No research can be counted as low risk if it involves:

(i) Invasive physical procedures or potential for physical harm

(ii) Procedures which might cause mental/emotional stress or distress, moral or cultural offence

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(iii) Personal or sensitive issues

(iv) Vulnerable groups

(v) Cross cultural research

(vi) Investigation of illegal behaviour(s)

(vii) Invasion of privacy

(viii) Collection of information that might be disadvantageous to the participant

(ix) Use of information already collected that is not in the public arena which might be disadvantageous to the participant

(x) Use of information already collected which was collected under agreement of confidentiality

(xi) Participants who are unable to give informed consent

(xii) Conflict of interest e.g. the researcher is also the lecturer, teacher, treatment-provider, colleague or employer of the research participants, or there is any other power relationship between the researcher and the research participants.

(xiii) Deception

(xiv) Audio or visual recording without consent

(xv) Withholding benefits from "control" groups

(xvi) Inducements

(xvii) Risks to the researcher

This list is not definitive but is intended to sensitize the researcher to the types of issues to be considered. Low risk research would involve the same risk as might be encountered in normal daily life.Please check that your application I summary has discussed:

☐ Procedures for voluntary, informed consent

☐ Privacy & confidentiality

☐ Risk to participants

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- Needs of dependent persons
- Conflict of interest
- Permission for access to participants from other institutions or bodies
- Inducements

In some circumstances research which appears to meet low risk criteria may need to be reviewed by the IEC. This might be because of requirements of an organisation which is providing funding resources, existing data, access to participants etc.

- The publisher of the research

CHECK LIST

(To be filled and duly signed by the Student Researcher and Guide)

Title of the study:

Name of the Student Researcher/Guide:

Designation & Department:

S.No	Items	Yes/No
1	Exact title as approved by PGRMC (PG RESEARCH MEDICAL COMMITTEE)/ UGRMC (UG RESEARCH MEDICAL COMMITTEE)	
2	Date of PGRMC/ UGRMC approval mentioned in proper format (dd/mm/yyyy)	
2	Source of funding mentioned	
3	Adequate literature review with justification for the study mentioned	
4	Detailed description about methodology (Study design, number of groups, sample size etc)	
5	No mirror statement in Inclusion/Exclusion criteria (Ex: Age < 18 in inclusion & Age > 18 in exclusion)	
	Permission from DCGI (if applicable).	
6b	DCGI approval for the mentioned indication in the study (for drugs, devices, cosmetics etc)	
7	Adequate justification for exemption from obtaining informed consent given (if applicable).	
8	Details regarding co-enrollment of research participants (if applicable)	
9	Informed Consent Document in both English and Tamil attached as per SOP format.	
10	Information to the participant/ parent/guardian in layman (simple) language.	

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1 1	Validated questionnaire both in Tamil and English attached (if study involves interview/ questioning)	
12	Signature of all investigators (Principal & Co-investigator) and Head of corresponding department obtained with date	
13	Compensation mentioned as per guidelines in consent form part 1	
14a	Confidentiality mentioned as per guidelines in consent form part 1	
14b	Separate consent form for subjects < 7 yrs attached (if applicable)	
15	Separate assent form for subjects > 7 yrs < 18 yrs attached (if applicable)	
16	Separate consent form for cases and controls attached (if applicable)	
17	Ethical issues explained in detail with level of risk	
18a	No discrepancy between tamil and English consent form	
18b	Declaration form from Guide (for all UG/PG/PhD/DM,MCh projects) regarding overall responsibility for the research	
19	Declaration form from principal investigators / Guide stating that all procedures used in the study are standard and professionally acceptable (for faculty projects / for all UG/PG/PhD/DM,MCh)	

Date: Signature of Student Researcher/Guide

(It is mandatoty to submit this form along with proforma)

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SECTION - 3

FOR INTRAMURAL RESEARCH FUND COMMITTEE

BUDGET DETAILS

1. Title of the Project:
2. Total amount Required:
3. Year wise break-up of the amount:
4. Budget requirement:
    a. Consumable (Provide the list of items required with all relevant details)
    b. Non-consumable (Detailed justification required)
    c. Travel (Not for attending conference) — field work etc. 5. Justification for the budget:
6. For Faculty project:
    a. No. of intramural grants received in last five years:
    b. Enclose order copy of last intramural grant:
    c. Enclose copy of UC, SOE and progress report of last intramural grant:
    d. No. of extramural grants received in last five years:
    e. Enclose order copy of last extramural grant:
    f. Enclose copy of UC, SOE and progress report of last extramural grant:
7. For projects where faculty as a guide:
    a. Name of the Candidate:
    b. Study course:
    c. Year of the study:
    d. No. of previous intramural grant received:
    e. Enclose order copy of last intramural grant:

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f. Year of receiving the last intramural grant:

g. Amount of receiving the last intramural grant

h. Enclose copy of UC, SOE and progress report of last intramural grant:

Declaration:

A) I/we declare that the infrastructure necessary for carrying out the above-mentioned research scheme are available with me/us.

B) I/we agree to submit within, one month of termination of the scheme a final report on the work and an annual report within one month of expiry of a year if the project goes for more than one year. Extension of the project will be subject to approval of the report by the expert committee.

C) The faculty members those who have not submitted the final reports in respect of earlier projects granted by the Institute, are not entitled for the Institute Grant in future till they submit the report.

Principal Investigator (Guide)

Co-Investigator (S)

Forwarded with remarks from Head of the Department (in which the principal Investigator is working)

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1. Purpose

The purpose of this SOP is to describe the procedure to categorize new research study protocols submitted by investigators for initial review into full board / expedited review or exemption from review process to Institutional Ethics Committee (IEC).

2. Scope

This SOP covers the process of categorization of new research study protocols submitted to IEC for initial review. It does not cover subsequent submissions.

3. Responsibility

It is the responsibility of the Member-Secretary [in consultation with Chairperson (as applicable)] to categorize the research studies in one of the three types of reviews, depending on the risks involved for prospective research participants: Full board review, expedited review and exemption from review.

4. Detailed Instructions

1. New proposals received for initial review

- New research study proposals received by 5 th of the month will be considered for review in that monthly meeting of the IEC. Secretariat will ensure that application of research proposal is complete in terms of required documents (if any essential document is not available, explanation must be sought in writing for IEC to review).

2. New proposals forwarded to Member Secretary

- Secretariat will forward the copy of research proposal to Member Secretary for initial screening within 2 working days of receiving proposal. Member Secretary

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will screen the research proposals and categorize the proposals as elaborated in Section 4.3 within 2 working days of receipt.

3. Categorization of New proposals for review by IEC

- The Member Secretary [in consultation with Chairperson (as applicable)] will categorize the proposals into three types. The types of review processes and the criteria to decide the type of review are explained below (www.icmr.nic.in, National Ethical Guidelines for Biomedical and Health Research Involving Iluman Participants, Indian Council ofMedical Research, 2017):

- Full Board Review: When new research proposals and other related documents are tabled in a formally convened meeting of the Ethics Committee for detailed discussion and decision, this is called Full Board Review.

- Research studies involving more than minimal risk to human study participants are required by national and international regulations to be reviewed by the Ethics Committee full board. o Research that is considered minimal risk but involves vulnerable populations may be referred for Full Board Review. o Research proposals that have undergone expedited review and are referred to Full Board as no decision could be reached.

- Expedited Review: When new research proposals and related documents undergo a speedy review process by only two or three designated (by the Chairperson) Ethics Committee members this is called Expedited Review.

  - Proposals involving instructional techniques, curricula or class room management methods.
  - Minor modifications of proposals already approved by full review Institutional Ethics Committee (IEC).
  - Change in the name, address of sponsor /PI, contact details of PI, Chairperson and or Member Secretary of IEC,
  - Request for change in principal investigator, co-investigator, change in any member involved in the research
  - Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.
  - Minor amendments in the protocol, case record forms,

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- Minor corrections in budget, Other administrative changes in investigator brochure, informed consent document
- Proposals involving clinical materials that have been collected for non-research or clinical purposes (i.e. patient care records and specimens).
- Proposals involving emergency outbreaks and disasters for pilot study if IEC full review is not possible.
- Proposals NOT involving therapeutic, diagnostic, prophylactic and screening interventions.
- Proposals NOT involving vulnerable and special groups.
- Collection of data for research purposes through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice and using medical devices which have been already approved for use. Examples of such procedures include collection of data through application of EEG or ECG electrodes, acoustic testing, tests using the Doppler principle, noninvasive blood pressure and other routine clinical measurements, exercise tolerance etc. However procedures involving the use of x-rays or microwaves are NOT recommended for expedited review.
- Clinical studies of drugs and medical devices only when research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or Research on Disaster management.

• Exemption from review: When research fulfils the following criteria, the IEC will grant an exemption from review:

- Research does not involve live human participants, is on data in the public domain or is on anonymised data derived from participants and the research has less than minimal risk to participants, an exemption from IEC review may be considered.
- Examples that may be eligible for exemption from review include: i

Audits of educational practices

ii Research on microbes cultured in the laboratory o Research on immortalized cell lines

iii Research on cadavers or death certificates provided such research reveals no identifying personal data o Analysis of data freely available in public domain.

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iv PI may also apply to IEC for exemption from review if he / she find that proposed research satisfies criteria for exemption.

6. Flow Chart

S.No	Activity	Responsibility
I	Receiving new research study proposal and related docunnents by a fixed date of the month	Secretariat
2	Verifying completeness of submitted research study documents	Secretariat
3	Forwarding of new proposals to Member-Secretary IEC	Secretariat
4	Categorization of the Protocols into 3 categories: full board, expedited review and exemption from review process	Member-Secretary

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the members of Institutional Ethics Committee (IEC) will perform an initial review on a new research study protocol using the assessment Form.

2. Scope

This SOP applies to the initial review and assessment of all research study protocols submitted for review and approval from the IEC. All research studies presented with more than minimal risk and which do not qualify for exemption or expedited review are covered in this SOP.

3. Responsibility

- Member Secretary is responsible, after categorization of studies to forward the studies to Secretariat.
- Secretariat is responsible for creation of a study specific file, distribution of packages along with study assessment forms to IEC members for review (If the study is categorized for Full Board review), and communicate the review results to the investigators.
- IEC members (including Member Secretary) will be responsible for reviewing the research protocols and related documents within the given time frames.
- The IEC members are responsible for attending and participating actively in the discussion at the full Board Meeting.
- The Member Secretary is responsible for setting up the Full Board Meeting.
- IEC Secretariat is responsible for recording and filing the decision, relevant points and deliberation about a specific protocol, including the reasons for that decision.

Member Secretary is responsible to sign and date the decision in the IEC Decision Form.

4. Detailed instructions

4.1 Appointment of primary reviewers

The Member Secretary/Chairperson will appoint two or more primary reviewers for each study on the basis of expertise in the related field and experience. They will include one clinician and one non-technical person as applicable. More than two may be appointed if necessary.

4.2 Distribute the protocol package

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- The Secretariat will fill in the required details in the cover letter to the IEC Members requesting initial review along with study assessment form. Secretariat will send a packet (hard or soft copy) to the IEC members.
- Letter to IEC Members requesting Initial Review
- Study assessment form
- Study Submission Application Form
- Protocol and related documents

4.3 Receive the distributed protocol package • IEC members will receive the protocol package with the Study Application Form as hard copy or through email (if desired so).

- Designated primary reviewers will also receive Study Assessment Form for Initial review

4.4 Verify the contents of the package

- IEC member will verify all the contents.
- IEC member will check the meeting date to see if it is convenient to attend the meeting.
- IEC member will notify the IEC Secretariat if any documents are missing or if the specified date of the IEC meeting is not convenient to attend.

4.4 Review by the IEC members

Review of the protocol

The protocol will be reviewed by each member as per guidelines to review study protocol. The IEC member will consider the following criteria when performing the review of the study protocol and the study related documents: o Scientific design and conduct of the study o Risks and potential benefits

- Selection of study population and recruitment of research participants o Inducements, financial benefits and financial costs o Protection of research participants' privacy and confidentiality o Community considerations
- Qualifications of Investigators and assess adequacy of study sites o Disclosure or declaration of potential conflicts of interest

The IEC member will consider the following criteria when performing the review of the Informed consent

- Voluntary, non-coercive recruitment, participation/ withdrawal
- Procedures for obtaining informed consent
- Contents of the patient information sheet - title, objective, study design and procedures
- Contents and language of the informed consent document
- Translation of the informed consent document in the local languages

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- Language used — plain and easy to understand by general public
- Contact persons with address and phone numbers for questions about research participants rights and study or injury
- Privacy and confidentiality o Risks and discomforts — physical / mental / social o Alternative treatment
- Benefits — to participants, community, institution and society o Compensation for participation: (Whether it will act as undue inducement) o Involvement of vulnerable participants o Provisions for medical/ psychosocial support of Treatment for study related injuries o Compensation for studyrelated injuries: as per applicable local regulations o Use of biological material
- Check for provision for signatures with dates of participant, person conducting informed consent discussion, investigator and witness o Provision for audiovisual recording of consent process in case of regulatory drug trials
- Use of study assessment form for reviewers

The assessment form is designed to standardize the review process.

- All reviewers will fill out the form / letter to IEC members requesting initial review with study assessment form) and write their comments related to review of the research proposal.
- In addition, primary reviewers will use the study assessment form
- Ensure that all elements of research study are reviewed and are accordingly documented during the discussion / meeting.
- The duly filled, signed and dated assessment forms will be submitted to the Secretariat 3 days prior to the meeting.

4.7 Gather the assessment reports

The IEC Secretariat will collect the assessment forms, comments from each reviewer and file in the original study file and converted into a soft copy for discussion at the meeting. If the comments come as a soft copy these will be collated for discussion at the meeting.

4.8 IEC meeting

o During the discussion at the meeting, the primary reviewer shall brief the members about summary of the study protocol and read out the comments and evaluation provided on the assessment form. o The comments of an independent consultant (if applicable) will be discussed by member secretary. o The other IEC members shall give their comments right after the presentation. o The investigator/sub-investigator may be called in to provide clarifications on the study protocol that he/she has submitted for review to the IEC.

o The IEC members will discuss and clarify the comments and suggestions.

o The Member secretary (assisted by the Secretarial staff) shall record the discussions o The final decision on the study will be recorded as: "Approved/ Disapproved/ Suggested recommendations or any other as per IEC policy" in the meeting shall be made by voting or by majority consensus

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(as per the IEC policy) and will be recorded in the IEC Decision Form by the Member Secretary. o A mqjority vote for approval, disapproval or request for modifications of a study suspension or termination of an ongoing study is defined as 2/3[d] of the voting members present at the meeting.

The following will not be eligible to vote

o Member(s) of the committee who is/are listed as investigator(s) on a research proposal o An investigator or study team member invited for the meeting.

o An independent consultant invited for the meeting to provide opinion

o Specific patient groups invited for the meeting will not vote or participate in the decision making procedures of the committee. o The Committee will decide whether the query responses and (if applicable) revised protocol will go only to Member Secretary, to primary reviewers or to Full Board before final approval. o The response and changes carried out may be considered for discussion at a future IEC meeting.

o If the IEC decision is 'Disapproved' or any other, the decision should be made on the basis of specific reasons, which are communicated by the IEC to the principal investigator in the letter of notification.

o The Secretariat will obtain the signature of all the members and of the Chairperson of the IEC on the IEC Decision Form. o If the study is approved, the Committee will recommend monitoring for a study if it is so determined at the meeting depending on factors like risk is high in the protocol, the PI has a history of repeated protocol violations; PI has many protocols and any other reason so deemed.

o The Secretariat will list participating members in the meeting and summarize the guidance, advice and decision reached by the IEC members. o With the study protocol, the Assessment Form from all members and IEC Decision Form will be filed in the study file by the Administrative Officer.

o The Administrative Officer will return the file and the protocol to the appropriate shelves.

4.9 Final communication of the IEC decision taken on the study to the Principal Investigator o The Secretariat will prepare an approval letter to be sent to the Principal Investigator when the study is approved at an IEC meeting.

o The letter contains:

- Study reference number
- Study title
- A listing of each document approved, the date set by the Committee for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study.

o The approval is provided for the entire duration of the study. o List of IEC members present at the meeting when the study was approved.

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o The Chairperson / Member Secretary will sign the approval letter and the Secretariat will give it to the Principal Investigator within 14 days.

If committee disapproves a study, Secretariat immediately notifies investigator in writing about the decision and the reason/s for not approving the study within 7 working days.

A notifying letter to the investigator should state the following:

- "If you wish to appeal to this decision, please contact the IEC and submit your appeal in writing within twelve (12) weeks of the receipt of the committee's decision, addressed to the IEC Chairperson with justification as to why the appeal should be granted. In absence of appeal, the study will be declared closed for the IEC office records."
- If the Committee requires modifications to any of the documents, the Secretariat will send a written request for carrying out specific changes to the investigator asking him or her to make the necessary changes and resubmit the documents to the IEC. The Principal Investigator will be asked to respond to the letter of comments/queries within 60 days of the receipt of the letter by the investigator. In the absence of any response, the study will be declared closed for the IEC office records.
- The Secretariat will verify the correctness of the wordings and spelling in all the letters and process all the above tasks within 14 days after the meeting.

4.10 Storage of Documents

- The Secretariat will keep a copy of the Approval letter/Query letter/Disapproval letter in the study file along with all the reviewed documents. The Administrative officer will store the file on an appropriate shelf in the designated cabinet.

5. Annexures

Annexure l : AX Ol /JKKNIEC /SOP 05c - Letter to IEC Members requesting initial review with study assessment form

Annexure 2: AX 02/ JKKNIEC /SOP 05c - Study assessment form for primary reviewer

Annexure 3: AX 03/ JKKNIEC /SOP 05c - IEC decision form

Annexure 4: AX 04/ JKKNIEC /SOP 05c - Format of study approval letter

Annexure 5: AX 05/ JKKNIEC /SOP 05c - Guidelines for reviewing a study protocol

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Annexure 1: AX 01/ JKKNIEC /SOP 05c

Letter to IEC Members requesting initial review with study assessment form

Dear member,

The next meeting of the IEC will be held on. …….. At_____ in ……..

Please note that the package of research proposals is to be circulated in the following order. You are requested to review the same preferably within 5 working days of receiving the package. Please review the protocol and related documents as per the guidelines attached with Annexure I and provide your comments below and fill the study assessment form (for primary reviewers only) provided with the package. Kindly confirm your availability for the meeting.

Name of Member	Date of Receipt	signature	Attending meeting (YIN)

1. Protocol Number (as per IEC records):
2. Date of receipt at IEC office after review by member (DD/MM/YY):
3. Protocol Title
4. Name of the Principal Investigator:
5. Designation:
6. Department:
7. Name of the Reviewer: 8. Comments:

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Annexure 2: AX 02/ JKKNIEC /SOP 05c

Study assessment form for primary reviewer

Protocol Number :			Date (DD/MM/YY :	
Protocol Title .				
Principal Investigator:				
Department :				
No. of Participants at the site:			No. of Study site(s):	

Mark and comment on whatever items are applicable to the study.

I	Objectives of the Study clear unclear	What should be improved?
2	Need for Human Participants Yes No	Comments:
3	Methodology: clear unclear	What should be improved?
4a	Background Information and Data sufficient insufficient	Comments:
4b	Risks and Benefits Assessment acceptable unacceptable	Comments:
4c	Inclusion Criteria appropriate inappropriate	Comments:
4d	Exclusion Criteria appropriate inappropriate	Comments:
4e	Discontinuation and Withdrawal Criteria appropriate inappropriate	Comments:
5	Involvement of Vulnerable Participants: Yes No	Comments:
6	Voluntary, Non-Coercive Recruitment of Participants Yes No	Comments:
7	Sufficient number of participants? Yes No	Comments:

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8	Control Arms (placebo, if any) Yes No	Comments:

9.	Are qualifications and experience of the participating investigators appropriate? Yes No	Comments
10.	Disclosure/ Declaration o potential conflict of Interest? Yes No	Comments
11.	Facilities/ Infeastructure of the participating sites appropriate? Yes No	Comments
12.	Community consultation – Yes No NA	Comments:
13.	Benefits to local communities? Yes No	Comments:
14.	Contribution to development of local community for research and treatment? Yes No	Comments:
15.	Availability of similar studies? Results	Comments:
16.	Are blood tissue samples sent abroad? Yes No	Comments:
17.	Are procedures for obtaining informed consent appropriate? Yes No	Comments:

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18.	Contents of the informed consent document? Clear unclear	Comments:

19.	Language of Informed consent document? Clear unclear	Comments:
20.	Contact persons for participants? Yes No	Comments:
21.	Privacy and confidentiality? Yes No	Comments:
22.	Inducement for participation? Likely unlikely	Comments:
23.	Provision for participation for compensation? Appropriate inappropriate	Comments:
24.	Provision for treatmeny for Study Related Injuries appropriate inappropriate	Comments:
25,	Provision for Compensation for Study Related Injuries appropriate inappropriate	Comments:

Reviewer's Signature with date:

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Annexure 3: AX 03/ JKKNIEC /SOP 05c
IEC decision form

Date of IEC meeting: ————————Protocol number:

IEC Protocol No. and Title:	
Principal Investigator:	Department:
Final Decision at the meeting:	Approved — with or without suggestions or comments Revision with minor modifications/amendments Revision with major modifications for resubmission Not approved Reason:_____

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Annexure 4: AX 04/ JKKNIEC /SOP 05c

Format of study approval letter

Date: _____

To,

Dr. _____

Dept. of _____

Ref: Your project no. _____ entitled, "_____".

Dear Dr. _____,

The following documents of the above mentioned prqject were reviewed and approved through an full board review process.

I . _____
2._____
3._____

It is the policy of IEC that, it be informed about any onsite serious adverse event or any unexpected adverse event report within 24 hours as per the formats specified in SOP to IECor by email if there is holiday. The report of SAE or death after due analysis shall be forwarded by the Investigator to the chairman of IEC and the head of the institution where the research is been conducted within 14 calendar days of SAE or death.

In case of injury or death of participant(s) occurring during the research, the sponsor (whether a pharmaceutical company or an institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical research shall make payments for medical management of the subject and also provide financial compensation for the clinical research related injury or death.

No deviations from, or changes of the protocol and Informed Consent Document should be initiated without prior written approval by the IEC of an appropriate amendment. The IEC expects that the investigator should promptly report to the IEC any deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants and about any new

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information that may affect adversely the safety of the research participants or the conduct of the research.

For studies which will continue for more than a year, a continuing review report needs to be submitted (within I month of the due date i.e. I I months from the date of approval) on or before dd/mm/2020.

A copy of the final report should be submitted to IEC for review.

Sincerely yours

_____

Member Secretary/ Chairperson

Date of approval of the study: _____

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Annexure 5: AX 05/ JKKNIEC /SOP 05c

Guidelines for reviewing a study protocol

Reviewers should make use of the following points while reviewing research studies which relate to scientific validity, informed consent documents, placebo justification, suitability and feasibility of the study, advertisements review.

1. How will the knowledge, result or outcome of the study contribute to human well-being?
   - Knowledge from the basic research may possibly benefit.
   - A new choice of method, drug or device that benefits the research participants during the study and others in the future.
   - Provide safety data or more competitive choices.
2. Does the study design will be able to give answers to the objectives? Whether
   - The endpoints are appropriately selected.
   - The participating duration of a study participant is adequate to allow sufficient change in the endpoints.
   - The control arm is appropriately selected for best comparison.
   - The placebo is justified.
   - The number of study participants in non-treatment (or placebo) arm is minimized.
   - Unbiased assignment (e.g. randomization, etc.) is in practice.
   - Inclusion and exclusion criteria are carefully selected to eliminate confounding factors as much as possible.
   - The sample group size appropriate with the given statistical assumptions.
   - Predictable risks are minimized.
   - The tests and procedures that are more than minimal risk are cautiously used.
   - Research participants deception is avoid.
   - Instruction and counselling for study participants are included (if needed) when deception is integral to the study design.
   - The study participants are adequately assessed and provided follow-up care, if needed.
3. Who will be the participants in the study? Whether The described population is appropriate for the study.
   - Predictable vulnerabilities are considered.
   - It is completely necessary to conduct the study in a vulnerable population. If not, is there any other way to get the study answers? There will be secondary participants.
4. Do the inclusion and exclusion criteria
   - Selectively include participants most likely to serve the objective of the study?
   - Equitably include participants?

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Properly exclude participants who can predictably confound the results?

Properly exclude participants who may predictably be at increased risk in the study due to coexisting conditions or circumstances?

5. Does the study design have adequate built-in safeguards for risks?
   - Appropriate screening of potential participants? ○ Use of a stepwise dose escalation with analysis of the results before proceeding? Does the frequency of visits and biological samplings reasonably monitor the expected effects?
   - Are there defined stopping (discontinuation) / withdrawal criteria for participants with worsening condition?
   - Is there minimized use of medication withdrawal and placebo whenever possible?
   - Will rescue medications and procedures be allowed when appropriate?
   - Is there a defined safety committee to perform interim assessments, when appropriate?
   - Is appropriate follow-up designed into the study? For instance, gene transfer research may require following the participants for years or for their entire lifetime after they receive the gene transfer agent.
6. Is pre-clinical and/or early clinical studies sufficiently performed before this study?

   ○ The animal study and in vitro testing results? ○ Previous clinical results, if done?
   ○ Whether the proposed study is appropriately built on the pre-clinical and/or early clinical results. ○ The selected dose based on adequate prior results? ○ Monitoring tests designed to detect expected possible risks and side effects?

7. Do the study and the informed consent process include issues of special concern, such as:

   Waiver or alteration of consent?

   Delayed consent (e.g., emergency treatment, etc.)?

   Deception?

   Sensitive information of participants that may require a confidentiality statement?

8. Guidelines to review Informed Consent Document/Patient Information Sheet The actual process of informed consent should:

   ○ Give the participants significant information about the study. ○ Make sure the participants have enough time to carefully read and consider all options. ○ Answer all questions of the participants before making decision to participate. ○ explain risks or concerns to the participants.

Make sure that all information is understood and satisfied by the participants.

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Make sure the participants understand the study and the consent process. Obtain voluntary informed consent to participate.

Make sure the participants can freely consent without coercion, pressure or other undue influences.

Consent should be informally verified on a continuing basis.

Continue to inform the participants throughout the study.

Continue to re-affirm the consent to participate throughout the study.

9. Guidelines to Placebo Justification

Background conditions, such as benefits of standard treatment, risk of using placebo, risk management and disclosure should be considered.

I. Benefits of standard treatment

l) Is there a standard treatment?

2) Is the standard treatment widely accepted?

3) Has efficacy of the treatment been consistently proven?

4) Are all newly diagnosed patients with this condition put in standard treatment (versus observed or other)?

5) Does the treatment act on the basic mechanism of the disease (vs. symptoms)?

6) Are most (85%) of the patients with this condition responsive to standard treatment alternatives (vs. resistant or refractory)?

If the answers of (l) to (6) are "yes ", placebo is not recommended If any one or more answers are "no ", placebo may be possible.

7) Are the side effects of the standard treatment severe?

8) Does standard treatment have many uncomfortable side effects?

9) Does standard treatment have contraindications that prevent some research participants from being treated?

10) Is there substantial placebo response in this disease or synlptom? If the answer of (7) to (10) are "no ", placebo is not recommended. If any one or more answers are "yes ", placebo may be possible.

II. Risks of placebo

l) Is the risk of using placebo instead of treatment life threatening? If yes, placebo is not acceptable.

2) Is the use of placebo instead of treatment likely to lead to permanent damage? Ifyes, placebo is not acceptable.

3) Is the risk of using placebo instead of treatment likely to cause irreversible disease progression? If yes, placebo is not acceptable.

4) Can the use of placebo instead of treatment lead to an acute emergency?

5) Is the risk of using placebo instead of treatment the persistence of distressing symptoms?

6) Is the risk of using placebo instead of treatment severe physical discomfort or pain?

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If answers of (4) to (6) are "yes", placebo is not acceptable unless risk management is adequate,

III. Risk management

I) Is there benefit in the overall management of the research participants? Yes,
consider placebo

No, placebo not recommended.

2) Will the discontinuation of previous treatment put the participant in danger of acute relapse when transferred to placebo?

No, consider placebo

Yes, placebo not recommended.

3) Are research participants at high risk for the use of placebo excluded?

Yes, consider placebo

No, placebo not recommended.

4) Is the duration of the study the minimum necessary in relation to the action of the drug? Yes, consider placebo

No, placebo not recommended.

5) Are there clearly defined stopping rules to withdraw the research participants in case he/she does not improve?

Yes, consider placebo

No. placebo not recommended.

6) Is risk monitoring adequate to identify progression of the disease before the research participants experience severe consequences? Not applicable.

Yes, consider placebo

No, placebo not recommended.

7) Are there clearly defined stopping rules to withdraw the research participants before the advent of severe disease progression? Yes, consider placebo

No, placebo not recommended.

8) If the risk of placebo is an acute emergency, are rescue medication and emergency treatment available?

Not applicable.

Yes, consider placebo

No, placebo not recommended.

9) If the risk of placebo is the persistence of distressing symptoms, is concurrent medication to control them allowed? Not applicable.

Yes, consider placebo.

No, placebo not recommended.

10) If the risk of placebo is severely physical discomfort or pain, is there rescue medication?

Not applicable.

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Yes, consider placebo.

No, placebo not recommended.

IV. Risk disclosure in the consent form

1) _Are the risks of getting placebo instead of active treatment fully disclosed?

Yes, consider placebo.

2) Are the risks of the test drug disclosed?

Yes, consider placebo.

3) Are the advantages of alternative treatments explained?

Yes, consider placebo.

Conclusions:

The use of placebo is ethically acceptable when

- research participants are not exposed to severe or permanent harm by the use of placebo.
- research participants under placebo will benefit from the overall treatment of the disease.
- risks of the use of placebo are minimized.
- risks are adequately disclosed in the consent form.

Guidelines to review advertisements

Advertisements are limited to the information prospective participants need to determine their eligibility and interest, such as:

The name and address of the researcher or research facility.

The purpose of the research or the condition under study.

In summary form, the criteria that will be used to determine eligibility for the study.

A brief list of benefits to participants, if any.

The time or other commitment required of the participants.

The location of the research and the person or office to contact for further information

The IEC reviews advertising to ensure that advertisements DO NOT:

State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.

Include exculpatory language.

Emphasize the payment or the amount to be paid, by such means as larger or bold type

Promise "free treatment" when the intent is only to say participants will not be charged for taking part in the investigation.

7. Flow Chart

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	Activity	Responsibility
1	Receive package or research proposal and research related documents package	Secretariat
	Verify contents and distribute	Secretariat
	Appointment of primary reviewers	Member Secretary/Chairperson
	Initial review of documents, Fill review assessment form	IEC members
5	IEC board meeting, discussion and decision	IEC members, Member Secretary, Chairperson
	IEC decision communicated to PI	Secretariat
	Storage of study related documents with relevant correspondence	Secretariat

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Ethics Committee (IEC) members will perform an expedited review on a new research study protocol using the Assessment Form.

2. Scope

This SOP applies to the review and approval of research studies and documents, which qualify for expedited review by the IEC. Any protocol that carries not more than minimal risk and fulfil criteria for expedited review is covered in this SOP.

3. Responsibility

- The Member Secretary is responsible, after categorization of the projects to forward the projects to the Secretariat.
- The IEC Secretariat is responsible for creation of a study specific file, distribution of the packages along with study assessment forms to the designated IEC members for review (if the study is categorized for expedited review) and communicate the review results to the investigators. • Designated IEC members (including Member Secretary and/or Chairperson) will be responsible for reviewing the research protocols and related documents within the given time frames.
- It is the responsibility of all the designated IEC members to fill the Assessment form along with comments and recommendation they have after reviewing each study protocol.
- The IEC Secretariat is responsible for recording and filing the decision, relevant points and deliberation about a specific protocol, including the reasons for that decision.
- The Chairperson is responsible to sign and date the decision in the IEC Decision Form.

4. Detailed instructions

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4.1 Appointment of reviewers

After determining that the Protocol / Project qualifies for an expedited review, the Member Secretary (in consultation with Chairperson) will nominate two or more IEC members to review the amended protocol.

4.2 Distribute the protocol package

- The Secretariat will fill in the required details in the nomination form to the IEC Members requesting initial review and in the study assessment form.
- The Secretariat will send a packet (hard or soft copy) to the designated IEC members.
- Nomination letter to IEC Members requesting Initial Review,
- Study assessment form
- Project Submission Application Form
- Protocol and related documents

4.3 Receive the distributed protocol package:

Designated IEC members will receive the protocol package with the Project Application Form as hard copy or through email (if desired so).

4.4 Verify the contents of the package

- The IEC member will verify all the contents.
- The IEC member will notify the IEC Secretariat if any documents are missing

4.5 Review by the IEC members

- IEC members will review the protocol within the stipulated time line.
- The comments of the IEC members will be recorded..

4.6 Gather the assessment reports.

The IEC Secretariat will collect the Assessment Forms with the comments from each designated reviewer and file in the original study file

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4.7 Decision and Communication of decision to PI and IEC Full Board

- The Member Secretary will discuss the comments of the members with the Chairperson and a decision about the protocol will be taken.
- If there are queries these will be sent to the PI within one working day after receipt by the Secretariat in consultation with Member Secretary.
- The reply from the PI will be discussed by the Member Secretary with the Chairperson or the designated IEC members and a decision be reached.
- The final decision will be recorded on the Study Assessment Form for Expedited Review.
- The decision will be informed to the IEC members at the full board meeting.
- If deemed necessary by reviewer(s), Member Secretary/ Chairperson, the project shall be discussed at the forthcoming full board meeting before final decision. The final decision by the Chairperson is recorded on the Study Assessment Form for Expedited Review.
- The Secretariat will send the Study approval letter to the PI. If project is disapproved or requires resubmission after certain modifications, this will be informed to the Principal Investigator in writing. The reasons for disapproval of a project will be specified in the letter sent to PI. The expedited review process should be completed within 14 working days.

6. Annexures

Annexure l : AX 01/JKKNIEC /SOP05d - Form for nomination of IEC members for Review Annexure

Annexure 2: AX 02/ JKKNIEC /SOP05d -Study Assessment Form for Expedited Review

Annexure 3: AX 03/ JKKNIEC /SOP055d -Approval letter format in case of Expedited Review

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Annexure 1: AX 01/JKKNIEC /SOP 05d Form

for nomination of IEC members for Review

Date:

To,

_____

Member, IEC,

Ref: The project no. EC/ -XX/20XX entitled, "XXXXXXXX".

Sub: Review of XXXXXXX.

Dear Dr. XXXXXX,

The following document/s has/ have been submitted to the IEC for review.

1. _____
2. _____
3. _____

The following members are nominated to review/ carry out an expedited review of the abovementioned documents.

1. _____
2. _____
3. _____

For expedited review, you are requested to fill the study assessment form enclosed and send to the IEC office within 7 working days:

signature of Member Secretary / Chairperson with date

Annexure 2: AX 02/JKKNIEC /SOP 05d Study
Assessment Form for Expedited Review

IEC Protocol Number :	Date of receipt at IEC office (DD/MM/YY):

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Project Title : _____

_____

Name of the Principal Investigator	Department	Contact number

Total no. of Participants at the site:

No. of Study sites:

Sponsor:

Duration of the Study:

Reviewer's name:

Type of the Study:

Intervention | Epidemiology | Observation
Document based | Genetic
Social Survey | Others, specify. .....

Description of the Study in brief: Mark whatever applied to the study.

Randomized | Open-labeled

Double blinded | Placebo controlled | Treatment controlled
Cross-over | Parallel | Interim Analysis
Use of Tissue samples | Use of Blood samples | Use of genetic materials

Comments:

_____

(Review the protocol and related documents as per the guidelines stated in AX 05/SOP 06/V5)

Provisional Decision: Approved | Resubmission | Disapproved | Full Board

Approved with modifications

Reason for disapproval _____

_____

Name of the IEC member_____

Signature_____ Date_____

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Final decision:

Approved YES NO

If disapproved, reasons for disapproval _____

_____

Further Revision / modification required/ Resubmission ☐

_____

Any other

_____

Signature of the chairperson Date:

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Annexure 3: AX 03/JKKNIEC /SOP 05d

Approval letter format in case of Expedited Review

Date: xxxxxxxxx

Dr. xxxxxxxxxxxxx, Dept.

ofxxxxxxxxx.

Ref: Your project no. xxxxxxxx entitled, "xxxxxxxxxxxxxxx". Dear

Dr. xxxxxxxxx,

The following documents of the above mentioned project were reviewed and approved through an expedited review process.

I. xxx

2.xxxxxxx

3.xxxxxxxxx

It is understood that the study will be conducted under your direction, in a total of xxx research participants, at as per the submitted protocol.

The IEC approves the above mentioned study.

This approval is valid for the entire duration of the study.

It is the policy of IEC that, it be informed about any onsite serious adverse event or any unexpected adverse event report within 24 hours as per the formats specified in SOP 09 to IEC or by email if there is holiday. The report of SAE or death after due analysis shall be forwarded by the Investigator to the chairman of IEC and the head of the institution where the trial is been conducted within 10 calendar days of SAE or death.

In case of injury or death of participant(s) occurring during the trial, the sponsor (whether a pharmaceutical company or an institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial shall make payments for medical management of the subject and also provide financial compensation for the clinical trial related injury or death.

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No deviations from, or changes of the protocol and Informed Consent Document should be initiated without prior written approval by the IEC of an appropriate amendment. The IEC expects that the investigator should promptly report to the IEC any deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

For studies which will continue for more than a year, a continuing review report needs to be submitted (within I month of the due date i.e. I l months from the date of approval) on or before xxxxxx.

A copy of the final report should be submitted to IEC for review.

Sincerely yours xxxxxxxxxxx

Member Secretary/ Chairperson

Date of approval of the study: xxxxxx

7 . Flow Chart

No.	Activity	Responsibility
I .	Receive the submitted documents	Secretariat
2.	Determine protocols for expedited review	Member Secretary
3.	Approve the Secretary's recommendation regarding the protocols for expedited review	Chairperson
4.	Expedited process	IEC Members/Chairperson
5.	Decision of IEC	Chairperson
6.	Communicate with the IEC and the Investigator	Member Secretary/ Secretariat

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the administrative process and provide instructions for preparation, review, approval and distribution of meeting agenda, and minutes of IEC.

2. Scope

This SOP applies to processes concerning preparation of agenda and recording minutes of IEC, Human studies meetings. This is applicable to IEC JKKNIEC.

3. Responsibility

It is the responsibility of the Member Secretary assisted by Secretariat to prepare agenda for IEC meeting which will be reviewed and approved by chairperson. It is the responsibility of Member Secretary to ensure proper recording and dissemination of minutes after the meeting is over. It is the responsibility of all members to read and approve the minutes sent to them. The Chairperson will review and finally approve the minutes.

4. Detailed instructions

4.1 Before each Board meeting

IEC full Board meeting will be regularly scheduled once every month and the dates will be decided by the member secretary with the help of the secretariat at the beginning of the year. After discussing in the IEC meeting the approved dates will be given and the meetings will be held on those days.

4.2 Preparation of meeting agenda

The Member Secretary assisted by the Secretariat will prepare the meeting agenda, according to the format in annexure of this document. This should include:

a. Welcoming of all members by Chairperson

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b. Ensure quorum by Chairperson

c. Reading and approving minutes of the previous meeting.

d. All projects for Initial Review

e. All resubmitted protocols for full board review.

f. Review of Amended protocols or protocol-related documents for Full Board review. g. Issues for consideration.

h. Continuing review of study protocols.

i. Review of Study Completion Reports.

j. Review of premature study termination.

k. Review of Site Monitoring Visit Reports. l.SAE reports submitted.

m. Minutes of SAE committee

n. Issues to be discussed including emergency concerns/ IEC policies/ training of Members/ revising SOPs/ any other issues raised by member(s).

o. Any other matter referred for IEC opinion or issues to be informed to the members.

p. Report of any other subcommittee or group appointed/ designated by Chairperson for any specific or general purpose.

q. Any other matter

The Secretariat will collect and verify all documents submitted to IEC for completeness and keep it ready for the meeting.

- The Secretariat will schedule protocols in the agenda as per date of receipt.
- Answers to the IEC queries and amended study related documents (Protocol, ICD, CRF and 1B) from the investigators received 14 days before and other types of documents received 10 days prior to the date of full board IEC meeting will be included in the agenda. The agenda for the IEC meeting is prepared 3 days in advance before the date of meeting.

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- Any study-related document (except if related to safety of a participant including SAE report) received within 3 days preceding the date of meeting will not be considered for the meeting. It will be deferred to the next month's meeting for discussion except in some cases when the matter is urgent and important (having direct bearing on the safety of the research participants such as SAE report or major protocol violation) in the opinion of the IEC Secretary or Chairperson.

- In case a meeting is to be rescheduled due to unavoidable circumstances, the date and time will be informed to the IEC members via e-mail. The Secretariat will send via e-mail to members the agenda of the meeting at least I day in advance of the scheduled meeting. The Secretariat will make sure that the meeting venue, equipment and facilities are available for the meeting day.

4.3 For conducting the meeting

For IEC — Observational studies meeting, besides the Member Secretary and the Chairperson the quorum will consist of any 5 members as given below:

a. One basic medical scientist
b. A clinician,
c. A legal expert
d. Lay person
e. Social scientist/ philosopher/ ethicist/ theologian. The quorum should include both medical, non medical or technical or/and nontechnical members. Minimum one non-affiliated member should be part of the quorum. Preferably the lay person should be part of the quorum.

- Medical members are clinicians with appropriate medical qualifications.
- Technical members are persons with qualifications related to a particular branch in which the study is conducted, for example social sciences

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- Ref: ICMR 2017 guidelines

4.4 During the meeting

- The Chairperson will initiate the meeting after ensuring that the quorum has been met. The Chairperson at his/ her discretion will delegate the responsibility of conducting the meeting as per agenda to the Member-Secretary.
- The Chairperson will ask the members whether anyone has any conflict(s) of interest in the projects to be discussed and if so, to declare the conflict.
- The Secretariat will obtain signatures on the Conflict of Interest Agreement Form from members who declare a conflict (e.g. members who are PIs or CO-IS) prior to the start of the meeting.
- If a conflict of interest has been declared by a member, the Chairperson will ask the concerned member to leave the meeting room when the concerned issue is being discussed.
- The Secretariat will obtain the signatures of all IEC members on the attendance register.
- At the discretion of the Chairman, guests may be allowed to observe the board meetings. These guests may include a student, inspectors, auditors, members of other Ethics Committees, surveyors, regulators, members of regulatory agencies, representatives of patient groups, representatives of special interest groups, representatives of accrediting organizations, members of general public etc.
- All guests are required to sign a confidentiality agreement prior to attending the meeting. The Secretariat will obtain signatures of Guests/ observers/ Independent Consultants prior to the start of the meeting on the Confidentiality agreement.
- The Member Secretary will ask the members whether any points need to be discussed regarding minutes of the previous meeting. If no points are raised, the minutes will be considered as confirmed.
- The Member Secretary will present the agenda of the day's meeting for discussion.

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The meeting shall generally proceed in the order organized in the agenda. However, the Chairperson may allow adjustments in the order of issues to be discussed depending on the situation.

- Investigators who have been asked by IEC secretariat to provide additional information or clarifications related to their project may do so by attending IEC meeting. The discussion amongst IEC members will not be done while the investigator is in the meeting room.

- For other points on the agenda, the member secretary will present the gist of the matter/ read the relevant letters from the investigator (if deemed necessary) and request the members to give their comments. The Member-Secretary assisted by the secretarial staff will also record a gist of discussions and decisions arrived on other issues discussed at the meeting.

4.5 Decision making

- The final decision on each proposal/ issue discussed in the meeting shall be by voting. A majority vote is defined as 2/3rd of the members (who have reviewed the project), present at the meeting and voting.

- Decisions will include approval, disapproval, request for modifications of a study, suspension or termination of an ongoing study

- The following will not vote at the meeting:

- Member(s) of the committee who is/are listed as investigator(s) on a research proposal o An investigator or study team member invited for the meeting o An independent consultant invited for the meeting to provide opinion o Specific patient groups invited for the meeting, if any.

After the Board meeting

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- The Secretariat will compose the summary of each meeting discussion and decision in a concise and easy-to-read style in the minutes within 7 working days of the meeting day.

- The Secretariat will make sure to cover all contents in each particular category to include the following:

- Name of person preparing the minutes o Location where the meeting was held (city, state) o Meeting number, date/duration of the meeting (time of commencement and end) o Names of the IEC members and guests attending the meeting o Name of the individual serving as Chairperson of the meeting o Determination of a duly constituted quorum by Chairperson to proceed with meeting

- Requirements for each study or activity requesting approval:

- Sponsor's name, if applicable o Protocol number/date/version of protocol, when available o Investigator's name o Names of the Primary Reviewers who presented their findings o Discussion as deemed appropriate by the Chairperson o Follow-up action decided upon o Reference to the investigator approval letter that lists all changes requested by the board o Determination of the next requested continuing review.
- Requirements for each study or activity requesting expedited review:

- Sponsor's name; if applicable o Protocol number, if applicable o Investigator's name o Lists of expedited approval requests and outcomes.

- Requirements for each Continuing Review Report:

- Sponsor's name; if applicable o Protocol number, if applicable o Investigator's name o Indication of the Board's determination to continue, terminate, or amend the study o Lists of recommendations or actions to be taken up with the investigator, if applicable.

- Requirements for each Adverse Event notification and Final Report:

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- Sponsor's name; if applicable o Protocol number, if applicable

- Investigator's name o Report or summary of report provided by the SAE sub-committee o Actions deemed appropriate by the Board's review

- Requirements for Termination of Approval:

- Name of the Sponsor, if applicable o Protocol number, if applicable o Investigator's name; reason for termination

4.6 Approval of the minutes

- The Secretariat will check the correctness and completeness of the minutes and present the minutes to the Chairperson for review and approval within 7 working days of the meeting day.
- The Secretariat will email the minutes of the meeting to the IEC members.
- The Chairperson indicates approval by signing and dating the minutes (after approval in the next meeting).

4.7 Filing the minutes

- The Secretariat will place the original version of the minutes in the minutes file.
- The Secretariat will file the IEC Decision Forms in the project files and place all correspondence in the appropriate files.
- The Secretariat will send a list of the studies approved and rejected by the IEC at the monthly meetings (title of the study with name of the Principal Investigator) to the Head of the Institute every month within 21 days of the IEC meeting.

4.8 Calling an Emergency Meeting of IEC • The Member Secretary in consultation with Chairperson may decide to call an emergency meeting for any one or more of the following reasons.

- Urgent issues (which, if not decided upon early could adversely affect or have adverse impact on patient safety, public safety or national economy etc.)
- Occurrence of unexpected serious adverse event(s).

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- Other reasons, as deemed appropriate by the Member Secretary/Chairperson.
- The Secretariat will endeavour to contact each and every IEC member and inform about the date, time and venue of the meeting as well as the reason for calling for the meeting.
- The administrative officer will prepare packets for distribution to the members containing the information and documents about the matter(s) for which emergency meeting is scheduled or send the relevant details via email.
- During the meeting, the Chairperson/Secretary will determine if there is a quorum.
- If a quorum is not met, the meeting will be postponed for 15 minutes. However, if there is no quorum at the end of 15 minutes; the meeting would be held without a quorum provided at least four members (at least one scientific and one nonscientific member) are present, given the urgency of the matter under consideration. The IEC members will act according to the relevant IEC SOPs (Expedited Review, SAE review, Review of Protocol deviations/violations etc.) for discussion and decision-making on the matter under consideration. The minutes of the emergency meeting would be prepared, distributed, approved and filed as described in the steps above for regular full board meeting.

5. Annexures

Annexure 1: AX 01/JKKNIEC /SOP 05e -- Agenda format

Annexure 2: AX 02/JKKNIEC /SOP 05e -- Conflict of Interest form to be signed by IEC member before board meeting

Annexure 3: AX 03/JKKNIEC /SOP 05e -Agenda of the IEC Meeting

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Annexure 1: AX 01/JKKNIEC /SOP 05e -- Agenda format

Meeting No IEC meeting nn/yyyy

Location of the meeting

Meeting Date & Meeting time

The Board meeting will proceed in the following sequences:

Period 1: Discussion of the points arising from the minutes of the previous meeting and presentation of agenda of the day's meeting and Declaration of Conflict.

Period 2:

A] New Protocol Presentation, Review, Discussion and reaching decision by voting to approve/raise queries

B] Review responses forwarded by the principal investigator to the query letter/ resubmitted protocols

C] Approve protocol amendment and related documents.

D] To review the continuing review report/ completion report/ final clinical trial report/ Annual report / Termination reports.

E] To review Protocol Deviations / Violations

F] To review other Letters related to projects

G] To review Monitoring reports

H] To inform about the IEC meeting and to review the policy decisions

I] To inform about the SAE Subcommittee meetings and to review SAE/Safety reports.

J] Other points for discussion

Period 3: Issues reviewed and approved by the IEC member Secretary and Chairperson which are to be reported for consideration

Period 4: Issues to be informed to the members at Full Board which are approved by the IEC member Secretary and Chairperson and letters already sent to the principal investigator.

Period 5: Other issues of interest to the members.

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Annexure 2: AX 02/JKKNIEC /SOP 05e --

Conflict of Interest form to be signed by IEC member before board meeting

Date:

To

The Chairperson,

JKKNIEC ,
Kumarapalayam

I hereby declare the conflict of interest for the project no. EC/ /

Entitled as :

_____

l. I am the investigator / co-investigator/Author/study team
2. I have Financial interest 3.

_____

4.

_____

5.

_____

_____

in the project which will be discussed in today's meeting on . XX day of XX month XX year.

Dr.

_____

Member, IEC

_____

Chairperson, IEC

Flow Chart:		
	Activity	Responsibility
I	Preparation of meeting agenda prior to a board meeting	IEC Secretariat

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2	During the Meeting	IEC Secretariat, Members and Chairperson
3	After Board Meeting and Preparing the minutes	IEC Secretariat/ Member Secretary
4	Approval of minutes	IEC members / Chairperson
5	Filing the minutes	IEC Secretariat
6	Calling an emergency meeting	Member Secretary in consultation with Chairperson

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Ethics Committee (IEC) manages resubmitted & amended study protocols.

2. Scope

This SOP applies to the review of

A. Study protocols and related documents that have been resubmitted to the IEC by the Principal Investigator (PI) with clarifications and modifications sought by the IEC in initial review.

B. Amendments to study protocols and related documents that have been approved earlier.

3. Responsibility • It is the responsibility of the IEC Secretariat to ensure the completeness of the documents submitted to the IEC.

- A re-submitted protocol and related documents will be reviewed by two IEC members designated by the Member secretary as per the IEC decision determined by the IEC at the time of the initial review of the project during the full board as well expedited review meeting. This information would be recorded (during the meeting) on the IEC Decision Form.

In the case of an amended study protocol and related documents, Member Secretary/ Chairperson will decide whether the proposed protocol amendment(s) needs to undergo a full board review or expedited review. If the amendment(s) is / are of administrative nature the Member Secretary/Chairperson can recommend an expedited review, while if the amendment/s relate to participant safety or data capture, it should be recommended for full board review. Additionally, primary reviewers who had reviewed the initial submission may be asked to review the resubmitted protocol.

4. Detailed instructions

For resubmitted protocols

Receipt of resubmitted protocol and its distribution

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1. The Secretariat will verify if the PI has replied to IEC queries within 60 days of receipt of the letter of comments by the IEC.

2. The Secretariat will check the resubmitted protocol & related documents (hard and soft copy) for the following items o Reply to the IEC letter of comments o Revised version of protocol and/ or the informed consent document and /or any other related documents such as, case report forms, diary sheets, etc. are submitted with the changes made to the documents either underlined or highlighted.

3. The Secretariat will refer to the IEC Decision Form on the given protocol and distribute the documents containing the reply to the query letter, revised protocol and related documents along with Assessment Form for resubmitted protocol to

- Member Secretary for summarizing and including it on the agenda for full board discussion in the forthcoming meeting if the decision on the protocol was 'to be discussed at full board'

- Designated IEC members, if decision on protocol was 'to be reviewed by two or more IEC members'. o Chairperson/Member Secretary if the decision on the protocol was 'Approved with recommendations subject to review by Chairperson/Member Secretary only' as per IEC Decision Form.

4.1 Review of revised protocol by IEC member/ Member Secretary/Chairperson:

IEC member/ Member Secretary/ Chairperson will refer to query letter/ comments as guidance for review and consider whether recommendations of IEC have been followed or adequately responded to.

- IEC member/ Member Secretary/ Chairperson will make further comments where appropriate, in the Assessment Form for resubmitted protocol

- Secretariat will retrieve the Assessment Form for resubmitted protocol from the members/Member Secretary/Chairperson.

- In case the decision is to discuss the revised protocol at the full board meeting, Member Secretary will present a brief oral summary of the study design and

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the comments of the IEC members/Chairperson in the IEC Full Board meeting.

- Chairperson shall entertain discussion on the protocol revision from all the IEC members.

- The final decision regarding the research project shall be reached by voting (2/3rd majority of the members present and voting) and shall include one of the following:

a Approved

b Modifications to items noted at the convened meeting and follow-up by the Chairperson/ Member Secretary /IEC members after receipt of the requested modifications:

c Disapproved giving reasons for disapproval

- In case the revised protocol is already approved through expedited review, the decision is informed to the members at the full board meeting.

4.2 Receipt of protocol for amendments

- The documents for amendments (hard and soft copy) forwarded by the PI will be received by the Secretariat and verified.

- The Secretariat will confirm the request for review of amended Protocol/Protocol related documents from the Principal Investigator on previously approved Protocol/Protocol related documents as per the form.

- The administrative staff will confirm that the amended version of the protocol and related documents are attached with the application and that the changes or modifications in the protocol are underlined or highlighted in the amended version.

4.3 Notify Member Secretary

- The Secretariat will inform the Member Secretary of receipt of the protocol amendment

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4.4 Determine whether full review or review by designated members.

1. After review of the materials, the Member Secretary will determine whether the protocol requires a full board review or expedited review. The Member Secretary will indicate this decision on the Protocol Amendment Assessment Form AX 02/JKKNIEC /SOP 05 f

2. The amended protocol/ protocol related document will require Full Board review if any of the following criteria are met:

3. The Protocol amendment changes the risk-benefit assessment such as ➢ a change in study design,

➢ additional treatments or the deletion of treatments ➢

changes in inclusion/exclusion criteria.

➢ change in method of dosage formulation, such as, oral changed to intravenous ➢ significant change in the number of research participants (if the decrease/increase in the number of research participants alters the fundamental characteristics of the study, it is significant)

For regulatory studies, a protocol amendment with above changes would require DCGI approval

For expedited review, the concerned Form will be used to nominate members by the Chairperson/ Member Secretary.

4.5. Distribution to IEC members

The following documents will be distributed to the designated IEC members as per the decision regarding review. The amendment's revision documents to clearly identify each change.

Protocol Amendment Assessment Form

- Whenever the decision is Full Board review, the Secretariat shall summarize the points for discussion regarding the amended protocol/protocol related documents and shall place the protocol amendment request on the agenda for discussion at the next convened meeting.

4.6 Protocol Amendment Review Process • IEC member will review the amended documents and write his/her comments in the form AX 02/ JKKNIEC /SOP 05 f

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- Reviewer may request secretariat to keep the documents for full board discussion after review.

e IEC members performing the review must sign and date the form and return this to the Secretariat after the review.

4.7. IEC Decision on Amended Protocols

- In case the project is kept for full board review, the Member Secretary / designated member will present a brief oral summary of the study design and read the comments on the amended protocol/ protocol related documents in the meeting.

The decision by the designated reviewers may be

- Approved
- Disapproved

Suggested Recommendation

- Next full board discussion

The final decision regarding the research project shall be reached by voting (2/3rd majority of the members present and voting) and shall include one of the following:

- Approve the protocol amendment
- Require a modification to the proposed amendment or informed consent documents, stating the reason and action required to sustain the study with a follow-up full IEC review/ IEC review.
- Not approve the amendment request, stating the reason — but allow the study to continue as previously approved.
- Suspend the study, until further information is obtained

4.8. Recording of the decision

- This IEC decision will be recorded by the Secretariat in the IEC Decision Form.

4.9. Communication of the Decision to the Principal Investigator

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- If the IEC approves the protocol/ informed consent documents (ICDs) amendment, the Secretariat staff will send a signed and dated Amendment Approval Letter AX 03/ JKKNIEC /SOP 05 f to the Principal Investigator (PI) within 14 working days of the meeting. The decision regarding disapproval (stating reasons) or request for modifications (stating specific changes needed) shall be communicated in writing to the investigator within 14 working days of the meeting.

- The letter of comments sent to the investigator shall state that the reply to the letter is expected within 60 days of date of receipt of the letter and in the absence of any response, the project will be declared closed for the IEC office records.

- The Member Secretary shall inform other members about the decision taken on the amended document/s at the next full board meeting.

5. Annexures

Annexure I : AX 01/JKKNIEC /SOP 05 f - Assessment of resubmitted protocol
Annexure 2: AX 02/ JKKNIEC /SOP 05 f - Protocol amendment request and assessment form
Annexure 3: AX 03/ JKKNIEC /SOP 05 f - Protocol Amendment/Document Amendment Approval letter

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Annexure I: AX 01/JKKNIEC /SOP 05 f

Assessment of resubmitted protocol Protocol Number:

Protocol Title:

umber of review	Review	3 r Review	4t Review
Principal Investigator:			Department:
Date of Initial Review by IEC:		Date of Last Review:	
he IEC Decision recorded in the meeting inutes: (meeting held on)			

Opinion of the reviewer:

Revision or Modification according to the recommendation	Yes	No: Explain:
Approved	Yes	No
If disapproved, reasons for disapproval		
Further revision or modification required		
To be discussed at the forthcoming full board meeting		
Any Other		

Name of the Reviewer: 1) Signature: Date:

Name of the Reviewer: 2) Signature: Date:

Final Decision: Approved Yes / No

If disapproved, reasons for disapproval:

Further revision or modification required / Resubmission:

Any other reason(s):

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Signature of the Member Secretary/ Chairperson: Date:

Annexure 2: AX 02/JKKNIEC /SOP 05 f Protocol

amendment request and assessment form

IEC Protocol Number:

a) Protocol Title:

b) Principal Investigator and Department:

c) Approved date:

d) No. of amendment:

e) State/describe the amendment: type of document/ part of document amended:

f) Reasons for the amendment:

g) Impact of amendment on present study at this site: (modifications in the ICD, reconsent of research participants, untoward effects likely to occur because of amendment or any other):

h) Have the changes / modifications in amended versions been highlighted/ underlined?

Yes No

Name of Principal Investigator: Signature with Date:

Type of review :- (Decision by the Chairperson/ Member Secretary)

- Review by Member Secretary/ Chairperson
- Review by designated I EC members
- Full Board discussion and review

Comments of the reviewer :

Decision: Disapproved Next full board discussion
Approved Suggested Recommendation(s)

Name of IEC Member/ MemberSecretary/Chairperson reviewing project:

Signature with Date:

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Final Decision: Approved Yes No

If disapproved, reasons for disapproval:
Further revision or modification required: Any
Other

Signature of the Member Secretary: Date:

Annexure 3: AX 03/JKKNIEC /SOP 05 f
Protocol Amendment/Document Amendment Approval letter

To

Name of PI

Department

Ref: - IEC No. Project title Dear

Dr.

_____

We have received from you the following document(s).

1.

2.

At the Institute Review Board meeting held on _____ the above mentioned documents were reviewed.

After consideration, the IEC has decided to approve:

a) The aforementioned study-related documents and

(b) The following documents:

1.

2.

The members who attended this meeting held on_____at _____ which the above mentioned document was discussed are listed below.

It is to be noted that neither you nor any of your proposed study team members were present during the decision-making procedures of the Institutional Review Board. OR

After reviewing the documents, the IEC has decided to approve the aforementioned study-related documents.

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Yours truly,

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(Signature of Member Secretary with Date)

7. Flowchart

No.	Activity	Responsibility
1.	Receive the Protocol amendment / Resubmitted protocol	IEC Secretariat
2.	Notify the Member Secretary / Chairperson of the IEC	IEC Secretariat
3.	Determine whether full board review / review by designated members is needed	IEC Member Secretary / Chairperson
4.	Nomination of Members for review	IEC Chairperson
5.	Distribution to IEC members	IEC Secretariat
6.	Protocol Amendment/ Revised documents Review	IEC Members / Member Secretary / Chairperson
	IEC Decision	IEC Member Secretary / Chairperson
8.	Communication of the Decision to the Principal Investigator	IEC Secretariat
9.	Store documents	IEC Secretariat

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how continuing review of previously approved protocols should be managed by the Institutional Ethics Committee (IEC), JKKNIEC . The purpose of continuing review is to periodically monitor the progress of study, to ensure continuous protection of rights and welfare of research participants.

2. Scope

This SOP applies to conducting any continuing review of already approved study protocols at prespecified intervals by IEC, JKKNIEC . All the projects approved by the IEC will be reviewed at least once a year. Depending upon the degree of risk to the participants, the nature of the studies, the vulnerability of the study participants and duration of the study, the IEC may choose to review or monitor the protocols more frequently.

3. Responsibility

It is the responsibility of the IEC Secretariat to remind the PIs and Member Secretary regarding continued review of protocols at the correct interval. All the approved protocols will be reviewed annually. It is the responsibility of the Member Secretary to ensure a decision regarding whether the project needs to be reviewed more frequently is taken during the IEC meeting in which the project is finally approved. This must be recorded in the minutes. A fresh decision to increase review may be taken if required based on the SAE reports, monitoring reports, or safety concerns. This is responsibility of the SAE subcommittee and Member Secretary.

The IEC is responsible for reviewing the progress made in the protocol (number of patients recruited, dropped out, reasons for drop-out), the occurrence of unexpected events or problems, and compliance of the investigator regarding IEC communication.

4. Detailed instructions

4.1 Determining the date of continuing review

- The date of the continuing review will always be at least once in the year. • The IEC may recommend more reviews during the approval process depending on the level of risk.

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This will be documented in the minutes. • The Secretariat will inspect the minutes of meeting to set a timetable for continuing review. The Secretariat will identify and record the due dates for each project

4.2. Notifying the PI or the study team :

The Secretariat will send a reminder to the PI as per the format AX01/JKKNIEC /SOP 05 g one month prior (if an annual review) or less as appropriate (if any special additional reviews are required) to the due date of continuing review.

4.3 Managing the continuing review package upon receipt • Secretariat will receive a package (soft and hard copy) submitted by the PI for continuing review of each approved protocol. Only one set (soft and hard copy) of continuing review report shall be submitted by PI to IEC as per format continuing Review Application Form (AX 02/ JKKNIEC /SOP 05 g).

4.4 Verifying the contents of the package

- Secretariat will ensure that the contents of the package include the following documents:
  - Continuing Review Application Form (AX 02/ JKKNIEC /SOP 05 g)
  - Continuing Review Application Form duly filled with an explanation for any "yes" (ticked on the Continuing Review Application Form (AX 02/ JKKNIEC /SOP 05 g) answers on the application form and a discussion of scientific developments, either through the conduct of this study or similar research that may alter risks to research participants. The changes in the selection criteria of participants, protocol/Informed consent Document amendments, changes in the study team, any unexpected complications etc. must have been discussed in the attached narrative.

- The Secretariat will confirm complete information is appended and for the presence of the required signatures of the Principal Investigator in the Continuing Review Application Form (AX 02/ JKKNIEC /SOP 05 g).

4.5 Review process

e The Continuing review submission may undergo expedited review or full board review as deemed appropriate by the IEC Member Secretary.

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- The IEC Member Secretary/ Member/s will use the Continuing Review Application Form (AX 02/ JKKNIEC /SOP 05 g) to guide the review and deliberation process.

- The Secretariat will send the Continuing Review Application Form (AX 02/ JKKNIEC /SOP 05 g) to the designated IEC members.

- The IEC Chairperson/ Member Secretary/ Member/s could reach one of the following decisions after review: l . Noted - The IEC approves the continuation of the project without any modifications.

2. Modifications recommended: Study protocols that have been suggested modifications by IEC may not proceed until the conditions set by IEC in the decision have been met. The amendments and the required documents should be amended and submitted to the IEC within one month for re-review.

3. Project cannot be continued: The reasons for discontinuation of the project should be mentioned in the letter notifying the decision to the Principal Investigator. This decision shall be recorded by the Member Secretary on AX 02/ JKKNIEC /SOP 05 g. The IEC Chairperson will sign and date the IEC decision on Continuing Review Report after a decision has been reached. The decision on continuing review taken by the Chairperson/ Member Secretary/ Member/s will be informed to all IEC members at the next full board meeting. The continuing review report may be discussed at full board if deemed necessary by Chairperson/Member Secretary.

IEC Secretariat will maintain and keep the IEC Decision forms and minutes of the meeting relevant to the continuing review as part of the official record of the review process in the project file.

4.6 Communicating IEC Decision to PI • The Secretariat will notify the PI of the decision within 14 days of the meeting at which the report was discussed or of the date of review by the Chairperson/ Member Secretary/ IEC Member/s.

4.7 Non-submission of continuing review report by principal investigator before due date. • If a PI fails to submit continuing review report within one month of the due date (ie. I l months from the date of approval, or earlier on the dates as specified), Secretariat will send a email reminder at least 15 days prior to due date of review.

If there is no response, IEC secretariat will put up the matter for discussion at forthcoming full board meeting for appropriate action which may consist but not limited to sending:

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- A reminder letter again
- A letter asking explanation for non-submission
- A letter asking PI to put recruitment of new participants on hold till report is submitted
- Any other action as deemed appropriate by IEC

5. AnnexuresV5

Annexure l : AX 01/ JKKNIEC /SOP/05 g- Reminder letter by the IEC to principal investigator Annexure 2: AX 02/ JKKNIEC /SOP 05 g - Continuing Review Application Form

Annexure 1: AX 01/ JKKNIEC /SOP 05 g

Reminder letter by the IEC to principal investigator Date:

Name of Principal Investigator:

Department:

Ref: - Project no. Title:

The above referenced project was approved by the IEC on _____ and is due for Continuing Annual/ Periodic Review by the IEC. You are requested to submit an Annual/ Periodic status report in the prescribed format which is enclosed (Continuing Review Application Form) at the earliest, on or before …….. (l month period)

Member Secretary

_____

Signature with date

Annexure 2: AX 02/ JKKNIEC /SOP 05 g
Continuing Review Application Form

Summary of protocol participants:

- No. of participants screened
- No. of participants approved by IEC
- No. of recruited participants
- No. of ongoing participants
- No. of completed participants

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- No. of participants who refused to consent

Have any participants been withdrawn from this study? Yes .....N0.....
If no, (state the number and reasons for drop-outs of each participant, attach separate sheet if needed)

Have there been any amendments in protocol/ Inforlned Consent Document since the last review? Yes .. ....No..... ...

Were these protocol/ Informed Consent Document (ICD) amendments approved by IEC?

Yes . .....N0... . ... If no, mention the amendments not approved

Which protocol amendment is the site following at present?

Which ICD amendment is the site following at present?

Has any information appeared in literature, or evolved from this or similar research that might affect evaluation of the risk/benefit analysis of participants involved in this protocol?

Yes .....No. If Yes (attach separate sheet if needed)

Whether reports of SAEs so far have been reviewed by the IEC- Whether reports of SAEs at other sites have been submitted to the IEC

Have any participating investigators been added or withdrawn since last review? Yes . .. .No.....,. If Yes (Identify all changes in the attached narrative)

Is report of interim data analysis available?

Yes . No..... If Yes (submit as an attachment)

Is report of the data safety and monitoring board available?

Yes ..... No..... If Yes (submit as an attachment)

Have any investigators developed consultative relationship with or acquired equity / shares from a source related to this protocol which might be considered a conflict of interest?

Yes . .....No..... . If Yes (submit as an attachment)

Signature of the Principal Investigator with Date:

Assessment of Continuing Review Report by the IEC to be reviewed by

- Chairperson /Member Secretary' only and informed to the IEC members at Full Board
- Full Board
- Any 2 IEC members and informed to the IEC members at Full Board

Names of IEC members:

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Member Secretary
Signature with date

IEC Decision on the Continue Review Report
Date:

Decision:

- Approved and the project can be continued without any modifications
- Modifications recommended - requiring protocol resubmission
- State the recommendations:
  - Protocol should be discontinued

    State the reasons for discontinuation:

Date of Full Board discussion

Signature of reviewer/s with date:

Member Secretary Signature with date:

Signature of the chairperson with Date:

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe action(s) to be taken by the IEC when investigator(s)/ trial site(s) fail(s) to follow the procedures written in the approved protocol,

- comply with national and/ or international guidelines, statutory provisions, institutional guidelines or rules or procedures mandated by the Institutional Ethics Committee (IEC) for the conduct of human research,
- respond to the IEC requests regarding statutory, ethical, scientific or administrative matters. 2.

Scope

This SOP applies to all research protocols involving human research participants approved by

Responsibility

The IEC Secretariat is responsible for receiving deviation/ violation reports submitted by the Principal Investigator (PI) /others and placing it on the agenda of the meeting. Reporting of deviation/ violation in any other reporting format will not be accepted. The IEC members should review and take action on such reports.

Definitions
Protocol Deviation and Protocol Violation:
Protocol Deviation- A protocol deviation is any change, divergence, or departure 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. Upon discovery, the Principal Investigator is responsible for reporting protocol deviations to the IEC using the standard reporting form.

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.

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 treatnwnt or incorrect 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 inclusion/exclusivity criteria.

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- Failure to treat research subjects 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.

111. 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

IV. The deviation involves a serious or continuing noncompliance with federal, state, local or institutional human subject protection regulations, policies, or procedures. For example

- Working under an expired professional license or certification
- Failure to follow federal and/or local regulations, and intramural research policies
- Repeated minor deviations.

V. The deviation is inconsistent with the NIH Human Research Protection Program's research, medical, and ethical principles. For example

- 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.

5. Detailed instructions

5.1 Detection of Protocol deviation/ violation

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

a. Protocol deviation/ violation may be reported by Investigator/ study site/ sponsor/ Contract-Research Organization to the IEC.

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b. The IEC members performing monitoring of the project at trial site may detect protocol deviation/violation if the project is not been conducted as per protocol/ national/ international regulations.

c. The Secretariat may detect protocol deviation/ violation from failure to comply with statutory requirements/ failure to respond to requests from IEC within reasonable time limit/ failure to respond to communication made by IEC.

d. 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.

e. The IEC Secretariat and/ or IEC members may become aware of a protocol deviation/ violation while reviewing study-related documents including reports filed in by the Principal Investigator (PI).

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

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

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

5.2 Receipt of protocol deviation / violation report by the Secretariat l . The PI will report the protocol deviation/violation as per Annexure I AX 01/' JKKNIEC / SOP 05h. 2. In case protocol deviation/violation is detected by any other person (See Section 5.1) and reported to the IEC (there is no format for this), the Member Secretary will write to the PI to submit a protocol deviation/violation as per Annexure I AX 01/ JKKNIEC / SOP 05h.

3. The Secretariat will notify the Member Secretary of any protocol deviation/violation report received from the PI/ from any source within 2 working days of receipt of the notification.

5.3 Actions to be taken

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

- The nature and seriousness of the deviation / violation.

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- Frequency of deviation/ violation in the study in the past.
- Frequency of deviation/ violation in previous studies conducted by the same PI/ CO-PI or in the same department.

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 (not limited to these actions):

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

- If the impact is serious, this report will be shared with the Chairperson and two or more IEC members designated by the Chairperson.
- If the impact of the protocol deviation is serious enough, the Member Secretary will instruct the Secretariat to call for and schedule a full-board meeting specifically to discuss the issue within 7 working days of the initial scrutiny.

The Secretariat will put up the information and communication at the next full board meeting for discussion.

3. The Member Secretary in consultation with IEC members will review the information available and deliberate on it.

4. 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 voting. A majority vote for approval, disapproval or request for modifications of a study suspension or termination of an ongoing study is defined as 2/3rd of the voting members present at the meeting.

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

- Determine that no further action is required, or take other actions as appropriate.
- 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.
- Enlist measures that the PI would undertake to ensure that such deviations / violations do not occur in future.
- Observe the research or consent process (depending on the nature and frequency of the deviation).
- Suggest modifications to the protocol.
- Alter interval for submission of the continuing review/ annual project status.
- Ask for additional training of investigator and study team.
- Reprimand the PI.

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- Seek additional information from the PI. Conduct audit of trial by the IEC.
- Suspend the study till additional information is made available and scrutinized.

o Suspend the study till recommendations made by the IEC are implemented by the PI and found to be satisfactory by the IEC. o Suspend the study for a fixed duration of time. o Suspension or termination of the study. o Revoke approval of the current study.

- o Inform DCGI/ other relevant regulatory authorities.
- o Keep other research proposals from the PI/ Co-Pl under nonobeyance. Review and/ or inspect other studies undertaken by PI/Co-PI.

6. This final decision will be recorded on AX 01/ JKKNIEC /SOP 05h by the Member Secretary.

5.4 Procedure for notifying the PI and other concerned authorities

- The Member Secretary will draft a notification letter.
- The signed letter by Member Secretary will be sent to the PI and Department Head(s) (if required on case to case basis) and Institutional Officials (if required on case to case basis).
- The IEC secretariat will send a copy of the notification to the relevant national authorities (if required on case to case basis) and institutes (if required on case to case basis in case of multicentric trials).

5.5 Records and follow up to be kept by IEC secretariat

The Secretariat will keep a copy of the notification letter in the respective project file.

6. Annexure

Annexure 1: AX 01/ JKKNIEC /SOP 05 h – Deviation/ Violation Record

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Annexure 1: AXO1/JKKNIEC / SOP 05h

Deviation/ Violation Record

IEC Protocol no: study
Title:
Principal Investigator:
Department:
Deviation from protocol:
Protocol violation:
Description of deviation (s)/violation(s):
Corrective Actions Taken by the Principal Investigator:
Reported by (Name of Principal Investigator/ Study Team Member): Signature
with date:

Provisional Decision by Reviewer (Member Secretary and/or Chairperson and/or IEC Member/s) e Noted

- Request the PI not to perform such deviations/ non compliances/ violations in future
- Specific recommendations stated below to be followed

Specific recommendations stated below to be followed

- Suspend the study till the IEC recommendations are implemented
- Suspend the study till information available
- Terminate approval of the current study Reasons for termination
- Refuse subsequent applications from PI
- To discuss at the full board meeting Any other

Reviewed by Name/s:
Signature/s with date:

Discussion of the protocol deviation/violation at the

Emergency meeting on
Next Scheduled full board meeting on

- Final decision at the full board meeting held on

Signature with date
IEC Member Secretary

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7. Flow Chart

No.	Activity	Responsibility
1	Detection and reporting of Protocol deviation/ violation	IEC members/ Secretariat/ principal investigator
2	Receipt of protocol deviation / violation report	Secretariat
3	Review, board discussion, decision and action	IEC Members, Member Secretary and Chairperson
4	Notify Principal Investigator/ concerned authorities of IEC action	Secretariat
5	Maintain records	Secretariat

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures for the review of initial and follow-up reports of serious adverse events (SAE) reported to the IEC for any study under the oversight of the Institutional Ethics Committee (IEC).

2. Scope

This SOP applies to the review of SAE reports (Adverse events/ SAE onsite as well as SAEs of the multicenter studies occurring at other sites offsite) submitted to the JKKNIEC

3. Responsibility It is the responsibility of the IEC to review all SAEs reported to the JKKNIEC in a timely manner.

4. Definitions

1] Serious Adverse Event:

Any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect

2/ Serious Adverse Event or Serious Adverse Drug Reaction

An AE or ADR that is associated with death, inpatient hospitalization (in case the study was being conducted on out-patients), prolongation of hospitalization (in case the study was being conducted on inpatients), persistent or significant disability or incapacity, a congenital anomaly or birth defect, or is otherwise life threatening.

3/ Adverse Event

An AE is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

5. Detailed instructions

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5.1 SAE Subcommittee • Serious Adverse Event (SAE) Subcommittee of the IEC will review all serious adverse events (SAE) at the site / other sites involving human participants approved by IEC. • The committee will consist of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of adverse event reports involving human participants.

Composition of the SAE Subcommittee

- SAE Subcommittee will be appointed by the Chairperson of IEC
- SAE Subcommittee will be multidisciplinary and multi-sectoral in composition.
- SAE Subcommittee will be composed of at least 5 and a maximum of 10 individuals who are members of the TEC.

The composition shall be as follows:

- Chairperson of the SAE Subcommittee
- One Member Secretary
- At least one member with post graduate qualification in the discipline of
  - Medicine
  - Clinical Pharmacology
  - Any other relevant clinical specialties in the institution
  - IEC Secretary will be Ex-Officio member of the SAE Subcommittee.

- SAE Subcommittee may invite legal expert of IEC to provide opinion on legal implication of adverse event.
- Head of the SAE Subcommittee will be responsible for conducting SAE subcommittee meetings, and will lead all discussions and deliberations pertinent to the review of adverse event reports.
- Head of the SAE Subcommittee/ Executive Secretary will sign minutes of the SAE Subcommittee meeting.

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- In case of anticipated absence, the Head of SAE subcommittee will nominate a SAE subcommittee member as acting head. The acting Head will have all the powers of the Head of SAE subcommittee for that meeting.

- For the SAE Subcommittee meeting, a quorum will consist of at least 4 members as follows- one member (preferably pharmacologist), one member (preferably clinician), executive secretary and Head/ Acting head of the SAE subcommittee.

- SAE subcommittee will meet at least once in a month (or as often as required) Membership requirements

- IEC Members will be appointed to the SAE Subcommittee if they show willingness and commitment in terms of time to perform the role and responsibility as SAE Subcommittee member.

e The Head of the Institute (HOI) is responsible for appointing the SAE Subcommittee members. The names of new members to be appointed may be suggested by the IEC members and the Chairperson to the Head of the Institution.

- The tenure of SAE Subcommittee will be for a continuous period of two (2) years from the date of appointment.

- The retiring member will be eligible to be appointed for the new tenure consecutively four times.

- An SAE Subcommittee member may resign from membership by submitting a letter of resignation to the Executive Secretary of the SAE Subcommittee. The member may or may not assign reasons for resignation.

- A SAE Subcommittee member may be disqualified from SAE Subcommittee membership if the member fails to attend more than 5 regular consecutive SAE Subcommittee meetings without prior intimation. The Head of SAE Subcommittee will inform Chairperson, in writing, if a member has not attended more than five consecutive regular meetings of the SAE Subcommittee. The Chairperson will take up the issue of disqualification for discussion at the

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full board meeting and allow the concerned SAE Subcommittee member to state his reasons for unauthorized absence.

Functions of the Executive Secretary of the SAE Subcommittee I

. To schedule and organize the SAE Subcommittee meetings.

2. To prepare and maintain meeting agenda and minutes.
3. To conduct SAE subcommittee meetings
4. To prepare the communication letters related to the adverse event reports.
5. To communicate with IEC members, regulatory authorities and investigators in timely manner.
6. To provide necessary administrative support for SAE Subcommittee related activities.
7. To ensure adherence of the SAE Subcommittee functioning as per SOPs

5.2 Onsite SAE

5.2.a. Receipt of SAE report • The IEC Secretariat will receive the following documents within the specified time frame if an SAE is experienced by any research participant:

i.Initial SAE report to be submitted by the Principal Investigator (PI) within 24 hours of occurrence as per the format specified. ii. Due analysis should be submitted by the PI within 14 days from the occurrence of the SAE along with the format specified, iii. Due analysis will also be submitted by the sponsor within 14 days in the format specified.

iv. The follow up reports of all on-site SAE till the event is resolved.

- The IEC Secretariat will verify that the report is complete in all respects and that it has been received at the IEC office within the specified timelines.
- If the report has been received beyond the specified time, it will be considered as a protocol violation and action should be taken.
- The IEC Secretariat will sign and write the date on which the report is received.
- The Secretariat will forward these reports to the IEC Member Secretary or Executive Secretary of the SAE Subcommittee (if constituted) within two working days.

5.2 b. Review and Decision on SAE Reports and Communication to PI and Regulatory Authority by IEC

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- Member Secretary or Executive Secretary of the SAE will review the SAE report and present to the full board / SAE subcommittee (as applicable) for review and opinion.

- At the meeting of IEC or SAE subcommittee, the SAE reports will be reviewed with a special focus on relatedness to the clinical trial, medical management and financial compensation to be given to the research participants. The applicable formulae and guidelines from the regulatory authority will be used during this discussion.

If deemed necessary, a decision to hold emergency IEC meeting may be taken to discuss about financial compensation. An emergency IEC meeting will be scheduled within 7 days for the same.

- The Executive Secretary of the SAE subcommittee may refer the SAE report to full board for review if deemed necessary

- The minutes of the SAE Subcommittee/ IEC meeting will include the information on SAE at the site along with the opinion on the above points on the onsite SAE.

Participant ID	Letter no. and date of reporting	Type Of Report (I,FU)	Date Of onset	whether study drug withheld	SAE Outcome	Causality and the Opinion of PI	Recommendation (s) by SAE Subcommittee

I-initial, FU- Follow-Up

The minutes will be circulated to the IEC members via email and approval/ objection will be sought from the members in a period of 5 working days.

- The IEC secretariat will draft a formal letter to the concerned PI and inform him/ her about the IEC decision. This letter will be signed and dated by the Member-Secretary or Chairperson (IEC) and will be sent to the PI within a period of 7 days from the date of the SAE subcommittee meeting.
- The PI will be requested to reply to the query letter on the SAE report within 7 working days.
- The opinion regarding relatedness, medical management and compensation for research related injury will be communicated to the Licensing authority (DCGI) within 30 calendar days of the occurrence of the SAE in case of regulatory clinical trials.
- The Administrative Officer will file a copy of these letters in the study file.

5.2. Reports of SAE Occurring at other Sites

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The investigator will need to submit the SAEs occurring at other sites (CIOMS and SUSARS) in the form of soft copies only (CD) along with the appropriate covering letter (hard copy) mentioning the total number of reports and its details in the following format:

SN0.	Country	Type of Report (I/FU)	SAE event	Date of onset	Date of report	Outcome	Causality	
							Investigator	Sponsor

I-initial, FU- Follow-Up

- For every SAE term, a separate row of the above table is to be used (the SAE terms should not be combined).

- Causality to be stated as related (R) or not related (NR)

- The SAEs occurring at other sites will be reviewed by the Secretary of the IEC / SAE Subcommittee (as applicable) and informed to other members and discussed in the forthcoming scheduled meeting. The agenda and minutes of the meeting will include the information on SAEs at other sites.

5.4. Onsite AE

The IEC Secretariat will receive the following documents pertaining to AE experienced by the research participants for research proposals approved by the IEC:

l . On site AE reports to be submitted by the PI annually in the continuing review report.

2. In view of the risk assessment of a given research proposal the IEC can request adverse events to be reported earlier, if deemed necessary at specified timelines in the project approval letter.

- The IEC Secretariat will verify that the report is complete in all respects and signed and dated by the PI and that it has been received at the IEC office within the specified timelines. If the report has been received beyond the specified time, it will be considered as deviation.

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- For all the onsite AE reports received at the IEC office, the Administrative Officer will forward these reports to the Member Secretary of IEC for review.

- Member Secretary of IEC may put the AE reports for discussion at full board if deemed necessary

- Queries, if any on the report will be communicated to the PI by the Member Secretary of IEC following full board meeting • The Administrative Officer will file a copy of these letters in the study file.

5.5. Review During the Full board IEC meeting

- The IEC Member Secretary will read out the minutes of all the weekly SAE Sub-committee meetings including the recommendations/ decisions of the SAE sub-committee (if constituted).

- In case of the SAE occurring at the site to be discussed at the full board meeting, the member secretary will also provide the relevant information including updates on SAE that have occurred earlier at the site. The Chairperson will invite members to voice their opinions and ensure free and frank discussion.

- The decision can be arrived at by consensus. If not agreed by consensus, the issue would be put for voting. (a majority vote for a decision is 2/3rd majority of the members present and voting)

5.6 Decision of IEC on SAE review

The SAE Subcommittee/IEC may take one or more of the following decisions on review of the SAE reports.

5.6a. Type of Actions Taken by IEC/ SAE Subcommittee on Review of SAE Report:

Following detailed review of the SAE reports and related documents, the IEC/ SAE Subcommittee (if constituted) can suggest one of the following actions:

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- Note the information about the SAE in records for future reference.
- Request further follow up information and/ or additional details.
- Ask for periodic follow-up of the research participant till SAE is resolved
- Depending on complexities of issue, IEC/ SAE Subcommittee may decide to seek opinion of outside expert consultant who is requested to respond within 14 working days.
- Provide recommendations regarding/ raise queries related to compensation for study related injury and death

5.6b. Type of Actions Taken by IEC following full board review

- Suggest changes/ amendments in protocol, Patient Information Sheet/ Informed Consent Document/ Investigators' Brochure/ any other study-related documents.
- Suspend the study till additional information is available.
- Suspend the study till review is completed (safety monitoring of ongoing patients to be continued).
- Suspend the study till amendments requested for by the IEC are carried out.
- Suspend enrollment of new participants.
- Suspend certain activities under the protocol.
- Direct the PI to inform participants already enrolled in the study about the AES and if required obtain their consent again (re-consent) regarding continuation in the research trial.
- Direct the PI to inform participants already enrolled in the study about the AE and request them to undertake additional visits, additional procedures, additional investigations, etc. as prescribed in the amendment. Terminate the study.
- Any other appropriate action.
- The decision shall be recorded in the minutes of the full board IEC meeting.

If the recommendation from the IEC includes suspension of the study or suspension of any one or more of the study-related procedures or activities, amendments in the protocol or other study related documents (excluding Investigators' brochure), re-consenting of research

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participants, the decision will be conveyed to the PI through telephone, fax or email within 24 hours. Such a communication will be documented by the IEC Member-Secretary in the study file. A formal letter to the PI informing about the IEC recommendations in such situations will be sent within 5 working days of the IEC meeting having taken place.

6. Annexures

Annexure 1 AX 01/ JKKNIEC /SOP/05 i—Data Elements for Reporting serious adverse events occurring in a clinical trial (As per Schedule Y Appendix XI)

Annexure 2A AX 02A/ JKKNIEC /SOP/05 i - Checklist for Onsite Serious Adverse Event submission

Annexure 2B AX02B/ JKKNIEC /SOP/05 i — Onsite Serious Adverse Event Analysis Report

Annexure 1: AX 01/ JKKNIEC /SOP/05 i

Data Elements for reporting serious adverse events occurring in a clinical trial

1. Patient Details
   - Initials & other relevant identifier (hospital/OPD record number etc.)
   - Gender
   - Age and/ or date of birth
   - Weight
   - Height
2. Suspected Drug(s)
   - Generic name of the drug
   - Indication(s) for which suspect drug was prescribed or tested
   - Dosage form and strength
   - Daily dose and regimen (specify units - e.g., mg, ml, mg/kg)
   - Route of administration
   - Stalling date and time of day
   - Stopping date and time, or duration of treatment
3. Other treatments
   - Provide the same information for concomitant drugs (including non-prescription / OTC drugs) and non-drug therapies, as for the suspected drug(s).
4. Details of Suspected Adverse Drug Reaction(s)
   - Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious, In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.
   - Start date (and time) of onset of reaction.
   - Stop date (and time) or duration of reaction.
   - Dechallenge and rechallenge information.
   - Setting (e.g. hospital, out-patient clinic, home, nursing home)
5. Outcome

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

6. Details about the Investigator
   - Name
   - Profession (speciality)
   - Address, Telephone number
   - Date of reporting the event to Licensing Authority:
   - Date of reporting the event to Ethics Committee overseeing the site: Signature of

the Investigator

Annexure 2A AX 02A/ JKKNIEC /SOP/05 i

Checklist for Onsite Serious Adverse Event submission

SNO.	Details		
	Country (Name of the country should be specified)		
	SAE report of death or other than death	Death	Other than Death
Please tick (v/)		yes / No	Page No.
	In case of Serious Adverse Event (SAE), please specify if there is any injury o the participant (Please specify Yes/No) in the box		
	Protocol Title		
	Protocol study No./ ID (Code		
	Copy of Clinical Trial permission obtained from CDSCO		
7.	CTRI Registration No.		
8.	Sponsor (Address with contact no and Email)		
9.	RO (Address with contact no and Email)		
10.	Initial / Follow-u (FU)		
l l .	In case of follow-up: Date & Diary no of initial or recently submitted report information		
12.	Patient Details		
a)	Initials & other relevant identifier (hospital/OPD record number etc)		
b)	Gender		

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c)	Age and/or date of birth		
d)	Weight		
e)	Height		
13.	suspected drugs		
a)	Generic name of the drug		
b)	Indication(s) for which suspect drug was prescribed or tested		
c)	Dosage form and strength		
d)	Daily dose (specify units - e. . , m , ml, m kg)		
e)	Route of administration		
f)	Starting date and time of day		
g)	Stopping date and time, or duration of treatment		
14.	Other Treatment(s)		
	Provide the same information for concomitant drugs (including non prescription/OTC Drugs) and non- drug therapies, as for suspected drug(s)		
15	Details of the events		
a)	Full description of event (s) including body site and severity, as well as the criterion (or criteria) for recording the report as serious.		
b)	In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.		
c)	Stan date (and time) of onset of reaction.		

d)	Start date (and time) or duration of reaction.		
e)	DE challenge and rechallenge information.		
	Setting (e.g., hospital, out-patient clinic, home, nursing home).		
16.	Outcome		
a)	Information on recovery and any sequelae results of specific tests and/or treatment that may have been conducted.		

b)	For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings.		
c)	Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family histo ; findin s from s ecial investigations etc.		
17	Details about the Investigator		
d)	CT Site Number, if any		

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e)	Name		
f)	Address		
g)	Telephone/Mobile Number & Email		
h)	Profession (specialty)		
	Date of re ortin the event to Licensin Authorit		
j)	Date of reporting the event to Ethics Committee overseeing the site:		
k)	Signature of the Investigator		
18.	Details about the Ethics Committee		
a)	Name & Address		
b)	Name of Chairman & Address		
c)	Telephone/Mobile Number		
d)	Email		
19.	Adverse Event Term/ Details of SAE		
20.	Causality Assessment (Related/Unrelated) by Investigator		
21.	Causality Assessment (Related/Unrelated) by Sponsor/ CRO		
22.	Details of compensation provided for injury or death. In case no compensation has been paid, reason for the same		
23.	Duly filled SAE Form as per Appendix XI of Schedule Y		
24.	Laboratory investigations report /Discharge summary (if available and a licable)		
25.	Post-mortem re ort (if applicable)/ Any additional documents)		

Note: Information not relevant to a particular SAE should be marked with NA **Annexure 2B AX02B/ JKKNIEC /SOP/05 i Onsite Serious Adverse Event Analysis Report**

No.	Details		
1.	Country (Name of the country should be specified)		
2.	SAE report of death or other than death	Death	other than Death
Please tick (v/)		yes / No	Page No.
3.	n case of Serious Adverse Event(SAE), please specify if there is any injury o the participant (Please specify Yes/No) in the box		
4.	Protocol Title		
5.	Protocol Study No./ ID /Code		
6.	o of Clinical Trial permission obtained from CDSCO		
7.	TR Registration No.		
8.	Sponsor(Address with contact no and Email)		
9.	RO (Address with contact no and Email)		

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10.	Initial / Follow-up (F U)		
11.	In case of follow-up: Date & Diary no of initial or recently submitted report information		
12.	Patient Details		
	Initials & other relevant identifier (hospital/OPD record number etc.)		
	Gender		
	Age and/or date of birth		
	Weight		
	Height		
13.	Suspected drugs		
	Generic name of the drug		
	Indication(s) for which suspect drug was prescribed or tested		
	Dosage form and strength		
	Daily dose and regimen (specify units -e. .,m , ml, m kg)		
	Route of administration		
	Starting date and time of day		
	Stopping date and time, or duration of treatment		
14.	Other Treatment(s)		
	Provide the same information for concomitant drugs (including nonprescription/OTC Dru s and non- drug therapies, as for suspected drugs)		
15	Details of the events		
)	Full description of event (s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious.		
	In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.		
	Stan date (and time) of onset of reaction.		
	Stop date (and time) or duration of reaction.		
	Dechallenge and rechallenge information.		
	Setting (e.g., hospital, out-patient clinic, home, nursing home).		
16.	Outcome		
	Information on recovery and sequalae: results of specific tests and / or treatment that may have been conducted		
	For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction, any post mortem findings.		
	Once information anything relevant, to facilitate assessment of the case such as medical history including allergy, alcohol or drug abuse, family history, findings from special investigations etc...		

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17.	Details about the investigator		
	Ct site No. if any		
	Name		
	Address		
	Telephone mobile No. and e mail		
	Profession (specialty)		
	Date of reporting the event to the licensing authority		
	Date of reporting the event to the IEC overseeing the site.		
	Signature of the investigator		
18	Details of the Ethics committee		
	Name and address		
	Nameof the chairman and address		
	Telephone mobile No.		
	e mail		
19	Adverse events team /details of SAE		
20	Casualty assessment (related/unrelated) by the investigator		
21	Casualty assessment (related/unrelated) by the sponsor/CRO		
22	Details of compensation provided for death, in case no compensation has been paid, reasons for the same		
23	Duly filled appendix form as per schedule XI of appendix Y		
24	Laboratory investigations report/ discharge summary – if available		
25.	Post mortem report – if available/ any other documents.		

Details of payment for medical management of SAE? (please give information who paid how much was paid, to whom, with evidence of the same)

What is the investigator's assessment for the amount of compensation to be paid?
What is the sponsor's assessment for the amount of compensation to be paid?

Has the participant made a claim?

Yes No

[f yes, for how much amount _____

If no, please ensure that the participant / nominee have been made aware of his/her' rights regarding compensation. lease submit documentation regarding the same _____

Signature of the Principal Investigator . Date:

6. Flowchart

No.	Activity	Responsibility

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1	Receipt of SAE report	IEC Secretariat
2	Submission of SAE report to SAE Subcommittee	Executive Secretary of SAE Subcommittee
3.	Agenda and Minutes of the Subcommittee	Executive Secretary of SAE Subcommittee
4.	Review and discussion of SAE report at Subcommittee meeting	SAE Subcommittee members
5.	Review and discussion of SAE report at full Board meeting	Member Secretary
6.	Communication of the IEC decision about SAE review to the Licensing authority	Executive Secretary of the SAE Sub-committee
7.	Communication of the IEC decision about SAE review to the principal investigator	Executive Secretary of the SAE Sub-committee

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide instructions on the review of Study Completion Report submitted for studies approved by the Institutional Ethics Committee (JKKNIEC)

2. Scope

This SOP applies to the review of Study Completion Report of every completed study submitted by Principal Investigator (PI) and is applicable only to JKKNIEC.

3. Responsibility

It is the responsibility of the Secretariat/ IEC Chairperson/ Member Secretary/ Member/s to review the study report and act on it.

4. Detailed instructions

4.1 Receipt of Study Completion Report

- The Secretariat will receive I copy (soft and hard) of Study Completion Report filled as per the format — AX 01/JKKNIEC /SOP 05 j from the Pl. The study completion report is expected from the investigator within I month of completion of the study at the site. The Secretariat will follow instructions as in "Management of Protocol Submission" for receiving and checking the report package. It is the responsibility of the IEC Secretariat to review the report for completeness. The Secretariat shall verify the submitted Study Completion Report along with Study Completion Report Form and forward it to the Member Secretary within 7 working days of receipt.

- The Member Secretary will review the Study Completion Report, confirm that it is complete and present it at the next full board meeting. If there is a need felt (e.g. a deviation/ violation is noted), the Member Secretary will handle it as per the annexure.

- The Secretariat shall include the Study Completion Report Form in the agenda for IEC members for discussion at the full board meeting.

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4.2 During the Board meeting

The Member Secretary will present the report and members can discuss as needed. Following the discussion, the Chairperson may take one of the following decisions:

- noted / approved
- request for additional information / clarification

The Secretariat will note the decision in the meeting minutes. The Member Secretary will draft a letter to the PI conveying decision on the study completion report. The study shall be considered as closed if the decision by IEC is "Noted" or "Approved". The Secretariat will accept and file the report and get the Study Completion Report Form signed by the Chairperson. The final report will be placed in the master file and kept in the archival area. The Administrative Officer will archive the entire study for a period of 5 years from the date of completion of the project if the decision is noted and closed.

6. Annexures

Annexure 1: AX 01/JKKNIEC /SOP 05 j - Study Completion Report

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Annexure 1: AX 01/JKKNIEC /SOP 05 j

Study Completion Report

(To be filled by principal Investigator)

IEC Project No.

Project Title:

Principal Investigator:

Department:

Total no. of study participants recruited:

Total no. of study participants approved by the IEC for recruitment:

Duration of the study:

*Results (summary) with Conclusion: (use extra blank paper, if more space is required):

*Note: If final report is not available from sponsor for sponsored clinical trial, it may be submitted later to IEC once it is ready.

Number of SAEs at our center:

Whether all SAE submitted to IEC: Yes:

No: (if no, reason(s) for the same)

No. of patients withdrawn:

Reasons for Withdrawal of Patients:

Signature of Principal Investigator: Date:

To be filled by IEC office only Action taken:

Noted:

Requires more information/ action as follows: IEC Meeting date (If reviewed in meeting):

Final Decision:

Signature of Member Secretary with date:

7. Flow chart

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No.	Activity	Responsibility
I	Receipt of the study completion report	IEC Secretariat
2	checking the contents of the report packages and assess adequacy of contents	IEC Secretariat
3	Verification of the study completion report, reparation of the study completion statement and sending them to the Member Secretary	IEC Secretariat
4	Review of Study completion report for completeness and informing members at full-board meeting	Member-Secretary/ hairperson
5	conclusion of report/ review at full-board meeting	IEC Secretariat
6	Discussion and decision at the full board meeting	Member Secretary/ hairperson
7	quoting the decision in the minutes of the Meeting	IEC Secretariat
8	Conveying decision to the Principal Investigator	IEC Secretariat
9	Archiving all the study-related documents along with the Study completion report	Administrative Officer

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Ethics Committee (IEC) manages premature termination/suspension/discontinuation of a research study. Protocols may be terminated/suspended/discontinued at the recommendation of the IEC, Data Safety Monitoring Board (DSMB), Principal Investigator (PI), Sponsor, Regulator or other authorized bodies wherein participant enrolment and follow-up are discontinued before the scheduled end of the study.

2. Scope

This SOP applies to any study previously approved by IEC that has been recommended for termination/suspension/discontinuation before its scheduled completion.

3. Responsibility

It is the responsibility of the IEC to manage the termination of any study (recommended for termination by Data Safety and Monitoring Board, Principal Investigator, Sponsor or other authorized bodies or by the IEC) that has been previously approved. The Secretariat is responsible for management of the premature termination/ suspension/discontinuation process.

4. Recommendation for Termination/ Suspension/ Discontinuation

4.1 By PI / Sponsor

An investigator/ Sponsor may put on hold a previously approved research when in the judgment of investigator/ Sponsor this is appropriate to protect the rights or welfare of participants or when new safety information has appeared in the literature, or evolved from this or similar research.

4.2 By IEC

IEC members/Chairperson can prematurely terminate/ suspend/ discontinue the study in the following situations:

- protocol non-compliance/violation following which IEC decides in full board meeting to terminate/ suspend/ discontinue the study.
- SAEs occurring at trial site may require the study to be prematurely terminated for the safety of the patients.

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- When research is not conducted in accordance with IEC policies, is not in compliance with the local regulations or that has been associated with unexpected serious harm to participants.
- Zero accrual for 1-2 years or long-term, low accrual.
- Suspended protocols remain open and require continuing review.
- IEC may revoke approval and recommend to stop pernnanently all activities in previously approved research protocol. Terminated protocols are considered closed and no longer require continuing review.

5 Detailed instructions

5.1. Receipt of Recommendation for Study Termination.

Secretariat will receive study protocol termination/suspension/discontinuation report submitted by PI and verify the contents of report for completeness (AX 01/ JKKNIEC /SOP 05 k) and/or other documents (letter from PI / sponsor).

5.2. Review by the IEC

- Secretariat will inform Chairperson and Member Secretary regarding recommendation for premature termination/ suspension/ discontinuation of study protocol and termination/ suspension/ discontinuation report within 3 working days of receipt of report.
- Member Secretary/ Chairperson shall review the report and either call for an emergency meeting or discuss the report at the regular full board meeting.
- Secretariat will arrange for an Emergency meeting/ keep matter for discussion at full board meeting.
- Member Secretary in the meeting will inform members of the premature termination/ suspension/ discontinuation of the project and the reasons for the same.
- If the premature termination/ suspension/ discontinuation report is unclear or more information is required from the PI, the Chairperson shall instruct the Secretariat to seek clarifications/ additional information from the Principal Investigator.
- Chairperson shall sign and date the study termination/ suspension/ discontinuation report in acknowledgement.
- If the IEC has revoked approval/suspended the study, regulatory authorities and Head of the institution must be informed within 14 working days of the full board meeting.

5.3. Notifying the Principal Investigator

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- Secretariat will prepare a notification letter and send to the PI within 14 working days after the meeting acknowledging the approval of termination/ letter seeking clarifications/information regarding the premature termination.
- In case a letter is sent seeking clarifications/information regarding the premature termination/ suspension/ discontinuation, the PI shall send a written response within 60 days of receiving the letter.
- If the PI does not comply, the matter will be put to the full board meeting for discussion.
- The investigator may appeal or respond to the convened IEC in writing.

5.4. Store the Protocol Documents

- The Secretariat will keep the original version of the Premature Termination Report in the Protocol file and send the file to archive.
- The protocol documents will be stored for a period of 5 years from the date of project termination.

6. Annexure 1: AX 01/ JKKNIEC /SOP 05 m- Premature Termination Report

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Annexure 1: AX 01/ JKKNIEC /SIO 05 k

Premature Termination Report

IEC Protocol no			
Protocol title:			
Principal Investigator:			
Department:			
IEC approval date:		Date of last Annual/ Periodic status report submitted to IEC: Termination/suspension [discontinuation date:	
Date of initiation of Study:			
No. of participants enrolled:		No. of participants completed:	
No. of ongoing participants:		No. of drop outs:	
		Reason for each drop-out:	
SAEs (total no.):	Whether SAEs were reported to the IEC?		
	Yes	No	
Brief summary of results: (use extra blank paper, if more space is required)			

Reason/s for termination/suspension/discontinuation:

Signature of Principal Investigator with date

Discussed at the IEC meeting held on

Action taken:

- Approval of Premature Termination / suspension / discontinuation of project:
- Requires more information/ action as follows:

Signature of Chairperson, IEC with date:

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7. Flowchart

No.	Activity	Responsibility
1	Receive recommendation for study termination/ suspension / discontinuation	IEC Secretariat
2	Review and Discuss the Termination/ suspension/ discontinuation report	IEC members, Member Secretary and Chairperson
3	Notify the Principal Investigator	IEC Secretariat
4	Store the Protocol Documents	IEC Secretariat

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the type of research projects for which the Institutional Ethics Committee (IEC) may grant waiver for requirement of obtaining written or verbal informed consent.

2. Scope

This SOP applies to the all protocols submitted for review by the IEC that ask for consent waiver.

3. Responsibility

It is the responsibility of the IEC to review and approve a request for verbal/written consent waiver. The Member Secretary will record the decision in the minutes and in the application Form. The Chairperson will sign and date letter conveying the decision

4. Detailed instructions

- The Application Form AX 01/ JKKNIEC /SOP 05 l is designed to standardize the process of applying for consent waiver.
- When a request for waiver of consent is received from the Principal Investigator (PI) to the IEC in the given format AX 01/ JKKNIEC /SOP 05 l , the following steps are taken:
- The IEC Secretariat will check if the concerned documents are filled completely and the required list of documents is enclosed.
- The IEC members will review the request taking into consideration the types of studies for which waiver of consent may be granted. (as described in Annexure).
- The IEC will ensure that there are adequate mechanisms described in the protocol for protection of the identity of the research participants and maintaining confidentiality of the study data. (This is necessary as the participant cannot be assured directly about confidentiality / health data through a formal informed consent process, when consent waiver is granted).
- The final decision whether to grant the waiver is taken at a full board meeting unless the project is considered under expedited review.
- D The decision regarding approval / disapproval of waiver is informed to the Principal Investigator in writing. If the waiver is not granted, the IEC will provide reasons for the same.

5. Annexures

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Annexure 1: AX 01/ JKKNIEC /SOP 05 l - Application form for requesting waiver of consent
Annexure 2: AX 02/ JKKNIEC /SOP 05 l -Type of research projects which may qualify for consent waiver

Annexure 1: AX 01/ JKKNIEC /SOP 05 l

Application form for requesting waiver of consent

l .l .Principal Investigator's name:

1. 2. Department:

l. 3. Title of project:

l .4. Names of co-investigators and Department/s:

1. 5. Request for waiver of informed consent:

- ☐ Please tick the reason(s) for requesting waiver (Please refer the back of this annexure for criteria that will be used by IEC to consider waiver of consent).

  [l] Research involves 'not more than minimal risk'

  [2] There is no direct contact between the researcher and participant

  [3] Emergency situations as described in ICMR Guidelines

  [4] Any other (please specify)

- ☐ Statement assuring that the rights of the participants are not violated:

- ☐ State the measures described in the Protocol for protecting confidentiality of data and privacy of research participant:

Principal Investigator's signature with date:

Final decision at full board meeting held on:

Waiver granted: Yes ..... No .....

If not granted, reasons,

Signature of the Chairperson with Date:

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Annexure 2: AX 02/ JKKNIEC /SOP 05 I

Type of research projects which may qualify for consent waiver:

A request to waive written informed consent must be accompanied by a detailed explanation. The investigator is also required to provide assurance regarding protection of identity of research participants and maintenance of confidentiality about the data of the research participants. The following criteria (ICMR 2017 guidelines) must be met for a research project so that it can qualify for granting a waiver of both written and verbal consent.

I. The proposed research presents no more than minimal risk to participants. e.g. a retrospective review of patient case records to determine the incidence of disease / recurrence of disease. [Minimal risk would be defined as that which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current everyday life].

2. When it is impractical to conduct research since confidentiality of personally identifiable information has to be maintained throughout research as maybe required by the sensitivity of the research objective. e.g. conducting interviews with citizens about their religious beliefs / people with HIV and AIDS / conducting phone interviews with homosexuals.

The only record linking the participant and the research would be the consent document and when there is a possible legal, social or economic risk to the participant entailed in signing the consent form as they might be identified as such by signing the consent form, the requirement for obtaining consent can be waived of by the IEC. [In case of telephonic interviews, waiver of written informed consent may be requested but verbal consent is mandatory].

a. The following documents need to be submitted for the IEC review for verbal consent:

- A script for verbal consent - a verbal consent script provides all of the elements of consent in a more informal style. In addition, each subject should be provided with an information sheet that describes the study and gives contact names and numbers.
- The interview schedule (questions to be asked) will confirm that the interview is a simple 5 minute call and that no questions are asked that compromise a person's confidentiality or position.
- Investigators will be asked to keep a log of those who were approached about the study, and offered verbal consent. A simple chart indicating the participants as participant I,

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participant 2, etc and a column indicating that verbal consent has been taken on the date of recruitment along with the date.

3. Research on publicly available information, documents, records, work performances, reviews, quality assurance studies, archival materials or third party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies.

4. Research on anonymized biological samples from deceased individuals, left over samples after clinical investigation, cell lines or cell free derivatives like viral isolates, DNA or RNA from recognized institutions or qualified investigators, samples or data from repositories or registries etc.

5 In emergency situations when no surrogate consent can be taken, when consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible, the IEC can allow waiver of consent for recruiting participant in a research study. However, information about the intervention should be given to the patients whenever he / she gains consciousness or to relative / legal guardian when available later.

6. Flow chart		
No.	Activity	Responsibility
	Receive the submitted documents	IEC Secretariat
	Review of protocol and application for waiver of consent	IEC Members
	Decision regarding waiver of consent	IEC Members
	Communicate the decision to the Investigator	IEC Secretariat
	Recording and filing the decision	IEC Secretariat

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1. Purpose

The purpose of this standard operating procedure (SOP) is to describe the procedures for site monitoring of an Institutional Ethics Committees (IEC) approved protocol.

2. Scope

This SOP applies to all IEC approved studies for which a routine or for-cause on-site monitoring may be undertaken by the IEC.

3. Responsibility

It is the responsibility of the Full Board or Chairperson and Member Secretary to decide to conduct on-site monitoring. It is further the responsibility of the designated IEC member(s) to perform onsite monitoring of selected study site(s).

4. Detailed instructions

4.1. Selection of study sites

- Routine monitoring for site may be decided at the time of approval of project by Full Board.
- This is recorded in IEC decision form and in the IEC minutes.
- "For-cause monitoring" will be performed at sites for reasons identified by any member of the IEC, after approval by the Chairperson.

The reasons for identifying a particular site for "for-cause monitoring" could include any one or more of the following:

- High number of protocol violations,
- Large number of studies carried out at the study site or by the investigator,
- Large number of Serious Adverse Events (SAE) reports, High recruitment rate,
- Large number of Protocol deviations,
- Complaints received from participants or any other person,
- Frequent failure to submit the required documents Any other cause as decided by IEC.

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4.2.Before the visit

1. Irrespective of the cause for conducting monitoring the following procedure will be followed:
2. Chairperson will identify and select one or more IEC members (henceforth referred to as monitors)
3. to conduct monitoring of a site.
4. Selected members will be given an appointment letter in this regard.
5. Agenda of monitoring will be decided by identified monitors in consultation with Member Secretary and Chairperson
6. Secretariat will decide date of monitoring in consultation with monitors and PI.
7. Final date will be communicated to the PI (with a request to be available) and monitors.
8. Monitor will receive from secretariat and review relevant project documents and make appropriate notes.
9. Secretariat will provide Monitors with relevant reference material / documents related to the project
10. Monitors will carry with them Site Monitoring Visit Report Forms and form for monitoring of audiovisual recording of AV consent Process (if applicable) collected from the Secretariat.

4.3. During the visit

The Monitor will follow the check list and check the log of delegation of responsibilities of study team,

- check if the site is using latest IEC approved current versions of the protocol, informed consent documents, case record forms, diaries, advertisements, etc
- observe the informed consent process, if possible
- review randomly selected participants files to ensure that participants are signing the correct informed consent
- check investigational product accountability is adequately controlled and documented throughout the product flow at the study site (arrival, dispensing, use, return from the subject and return/destruction after the study)
- check for storage times, conditions and expiry dates to be acceptable and sufficient supplies available, wherever applicable
- verify that the investigator follows the approved protocol and all approved amendment(s), if any
- ensure that investigator and investigator's trial staff are adequately informed about the trial,

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- verify that investigator and investigator's trial staff are performing the specified study functions, in accordance with the approved protocol and any other written agreement between the sponsor and the investigator/institution, and have not delegated these functions to unauthorized individuals
- verify that the investigator is enrolling only eligible subjects
- determine whether all SAEs are appropriately reported within the time as per the applicable regulatory requirement(s). Case record forms would be checked to review the safety data i.e. Adverse Events (AEs) and SAEs for the volume or severity of adverse events
- review the project files of the study to ensure that documentation is filed appropriately
- review the source documents for their completeness
- Collect views of the study participants, if possible

The Monitor will fill the Site Monitoring Visit Report Form and form for monitoring of audiovisual recording of AV consent Process (if applicable), sign and date it.

4.4. After the visit

The Monitor will submit the completed Site Monitoring Visit Report Form and form for monitoring of audiovisual recording of AV consent Process (if applicable) to the IEC secretariat within 7 working days of conducting a site monitoring visit or at the time of full board meeting (whichever is earlier).The report should describe the findings of the monitoring visit.

The Member-Secretary will present the monitoring report at the next full board IEC meeting and the concerned Monitor will provide additional details/ clarifications to members, as required.

The IEC will discuss the findings of the monitoring process and take appropriate specific action by voting or combination of actions, some of which are listed below:

Continuation of the project with or without changes,
Restrictions on enrollment,
Recommendations for additional training,
Recruiting additional members in the study team
Revising/ providing qualifications/ experience criteria for members of study team, termination of the study,
Suspension of the study, etc.

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If the Monitor has findings that impact on safety of the participant the Monitor will inform the Member Secretary on the same day. The Member Secretary will discuss with the Chairperson and any one of the actions described above will be taken.

The final decision taken at the full board IEC meeting by the Chairperson will be recorded in the Site Monitoring Visit Report Form.

The Secretariat will convey the decision to the Principal Investigator in writing within 14 working days of the meeting.

The Secretariat will place the copy of the report in the protocol file.

5. Annexures

Annexure l : AXOl/JKKNIEC /SOP 05 m - Site Monitoring Visit Report

Annexure 2: AX02/ JKKNIEC /SOP 05 m — Monitoring of Audiovisual recording of AV consent Process

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Annexure 1: AX01 /JKKNIEC /SOP 05 Site Monitoring Visit Report

IEC project no:	Date of visit
Study Title:	
Principal Investigator and Department:	
Government agency	others
Date of IEC approval	
Date of Initiation of the study	
Duration of study	
Reason for monitoring	Routine For- cause (state reasons)
Last monitoring done, if any	
Project Status	Ongoing Completed Recruitment Complete Follow-up, extension Suspended Terminated
In case of the response to the above question is option 5 or 6, kindly provide reason/s	
Are the present study team members as per the list approved by the IEC ?	Yes No comment
Are site facilities appropriate?	Yes . No . comment
Is the recent version of Informed Consent Document (ICD), after IEC approval, used?	. Yes . No . comment
Whether appropriate vernacular consent has been from all patients?	. Yes . No . comment
Any other findings noted about the ICDs?	. Yes . No . comment
Is recent IEC approved version of protocol used?	. Yes . No . comment

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Have the eligibility, inclusion exclusion criteria been adhered informed to IEC?	. Yes . No . comment
Any adverse events found?	. Yes . No
	. comment
Any SAEs found?	. Yes . No . Comment
Were the SAEs informed to IEC within timelines specified by CDSCO?	. Yes . No . Comment
No. of deaths reported?	. Yes . No . Comment
Any other non-death study related injury	. Yes . No . Comment
Compensation paid for study related injury or death	. Yes . No Comment
Are there any protocol noncompliance, deviations/violations?	. Yes . No Comment
Have the protocol non-compliance, deviations/violations been informed to IEC?	. Yes . No Comment
Are all case record forms up todate?	. Yes . No Comment
Are storage of data and investigating products locked?	. Yes . No Comment
How well are the participants protected?	Good Fair Not fair Comment

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Any other remarks	Yes No If yes, details
Duration of visit:_____ hours	Started at Finished at
Name of the study team member/s present	Signature with date
Name of IEC members and representatives who attended monitoring visit	Signature with date
Completed by	Signature with date

Completed by:

Final Decision at the IEC meeting held on:

Signature of Chairperson, IEC with date:

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Annexure 2: AX02JJKKNIEC /SOP 05 m

Monitoring of Audiovisual recording of AV consent Process

1. Facility where informed consent process should be carried out - (well lit, free from noise, privacy ensured):

Yes No ☐ Remarks: _____

_____

2. The consent is taken in language the participant/ legally acceptable representative (LAR) understands best and is literate in.

☐ _____

Yes No ☐

Remarks:

_____

3. Introduction of each person (person conducting the informed consent discussion participant/ legally acceptable representative (LAR) / impartial witness) involved during informed consent process and information about necessity for audiovisual recording

☐ _____

Yes No ☐

Remarks:

_____

4. Information to the participant/ LAR and impartial witness (as applicable) that the process of taking the consent is being recorded for the purpose of documentation as required by the government rules.

☐ _____

Yes No ☐

Remarks:

_____

5. Information to the participant/ LAR and impartial witness (as applicable) that the confidentiality of information and privacy of participants is assured.

☐ _____

Yes No ☐

Remarks:

_____

6. Information to the participant/ LAR and impartial witness (as applicable) that the recording may be shown to government agencies or members from the IEC.

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☐ _____ _____

Yes No ☐

Remarks:

_____

7. Explanation or narration by the person conducting the informed consent discussion.

☐ _____ _____

Yes No ☐

Remarks:

_____

8. Questions asked by the potential participant/LAR are answered satisfactorily.

☐ _____ _____

Yes No ☐

Remarks:

_____

9. Allowing ample time and opportunity to read/understand the information in the informed consent document or discuss the same with family members.

☐ _____ _____ Yes No ☐ Remarks:

_____

10. Reading out by the participant/LAR (or having read out by impartial witness) the statements mentioned in Informed Consent and stating whether participant agrees or not for each statement.

Yes _____ _____

No

Remarks:

_____

11. Documentation of signatures of all those involved in the Informed Consent Process.

☐ Yes_____ No_____

☐ Remarks:

_____

12. Clarity and completeness of AV recording

Yes No ☐ _____ _____

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Remarks:

13. Storage of recording in password protected laptop/ desktop computer and/ or hard drive and labelled CD with access allowed only to the principal investigator and designated members of the study team.

Yes
No
Remarks:

7. Flow chart

No.	Activity	Responsibility
1.	Selection of study sites	IEC Member Secretary Chairperson
2	Identification of IEC members for monitoring during meeting	Chairperson
3	Inform Principal Investigator in writing	Secretariat
4	Review of IEC protocol file prior to visit and collect Site Monitoring visit report from IEC office	IEC member
5.	Review or monitoring of site	IEC member
6.	Complete the monitoring report and present in IEC meeting	IEC member
7.	Communication of IEC decision to PI	Secretariat

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1. Purpose

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

2. Scope

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

3. Responsibility

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

4. Detailed instructions

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

In case of a complaint received from a research participant:

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

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- Appoint a subcommittee of two or more IEC members for enquiry in order to resolve the matter

- Call an emergency meeting of two or more IEC members for discussion or Consider the matter for discussion at the next full board meeting

The Chairperson/ Member Secretary/ designated IEC members will assess the situation and mediate a dialogue between the research participant and PI in an attempt to resolve the matter. The IEC will insist on factual details to determine gap, if any, between truth and individual perception. The final decision will be taken by the Member Secretary in consultation with the Chairperson based on the recommendation of any one of the above and it will be informed to the research participant and the PI by the Secretariat. The information including any action taken or follow-up and final decision will be recorded in the form and the form is signed and dated. The IEC members will be informed about the action taken and the outcomes in the forthcoming IEC meeting (in case of requests/ complaints not discussed in full board meeting) and minuted. The Secretariat will place all documents in the relevant study file.

5. Annexure : **Annexure 1: - AX01/JKKNIEC /SOP 05 n Request/ Complaint Form**

Date	
Received by	
Request/ Complaint received through	Telephone No: Mobile No: Fax No: Letter / Date: E-mail / Date: Walk-in / Date / Time: Other, specify:
Participant's Name	
Contact details	

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Address & Phone	
EC Project no	
Title of the Project	
Starting date of participation	
Information requested/ complaint/query	
Action taken	
Reviewed by	
Final Decision	
Date of IEC meeting (if applicable)	
Name & Signature of ember Secretary	Date

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1. Purpose

To provide instructions for preparation and maintenance of active study files and other related documents approved by the Institutional Ethics Committee (IEC), IEC administrative documents, archival of closed files and retrieval of documents.

2. Scope

This SOP applies to maintenance, archival and retrieval of all study files and study related documents and IEC administrative documents by the IEC Secretariat.

3. Responsibility

It is the responsibility of Member Secretary with assistance of Secretariat to ensure that all active study files and IEC records are prepared, maintained during the study period and kept securely for a period of five years after the closure/ termination of the project.

4. Detailed instructions

4.1. Maintenance of the Active Study Files

- A study master file is the file comprising all essential documents and correspondence related to the study. This should be created for all proposals at the time of initial submission to the IEC office.

- All related documents of the approved study will be gathered, classified appropriately and placed in the study master file: These could include copies of

  ✓ All original research proposals reviewed and approved

  ✓ Study approval letter

✓ Reviewed and approved consent documents
✓ Amendments and any other correspondence
✓ Study progress reports and interim reports
✓ Serious adverse event report forms submitted by investigators
✓ Any other reports s/ IEC correspondence

- Strict confidentiality will be maintained for the contents of the files
- All active files will be kept secured in a file cabinet with controlled access

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- A log book for accessing the files by authorized staff & members will be maintained.
- A register for documenting all communications including phone conversations (e.g. queries, complaints, questions, etc.) will be maintained.

4.2. Maintenance of the IEC Administrative Records.

The IEC records will include the following:

A. IEC members' records

i. Appointment and acceptance letters of each member

ii. Signed and dated confidentiality agreements iii.

Updated Curriculum vitae (hard copy or soft copy) iv.

Training records for each IEC member (GCP, SOP)

v.Documentation of resignations / terminations

B. IEC membership list - An IEC list will be maintained which will contain:

vi. Names of IEC members

vii. Age viii. Gender

ix. Evidence of qualifications x.

Role on the IEC

xi. Status of affiliation to institution (e.g., unaffiliated or affiliated) xii.

Regular/ Alternate member to the IEC (if applicable)

C. IEC mandate

D. Correspondence related to changes in IEC membership with DCGI

E. IEC attendance list

F. Agenda and Minutes of IEC meetings

G. Standard operating procedures (SOPs)

H. Annual reports

I. Documents related to Workshops & conferences organized by IEC (Continuing education for members & staff)

J. SOP training and distribution logs.

4.3. Maintenance of Closed Study Files

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- Once the study file is closed (following completion/ premature termination), the related study files will be shifted to the IEC archival room.

- All closed study files will be archived in the IEC archival room for a period of five years from the date of closure of the study.

- A log book for archival of study documents will be maintained.

4.4. Accessibility / Retrieval

- Study files and administrative records will be made available for audit, making photocopies (if requested by investigator) or any other purpose (e.g., research on SAEs) on request if authorized by Member Secretary/ Chairperson.

- Representatives of regulatory authorities may have access at all times.
- A log book of retrieval of documents will be maintained.

4.5. Disposal of Closed Files and Copies of Protocols and Documents Submitted for IEC Review e At the end of the archival period, the closed files will be shredded and disposed of by authorized IEC personnel.

- Extra copies of protocols and documents submitted for IEC review and any other extra copies will be shredded by authorized IEC personnel after the IEC meeting without any notification to Pl.

- A formal disposal log will be maintained, providing details of documents that will be disposed.

5. Annexures

Annexure 1 AX01/JKKNIEC /SOP 05 o - Document Request Form

Annexure 2 AX02/ JKKNIEC /SOP 05 o - Log for disposal of study documents

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Annexure 1 AX01/ JKKNIEC /SOP 05 o - Document Request Form

Project No.:	
Project Title:	
Name of Principal Investigator (PI) :	
Requested by :	
Documents requested	
Purpose of the Request	
Signature of Requesting person:	
Signature of PI:	
Signature of Member Secretary / Chairperson with date:	

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Annexure 2: AX02/ JKKNIEC /SOP 05 o Log
for disposal of study documents

Project No.	Title	Name of Principal Investigator	No. of files	Date of IEC Ap roval	Date of Study Initiation	Date of Study Closure	Disposed by (Name & Sign) of Authorized Individual

6. Flowchart

No.	Activity	Responsibility
I	Organize the contents of the active study files	IEC Secretariat
2	Maintain the active study files and Administrative Documents	IEC Secretariat
3	Archival of Stud files	IEC Secretariat
4.	Authorizing retrieval of archived Documents	IEC Member secretary / Chair person
5,	Disposing closed study files and maintaining Document disposal	IEC Secretariat

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1. Purpose

The purpose of this SOP is to guide an Institutional Ethics Committee (IEC) to prepare for an audit or inspection of the IEC.

2. Scope

The SOP applies to all the members and the secretariat staff of IEC (human studies).

3. Responsibility

It is the responsibility of the Member Secretary, Chairperson, IEC Members and the IEC Secretariat to keep IEC documents ready for audit and to be available to answer questions during audit or inspection by administrative and regulatory authorities.

4. Definitions and Mandate 4.1 Definitions

- Audit:

1. A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

II. Audit of a Trial- A systematic verification of the study, carried out by persons not directly involved, such as:

(a) Study related activities to determine consistency with the protocol

(b) Study data to ensure that there are no contradictions on source documents. The audit should also compare data on the source documents with the interim or final report. It should also aim to find out if practices were employed in the development of data that would impair their validity.

(c) Compliance with the adopted Standard Operating Procedures (SOPs).

- Inspection:

An official review/ examination conducted by regulatory authority(ies) of the documents, facilities, records and any other resources that are deemed by the authority(ies) to be related to the study. The inspection may be carried out at the site

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of the trial, at the sponsor's / CRO's facilities and Ethics Committee in order to verify adherence to Good Clinical Research Practice.

4.2 Mandate

- Drugs Controller General India (DCGI) in its gazette notification GSR 72E, dated 08 th February 2013, 122DD states; 'The Ethics Committee shall allow inspectors of officials authorized by the Central Drugs Standard Control Organization (CDSCO) to enter its premises to inspect any record, data or any document related to clinical trial and provide adequate replies to any query raised by such inspectors or officials, as the case may be, in relation to the conduct of the trial.'

5. Detailed instructions

5.1 Receipt of notification of an Audit / Inspection On receipt of written/ mailed communication regarding audit/ inspection visit, the Member Secretary will inform the Chairperson, IEC members and the Head of Institution, if applicable about the date and purpose of the audit/inspection.

5.2 Preparing for the audit

- On receiving information about the audit /inspection, IEC Member Secretary and/ or IEC member/s are given the responsibility by the Chairperson to prepare for the visit with assistance of the Secretariat.

- The Member Secretary and / or designated IEC member/s will make arrangements in accordance with the steps mentioned in the checklist.

Cl The studies with incomplete / missing documents will be dealt with separately and actions taken will be documented.

- Care should be taken to ensure that all documents are kept in the right order for easy and quick access.

5.3 On the day/s of Visit

- Chairperson / Member Secretary / designated IEC Member/s should welcome and accompany the auditors/inspectors to the reserved meeting room.
- Designated team members must be present in the meeting room.
- The conversation would start with the auditor/inspector stating the purpose of the visit and the type of information is needed.

D IEC Chairperson / Member Secretary / IEC Members must answer questions of the auditors/inspectors clearly, politely, truthfully and straight to the point.

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Information and files requested by auditors/inspectors should be made available by Secretariat.

The Member Secretary/ designated IEC member/ Secretariat will make note of the comments, recommendation of the auditors/inspectors.

5.4 Correction of deficiencies observed at audit/ inspection

- Member Secretary/ designated IEC member/ Secretariat will review comments and recommendations of the auditor/inspector.
- On receipt of Audit/ Inspection Report the Chairperson should implement corrective and preventive measures and set the timeline for implementation of corrections as stated by the auditor/inspector.
- Action plan should be communicated by the Member Secretary/ designated IEC member to the auditor/inspector after seeking approval of the Chairperson.
- A review date for an internal follow-up audit will be decided by the Chairperson (if applicable). C]

The Member Secretary/ designated IEC member should report the outcome of the internal followup audit to the Chairperson.

5.5 Recording the Audit/Inspection Visit

CJ The Member Secretary/ designated IEC member/ Secretariat must keep record of the audit/inspection visit reports and action plans in a separate audit/inspection file.

- The completed checklist and findings from the internal follow-up audit (if applicable) must also be maintained in the internal audit file.

6. Annexures: Annexure 1: AX01/JKKNIEC /SOP 05 p - Audit and Inspection Checklist

Annexure 1: AX01/JKKNIEC /SOP 05 p - **Audit and Inspection Checklist**

1. Date of letter of communication regarding audit/inspection
2. Date(s) on which the audit/inspection has been a reed on
3. To ensure the IEC members and staff have been informed about the date/s and time
4. To ensure availability of IEC related information — mandate, terms of reference, organization chart (in the print form) in the IEC office
5. To make sure of availability of latest copy [copies of signed SOPs in print form in the office and/ or in electronic form on the IEC computer/s
6. To review the SOPs and note details of an omissions or deviations, with reasons

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7. To ascertain availability of all national and international ethics guidelines and regulations in print form and / or in electronic form in the IEC office
8. To check the files of ongoing and complete research study files for the presence of all signed documents as stated below and to note any missing/ incomplete documentation and actions taken: Records regarding applications of research studies for review including protocols and related documents Protocol Assessment Records — Comments of IEC members, Meeting Agenda, Minutes (documented in individual study file or separately in meeting records file) Communication records with investigator (documented in individual study file) Amendment Approvals (documented in individual study file) SAE reports and SAE related communications with investigator and regulators Protocol deviation/violation/exception reports(documented in individual study file) Continuing and final completion/termination reports (documented in individual study file)
9. To ensure availability of documents regarding list of members, tenure, appointment details, CVs, baseline and periodic training of IEC members.
10. To ensure availability of documents regarding appointment, CVs and training of staff of secretariat
11. To ensure measures for maintaining security of electronic database and office records
12. To make sure that maintenance, retrieval, storage, archival and tracking of the study files are done as er the respective SOPs
13. To ascertain proper labelling and indexing of stud files and storage cabinets
14. To decide which members will communicate with auditors/ inspectors, be available for audit/inspection, re are action Ian and conduct follow-u audit (if applicable)
15. To report about findings and report received regarding audit/inspection to IEC members at the full board IEC meeting
16. To make other arrangements (meeting venue for review of documents, catering, accommodation, travel) for the visit, as applicable

7. Flow Chart

No.	Activity	Responsibility
1	Receipt of Audit/ Inspection notification	IEC Member Secretary
2	Preparing for the audit	IEC Member Secretary/ designated IEC Member / Secretariat
3	Presenting information and files to auditor/ inspector	
4	Review comments/ recommendation of auditor/ inspector	
5	Receipt of audit/ inspection report	

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6	Planning corrective/preventive actions and setting timeline for their implementation	IEC Chairperson/ IEC Member Secretary/ designated IEC Member
7	Conducting internal follow-up audit	IEC Member Secretary/ designated IEC Member
8	Recording the Audit/Inspection Visit	IEC Member Secretary/ Secretariat

Glossary

Adverse Event (AE):

An adverse event is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

Audit:

A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted. and the data were recorded, analyzed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

Clinical Trial:

Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

Confidentiality:

Prevention of disclosure, to other than authorized individuals, of a of a subject's identity.

Conflict of interest:

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A set of conditions in which professional judgment concerning a primary interest like patient's welfare or the validity of research tends to be or appears to be unduly influenced by a secondary interest like non-financial (personal, academic or political) or financial gain is termed as Conflict of Interest (CoI).

Exemption from review:

Proposals presenting with less than minimal risk will be exempted from review.

Expedited Review:

When new research proposals and related documents undergo a speedy review process by only two or three designated (by the Chairperson) Ethics Committee members this is called Expedited Review.

For-cause monitoring:

Performed at sites for reasons identified by any member of the IEC, after approval by the Chairperson.

Full Board Review:

When new research proposals and other related documents are tabled in a formally convened meeting of the Ethics Committee for detailed discussion and decision, this is called Full Board Review.

Good Clinical practice:

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

Independent Consultant:

An independent consultant is a subject expert in a specified field who gives advice, comments and suggestions upon review of the study protocols. He/she has no affiliation to the investigators proposing the research protocols.

Inspection:

An official review/ examination conducted by regulatory authority(ies) of the documents, facilities, records and any other resources that are deemed by the authority(ies) to be related to the study. The

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inspection may be carried out at the site of the trial, at the sponsor's / CRO's facilities and Ethics Committee in order to verify adherence to Good Clinical Research Practice.

Institution

Any public medical facility where clinical research in humans are conducted.

Institutional Ethics Committee

An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

Interim Study. Report

A report of intermediate results and their evaluation based on analyses performed during the course of a study.

Investigator:

A person responsible for the conduct of the clinical trial at a trial site.

Investigational Product:

A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

Minimal risk:

Anticipated as harm or discomfort not greater than that encountered in routine daily life activities of general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current everyday life.

Protocol Deviation:

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A protocol deviation is any change, divergence, or departure 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. Upon discovery, the Principal Investigator is responsible for reporting protocol deviations to the IEC using the standard reporting form.

Protocol Violation:

A protocol violation is a deviation from the IEC approved protocol that may affect the suhject'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.

Serious Adverse Event (SAE):

Any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.

Study master file:

The file comprising all essential documents and correspondence related to the study. This should be created for all proposals at the time of initial submission to the IEC office.

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SOP for vulnerable population

1. The word vulnerability is derived from the Latin word vulnarere which means 'to wound'. Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests because of personal disability; environmental burdens; social injustice; lack of power, understanding or ability to communicate or are in a situation that prevents them from doing so.
2. Individuals may be considered to be vulnerable if they are:
   • socially, economically or politically disadvantaged and therefore susceptible to being exploited;
   • incapable of making a voluntary informed decision for themselves or whose autonomy is compromised temporarily or permanently, for example people who are unconscious, differently abled;
   • able to give consent, but whose voluntariness or understanding is compromised due to their situational conditions; or
   • 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
3. Principles of research among vulnerable populations
   A. Vulnerable populations have an equal right to be included in research so that benefits accruing from the research apply to them as well.
   B. If any vulnerable group is to be solely recruited then the research should answer the health needs of the group.
   C. Participants must be empowered, to the maximum extent possible, to enable them to decide by themselves whether or not to give assent/consent for participation.
   D. In vulnerable populations, when potential participants lack the ability to consent, a LAR should be involved in decision making.
   E. Special care must be taken to ensure participant's privacy and confidentiality, especially because breach of confidentiality may lead to enhancement of vulnerability.
   F. If vulnerable populations are to be included in research, all stakeholders must ensure that additional protections are in place to safeguard the dignity, rights, safety and wellbeing of these individuals.
4. Examples of vulnerable populations or groups:
   • economically and socially disadvantaged (unemployed individuals, orphans, abandoned individuals, persons below the poverty line, ethnic minorities, sexual minorities – lesbian/ gay/bisexual and transgender (LGBT), 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;

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• 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).

5. Additional safeguards/protection mechanisms

When vulnerable individuals are to be recruited as research participants additional precaution should be taken to avoid exploitation/retaliation/reward/credits, etc., as they may either feel intimidated and incapable of disagreeing with their caregivers, or feel a desire to please them. In the first case, they may be subjected to undue pressure, while in the second, they may be easily manipulated. If they perceive that their caregivers want them to participate in research, or if the caregiver stands to benefit from the dependant's participation, the feeling of being pressed to participate may be irresistible which will undermine the potential voluntariness of the consent to participate.

1. Researchers must justify the inclusion of a vulnerable population in the research.
2. ECs must satisfy themselves with the justification provided and record the same in the proceedings of the EC meeting.
3. Additional safety measures should be strictly reviewed and approved by the ECs.
4. The informed consent process should be well documented. Additional measures such as recording of assent and reconsent, when applicable, should be ensured.
5. ECs should also carefully determine the benefits and risks of the study and examine the risk minimization strategies.
6. As potential participants are dependent on others, there should be no coercion, force, duress, undue influence, threat or misrepresentation or incentives for participation during the entire research period.
7. Vulnerable persons may require repeated education/information about the research, benefits, risks and alternatives, if any.
8. Research on sensitive issues such as mental health, sexual practices/preferences, HIV/ AIDS, substance abuse, etc. may present special risks to research participants.
9. Researchers should be cognisant of the possibility of conflicting interests between the prospective participant and LAR and should be more careful.
10. Participants may be prone to stigma or discrimination, specifically when the participant is enrolled as a normal control or is recruited from the general population in certain types of research.
11. Efforts should be made to set up support systems to deal with associated medical and social problems.
12. Protection of their privacy, confidentiality and rights is required at all times – during conduct of research and even after its completion.

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13. Whenever possible, ancillary care may be provided such as setting up of a facility, school for unattended children of the participants or a hospital, or counselling centre.

6. Obligations/duties of stakeholders

Stakeholders	Obligations / duties
Researchers	• Recognize the vulnerability of the participant and ensure additional safeguards are in place for their protection. • Justify inclusion/exclusion of vulnerable populations in the study. • COI issues must be addressed. • Have well defined procedures (SOPs) to ensure a balanced benefit-risk ratio. • Ensure that prospective participants are competent to give informed consent. • Take consent of the LAR when a prospective participant lacks the capacity to consent. • Respect dissent from the participant. • Seek permission of the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities, etc. • Research should be conducted within the purview of existing relevant guidelines/regulations
Ethics Committees	• During review, determine whether the prospective participants for particular research are vulnerable. • Examine whether inclusion/exclusion of the vulnerable population is justified. • Ensure that COI do not increase harm orlessen benefits to the participants. • Carefully determine the benefits and risks to the participants and advise risk minimization strategies wherever possible. • Suggest additional safeguards, such as more frequent review and monitoring, including site visits.

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	• Only the full committee should do initial and continuing review of such proposals. It is desirable to have empowered representatives from the specific populations during deliberations. • ECs have special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment. They should exercise caution and require researchers to justify cases for exceptions to the usual requirements of participation or essentiality of departure from the guidelines governing research. ECs should ensure that these exceptions are as minimal as possible and are clearly spelt out in the ICD. • ECs should have SOPs for handling proposals involving vulnerable populations.
Sponsors	• The sponsor, whether a government, an institution or a pharmaceutical company, should justify the inclusion of vulnerable groups in the protocol and make provisions for protecting their safety. • The sponsor must enable monitoring and ensure that procedures are in place for quality assurance (QA) and quality control (QC). • The sponsor should ensure protection of the participants and research team if the research is on sensitive topics.

7. **Women in special situations**:

Women have equal rights to participate in research and should not be deprived arbitrarily of the opportunity to benefit from research. Informed consent process for some women can be challenging because of cultural reasons. Hence, the women may consider consulting their husbands or family members, if necessary. Although autonomy of the woman is important, the researcher must follow the requirements of local cultural practices so as not to disturb the harmony in the household/family/community.

A. Risks for women participants in clinical trials/intervention studies

1. Researchers must provide the EC with proper justification for inclusion of pregnant and nursing women in clinical trials designed to address the health needs of such women or their fetuses or nursing infants. Some examples of justifiable inclusion are trials designed to test the safety and efficacy of a drug for reducing perinatal transmission of HIV infection from

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mother to child, trial of a device for detecting foetal abnormalities or trials of therapies for conditions associated with or aggravated by pregnancy, such as nausea, vomiting, hypertension or diabetes.

2.If women in the reproductive age are to be recruited, they should be informed of the potential risk to the foetus if they become pregnant. They should be asked to use an effective contraceptive method and be told about the options available in case of failure of contraception.

3. A woman who becomes pregnant must not automatically be removed from the study when there is no evidence showing potential harm to the foetus. The matter should be carefully reviewed and she must be offered the option to withdraw or continue. In case the woman opts for continued participation, researchers and sponsors must adequately monitor and offer support to the woman for as long as necessary.

B. Prenatal diagnostic studies

Research related to prenatal diagnostic techniques in pregnant women should be limited to detecting foetal abnormalities or genetic disorders as per the Pre-Conception and Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994, amended in 2003 and not for sex determination of the foetus.

C. Research on sensitive topics

when research is planned on sensitive topics, for instance, domestic violence, genetic disorders, rape, etc., confidentiality should be strictly maintained and privacy protected. In risk mitigation strategies, appropriate support systems such as counselling centres, police protection, etc. should be established. At no time should information acquired from a woman participant be unnecessary, hurtful or appear voyeuristic. The EC should be especially vigilant regarding these sensitive issues.

8. **Children**:

Children are individuals who have not attained the legal age of consent (up to 18 years). At younger ages, children are considered vulnerable because their autonomy is compromised as they do not have the cognitive ability to fully understand the minute details of the study and make decisions. At older ages, although they may attain the cognitive ability to understand the research, they still lack legal capacity to consent. Therefore, the decision regarding participation and withdrawal of a child in research must be taken by the parents/ LAR in the best interests of their child/ward.

Children can be included in research if the situation, condition, disorder or disease fulfils one of the following conditions:

1. It is exclusively seen in childhood.
2. Both adults as well as children are involved, but the issues involved are likely to be significantly different in both these populations.

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3. Both adults as well as children are involved in a similar manner and are of similar nature in terms of morbidity, severity and/or mortality, wherever relevant, and studies in adults have demonstrated the required degree of safety and efficacy.

4. Test interventions are likely to be at least as advantageous to the individual child participant as any available alternative intervention.

5. Risk of test interventions that is not intended to benefit the individual child participant is low as compared to the importance of the knowledge expected to be gained (minor increase over minimal risk).

6. Research is generally permitted in children if safety has been established in the adult population or if the information likely to be generated cannot be obtained by other means.

7. The physiology of children is different from that of adults, and the pharmacokinetics of many drugs is age-dependent based on the maturation of the drug metabolism pathways. For example, children metabolize many drugs much more rapidly as compared to adults, hence the dose of the drug per kg of body weight that needs to be given, is much higher in children as compared to adults. The absorption of drugs also varies with age. Pharmacokinetics and toxicity profile varies with growth and maturation from infancy to adulthood.

8. The adverse effects of many drugs may also be different in children as compared to adults. For instance, tetracyclines cause teeth discoloration in young children, aspirin use is associated with Reye's syndrome in children.

9. Age-appropriate delivery vehicles and formulations (e.g. syrups) are needed for accurate, safe, and palatable administration of medicines to infants and children.

10. The pathophysiology of many disorders is dependent on a child's growth, development and adaptive plasticity. Examples include adaptive changes in the motor system following a perinatal stroke.

The EC should do the benefit–risk assessment to determine whether there is a need to put into place additional safeguards/protections for the conduct of research in children. For example, research should be conducted in child-friendly settings, in the presence of parent(s) and where child participants can obtain adequate medical and psychological support.

The EC should take into consideration the circumstances of the children to be enrolled in the study including their age, health status, and other factors and potential benefits to other children with the same disease or condition, or to society as a whole.

Consent of the parent/LAR is required when research involves children.

1. The EC should determine if consent of one or both parents would be required before a child could be enrolled.

2. Generally, consent from one parent/LAR may be considered sufficient for research involving no more than minimal risk and/or that offers direct benefit to the child. Consent from both parents may have to be obtained when the research involves more than minimal risk and/or offers no benefit to the child.

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3. Only one parent's consent is acceptable if the other parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child, irrespective of the risk involved.

4. Whenever relevant, the protocol should include a parent/LAR information sheet that contains information about specific aspects relevant to the child such as effects on growth and development, psychological well-being and school attendance, in addition to all components described in the participant information sheet.

5. When the research involves sensitive issues related to neglect and abuse of a child, the EC may waive the requirement of obtaining parental/LAR consent and prescribe an appropriate mechanism to safeguard the interests of the child.

6. Cognitively impaired children or children with developmental disorders form one of the most vulnerable populations. In fact, their parents are also vulnerable and there is a high likelihood of therapeutic misconception. The potential benefits and risks must be carefully explained to parents so as to make them understand the proposed research.

7. Research involving institutionalized children would require assent of the child, consent of parents/LAR, permission of the relevant institutional authorities (for example, for research in a school setting: the child, parents, teacher, principal or management may be involved)

Assent: In addition to consent from parents/LARs, verbal/oral or written assent, as approved by the EC, should be obtained from children of 7–18 years of age.

As children grow, their mental faculties develop and they are able to understand and respond. Respecting the child's reaction, the child is made a party to the consent process by the researcher, who explains the proposed research in a very simple manner, in a language that ensures, that the child understands the request to participate in the research.

A child's agreement to participate in research is called assent. If the child objects, this wish has to be respected. At the same time, mere failure to object should not be construed as assent. However, if the test intervention is likely to be lifesaving and is available only if the child participates in the study, the dissent by the child may be disregarded provided parental consent and prior approval from the EC is obtained.

Requirements of assent:

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.

• Adolescents may have the capacity to give consent like adults. However, as they have not attained the legal age to provide consent, it is termed as assent and the consent of the parents/LAR should be obtained. If the latter will affect the validity of the study, waiver of consent from the relevant adult should be taken and recorded with the approval of the EC, for example, in behavioural studies in IV drug users where parental consent may not be possible.

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Content of the assent form has to be in accordance with the developmental level and maturity of the children to be enrolled and explained while considering the differences in individual understanding.

The language of the assent form must be consistent with the cognitive, social and emotional status of the child. It must be simple and appropriate to the age of the child. Points to be included in the assent form are as given below:

- an explanation about the study and how it will help the child;
- an explanation of what will be done in the study, including a description.
- of any discomfort that the child is likely to feel; m the contact information of the person whom the child can approach if she/ he needs an explanation; and m a paragraph emphasizing that the child can refuse to participate in the study and if she/he chooses to do so, the treatment at the centre will not be compromised. The above list is not exhaustive and may be dealt with on a case to case basis.
- Waiver of assent: All the conditions that are applicable to waiver of informed consent in adults also apply for waiver of assent in children. See section 5.7 for further details. If the available intervention is anticipated to definitely benefit the child but would be available only if the child participates in the study, waiver of assent could be allowed. However, this situation should be accepted only in exceptional cases where all forms of assent/consent have failed. In such cases, approval of the EC should be obtained.

9. **Research involving sexual minorities and sex workers**:
   There are unique challenges associated with research on sexual minorities and sex workers such as privacy, confidentiality, possibility of stigma, discrimination and exploitation resulting in increased vulnerability.
   a. Protection of their dignity and provision of quality healthcare under these circumstances should be well addressed in the research proposal, preferably in consultation with the community before the proposal is finalized.
   b. It would be advisable to have a representative of the sexual minority group/ lesbian/ gay/bisexual and transgender (LGBT) community as a special invitee/member to participate in the meeting of the EC if there is a research proposal involving these participants.
   c. The EC can suggest setting up of a community advisory board to act as an interface between the researcher(s) and the community.
   d. Among the LGBT community there are inhibitions between the different groups, so details of the research should be explained to each group separately.
   e. Peer educators or champions among the LGBT community could be educated and sensitized first. They would in turn explain the details to the potential participants from the community who would then understand them better.
10. **Research among tribal population**

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a. Research on tribal populations should be conducted only if it is of a specific therapeutic, diagnostic and preventive nature with appropriate benefits to the tribal population.
b. Due approval from competent administrative authorities, like the tribal welfare commissioner or district collector, should be taken before entering tribal areas.
c. Whenever possible, it is desirable to seek help of government functionaries/local bodies or registered NGOs who work closely with the tribal groups and have their confidence.
d. Where a panchayat system does not exist, the tribal leader, other culturally appropriate authority or the person socially acceptable to the community may serve as the gatekeeper from whom permission to enter and interact should be sought.
e. Informed consent should be taken in consultation with community elders and persons who know the local language/dialect of the tribal population and in the presence of appropriate witnesses.
f. Even with permission of the gatekeeper, consent from the individual participant must be sought.
g. Additional precautions should be taken to avoid inclusion of children, pregnant women and elderly people belonging to particularly vulnerable tribal groups (PVTG).
h. Benefit sharing with the tribal group should be ensured for any research done using tribal knowledge that may have potential for commercialization.

11. **Research involving individuals with mental illness or cognitively impaired/affected individuals**

Mental illness:

According to the World Health Organization, mental disorders comprise a broad range of problems, with different symptoms. They are generally characterized by some combination of abnormal thoughts, emotions, behaviour and relationships with others. According to the Mental Healthcare Act, 2017,26 “mental illness” means a substantial disorder of thinking, mood, perception, orientation or memory that grossly impairs judgment, behaviour, capacity to recognize reality or ability to meet the ordinary demands of life, mental conditions associated with the abuse of alcohol and drugs, but does not include mental retardation which is a condition of arrested or incomplete development of the mind of a person, specially characterized by sub normality of intelligence.

Presence of a mental disorder is not synonymous with incapacity of understanding or inability to provide informed consent. Cognitively affected or impaired: Conscious mental activities such as thinking, understanding, learning and remembering are defined as cognition. Those in whom these activities are not fully functional are regarded as cognitively impaired. Such individuals or groups include people who are without full intellectual potential (intellectually disabled, previously called mentally retarded), unconscious, suffering from a number of neuropsychological disorders such as dementia or delirium, and those who cannot fully comprehend or participate in the informed consent process, either temporarily or permanently.

Other sources or reasons for cognitive impairment affecting the ability to give informed consent include, but are not limited to, being too young (children do not yet develop the necessary cognitive abilities to give informed consent); being in extreme pain; being under the influence of medication, illicit drugs or alcohol; mental retardation; and traumatic brain injury (that causes unconsciousness or cognitive impairment while conscious).

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There are some psychiatric conditions that may lead people to cause risk or harm to themselves or others.

- During the informed consent process, prospective participants must be informed about how the researcher will address a participant's suicidal ideation or other risks of harm to themselves or others.
- It should be disclosed to the participant that her/his confidentiality may be breached for reporting to family members, police, or other authorities or they may have to be admitted in the hospital upon expression of such thoughts of harm to self or others.
- While some interventions, like hospitalization and treatment for suicidality/ homicidal ideas, may be primarily for the participants' own benefit, they themselves may not perceive these as such and may want to refuse to participate in a study if any such interventions are required.
- Interventions should be of short duration, as least restrictive as possible and invoked only when necessary, in accordance with relevant laws.
- Some research designs may reduce or violate human participant protections/rights or specific requirements of informed consent by resorting to deception in order to achieve the objectives of the research for public good.. All such studies should be reviewed by the EC very carefully before approval.

12. **Individuals who have diminished autonomy due to dependency or being under a hierarchical system**

While reviewing protocols that include students, employees, subordinates, defence services personnel, healthcare workers, institutionalized individuals, under trials, prisoners, and others the EC must ensure the following:

- Enrolling participants as described above is specifically pertinent to the research questions and is not merely a matter of convenience.
- Individuals in a hierarchical position may not be in a position to disagree to participate for fear of authority and therefore extra efforts are required to respect their autonomy.
- It is possible for the participant to deny consent and/or later withdraw from the study without any negative repercussions on her/his care.
- Mechanisms to avoid coercion due to being part of an institution or hierarchy should be described in the protocol.

13. **Patients who are terminally ill**

Terminally ill patients or patients who are in search of new interventions having exhausted all available therapies are vulnerable as they are ready to give consent for any intervention that can give them a ray of hope. These studies are approved so that the scientific community or professional groups do not deny such patients the possible benefit of any new intervention that is not yet validated.

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Since therapeutic misconception is high there should be appropriate consent procedures and the EC should carefully review such protocols and recruitment procedures.

Additional monitoring should be done to detect any adverse event at the earliest.

Benefit-risk assessment should be performed considering perception of benefits and risks by the potential participant The EC should carefully review post-trial access to the medication, especially if it is beneficial to the participant.

14. **Other vulnerable groups**

Other vulnerable groups include the economically and socially disadvantaged, homeless, refugees, migrants, persons or populations in conflict zones, riot areas or disaster situations. Additional precautions should be taken to avoid exploitation/retaliation/ reward/credits and other inducements when such individuals are to be recruited as research participants.

Autonomy of such individuals is already compromised and researchers have to justify their inclusion.

ECs have to satisfy themselves with the justification provided to include these participants and record the same in the proceedings of the EC meeting.

Additional safety measures suggested earlier in the guidelines should be strictly followed by the ECs.

The informed consent process should be well documented. There should not be any undue coercion or incentive for participation. A person's refusal to participate should be respected and there should be no penalization.

The EC should also carefully determine the benefits and risks of the study and examine risk minimization strategies.

Annexure I : AXOI/JKKNIEC/SOP 06 - Checklist: Requirements for research involving children

Annexure 2: AX02/ JKKNIEC/SOP 06 - Checklist: Requirements for research involving pregnant women & fetuses

Annexure 3: AX03/ JKKNIEC/SOP 06 - Checklist: Research involving cognitively impaired adults

Annexure 4: AX04/ JKKNIEC/SOP 06 - Checklist-Research involving students, employees or residents

Annexure 5: AX05/ JKKNIEC/SOP 06 - Checklist: Considerations for genetic research

Annexure 1: AX01/ JKKNIEC/SOP 06

Checklist: Requirements for research involving children

Name of Principal Investigator: Study Title:

Sno	Questions	Yes		
	Does the research pose greater than minimal risk to children?			
2	If yes: Are convincing scientific and ethical justifications given?			

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3.	If yes: Are adequate safeguards in place to minimize these risks?			
4.	Does the study involve healthy children?			
5.	If yes: Is the inclusion of healthy children justified?			
6.	Are the studies conducted on animals and adults appropriate and justified?			
7.	If No: Is the lack of studies conducted on animals and adults justified?			
8.	Will older children be enrolled before younger ones?			
9.	Is permission of both parents necessary?			
10.	If Yes: Are conditions under which one of the parents may be considered: "not reasonably available" described?			
l l .	If Yes: Are the conditions acceptable?			
12.	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?			
13.	Are provisions made to obtain the assent of children over 7 and, where appropriate, honoring their dissent?			
14.	Are provisions made to protect participants' privacy and the confidentiality of information regarding procedures?			
15.	Are there special problems that call for the presence of a monitor or IEC member during consent procedures?			
16.	Are special needs of adolescents such as counselling and confidentiality accounted for in the research desi n?			
17.	Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?			
18.	Does the research involve possibility of findings which may have implications for other family members?(for eg: genetic risk, HIV infection, Hepatitis C)			
19.	If Yes: Are there adequate mechanisms in place to deal with other members of the family?			
20.	Are parents required to be present during the conduct of the research?			

Signature of Principal Investigator: Date

Comments of Primary Reviewer:

Primary Reviewer's Signature and Date:

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Checklist: Requirements for research involving pregnant women & fetuses

Name of Principal Investigator:

Study Title:

S no	Questions	Yes		
I.	Where scientifically appropriate preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women have been conducted and provide data for assessing potential risks to pregnant women and fetuses?			
2.	Is the risk to the fetus not greater than minimal, or any risk to the fetus which is greater than minimal caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus?			
3.	Any risk that is the least possible for achieving the objectives of the research?			
4.	Is the woman's consent or the consent of her legally authorized representative obtained in accordance with the informed consent provisions, unless altered or waived?			
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.	Will any inducements, monetary or otherwise, be offered to terminate a pregnancy?			
7.	Do individuals engaged in the research have a part in any decisions as to the timing, method, or procedures used to terminate a pregnancy?			
8.	Do individuals engaged in the research have a part in determining the viability of a fetus?			

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

Signature of Principal Investigator: Date

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Comments of Primary Reviewer:

Primary Reviewer's Signature and Date:

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Annexure 3: AX03/ JKKNIEC/SOP 06 - Checklist: Research involving cognitively impaired adults

Name of Principal Investigator:

Study Title:

S.no	Queries	Yes	No	
	Are scientifically appropriate, preclinical and clinical studies, conducted and provide data for assessing potential risks to neonates?			
2.	Is the individual providing consent, fully informed regarding the reasonably foreseeable impact of the research on neonate?			
3.	Will any inducements, monetary or otherwise, be offered to terminate a pregnancy?			
4.	Do individuals engaged in the research have a part in any decisions as to the timing, method or procedures used to terminate pregnancy?			
5,	Do individuals engaged in the research have a part in determining the viability of a fetus?			
6.	In research involving fetuses of uncertain viability,			
	does the research hold out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, and is any risk least possible for achieving the objectives of the research?			
6b	Or The purpose of the research is development of important biomedical knowledge which cannot be obtained by other means.			
7.	Will there be a risk to the fetus from the research?			
8.	Is the legally effective informed consent of either parent of neonate or, if neither parent is able to consent because of unavailability, incompetence or temporary incapacity, legally effective informed consent of either parent's legally authorized representative obtained?			
9.	In research involving nonviable fetuses			
	Will vital functions of the neonate be artificially maintained?			
9b	Is there any risk to the neonate resulting from the research?			
9c	The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means			
9d	The legally effective informed consent of both parents of the neonate will be obtained except that the waiver and alteration provisions do not apply. However, 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 should not be approved by the IEC.

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This type of research can be conducted only after The IEC finds 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 Principal Investigator: _____ Date_____

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Comments of Primary Reviewer:

Primary Reviewer's Signature and Date:

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Annexure 3: AX03/JIH019/V5

Checklist: Research involving cognitively impaired adults

Name of Principal Investigator:

Study Title:

1. Research Involving Cognitively Impaired Adults in which there is Anticipated Direct Benefit to the participant (All items must be "Yes")

Items	Yes	
A. Is the recruitment of participants justified considering rationale and objectives of study?		
B. Is the risk justified /anticipated benefit to the participants?		
C. The relation of anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.		
D. Will the participants be withdrawn if they appear to be unduly distressed?		
E. The proposed plan for the assessment of the capacity to consent is adequate.		

2. Research Involving Cognitively Impaired Adults in which there is No Anticipated Direct Benefit to the participant (All items must be "Yes")

Items	Yes	
A. Is the recruitment of participants justified considering rationale and objectives of study?		
B. Are the foreseeable risks to the participants low?		
C. Is the negative impact on the participant's well-being minimized and low?		
D. Will the participants be particularly closely monitored?		
E. Will the participants be withdrawn if they appear to be unduly distressed?		
F. The proposed plan for the assessment of the capacity to consent is adequate.		
G. Consent will be taken from participants capable of being consulted.		

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H. Does consent document include provision for legally acceptable representative in case the participants are not capable of being consulted?		

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Annexure 4: AX04/JKKNIEC/SOP 06

Checklist-Research involving students, employees or residents

Name of Principal Investigator:

Study Title:

Research involving participants who are students, employees or residents require special considerations (All items must be "Yes")

Items	Yes	No
A. Have the participants been assured that their status (education, employment and/or promotion) will not be affected by any decision to participate or not?		
B. Have the risks to participants been minimized?		
C, Have participants been assured that participation is voluntary (no signs of coercion)?		
D. Have participants been assured that privacy and confidentiality will be protected?		

signature of Principal Investigator: Date:

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Annexure 5: AX05/JKKNIEC/SOP 06

Checklist: Considerations for genetic research

Name of Principal Investigator:

study Title:

Considerations for genetic research (All items must be "Yes")

Items	Yes	No
A. Will samples be made anonymous to maintain confidentiality? If yes, then the following checklist points are not applicable.		
B. Will the results be disclosed? If yes, a) has the investigator established clear guidelines for disclosure of information, including interim or inconclusive research result? b) Will the results be used in management of current condition of patient?		
C. Has the appropriateness of the various strategies for recruiting participants and their family members been considered?		
D. Does the proposed study population comprise family members?		
E. Will family members be implicated in the studies without consent?		
F. Will the samples be destroyed in the future?		
G. Will the samples be used for future research?		
H. Is genetic counselling being offered?		

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Comments of Primary Reviewer:

Primary Reviewer's Signature and Date:

7. Flow Chart

No.	Activity	Responsibility
	Appoint reviewers	Chairperson/ Member Secretary
2	Review the protocol	IEC members
3	Discussion at IEC meeting	IEC member

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4	Communicating decisions to principal investigator	IEC Secretariat

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