INSTITUTE ETHICS COMMITTEE

ALL INDIA INSTITUTE OF MEDICAL SCIENCES, VIJAYPUR, JAMMU

Standard Operating Procedures

Effective Date: 10-04-2023

The location and business address of the committee:

Institute Ethics Committee
All India Institute of Medical Sciences, Vijaypur, Jammu.
Pincode: 184120

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1. INTRODUCTION OF THE INSTITUTE ETHICS COMMITTEE

The Institute Ethics Committee, All India Institute of Medical Sciences (AIIMS), Vijaypur, Jammu has been constituted for review and approval of institutional/ collaborative research projects with respect to safeguard dignity, rights, safety and well-being of all research participants and to ensure that the research is carried in accordance to prescribed guidelines.

The Institute Ethics Committee, All India Institute of Medical Sciences, Vijaypur, Jammu is constituted and shall operate as per National Ethical Guidelines for Biomedical Research involving Human Participants 2017, International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) Guidelines, Indian GCP guidelines and the New Drugs and Clinical Trial (NDCT) Rules, 2019.

The Head of the Institution All India Institute of Medical Sciences, Vijaypur, Jammu as per the new guidelines has constituted the IEC AIIMS Jammu vide Order No. F. No. AIIMS/JMU/Admin /2022/591-A dated 21st November 2022**. Same has been reconstituted vide Order no. …….dated …… in accordance to the New Drugs and Clinical Trial rules 2019 and National Ethical Guidelines for Biomedical Research involving Human Participants 2017.**

2. BASIC RESPONSIBILITIES OF ETHICS COMMITTEE

- To ensure the competent review and evaluation of all ethical aspects of research projects received in an objective manner.
- To protect the safety, rights and well-being of the potential research participants.
- To conduct scientific evaluation and ensure technical appropriateness of the proposed study.
- To ensure that universal ethical values and international scientific standards are expressed interms of local community values and customs.
- To assist in the development and the education of a research community responsive to localhealth care requirements.
- To create, develop, revise and implement the ethical guidelines

3. STANDARD OPERATING PROCEDURES (SOPs) OF INSTITUTE ETHICS COMMITTEE (IEC)

3.1 Establishing and Constituting the Institute Ethics Committee

PURPOSE

To establish and constitute the Institute Ethics Committee for AIIMS Vijaypur, Jammu as per the

National Ethical Guidelines for Biomedical Research involving Human Participants 2017, International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) Guidelines, Indian GCP guidelines and the New Drugs and Clinical Trial (NDCT) Rules, 2019.

RESPONSIBILITY

The Director (Head of the Institute) is responsible to initiate the process of constitution of Institute Ethics Committee.

PROCEDURE-

- The Director will select and nominate the Chairperson (from outside the Institute) and Member Secretary (from the Institute) for IEC, AIIMS, Vijaypur, Jammu.
- The IEC will be constituted by the Director in consultation with the Chairperson.
- The Director will invite the members to join the IEC by sending the official request letter (**Annexure-1**)
- Members will confirm their acceptance to the Director by providing all the required information for membership (**Annexure- 2**)

3.2 Procedure for appointing members of the IEC

PURPOSE

To appoint suitable members for review and approval of research projects submitted to IEC, AIIMS, Vijaypur, Jammu.

RESPONSIBILITY

The Director (Head of the Institute) and Chairperson are responsible for implementing this SOP.

PROCEDURE

The Director in consultation with Chairperson will nominate the members of IEC, who have the education, qualification and experience to review and evaluate the scientific, medical and ethical aspects of proposed study.

The committee shall comprise of at least seven to fifteen members as follows:

1. The Chairperson (from outside the Institute)
2. The Member Secretary (from the Institute)
3. Basic Medical Scientist(s)

4. Clinician(s)
5. Legal expert/s
6. Social scientist/ philosopher/ethicist/theologian
7. Lay person(s)

3.3 Training of the IEC members

PURPOSE

All IEC members are conversant with relevant guidelines for research involving human subjects.

RESPONSIBILITY

A team of trainers chosen for this purpose by member secretary will ensure that new members get trained after being inducted.

PROCEDURE

All IEC members will be made conversant with National Ethical Guidelines for Biomedical Research involving Human Participants 2017, International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) Guidelines, Indian GCP guidelines and the New Drugs and Clinical Trial (NDCT) Rules, 2019.

Training schedule for new members of IEC, AIIMS, Vijaypur, Jammu

S.No	Session Topic	Facilitator	Time period
1.	Roles & responsibilities of IEC and its members	Member Secretary	1 hour
2.	Discussion on regulatory guidelines on IEC	IEC member nominated by Member Secretary	2 hours
3.	Interactive session	With at least two members nominated by Member Secretary	2 hours

Additionally, the Institute Ethics Committee will hold retraining for all the members of IEC once in 6 months for 2-3 hours on the topics listed in the above table.

3.4 Term of appointment, policy for removal or resignation/replacement of members

PURPOSE

To establish polices for removal or resignation / replacement of members

RESPONSIBILITY

The Director in consultation with Chairperson and Member Secretary are responsible for implementing this SOP.

PROCEDURE

Term of appointment of members of IEC will be for a period of 2 years initially which could be extended for another 1 year. Extension of membership will be based on the recommendation of the Chairperson and Member Secretary of IEC.

Resignation / Replacement procedure

- The members who have resigned may be replaced at the discretion of the appointing authority for the same.
- The IEC members who decide to resign must provide the Chairperson & member secretary of IEC the written notification of their proposed resignation date at least 30 calendar days prior.
- In case of resignation, the Director in consultation with Chairperson would appoint a new member, falling in the same category of membership ex. NGO representative with NGO representative.
- In case of some insinuation against Chairperson, the Member Secretary will organize and coordinate the Full Board IEC meeting and submit the recommendations to Head of Institution and vice versa. The meeting shall be organized and coordinated by the Chairperson. In the unfortunate scenario of both being under scanner, the existing IEC Members shall approach Head of institution for nomination of an IEC member to organize and coordinate IEC Meeting to resolve the issue.

Policy for removal of member

- A member may be relieved or terminated of his/her membership in case of conduct unbecoming for a member of the Ethics Committee.
- Inability to participate in the meetings on any grounds for more than 3 meetings of the IEC.
- The membership shall be reviewed by the Director and Chairperson, if the member is a regular defaulter.
- If deemed necessary, the IEC may decide to terminate the membership and recommend to the Chairperson IEC for necessary action.
- In all such situations/circumstances, Director will serve a letter of termination to the member on the recommendation of Member secretary.
- Documentation of the termination will be recorded in the meeting minutes of the next duly constituted IEC meeting and IEC membership circular/roster will be revised, if needed.

3.5 Procedure for convening and conducting IEC meetings

PURPOSE

To hold regular IEC meetings

RESPONSIBILITY

The Chairperson and member secretary are responsible for implementing this SOP

PROCEDURE

- The Member Secretary in consultation with the Chairperson may convene the IEC meeting once in every six months or when the number of applications for research proposals reaches a predefined number of 10.

- Additional review meeting can also be held with short notice as and when required.
- All members will receive notification of meeting schedule in advance.
- A minimum of five persons is required to form the quorum without which a decision regarding the research would not be taken. The quorum would have at least one representative from the following group:

    - One basic medical scientist (preferably one Pharmacologist)
    - One Clinician
    - One legal expert or retired Judge
    - One social scientist/ representative of non-governmental organization/Philosopher/ Ethicist/ Theologian or a similar person
    - One lay person from the community.

Minutes of the IEC meetings, all the proceedings and deliberation will be documented.

- Applicant investigator may be invited to present the proposal or elaborate on specific issue.
- All the members should disclose their conflict of interest at the start of the meeting as per the proforma attached **(Annexure- 3)**

3.6 Procedure for submission of proposal of research project/Clinical trial

3.6.1 Procedure for submission of research proposal

PURPOSE

To submit a research proposal for review by IEC

RESPONSIBILITY

All investigators are responsible for implementing this SOP. All research proposals must be submitted in the prescribed application format, duly filled, along with all necessary documents.

PROCEDURE

- Project investigator has to submit an application in prescribed format **(Annexure- 4)** along with the study protocol and other study related document necessary for review by IEC.
- All research proposals must be submitted in English language only.
- Application may be submitted to the office of member secretary, IEC AIIMS, Vijaypur, Jammu (minimum three hard copies along with electronic of the same) at least 14 days prior to the date of proposed ethics committee meeting.
- Receipt of application will be acknowledged by IEC office. **[Annexure- 5]**
- Every application will be allotted an IEC registration number to be used for future correspondence.
- The following documents at minimum will be reviewed by ethics committee

- Documents

- Cover Letter to the Member Secretary

- Proforma to be submitted to the AIIMS, Vijaypur, Jammu IEC (including protocol amendments): (**Annexure- 4)**
- Patient Information Sheet, Checklist of Informed consent document for clinical trial subjects **(Annexure-6),** Format of Informed Consent Form for subjects participating in a clinical trial **(Annexure- 7)** and Patient diaries (including updates if any) in English and/or vernacular language.
- Investigator's Brochure and available safety information
- Proposed methods for patient accrual including advertisement (s) etc. proposed to be used for the purpose (if applicable)
- Principal Investigator's current Curriculum Vitae (CV) and any document evidencing qualifications
- Insurance Policy/ Compensation for participation and for serious adverse events (SAE) occurring during the study participation **(Annexure -8)**
- Details of funding agency/ sponsor and fund allocation (for funded proposals)
- Investigator's Agreement with the Sponsor (for funded proposals)
- Undertaking with signatures of investigators **(Appendix VII)**
- Any other documents that ethics committee may require to fulfil its responsibilities.
- A statement of conflict of interest **[Annexure- 3]**
- Declaration by the investigator **[Annexure- 9]**

3.6.2 Contents of the proposed protocol for conducting clinical trials

Title Page

a) Full title of the clinical study,
b) Protocol, Study number, and protocol version number with date.
c) The Investigational New Drug (IND) name/number of the investigational drug.
d) Complete name and address of the Sponsor and contract researchorganization, if any.
e) List of the investigators who are conducting the study, their respective institutional affiliations and site locations
f) Name of clinical laboratories and other departments and/or facilitiesparticipating in the study.

Table of Contents

1. Background and introduction
    a) Preclinical experience
    b) Clinical experience
2. Study rationale : This section should describe a brief summary of the background information relevant to the study design and protocol methodology. The reasons for performing this study in the particular population included by the protocol should be provided.
3. Study objective (primary as well as secondary) and their logical relation to the study design
4. Study design
    a. Overview of the study design
    b. Flow chart of the study.
    c. A brief description of the methods and procedures to be used during the study.
    d. Discussion of study design: This discussion details the rationale for the design chosen for this study.
5. Study population: the number of subjects required to be enrolled in the study at the investigative

site and by all sites along with a brief description ofthe nature of the subject population required is also mentioned.

6. Subject eligibility—
    a. Inclusion criteria
    b. Exclusion criteria
7. Study assessments—plan, procedures and methods to be described in detail.
8. Study conduct stating the types of study activities that would be included along with explanation for subjects who discontinued from the trial for various reasons. This should also include how protocol violations will be treated.

    The template for treating protocol violations is as under:

    - Protocol violations are required to be reported to the IEC within 10 working days of becoming knowledgeable of the violation.
    - A letter signed by the Principal Investigator must be submitted, which contains the following information:
    - IEC Project Number, Subject ID Number, Date(s) of the Event(s)
    - Description of the protocol violation
    - How the event deviated from the protocol
    - Date the study sponsor was notified of the violation
    - Investigator's assessment regarding any effect on subject risk as a result of the violation. Include description of additional treatment the subject required as a result of the violation.
    - Corrective action plan describing what will be implemented in order to avoid the violation from reoccurring in the future.

9. Study treatment—
    a. Dosing schedule (dose, frequency, and duration of the experimental treatment)
    b. Study drug supplies and administration.
    c. Dose modification for study drug toxicity: Rules for changing the dose or stopping the study drug should be provided.
    d. Possible drug interactions
    e. Concomitant therapy
    f. Blinding procedures
    g. Un-blinding procedures

10. Adverse Events:
    Description of expected adverse events should be given **(Annexure-10)** along with procedures used to evaluate an adverse event.
11. Ethical considerations: Give the summary of:

a. Risk / benefit assessment
b. Ethics committee review and communications
c. Informed consent process
d. Statement of subject confidentiality including ownership of data andcoding procedures.

12. Study monitoring and supervision:

A description of study monitoring policies and procedures should be provided along with the proposed frequency of site monitoring visits, and who is expected to perform monitoring.

Case Record Form (CRF) completion requirements, including who gets which copies of the forms and any specific required in filling out the forms Case Record Form correction requirements, including who is authorized to make corrections on the Case Record Form and how queries about study data are handled files, including what needs to be stored following study completion should be described.

13. Investigational Product Management:
    a. Give investigational product description and packaging (stating all ingredients and the formulation of the investigational drug and any placebos used in the study).
    b. The precise dosing required during the study.
    c. Method of packaging, labelling, and blinding of study substances.
    d. Method of assigning treatments to subjects and the subject identification code numbering system.
    e. Storage conditions for study substances.
    f. Investigational product accountability: Describe instructions for the receipt, storage, dispensation, and return of the investigational products toensure a complete accounting of all investigational products received, dispensed, and returned or destroyed.
    g. Describe policy and procedure for handling unused investigational products.
14. *Data Analysis*: Provide details of the statistical approach to be followed including sample size, how the sample size was determined, including assumptions made in making this determination, efficacy endpoints (primary as well as secondary) and safety endpoints and details of statistical analysis including statistical considerations for Pharmacokinetic (PK) analysis, if applicable.
15. Undertaking by the Investigator (**Appendix VII)**
16. Appendices*:* Provide a study synopsis, copies of the informed consent documents (patient information sheet, informed consent form etc.); Case RecordForm (CRF) and other data collection forms; a summary of relevant preclinical safety information and any other documents referenced in the clinical protocol.
17. Upon completion of the clinical Trial, the report has to be submitted **(Annexure 11)**

3.7 Procedure for initial scrutiny of proposal

RESPONSIBILITY

Office of IEC/Member Secretary

PROCEDURE

- Application may be submitted to the office of member secretary, IEC AIIMS, Vijaypur, Jammu (minimum three hard copies along with electronic of the same) at least 14 days prior to the date of

proposed ethics committee meeting.

- Receipt of application will be acknowledged by IEC office. **[Annexure- 5]**
- Every application will be allotted an IEC registration number to be used for future correspondence
- A trained support staff will verify the proposal for completeness as per check list **(Annexure- 12)**
- Only fully completed applications shall be taken up for review.

3.8 Procedure for reviewing the research proposals

RESPONSIBILITY

All members of IEC are responsible for implementing this SOP.

Elements of Review

The submitted proposal shall be reviewed both for scientific content and ethical principles.The committee members shall review the proposal with reference to the following parameters including but not limited to:

a. Scientific design of the study
b. Justification/Rationale of the study
c. Selection criteria for potential participant
d. Justification for use of placebo, if any
e. Potential benefits to the study participants
f. Predictable risks to the study participants
g. Criteria for discontinuation/withdrawal of participants
h. Monitoring of serious adverse events
i. Participant recruitment procedures
j. Participant retention activities.
k. Compensation for study related injury
l. Post trial benefits
m. Protection of privacy and confidentiality
n. Statistical analysis
o. Informed consent document in English and regional languages
p. Competence of investigators, supporting staff and infrastructure facility
q. Approval of regulatory authorities wherever applicable.

PROCEDURE

- Every proposal will be evaluated by IEC members on ethical issues as per National Ethical Guidelines for Biomedical Research involving Human Participants 2017, International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) Guidelines, Indian GCP guidelines and the New Drugs and Clinical Trial (NDCT) Rules, 2019 as amended thereafter, scientific soundness and technical excellence of the proposed research, before it is taken up for main IEC meeting. The evaluation shall be as per procedure laid under section (iv).

- The IEC review will be done through formal meetings and will not resort to decision through circulation of proposal.
- The meetings can be conducted in both online and offline modes.
- Expert opinion of additional members would be obtained by inviting them for the discussion for concerned proposal, if necessary.
- Summary of the procedure adopted with special reference to Postgraduate Thesis.
    - Every head of department (HOD) should ensure that candidate undertaking ***any kind of research on humans (interventional/ non interventional/observational/investigational or any kind of study directly or indirectly dealing with humans)*** should submit a fully complete copy of protocol along with application (in person or electronic version) (in pen drive or can e-mail us at IEC official email) of the same in prescribed Proforma, 15 days in advance to the member secretary for IEC approval.
    - ii)For Postgraduate thesis, *IEC review shall be considered mandatory before it is submitted to the Board of Studies.*
    - Every candidate appearing before IEC should be directed to submit their presentation in electronic format to member secretary one week prior to the meeting which shall be circulated to all worthy members and Chairperson for reference well in advance.

iv) The research proposal shall be reviewed as per the procedure detailed below:

Type of risk	**Definition/description**	**Type of review to be conducted**
Less than minimal risk	Probability of harm or discomfort anticipated in the research is nil or not expected. For example, research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc	Exemption from Review
Minimal risk	Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely. Examples include research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc.	Expedited Review/ Full Committee review
Minor increase over minimal risk or Low risk	Increment in probability of harm or discomfort is only a little more than the minimal risk threshold. This may present in situations such as routine research on children and adolescents; research on persons incapable of giving consent; delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials; use of minimally invasive procedures that might cause no more than brief pain or tenderness, small bruises or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing; trying a new diagnostic technique in pregnant and breastfeeding women, etc. Such research should have a social value. Use of personal identifiable data in research also imposes indirect risks. Social risks, psychological harm and discomfort may also fall in this category.	Full Committee review
More than minimal risk or High risk	Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. Examples include research involving any interventional study using a drug, device or invasive procedure such as lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures, etc.	Full Committee Review (all research proposals presenting more than minimal risk that are not covered under exempt or expedited review)

- **Expedited Review Procedures**

  - The committee may use expedited review procedure in case of minor changes/ amendments in the previously approved research proposal that appear to involve no more than minimal risk to the study subjects.
  - Under an expedited review procedure, the review may be carried out by the Chairperson of the committee, or by one or more experienced reviewers designed by the chairperson from among the members of the committee. The reviewers may exercise all of the authorities of the committee except that the reviewers may not disapprove the research.
  - These expedited review procedure approvals should be informed to all members of the IEC.
  - Only the Chairperson and Member Secretary shall make the decision to allow an expedited review

v) For Vulnerable Groups

The et**h**ics committee will exercise particular care to protect the rights, safety and well-being of all vulnerable participants of the study as per Good Clinical Practices for Clinical Research in India;

Effort will be made to ensure that individuals or communities invited for research are selected in such a way that the burdens and benefits of the research are equally distributed.

a. Research on genetics does not lead to racial inequalities;
b. Persons who are economically or socially disadvantaged are not used to benefit those whoare better off than them;
c. Rights and welfare of mentally challenged and mentally differently abled persons who areincapable of giving informed consent or those with behavioral disorders is protected.
d. Adequate justification is made for the involvement of participants such as prisoners, students, subordinates, employees, service personnel etc. who have reduced autonomy as research subjects.

3.9 Procedure for decision making regarding the research Project and communicating the decision of IEC to the Investigator

RESPONSIBILITY

All members of IEC of AIIMS Vijaypur, Jammu

PROCEDURE

1. A decision will only be taken when sufficient time has been allowed for review and discussion on application in the absence of investigator after meeting
2. Decision will only be taken at meeting where quorum (minimum of five members) is complete
3. Decision will only be taken after reviewing complete application with all required documents necessary for proposal **(Annexure- 12)**
4. Decision will be arrived with consensus of members; if consensus appears unlikely voting can be resorted to. Decision will be taken in specified format **(Annexure- 13)**

5. A negative decision would always be supported by clearly defined reason.
6. The Member Secretary would communicate the decision in writing to the Principal Investigator in prescribed format **(Annexure- 14)**
7.If one of the members has her/his own proposal as PI/ Co PI/ Investigator for review then he/she would be allowed to participate in the meeting but shall not have any voting right for that proposal.

4.0 Procedure for documentation & archiving of documents

PURPOSE

To archive the study related documents, procedings and communication.

RESPONSIBILITY

The office of the member secretary is responsible for implementing this SOP

PROCEDURE

- The support staff will help the IEC Member Secretary in executing functions of the IEC documentation and archiving.
- All documents, communication of IEC will be dated, filed and archived in a secure place.
- Only persons who are authorized by Member Secretary of IEC will have access to various documents.
- All documents related to research project will be archived for a minimum period of three years in Institute following completion or termination of project.
- All the agenda & minutes of meeting will be filed & archived

The records shall be made available to relevant statutory authorities upon request.

Annexure– 1: Request letter by the Director to the members.

Letter Ref. No:

From
The Director,
AIIMS Vijaypur, Jammu

To

_____
_____
_____

Sub: Constitution of Institute Ethics Committee (Human studies)

Dear Sir/Madam,

I am pleased to inform you that your name has been selected for the post of Chairperson/ Member Secretary /Member of IEC. Kindly send your written acceptance in enclosed format. On receipt of your acceptance, I shall send you the formal appointment letter.

We sincerely hope your association with the IEC, AIIMS, Vijaypur, Jammu will be fruitful to the Institution and the community we serve.

Signature

Annexure- 2: Consent letter by members of IEC

From,

……..

To
The
Director
AIIMS, Vijaypur, Jammu

Sub: Consent to be a member of Institute Ethics Committee (Human Studies)Reg.

Ref: Your Letter No:

Dear Sir,

In response to your letter stated above, I give my consent to become a Chairperson/ Member Secretary /Member of IEC of AIIMS Vijaypur, Jammu. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues. I shall not keep any literature or study related documents with me after the discussion and final review. I shall maintain all the research project related information confidential and shall not reveal the same to anybody other than project related personnel.

Thanking you

Yours Sincerely

Signature
Date
Name:

Department & designation:

Annexure-3

Declaration of Conflict of Interest by members of IEC, AIIMS, Jammu

I, ……..……., have the following proposal(s) as Principal Investigator/Co-investigator or real/potential/perceived competing research program under review by the IEC AIIMS ,Vijaypur, Jammu. I shall abstain from any participation in discussions or recommendations in respect of the proposal. I also undertake to keep all the project-related documents and information confidential and shall not share or reveal the same to anyone other than the project-related personnel

Research Proposal No.

Research Proposal Title

Signature

Annexure – 4:

Proforma to be submitted to the AIIMS Vijaypur, Jammu Institute Ethics committee

1. Title of the Project	
2. Name of the chief investigator & Department	
3. Name of co-investigator (s) & Department	
4. Source of funding	
5. Objectives of study	
6. Justification for conduct of study	
7. Methodology – it should provide detail of number of patients,inclusion criteria, exclusion criteria, control(s), study design	
8. Ethical issue involved in study	
9. Cost involved	
10. Permission from Drug Controller General of India, if applicable	
11. Whether consent form in local language is enclosed	
12. Conflict of interest for any other investigator, if any	
Signature of investigator	

Annexure- 5:

Acknowledgement Letter

IEC has received research proposal entitled _____

_____

_____

Registration Number of the above research proposal is _____.

_____

Member Secretary

Annexure- 6:

Checklist of informed consent documents for clinical trial subject,—

1.1 Essential elements:

(i) Statement that the study involves research and explanation of the purpose of the research.
(ii) Expected duration of the participation of subject.
(iii) Description of the procedures to be followed, including all invasive procedures
(iv) Description of any reasonably foreseeable risks or discomforts to the Subject.
(v) Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.
(vi) Disclosure of specific appropriate alternative procedures or therapies available to the Subject.
(vii) Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject's medical records.
(viii) Trial treatment schedule and the probability for random assignment to each treatment (for randomized trials).
(ix) Statement describing the financial compensation and the medical management as under:

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

(b) In the event of a trial related injury or death, the sponsor or his representative or the investigator or centre, as the case may be, in accordance with the New Drugs and Clinical trial rules 2019, as the case may be, shall provide financial compensation for the injury or death.

(x) An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury.
(xi) The anticipated prorated payment, if any, to the subject for participating in the trial.
(xii) Responsibilities of subject on participation in the trial.
(xiii) Statement that participation is voluntary, that the subject canwithdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled.
(xiv) Statement that there is a possibility of failure of investigational product to provide intended therapeutic effect.
(xv) Statement that in the case of placebo controlled trial, the placebo administered to the subjects shall not have any therapeutic effect.
(xvi) Any other pertinent information.

1.2 Additional elements, which may be required:

(a) Statement of foreseeable circumstances under which the participation of the subject may be terminated by the Investigator withouthis or her consent.
(b) Additional costs to the subject that may result from participation in the study.
(c) The consequences of a Subject's decision to withdraw from the research and procedures for orderly termination of participation by Subject.
(d) Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect

the Subject's willingness to continueparticipation will be provided.

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

(f) Approximate number of Subjects enrolled in the study

Annexure- 7:

Format of informed consent form for Subjects participating in a Clinical Trial—

Study Number:

Subject's Initials: .....
Subject's Name: .....
Date of Birth/ Age: .....
Address of the Subject .....
Qualification .....

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

Annual Income of the subject:

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

Place Initial box (Subject)

(i) I confirm that I have read and understood the information [ ]

Sheet dated..... for the above

study and have had the opportunity to ask questions.

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

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

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

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

Signature (or Thumb impression) of the

Subject/Legally Acceptable Representative:

Date: ...../…../

Signatory's Name: .....

Signature of the Investigator: .....

Date: ...../…./…….

Study Investigator's Name: .....

Signature of the Witness.....

Date :...../..... /

Name of the Witness:.....

Copy of the Patient Information Sheet and duly filled Informed Consent Form shall

be handed over to the subject his or her attendant.

Annexure- 8:

Procedure for compensation in case of injury or death during clinical trial, bioavailability and bioequivalence study

(1) The investigator shall report all serious adverse events to the Central Licencing Authority, the sponsor or its representative, who has obtained permission from the Central Licencing Authority for conduct of clinical trial or bioavailability or bioequivalence study, as the case may be, and the Ethics Committee that accorded approval to the study protocol, within twenty-four hours of their occurrence; and if the investigator fails to report any serious adverse event within the stipulated period, he shall have to furnish the reasons for delay to the satisfaction of the Central Licencing Authority along with the report of the serious adverse event.

(2) A case of serious adverse event of death shall be examined in the following manner, namely:—

(i) the Central Licencing Authority shall constitute an independent expert committee to examine the cases and make its recommendations to the said authority for arriving at the cause of death and quantum of compensation in case of clinical trial related death;

(ii) the sponsor or its representative and the investigator shall forward their reports on serious adverse event of death after due analysis to the Central Licencing Authority and the head of the institution where the clinical trial or bioavailability or bioequivalence study has been conducted within fourteen days of the knowledge of occurrence of serious adverse event of death;

(iii) the Ethics Committee for clinical trial shall forward its report on serious adverse event of death after due analysis along with its opinion on the financial compensation, if any, determined in accordance with the formula specified in the Seventh Schedule, to be paid by the said sponsor or its representative, who has obtained permission from the Central Licencing Authority for conduct of clinical trial or bioavailability or bioequivalence study, as the case may be, to the Central Licencing Authority within a period of thirty days of receiving the report of the serious adverse event of death from the investigator;

(iv) the Central Licencing Authority shall forward the report of the investigator, sponsor or its representative and the Ethics Committee to the Chairperson of the expert committee;

(v)the expert committee shall examine the report of serious adverse event of death and make its recommendations available to the Central Licencing Authority for the purpose of arriving at the cause of the serious adverse event of death within sixty days from the receipt of the report of the serious adverse event, and the expert committee while examining the event, may take into consideration, the reports of the investigator, sponsor or its representative and the Ethics Committee for clinical trial;

(vi) in case of clinical trial or the bioavailability or bioequivalence study related death, the expert committee shall also recommend the quantum of compensation, determined in accordance with the formula specified in the Seventh Schedule, to be paid by the sponsor or his representative who has

obtained the permission to conduct the clinical trial or the bioavailability or bioequivalence study, as the case may be;

(vii) the Central Licencing Authority shall consider the recommendations of the expert committee and shall determine the cause of death with regards to the relatedness of the death to the clinical trial or the bioavailability or bioequivalence study, as the case may be;

(viii) in case of clinical trial or the bioavailability or bioequivalence study related death, the Central Licencing Authority shall, after considering the recommendations of the expert committee, by order, decide the quantum of compensation, determined as per the formula specified in the Seventh Schedule, to be paid by the sponsor or its representative and shall pass orders as deemed necessary within ninety days of the receipt of the report of the serious adverse event;

(ix) the sponsor or its representative shall pay the compensation in case the serious adverse event of death is related to clinical trial or the bioavailability or bioequivalence study, as specified in the order referred to in clause (viii) of the Central Licencing Authority within thirty days of the receipt of such order.

(3) Cases of serious adverse events of permanent disability or any other injury other than deaths shall be examined in the following manner, namely:—

(i) the sponsor or its representative, and the Investigator shall forward their reports on serious adverse event, after due analysis, to the Central Licencing Authority, chairperson of the Ethics Committee for clinical trial and head of the institution where the trial or bioavailability or bioequivalence study has been conducted within fourteen days of the reporting of serious adverse event;

(ii) the Ethics Committee for clinical trial shall forward its report on serious adverse event of permanent disability or any other injury other than deaths, as the case may be, after due analysis along with its opinion on the financial compensation, if any, determined in accordance with the formula specified in the Seventh Schedule, to be paid by the sponsor or its representative who has obtained permission to conduct clinical trial or the bioavailability or bioequivalence study, as the case may be, within thirty days of receiving the report of the serious adverse event;

(iii) the Central Licencing Authority shall determine the cause of the injury and pass order as specified in clause (iv), or may constitute an independent expert committee, wherever it considers necessary, to examine such serious adverse events of injury, and such independent expert committee shall recommend to the Central Licencing Authority for the purpose to arrive at the cause of the serious adverse event and also the quantum of compensation, as determined in accordance with formula as specified in the Seventh Schedule in case of clinical trial or bioavailability or bioequivalence study related injury, within a period of sixty days of receipt of the report of the serious adverse event;

(iv) in case of clinical trial or the bioavailability or bioequivalence study related injury, the Central Licencing Authority shall, by order, decide the quantum of compensation, determined in accordance with the formula specified in the Seventh Schedule, to be paid by the sponsor or his representative who has obtained the permission to conduct the clinical trial or the bioavailability or bioequivalence study, as the case may be, within a period of ninety days of receipt of the report of the serious adverse event;

(v) the sponsor or its representative, who has obtained permission to conduct the clinical trial or bioavailability or bioequivalence study, as the case may be, shall pay the compensation in case of clinical trial or bioavailability or bioequivalence study related injury, as specified in the order of the Central Licencing Authority referred to in clause (iv) within thirty days of receipt of such order

Annexure- 9:

Declaration Form

I Dr…… hereby declare that I will not disclose identity of research participants anytime during or after the study period or during publication.

Signature of investigator

Annexure- 10:

SAE reporting

Data Elements For Reporting Serious Adverse Events Occurring In A Clinical Trial Or Bio Availability Or Bioequivalence Study

1.Patient Details:

Initials and other relevant identifier (hospital or out-patient department (OPD) record number etc.)*

Gender

Age or date of birth Weight

Height

2.Suspected Drug(s):

Generic name of the drug*

Indication(s) for which suspect drug was prescribed or tested. Dosage form and strength.

Daily dose and regimen (specify units - e.g., mg, ml, mg /kg). Route of administration.

Starting date and time of day.

Stopping date and time, or duration of treatment

3.Other Treatment(s):

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

4.Details of Serious Adverse Event:

Full description of the event including body site and severity, as well as the criterion (or criteria) for considering the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the event*

Start date (and time) of onset of event. Stop date (and time) or duration of event. Dechallenge and rechallenge information.

Setting (e.g., hospital, out-patient clinic, home, nursing home).

5.Outcome

Information on recovery and any sequelae; results of specific tests or treatment that may have been conducted.

For a fatal outcome, cause of death and a comment on its possible relationship to the suspected event; Any post-mortem findings.

Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.

6.Details about the Investigator* Name and Address

Telephone number Profession (specialty)

Date of reporting the event to Central Licencing Authority:

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

Signature of the Investigator or Sponsor

Annexure 11:

Clinical Trial Reporting

Structure, Content And Format For Clinical Trial Report

1. Title Page: This page should contain information about the title of the study, the protocol code, name of the investigational product tested, development Phase, indication studied, a brief description of the trial design, thestart and end date of patient accrual and the names of the Sponsor and the participating Institutes (Investigators).

2. Study Synopsis (1 to 2 pages): A brief overview of the study from the protocol development to the trial closure should be given here. This section will only summarise the important conclusions derived from the study.

3. Statement of compliance with the Good Clinical Practices Guidelines:

4. List of abbreviations and definitions:

5. Table of contents:

6. Ethics Committee: This section should document that the study was conducted in accordance with the ethical principles of Declaration of Helsinki.A detailed description of the Ethics Committee constitution and dates of approvals of trial documents for each of the participating sites should be provided. A declaration should state that Ethics Committee (EC) notifications asper Good Clinical Practice Guidelines and Ethical Guidelines for Biomedical Research on Human Subjects, issued by Indian Council of Medical Research have been followed.

7. Study Team: Briefly describe the administrative structure of the study (Investigators, site staff, Sponsor or designates, Central laboratory etc.).

8. Introduction: A brief description of the product development rationale should be given here.

9. Study Objective: A statement describing the overall purpose of the study and the primary and secondary objectives to be achieved should be mentioned here.

10. Investigational Plan: This section should describe the overall trial design, the Subject selection criteria, the treatment procedures, blinding or randomization techniques if any, allowed or disallowed concomitant treatment, the efficacy and safety criteria assessed, the data quality assurance procedures and the statistical methods planned for the analysis of the data obtained.

11. Trial Subjects: A clear accounting of all trial Subjects who entered the study will be given here. Mention should also be made of all cases that were dropouts or protocol deviations. Enumerate the patients screened, randomized, and prematurely discontinued. State reasons for premature discontinuation of therapy in each applicable case.

12. Efficacy evaluation: The results of evaluation of all the efficacy variables will be described in this section with appropriate tabular and graphical representation. A brief description of the demographic characteristics of the trialpatients should also be provided along with a listing of patients and observations

excluded from efficacy analysis.

13. Safety Evaluation:

This section should include the complete list

13.1 all serious adverse events, whether expected or unexpected and

13.2 unexpected adverse events whether serious or not (compiled from data received as per Table 5 of this Schedule)

The comparison of adverse events across study groups may be presented in a tabular or graphical form. This section should also give a brief narrative of all important events considered related to the investigational product.

14. Discussion and overall Conclusion: Discussion of the important conclusions derived from the trial and scope for further development.

15. List of References:

16. Appendices: List of Appendices to the Clinical Study Report

(a)	Protocol and amendments
(b)	Specimen of Case Record Form
(c)	Investigators' names with contact addresses, phone, e-mail etc.
(d)	Patient data listings
(e)	List of trial participants treated with investigational product
(f)	Discontinued participants
(g)	Protocol deviations
(h)	Case Record Forms of cases involving death and life threatening adverseevent
	Cases
(i)	Publications from the trial
(j)	Important publications referenced in the study
(k)	Audit certificate, if available

(1) Investigator' certificate that he /she has read the report and that the reportaccurately describes the conduct and the results of the study.

Annexure- 12:

Initial check list to verify completeness of documents submitted (including those for PG dissertation/ Ph.D thesis/ ICMR studentship)

For office use only-

S. No.	Documents	Submitted	Not submitted
1.	Three (for) copies of proposal for Ethics sub committee		
2.	Proforma completely filled & duly signed by the investigators		
3.	Patient information sheet		
4.	Consent form for patients in English / Hindi / Local Language		
5.	Consent form completely filled with all the question answered in complete sentence & simple language		
6.	Investigator's Brochure, dated……, version no……. proposed methods for patients's accrual including advertisements etc. proposed to be used for the purpose.		
7.	In case the research involves a study product (such as a pharmaceutical or device under investigation, an adequate summary of all safety, pharmacological pharmaceutical and toxicological data available on the study product, together with a summary of clinical experience with the study product to date (e.g.: recent investigator's brochure published data, a summary of the product's characteristics); (Product information)		
8.	Investigator(s) curriculum vitae (updated, signed and dated)		
9.	Material to be used (including advertisements) for the recruitment of potential research participants;		
10.	A statement describing any compensation for study participation (including expenses and access to medical care) to be given toresearch participants;		
11.	A description of the arrangements for indemnity/insurance, if applicable;		
12.	Undertaking by the investigators		
13.	Investigators agreement with the sponsor		

Annexure- 13: AIIMS Vijaypur, Jammu IEC Review Letter

Review letter No of IEC ……..

To,

The meeting of the IEC for the year_____was held in AIIMS Vijaypur Jammu on_____under the Chairpersonship of_____. Following members attended the meeting

S.No	Name of the member	Signature
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		

The proposals listed for meeting were taken up for discussion and deliberation.
The following decisions were arrived at

No. of proposal received-
No. of proposals approved_____
No. of proposals approved subject to correction_____

The recommendation made by the committee to each proposal is detailed below:

S. No.	Reg. No. of proposal	Name of Principal investigator	Title of Research Proposal	Recommendations of the committee

Member Secretary

Ethical Committee

Annexure- 14: Format for approval of the Ethics Committee

To
Dr. ……
……..
……..

Dear Dr. _____

The Institute Ethics Committee reviewed and discussed your application toconduct the study titled "……" on …….(date).

The following documents were reviewed (as applicable):

a. Study Protocol (including protocol amendments), dated Versionno (s).____
b. Patient Information Sheet and Informed Consent Form (including updates if any) in English and/or vernacular language.
c. Investigator's Brochure, dated_____, Version no._____
d. Proposed methods for patient accrual including advertisement (s) etc. proposedto be used for the purpose.
e. Principal Investigator's current CV
f. Insurance Policy/ Compensation for participation and for serious adverseevents occurring during the study participation.
g. Investigator's Agreement with the Sponsor.
h. Investigator's Undertaking (Appendix VII).

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

_____Chairperson of the Ethics Committee

_____Member secretary of the Ethics Committee

.

_____Name of each member with designation

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

The Institute Ethics Committee expects to be informed about the progress of the study, any serious adverse event (SAE) occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

Yours sincerely,

Member Secretary, Ethics Committe

Appendix VII

UNDERTAKING BY THE INVESTIGATOR

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

2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, or any other statements of qualifications)

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

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

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

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

7. Commitments:

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

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

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

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

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

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

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

(viii) I agree to maintain adequate and accurate records and to make those records available for audit or inspection by the Sponsor, ethics committee, Central Licencing Authority or their authorised

representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorised representatives of the Sponsor.

(ix) I agree to promptly report to the ethics committee all changes in the clinical trial activities and all

unanticipated problems involving risks to human subjects or others.

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

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

(xii) I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data.

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

Signature of Investigator with date