	"INSTITUTIONAL ETHICS COMMITTEE" ALL INDIA INSTITUTE OF MEDICAL SCIENCES, BATHINDA	SOP No.
Purpose	The "INSTITUTIONAL ETHICS COMMITTEE" AIIMS, Bathinda aims to ensure a competent review of scientific and ethical aspects of the projects/ research proposals including drug trials received. The committee shall safeguard the rights, safety, and well-being of all the trial subjects. Special attention shall be paid to trials that include vulnerable subjects and conduct ethical review in an emergency situation such as the one that occurred after the recent pandemic.	
Scope	The procedure covers a competent review of the research projects/ proposals in human subjects and/or patients (including medical education projects, STS projects, Human studies, file audit, Registries etc.).	
Preparation/Revision Date	7-9-2020, Revised 12-09-2023	
Name of Ethics Committee	INSTITUTIONAL ETHICS COMMITTEE, AIIMS BATHINDA	
Address of Ethics committee	All India Institute of Medical Sciences, Bathinda; Jodhpur Romana, Mandi Dabwali Road, Bathinda, Punjab- 151001.	

Approvals

	Name	**Designation**	**Date**
Prepared by	Dr Priti Chaudhary & Dr. Jitender Aneja	Former and Present Member Secretaries respectively	7-9-2020; revised 12-09-2023
Reviewed by	Dr. Joseph Mathew	Chairman, IEC	
	Joseph Mathew 30 Nov 2023	Also reviewed by all the Committee members, mentioned in the list.	
Authorized by	Dr Dinesh Kumar Singh	Executive Director& CEO	
Accepted by			

Joseph Mathew 30 Nov 2023

Abbreviations

- **ADR** **Adverse Drug Reaction**
- **AE** **Adverse Event**
- **CDSCO** **Central Drug Standard Control Organization**
- **CFR** **Code of federal Regulation**
- **CRF** **Case Record Form**
- **CTA** **Clinical Trial Agreement**
- **CV** **Curriculum Vitae**
- **DTEC** **Drug Trial Ethics Committee**
- **DCGI** **Drug Controller General of India**
- **DCR** **Drug and Cosmetic Rules**
- **DGFT** **Director General of Foreign Trade**
- **EC** **Ethics Committee**
- **GCP** **Good Clinical Practices**
- **GOI** **Government of India**
- **IB** **Investigator Brochure**
- **ICF** **Informed consent form**
- **ICH-GCP** **International Committee for Harmonization-Good Clinical Practices**
- **ICMR** **Indian Council of Medical Research**
- **IEC** **Institutional Ethics Committee**
- **PI** **Principal Investigator**
- **RCT** **Randomized Controlled Trial**
- **SAE** **Serious Adverse Event**
- **SOP** **Standard Operating Procedure**
- **WHO** **World Health Organization**

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Definitions:

- **Standard Operating Procedure (SOP):** Detailed written instructions to achieve uniformity of the performance of a specific function.
- **Good Clinical Practices (GCP):** A standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

- **Clinical Trial:**
  Clinical trial in relation to a new drug or investigational new drug means, any systematic study of such new drug or investigational new drug in human subjects to generate data for discovering or verifying its-
  (i) Clinical or
  (ii) Pharmacological, including pharmacodynamics, pharmacokinetics or
  (iii) Adverse effects
  with the objective of determining the safety, efficacy or tolerance of such new drug or investigational new drug.

  Clinical Trial/study: Any investigation in human subjects intended to discover or verify the clinical pharmacological and other pharmacodynamic effect of 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.
  Clinical Trials covered under various phases:

  - **Phase I**: Researchers test a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify adverse effects.
  - **Phase II**: The drug or treatment is given to a larger group of people to further evaluate its safety.
  - **Phase III**: The drug or treatment is given to large groups of people to confirm its effectiveness, monitor adverse effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.
  - **Phase IV**: Studies are done after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any adverse effects associated with long term use.

- **Orphan Drug**
  Orphan drug means a drug intended to treat a condition which affects **not more than five lakh persons in India**.

- "**Post-trial access**" means making a new drug or investigational new drug available to a trial subject after completion of clinical trial through which the said drug has been found beneficial to a trial subject during clinical trial, for such period as considered necessary by the investigator and the Ethics Committee.

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- **New Drug**
  i. a drug, including active pharmaceutical ingredient or phytopharmaceutical drug, which has not been used in the country to any significant extent, except in accordance with the provisions of the Act and the rules made thereunder, as per conditions specified in the labelling thereof and has **not been approved** as safe and efficacious by the Central Licensing Authority with respect to its claims; or

  ii. a drug **approved** by the Central Licensing Authority for certain claims and proposed to be marketed with modified or new claims including indication, route of administration, dosage and dosage form; or

  iii. a fixed dose combination of two or more drugs, approved separately for certain claims and proposed to be combined for the first time in a fixed ratio, or where the ratio of ingredients in an approved combination is proposed to be changed with certain claims including indication, route of administration, dosage and dosage form; or

  iv. a modified or sustained release form of a drug or novel drug delivery system of any drug approved by the Central Licensing Authority; or

  v. a vaccine, recombinant Deoxyribonucleic Acid (r-DNA) derived product, living modified organism, monoclonal anti-body, stem cell derived product, gene therapeutic product or xenografts, intended to be used as drug.

- **Protocol**: A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the International Conference on Harmonization Good Clinical Practice Guidelines the term protocol refers to protocol and protocol's amendments.

- **Protocol Amendment**: A written description of a change(s) to or formal clarification of a protocol.

- **Investigator Brochure (IB)**: A compilation of the clinical and nonclinical data on the investigational products which is relevant to the study of the investigational product(s) in human subjects.

- **Case Report form (CRF):** A printed, optical, or electronic document designed to record all the required information to be reported on each trial subject.

- **Informed Consent:** A process by which a subject, voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate along with the signatures of his/her nominee. Informed consent is documented by means of a written, signed and dated informed consent form also showing the name of nominees and their signatures.

- **Adverse event (AE):** Any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether related to the medicinal/investigational product.

- **Adverse Drug Reaction (ADR):** All noxious and unintended response to a medicinal product related to any dose should be considered adverse drug reactions.

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- Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR): Any untoward medical occurrence that at any dose:
  - Results in death
  - Is life-threatening.
  - Require inpatient hospitalization or prolongation of existing hospitalization.
  - Results in persistent or significant disability/incapacity.
  - Is a congenital anomaly/birth defect.
- **Investigational Product:** A pharmaceutical or biopharma 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/ 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.
- **Subject/Trial Subject:** An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.
- **Principal Investigator (PI):** If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.
- **Sponsor:** An individual, company, institution, or organization which takes responsibility for the initiation, management and/or financing of a clinical trial.
- **Clinical Trial/study report:** A written description of a trial /study of any therapeutic, prophylactic, or diagnostic agent conducted in human subjects in which the clinical and statistical description, presentations and analysis are fully integrated into a single report.
- **Inspection:** The act by a regulatory authority/ies of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority/ies to be related to the clinical trial and that may be located at the site of the trial, at the sponsors and/or contract research organizations (CROs), facilities, or at other establishments deemed appropriate by the regulatory authorities.

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The standard operating procedures to be followed by the committee in general-

	STANDARD OPERATIVE PROCEDURES ALL INDIA INSTITUTE OF MEDICAL SCIENCES, BATHINDA	SOP No.
	Procedures & Responsibilities:	
	❖ Chairman I. The Chairman of the IEC shall be presiding overall meetings of IEC. II. The Chairman will be responsible for affixing the date of meeting(s) of EC in consultation with member secretary of EC. III. The Chairman will be responsible to sign the letters/applications/notices/circulars on behalf of IEC to be sent to offices outside institution. However, in absence of Chairman, the Member Secretary may sign on the behalf of the Chairman, In absence of Chairman, other members outside institution among the members present for the IEC meetings, will be nominated as acting Chairman for that meeting. ♦ Member Secretary /Convener: I. Co-ordinates activity of writing, reviewing, distributing, and amending SOPs II. Maintains files of all previous SOPs and current SOP III. Receive, record, verify completeness and allot reference no. IV. Schedule meeting (physical/virtual), Prepare Agenda, invite members. V. Record agenda and Minutes of meeting. VI. Arrange meeting at an earlier date to evaluate SAE as per notification in consultation with the Chairman. VII. Circulate agenda/minutes of meeting/ other correspondence on the behalf of chairman for internal circulation among members/PI/Stakeholder in consultation with Chairman. ♦ IEC Members: All IEC members at the time of enrollment shall provide a copy of their CV as per the ICMR format. They shall be introduced and trained in appropriate Ethical Guidelines of the Indian Council of Medical Research (ICMR 2017) as well as other relevant guidelines such as New Drugs and Clinical Trial Rules, 2019 followed by discussion on all the contents of the SOP and shall be provided a copy of the current SOP. In case, SOP is revised, all the members shall be made aware of the changes and a copy of amended SOP shall be provided to them.	

- Principal Investigator: The application duly completed should be submitted to the office of IEC at least two weeks in advance of the scheduled IEC meeting. In addition to regulatory and other document submission, the PI will submit the following information.

1. Each subject in clinical trial to be enrolled only after obtaining audio and video consent as per DCGI guidelines.
2. Sponsor to provide free medical management in case of injury in clinical trial to the subject as per New Drugs and Clinical Trial Rules, 2019 (Reference: New Drugs and Clinical Trials Rules, 2018-Gazettee Notification-March 19, 2019, No. 200)
3. if required "as per the opinion of investigator", or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.
4. Undertaking from the PI for the vernacular translations of the concerned trial documents (Annexure VII)
5. Undertaking from the PI that the data acquisition for the current study/trial will not start prior to provision of IEC approval (Annexure VI)
6. A report of the clinical trial on a quarterly basis. (Annexure IV)
7. A report of the clinical trial six monthly. (Annexure V)
8. A report of each serious adverse event (requiring hospitalization, additional treatment, resulting in disability or death) about the study.
9. IEC to be mandatorily informed of the amendment/revisions to any study related document as well as patient safety related information.
10. In case of need for hospitalization of the subject in study/ trial, the PI shall report all serious adverse events (SAE) to the IEC and the licensing authority within 24 hours.
11. In case of any serious adverse event occurring in the clinical trial a narrative report after due analysis shall be forwarded by the PI to chairman of EC and the chairman of the expert committee constituted by licensing authority within 07 calendars days.
12. SAE reporting timeline for sponsor: 14 calendar days from "awareness of SAE/Death" and not "Occurrence/onset of SAE."
13. The sponsor or its representative and the investigator shall forward their reports on SAE of death after due analysis to DCGI, HOI, EC within fourteen days of the "knowledge of occurrence of SAE of death"
14. Study completion and discontinuation along with reasons.
15. To submit justification for approval to restart study discontinued earlier.

Procedure:

(I) Projects must be approved by the IRC (Institute Research Committee) for administrative assessment of justification, relevance, and benefits to institution, before presentation to Ethics Committee.

		(II) All funds should be routed through finance and accounts Department, under separate head for each project. (III) No direct/indirect individual financial benefit should be taken by any faculty member. (IV) The project personnel/s, if involved should be duly approved by IRC. Appointment of medical person should be routed through MS and non- medical person through HRD. (V) It should be ensured that the project work by the AIIMS Bathinda faculty/staff is not carried out at the expense of medical care of other patients or routine departmental work during duty hours. (VI) At the end of the project, the report should be submitted on the prescribed format. (VII) In case of Serious Adverse Event occurring in clinical trial after due analysis along with opinion on financial compensation will be forwarded to the licensing authority within 14 calendar days of the occurrence of the SAE.	

Submission of Proposal by PI:

(I) Submission for RAC approval (Annexure II)

(II) All documents will be addressed to the Chairman, Institutional Ethics Committee.

(III) PI is required to submit the proposal by himself or nominee to the IEC with two hard copies of his/her application letter and two hard copies each of the following documents along with soft copies of these documents at least four weeks before the scheduled meeting in a prescribed format. (Annexure III)

(IV) Final protocol with all amendments, investigator's Brochure, safety mailing, Drug Controller General of India (DCGI) approval, Directorate General of Foreign Trade (DGFT) approval (where applicable), Complete insurance Policy (with schedule note showing the name of the PI and the name of the Institute along with insurance certificate of trial etc, and any other safety related information

(V) Informed consent form (in Hindi, Punjabi, English), patient questionnaires, patient diaries and patient information sheet in English and its translations in local vernacular languages and their back translation with appropriate translation certificates.

(VI) Any other project-specific document (s).

(VII) After the approval, one copy of Serious Adverse Effects (SAE)/Council for International Organizations of Medical Sciences (CIOMS)/Appendix needs to be submitted.

(VIII) Self-certification of the vernacular translation for validity of content and Intent of various documents (Annexure VII).

(IX) Self-certification that the work will be started only after the approval and that no participant enrollment has been done before the ethical approval (Annexure VI)

(X) Registration with CTRI when required and an undertaking in this regard shall be submitted to the IEC before the start of the trial.

(XI) Expedited reviewed (In case any addition / deviation/ SAE). No expedited approval will be given without the above-mentioned documents.

(XII) Current resume/curriculum vitae of the Principal Investigator/Co Principal Investigators/ Co-Investigators/ Sub- investigator(s).

(XIII) All ADRs should be reported in a proper format as given below to give proper information on the first page of covering letter

Sr. No	Pt. ID	SAE No	Site (Country)	Event terminology	Type of report (initial/ follow up)	Study Drug relationship	Out come

(XIII) Any project personnel leaving or joining a particular protocol will be brought to the notice of IEC and status of trial to be decided by the IEC (within 24 hours).

(XIV) Information regarding the admission and discharge of all the trial subjects, in the event of an ADR,will be sent to IEC within 24 hours.

(XV) The Ethics committee is to be notified of any payments to be made to the study participants towards reimbursements of incidental expenses or otherwise.

(XVI) Clinical Trial Agreement (CTA).

a) All the Clinical Trial Agreements will be Tripartite and Principal Investigator as 2nd Party and "AIIMS Bathinda" as 3rd Party.

b) CTA (Draft) should be submitted before getting written approval of the trial.

c) The Tripartite CTA will be signed only after IEC approval.

d) Copy of CTA should be submitted to the office of IEC immediately.

(XVII) The INSTITUTIONAL ETHICS COMMITTEE is to be informed for any purposed retention items/gifts offered to the study participants. No retention items/gifts to be given to any study participant without the permission of INSTITUTIONAL ETHICS COMMITTEE.

Submission of Final Report of the Study : At the end of the study the PI shall submit final report (before Publishing the data) of the study to IEC (Annexure XI)

IEC Meeting: Time and frequency: The committee (Annexure I) will meet once in three months or as and when required. Advance notice 14 days before each meeting will be sent out to the IEC members, Principal Investigators along with the agenda. No protocol/documents shall be approved by circulation to the IEC members.

Quorum for the meeting : For review of each protocol the quorum of Institutional Ethics Committee should have at least 5 members with the following representations:

- Basic medical scientist (Preferably one Pharmacologist)
- Clinician
- Legal expert
- Social scientist/representative of non-governmental voluntary agency/philosopher/ethicist/theologian or a similar person.
- Lay-person from the community.

In addition to the medical experts the committee shall have:

- At least 1 member from a non-scientific field.
- At least 1 member from outside the institution
- At least 1 lady member

It is encouraged to invite non-member for formal opinion on specific indications in case-to-case basis. (Non-member experts will not be allowed to vote).

Procedure for the meeting:

(I) The meeting will be called to convey decisions on project submitted.
(II) Minutes of the last meeting will be approved.
(III) All the proposals (agenda wise) will be discussed in sequence.
(IV) The PI or study team member may be called to meeting to present the study or answer specific queries. However, he/she will not participate in the decision making/voting process of that study even if he/she is a regular member of the IEC.
(V) A study team member including the Principal Investigator will be deemed as an interested party about the review.
(VI) The Member Secretary designated by the Chairman, will record the minutes of the meeting, and circulate the same to the members within two weeks of the meeting.
(VII) The study team member's non-participation in the decision making/voting process will be recorded in the response letter from the IEC.
(VIII) The decision of the committee will be taken by a majority vote after the quorum requirements are fulfilled to recommend/reject/suggest modifications for a repeat review or advise appropriate steps. If subject experts are invited to offer their view, they will not take part in the voting process.

(IX) The committee will give its opinion on the project in one of the following ways (Annexure X)

- Approval
- Disapproval
- Needs Modification before approval
- Discontinuation of previously approved project.

(X) The IEC will issue its opinion (Approval, Disapproval, Needs Modification before approval, Discontinuation of previously approved project) to PI within 15 days of the meeting.

(XI) Any amendment to a study-related document will be discussed on the regular meeting of the committee. The decision will be minute recorded.

(XII) The Agendas/ Minutes/ Approvals/ Disapprovals/ letters/ Clarifications shall be signed by the Chairman/Member Secretary on behalf of IEC.

Note: The Institutional Ethics Committee working procedure compliance with ICH-GCP guidelines and trials are conducted as per guidelines of New Drugs and Clinical Trial Rules, 2019 and ICH- GCP.

Availability of the SOPs: A list of members, their qualification and affiliation is being maintained by the IEC. A copy of the IEC composting and operation procedures in to be made available to any member of the Hospital/Institute for filing of research projects, upon written request for the same to the IEC.

IEC Fees and Charge:

(I) The PI will also be responsible for submitting the fee for institutional overhead charges as well as fees for Ethical Committee in favor of "Institutional Ethics Committee Fund" The IEC will charge a fee as follows to cover the expenses and charges for the use of institutional infrastructure **(for the sponsored projects)**

- IEC Fees is Rs. 30,000/- (Exclude TDS / after all deductions) to be paid during the submission of the clinical trial.

- Institutional overhead charges as 10% of total budget (under special conditions, it can be modified on case-to-case basis)

(II) For the extension studies a fee of Rs. 30000/- will be charged and this extension study will be treated as separate study for the purpose of Ethical consideration.

(III) However, those projects involving human subjects which are funded by government/government aided/not for profit research agencies/organization or are PI initiated studies, submitted by faculty members/students will be exempted for this IEC fees of Rs. 30,000/- and institutional overhead charges. These Projects will be considered only after approval from RAC.

Financial Transactions:

(I) The amount of fee for clinical trial should be received in the name of institution "Institutional Ethics Committee Fund, AIIMS, Bathinda" and not in the name of PI. The cheque/DD received should be deposited with finance and accounts departments of the institution by the PI and the proof of the same to be submitted to IEC office.

(II) The PI should inform the Finance and Accounts Department with a copy of the agreement so that non-tax deduction Certificate is obtained from the Income Tax Department of non-deduction of TDS by the organization giving the payment to the institution.

(III) The Finance and Accounts Department will send the said certification to the PI for onward submission to the sponsor organization enabling the company not to deduct TDS on the amount paid to institution from time to time during the year for which the certification is issued.

(IV) The institution will open project wise separate accounts in the accounts books/subsidiary books of the institution.

(V) The PI will advise the Finance and Accounts Departments to make payments, with necessary supporting documents from time to time.

(VI) The Finance and Accounts Department will make the payment by way of Cheque/DD/Online mode as per advice of PI from time to time.

(VII) The Finance and Accounts Department will keep an account of all the transactions, make necessary TDS deductions deposit TDS so deduced, issue TDS certificates, file TDS returns etc and submit an account to the PI as and when required. The accounts of Institutional Ethics Committee will be audited every financial year by the Accounts Department of AIIMS, Bathinda.

(VIII) The PI can take imprest money out of the funds received to meet the petty cash expenses and will submit a monthly detail of such expenses to Finance and Accounts Department.

(IX) The PI will maintain all the records/documents with himself to the satisfaction of the sponsor organization.

(X) The PI should be managing the account and amount to be withdrawn will be signed by Principal Investigator and Medical Superintendent.

(XI) The distribution of amount should be as per CTA and PI should be responsible for the salaries of their concerned staff and other cost related to the trail. Institute shall not be responsible for any trial related expenditure. Charges to the patient' as mentioned in CTA will be paid by the PI through the funds earmarked for the same.

(XII) The PI will inform the Finance and Accounts Department. For the admission or investigation of subjects enrolled in trial for onward adjustment of funds for the same. No subject enrolled in the study pay for any services after giving informed consent for the participation in the trial.

….

Record:

All study related correspondence will identify the study documents by Version Number/Date and Title. Correspondence between the IEC and the PI/Study team and other relevant records (all the related documents regarding the protocol, minutes of meeting, composition etc.) will be retained for a minimum period of five years after completion of trial.

Audit and Inspection:

Internal Audit: The IEC can nominate an Inspection Team (at least 2 members) to inspect the documents pertaining to trial with prior intimation to principal Investigator (PI).

External Audit: The credentials of the officials shall be verified and letter for audit will be received. All the documents required by the auditors shall be provided to them under receipt.

Annexure-I

IEC Meeting

The Committee will meet on dated_____at_____

Total No. of Protocols_____

List of protocols to be discussed:

Sr. No.	Title of Study Protocol	Name of Principal Investigator	Name of Primary Reviewer	Name of Secondary Reviewer

All members are requested to attend the meeting in time.

Member Secretary

Annexure-II
Submission of Proposal for RAC Approval

DETAILS OF THE RESEARCH PROJECT

1. Title of the project
2. Objectives
3. Summary of the proposed research (up to 500-750 words) indicating overall aims of the research and importance of the research proposal and justification. Application of the work in the context of national priorities of medical research, if any, may also be mentioned.
4. Present knowledge and relevant bibliography including full titles of articles relating to the project.
5. Preliminary work already done by the Investigator on this problem.
6. Detailed research plan.
7. Facilities in terms of equipment, etc, available at the sponsoring institution for the proposed investigation.
8. Bio-data and List of important publications of last 5 years of the all the investigators in the relevant fields (enclose reprints, if available)
9. Budget requirements (with detailed break-up and full justification) including Institutional fee and IEC fee.

	Principal Investigator	

Annexure-III

Check list of required documents to be submitted: (Two Copies each) (Please Tick)

- RAC approval
- EC fees receipt (as per SOP)
- Undertaking by PI
- Curriculum Vitae of Principal Investigator/Co-investigators
- Investigator's Brochure (IB)
- Study protocol
- ICF in languages (English, Hindi, Punjabi)
- DCGI approval
- Import/Export license (where applicable)
- Serious Adverse Events at any other site where study is going on
- CTA (Clinical Trial Agreement) Draft for Approval
- Budget of the trial
- Complete Insurance Policy of the trial along with Insurance Certificate and schedule Showing the name of the Hospital/Principal Investigator's
- Name of project staff/personnel along with photocopies of their I-Card.
- CTRI no. (wherever Applicable)
- Self-Certificate for Current study Status
- Self-Certificate for Vernacular Translation
- Self-Declaration to submit complete report on study completion

Annexure-IV

Quarterly Study Status Report

Date of IEC approval
Study start date
Report for the period of of_____,20_____
Quarter No. …. Of …..
Number of the Protocol_____
Title:_"

PI Name in Study_____Department_____

Co-PI Name in Study_____Department_____
Co-PI Name in Study_____Department_____
Co-PI Name in Study_____Department_____

IEC Approval Letter No._____Dated_____

Heading	Number
Patients Screened	
Patients Enrolled	
Patients who completed the study/protocol	
Patients taken out form the study	
Patients who withdrew consent	
Patients lost to follow up	
Patients Died	
Patients of protocol Deviations/Violations	
SAE at study site	

	Sign of PI with Stamp	

Annexure-V

Annual Study Status Report

IEC approval letter No._____Date_____

- Proposed number of patients to be enrolled from this site.
- Number of patients screened till date.
- Number of patients who failed screening.
- Number of patients enrolled in the study till date.
- Number of patients who have completed the study.
- Number of patients who expired during study period.
- Number of patients who withdrew consent.
- Number of patients who were lost to follow up.
- Number of patients enrolled in this study all present.
- Date on which first patient was enrolled.
- Due date of last patient enrollment:
- Number of SAEs (at own site):
- Due date for end a study:
- Due date for last study related Procedure:

Date:

Sign of PI:

Annexure-VI

Undertaking by PI to initiate study/trial after IEC Approval

I Dr._____Presently employed in_____as_____and Principal Investigator for the protocol entitled "_____" here by certify that above mentioned study has not been started yet and it will be started only after approval of IEC (Institutional Ethics Committee)

Regards,

Sign of PI with designation (with date and stamp)

Annexure-VII

Self -Certificate of the Vernacular Translation

I Dr._____Presently employed in_____as_____and Principal Investigator for the protocol entitled "_____" here by certify that I am personally satisfied and have verified the translation and the back translation of the following documents:

Sr. No	Documents	Version/Date

Regards,

Sign of PI with designation (with date and stamp)

Annexure-VIII

Undertaking by IEC Member

I._____S/o D/o_____presently working as IEC member at _____hereby confirm that I have been introduced about the regulation regarding functioning of IEC and requirements expected of IEC member. I have been told about the current/SOP in place and received a copy of the same.

With regards,

Member's Name:

Designation:

Annexure-IX

Performa for Receipt of Updated SOP by IEC Member

I._____S/o D/o_____presently working as IEC member at _____ hereby confirm that I have been provided with Amended SOP and fully understood the same.

With regards,

Member's Name:

Designation:

Annexure X
IEC Assessment Report on Study Protocol

Protocol Number:

Protocol Title

Number of review	1st Review	2nd Review	3rd Review
Principal Investigator:			Department:
Date of Initial Review by IEC:		Date of Last Review:	
The IEC Decision recorded in the meeting minutes: (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**

Signature of the Member Secretary/ Chairperson:

Date:

Annexure XI

Submission of Final Report

1. Title of the Project:
2. Principal Investigator and Co-Investigators
3. Implementing Institution and other collaborating Institutions
4. Date of commencement
5. Duration
6. Date of completion
7. Objectives as approved
8. Deviation made from original objectives if any, while implementing theproject and reasons thereof.
9. Experimental work giving full details of experimental set up, methods adopted, data collected supported by necessary tables, charts, diagrams, and photographs.
10. Detailed analysis of results indicating contributions made towards increasing the state of knowledge in the subject.
11. Conclusions summarizing the achievements and indication of scope for future work.

(Principal Investigator) (Co-Investigator)

Annexure XII
ALL INDIA INSTITUTE OF MEDICAL SCIENCES, BATHINDA
INFORMED CONSENT FORM

Study Title_____
Study Number
Subject's Full Name
Date of Birth/Age
Address

1. I confirm that I have read and understood the information sheet dated___for the above study and have had the opportunity to ask questions.

OR I have been explained the nature of the study by the Investigator and had the opportunity to ask questions

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

3. I understand that the sponsor of the clinical trial/project, 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. However, I understand that my Identity will not be revealed in any information released to third parties or published.

4. 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) and does not reveal my identify or personal information without my permission.

5. I agree to take part in the above study

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:
Signatory's Name_____ Date
Signature of the Investigator_____ Date
Study Investigator's Name_____
Signature of the Witness_____ Date

Name of the Witness _____

ANNEXURE - XIII

Format for Participant Information Sheet

Study Title:

Principal Investigator's name:
Principal Investigator's title:
Principal Investigator's Telephone number:
Co-Investigator's Name:

You (For Children: Your Child; For unconscious participants and /or those unable to give consent (including fetuses): Your…….(state relationship is)….) is/are being invited to take part in a research study, before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP (doctor). Take time to ask questions – do not feel rushed or under pressure to make a quick decision.

- **Why is this study being done?**
- **Who is organizing and funding this study?**
- **Why am I being asked to take part?**
- **How will the study be carried out?**
- **What will happen to me if I agree to take part?**
- **What are the risks?**
- **Will it cost me anything to take part?**
- **Is the study confidential?**

Signature of Principal Investigator