Institutional Ethics Committee
Pt. B.D. Sharma Post Graduate Institute of Medical Sciences, UHS, Rohtak.

IEC SOP No: IEC-PGIMS SOP V3.0 26/June/2020

STANDARD OPERATING PROCEDURE (SOP) version 3.0 dated 26th June 2020

Complete Name of the Ethics Committee	:	Institutional Ethics Committee Pt. B.D. Sharma Post Graduate Institute of Medical Sciences, University of Health Sciences, Rohtak.
Complete address of the Ethics Committee	:	Office of Ethics Committee, Director office Pt. BD Sharma PGIMS, Rohtak, Haryana, India
Frequency of Ethics Committee Meeting	:	Once in three months; Expedited meeting is possible on as and when needed basis; Ethics Committee meeting can be held earlier if required or postponed if there is no new/amended protocol and if there is no specific agenda for the meeting.
Lead time required by the Ethics Committee before which they discuss documents submitted to them	:	10 days
Complete contact details of Ethics Committee member whose details will appear on the informed consent form	:	Dr. Savita Verma, Office of Ethics Committee, Director office Pt. BD Sharma PGIMS, Rohtak, Haryana, India +91-9812283746 msec.iecpgims@gmail.com
SOP effective date	:	1st July 2020

Author Name: Dr. Savita Verma (IEC Member Secretary) Dr. Aarti (IEC Member)	Sign and Date:  (26.06.2020)  (26.06.2020)
Approval Name: Dr. Yatish Agarwal (IEC Chairman)	Sign and Date:  (26.06.2020)

IEC-PGIMS SOP-V3.0

List of SOPs of Institutional Ethics Committee

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5	Exemption from the Ethical Review for Research Projects	V3/05
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16	Dealing with Research Participants Requests and Complaints	V3/16
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Chapter 1: Preparing Standard Operating Procedures (SOPs): Writing, Reviewing, Distributing and Amending SOPs For the Institutional Ethics Committee

Purpose:

These Standard Operating Procedures (SOPs) define the process for writing, reviewing, distributing, and amending SOPs of the Institutional Ethics Committee (IEC), Pt. B.D. Sharma Post Graduate Institute of Medical Sciences Rohtak.

Scope:

This SOP covers the procedures of writing, reviewing, distributing, and amending SOPs within Pt. B.D. Sharma Post Graduate Institute of Medical Sciences, Rohtak.

1.1 Responsibilities

It is the responsibility of Chairperson of the IEC to appoint a SOP team to formulate the SOP. SOP team drafts SOP, gets it reviewed and approved by the IEC members and amends it as and when required. All members of IEC will review the SOP and approval will be given by Chairperson of IEC. Then the SOP will be effective.

IEC office will:

- Co-ordinate activities of writing, reviewing, distributing, and amending SOPs.
- Maintain on file all current and past SOPs and the list of SOPs.
- Maintain a record of the investigators to whom SOPs are distributed against requisition.
- Ensure all IEC members and involved administrative staffs have access to the SOPs.
- Ensure the IEC members and involved staffs are working according to current version of SOPs.
- Assist in the formulation of SOP procedures.
- Ensure all the study is conducted in according to current version of SOPs.

SOP team

A team of members including the Member Secretary, administrative staff, and any other member of IEC as identified by the chairperson which oversees the creation, preparation, review, or revision of the designated IEC, Pt. B.D. Sharma Post Graduate Institute of Medical Sciences Rohtak SOP.

The Chairperson will constitute an SOP team consisting of the Member Secretary and one or more members of the IEC and/or the IEC office. The SOP team will carry out the subsequent steps.

- Assesses the request(s) for SOP revision in consultation with the IEC office and Chairperson.
- Proposes new/modified SOPs as and when required.
- Write down step by step all the procedures of the IEC.
- Organize, devise and, name each process.
- Make a list of SOPs with coding reference (IEC-PGIMS SOP-V3.0).

- Selects the format and coding system for SOPs.
- Drafts the SOP in consultation with the IEC members and involved administrative staff.
- Review of draft SOP by IEC.
- Submit the draft for approval to Chairperson.

Chairperson of the ethics committee:

- Appoints one or more SOP Teams.
- Reviews and approves the SOPs.
- Signs and dates the approved SOPs.

IEC members and involved administrative staff:

- Review, sign and date SOPs.
- Maintain a file of all SOPs received.
- Return all out of date SOPs to IEC office.

1.2 Detailed instructions

1.2.1 Identifying the need for new or amendment to SOP

Any member of the IEC, faculty members, or investigators, can make a request for revision or renewal of an inconsistency/discrepancy in the existing SOPs or requests to design new SOP.

If IEC members agree to the request, the Chairperson will appoint SOP team to revise/formulate the SOP. If IEC members do not agree to the request, no further action will be taken. The IEC member who made the request for modification of the SOP will be informed in writing by the Member Secretary about the decision.

1.2.2 List of relevant SOPs

The SOP team will:

- Write down step by step all the procedures of the IEC.
- Organize, devise and, name each process.
- Make a list of SOPs with coding reference (IEC-PGIMS SOP-V3.0).

1.2.3 Designing a format and layout

- Each SOP should be given a number and a title that is self-explanatory and is easily
- understood. Each SOP will be prepared according to the template for Standard Operating
- Procedures in AN2–V3/IEC-PGIMS SOP V3/01. Each page of the SOP will bear a header with the effective date. The SOP number will be on the left-hand corner of

the header while the left-hand corner of the footer will bear the title of the SOP and page number. A unique code number with the format IEC-PGIMS SOP Vy/xx will be assigned to each SOP by the Bioethics cell. xx will be a two-digit number assigned specifically to a SOP. "V" refers to version of the SOP and "y" will be a number identifying the version e.g. IEC-PGIMS SOPV3/01 is SOP number 01 with V=version no.6.

- Each Annexure (AN) will be given unique code number with the format ANn-Vp/IEC-PGIMS SOP Vy/xx. e.g. AN1–V3/IEC-PGIMS SOP V3/01 indicates AN is Annexure; n is Annexure no.1, 6 is version no. 6, belonging to the IEC-PGIMS SOP V3/01.
- Each Appendix (AP) will be given unique code number with the format APn/Vy e.g.
- AP1/V3indicates AP is Appendix, n is Appendix no 1, V3 is version no.6.
- The first page of SOP document will be signed and dated by the SOP team members, IEC Chairperson who has approved and accepted the SOPs. The SOP will be implemented within 2 weeks after acceptance by the Chairperson.

1.2.4 Review by consultation

- The draft SOP will be discussed with members of IEC, administrative staff and relevant faculty members.
- The final draft version will be forwarded to the Chairperson for review and approval by IEC.

1.2.5 Preparation and submission of final draft

- All the members of IEC will review the draft/revised SOP.
- During the IEC meeting, members can put forth their suggestions/comments on the draft/revised SOP.
- The suggestions agreed upon unanimously by all IEC members will be incorporated and the final draft SOP will be formulated.
- The SOP team would stand dissolved once the IEC takes final decision regarding the SOP.

1.2.6 Final Approval of new/revised SOP

- The final version of SOP duly approved by the IEC will be signed and accepted by the chairperson of the IEC.

1.2.7 Implementation, distribution, and filing all SOPs

- Approved SOPs will be implemented from the effective date and will be distributed to IEC members and IEC staff according to the distribution list (AN4-V3/IEC-PGIMS SOP V3/01).
- One complete original set of current SOPs will be archived in the SOP master file, by the IEC office and maintained in the IEC Office. Photocopies made from the

official paper versions of the SOP can be considered current or official, if stamped and signed by Member Secretary or authorized individual for distribution, a log of which should be maintained.

- SOPs are made available to all Investigators.

1.2.8 Management and archiving of superseded SOPs

Old SOPs should be retained and clearly marked "superseded" and archived in a file by the IEC office. The process of evolution of previous SOPs of the IEC will be documented in defined format (AN3-V3/IEC-PGIMS SOP V3/01).

AN2-V3/IEC-PGIMS SOP V3/01
Template for SOP

<table>
<tr><td colspan="2">Institutional Ethics Committee</td></tr>
<tr><td colspan="2">Title: Title which is self-explanatory and is easily understood
STANDARD OPERATING PROCEDURE (SOP)</td></tr>
<tr><td>SOP No.: IEC-PGIMS SOP 3.0/26/June/2020</td><td>Page : a of b</td></tr>
<tr><td colspan="2">Code: IEC-PGIMS SOP 3.0/26/June/2020</td></tr>
<tr><td colspan="2">Effective Date: 1st July 2020</td></tr>
<tr><td>Authors:

Dr. Savita Verma (IEC Member Secretary)

Dr. Aarti (IEC Member)</td><td>Sign and Date</td></tr>
<tr><td>Approved & Accepted by:

Dr. Yatish Agarwal (IEC Chairman)</td><td>Sign and Date</td></tr>
</table>

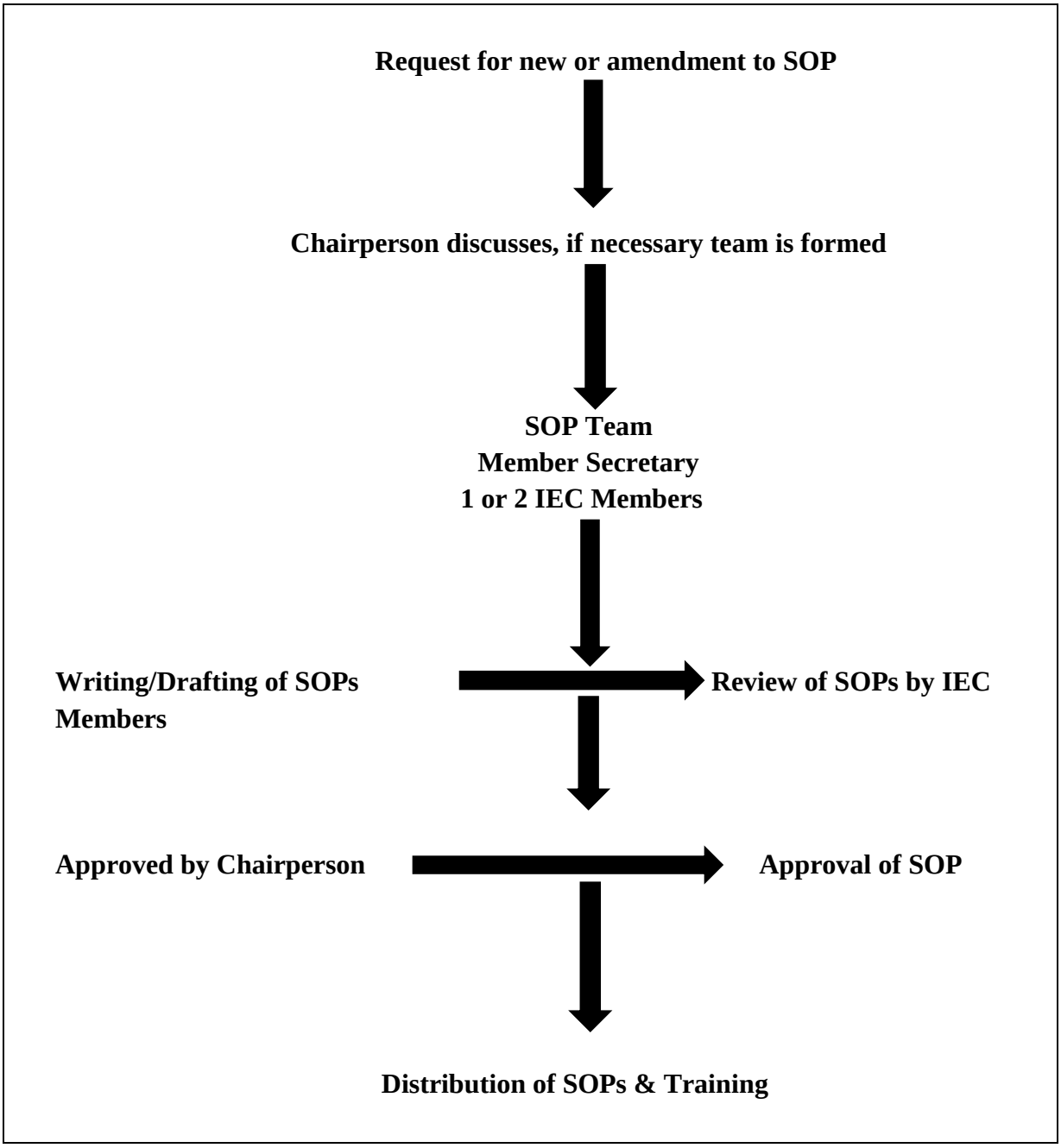
AN3–V3/IEC-PGIMS SOP V3/01
Document History of the SOPs

Name of the SOP	Version	Effective date (dd-mm-yy)

AN4–V3/IEC-PGIMS SOP V3/01
Log of the IEC Members Receiving Printed Copy of SOPs

No.	Name of recipients	Designation	SOP code number	No. of copies	Signature	Date
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						

FLOW CHART


Request for new or amendment to SOP
Chairperson discusses, if necessary team is formed
SOP Team
Member Secretary
1 or 2 IEC Members
Writing/Drafting of SOPs Members
Review of SOPs by IEC
Approved by Chairperson
Approval of SOP
Distribution of SOPs & Training

Chapter 2: Constitution of Institutional Ethics Committee

The IEC has been established to formalize and specify the Institution's commitment to promotion of high ethical standards in clinical research, and teaching. This SOP applies to the formation of the IEC. The Institutional Ethics Committee (IEC) is constituted by Vice Chancellor/ Director, Pt. B. D. Sharma University of Health sciences/ Pt. B.D. Sharma Post Graduate Institute of Medical Sciences, (UHS/PGIMS) Rohtak in accordance to the Gazette of India.

2.1 Mandate

- The IEC through its delegated sub-committee's functions independently for maintaining consistent ethical framework in research, and in the integration of ethical values into practice, policy relationships, and organizational activities.
- The purpose of IEC is to cultivate a pluralistic and democratic exchange of ethical values, concerns and to critically analyze them looking for opportunities to enhance the ethical integrity of the Institution.
- The mandate of IEC, Pt. B.D. Sharma Post Graduate Institute of Medical Sciences/ Pt. B. D. Sharma University of Health sciences, Rohtak essentially targets ethical aspects of research and education.

The terms of reference for the IEC are as follows:

- To ensure that all proposed research projects conform to standard national and international ethical guidelines and that dignity, right and wellbeing of research participants is protected.
- Continuing education in research bioethics and ethical aspects of clinical practice by seminars, workshops and interactive discussions for IEC members, investigators, study coordinators, research staff, and officials of IEC office.
- The committee does not address or interfere in matters of an administrative nature, nor does the committee function as a grievance cell for staff members.

2.2 Responsibility

IEC has responsibility within the institution with the following objectives:

- To ensure the competent review and evaluation of all ethical aspects of research projects received, to ensure compliance with the appropriate laws and safeguard welfare of participants.
- Continuing education and training programs to ensure that IEC members are qualified to perform their specific duties, by education of professional, administrative, and support staff about ethical issues and current ethical standards and guidelines.
- Creation, developing revising and implementing ethical guidelines (SOPs).

2.3 Ethical basis

- The committee consists of members who collectively have the qualifications and experience to review and evaluate the scientific, medical, ethical and legal aspects of a proposed research project/Clinical Trials.
- In collaborative research, the IEC recognizes that the protocol it approves has to be approved by national and/or institutional ethics committees prior to implementation/start of study.
- In evaluating protocols and ethical issues, the IEC is aware of the diversity of laws, cultures and practices governing research and medical practices in various countries around the world.
- The IEC also seeks to be informed, as appropriate, by national/other local ethics committees and researchers of the impact of the research it has approved.

The IEC is guided in its reflection, advice and decision by;

- The ethical principles expressed in WMA Declaration of Helsinki (Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, and finally amended by the 64th WMA General Assembly, Fortaleza, Brazil, October 2013).
- It makes further reference to the International Ethical Guidelines like. The Nuremburg Code (1945), the Belmont Report 1979, the CIOM International Ethical Guidelines for
- Biomedical Research Involving Human Subjects (Geneva 1993), European Convention on Human Rights and Biomedicine 1997, Standard and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (WHO 2011), International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use - Good Clinical Practice (ICH-GCP 2016).
- The IEC establishes its own Standard Operating Procedures taking recognition of Indian Good Clinical Practice Guidelines (2001) by Central Drugs Standard Control Organization (CDSCO) for clinical trials (and New Drugs and Clinical Trial Rules, 2019), National Ethical Guideline for Biomedical and Health Research Involving Human Participants by the Indian Council of Medical Research (ICMR 2017), National Ethical Guideline for Biomedical Research Involving Children (ICMR 2017), NABH Guidebook to standards for accreditation of Ethical Committees (1st ed., 2015) and Helsinki Declaration (Oct., 2015).
- The IEC seeks to fulfill the requirements for international assurances and is established and functions in accordance with the national law and regulations.

2.4 Composition

The Ethics Committee will be multidisciplinary and shall consist of not less than seven members and a maximum of 15 members. One among its members, who is from outside the Institute, shall be appointed as Chairperson, one member (faculty member of the Institute) as Member Secretary, and rest of the members shall be from Medical, Scientific, Non-medical and Non-scientific fields including clinical experts and

pharmacologist, persons of the community, a legal expert, a social worker/layperson/patient representative to represent different point of view. There shall be an appropriate balance of professional, ethical, legal, cultural, educational, and community interests with an equitable representation of all specialties and gender. The external members shall be in majority to ensure independence of the committee.
Members shall be conversant with the provisions of clinical trials and Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial participants. Members are expected to be aware of local, social and cultural norms, as this is the most important social control mechanism.

The composition of IEC, Pt. B.D. Sharma Post Graduate Institute of Medical Sciences/ Pt. B. D. Sharma University of Health sciences, Rohtak would be as follows:

1. Chairperson (Not affiliated to PGIMS)
2. Member Secretary (Affiliated to PGIMS)
3. One to two clinicians
4. Basic medical scientists
5. Pharmacologist(s).
6. At least one woman member;
7. One or two legal experts or retired judge or medico-legal expert
8. One social scientist/representative of non-governmental voluntary agency
9. One philosopher/ethicist/theologian
10. Lay person from the community

Criteria for selection of members:

- Members are selected on their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience in domain field and profile.
- Conflict of interest will be avoided when making appointments, but where unavoidable, there will be transparency with regard to such interests.
- The members representing medical scientist and clinicians should have postgraduate qualifications and adequate experience in their respective fields and be aware of their role and responsibilities as committee members.
- New members will be identified according to the requirement i.e. as per the composition specified in Section 2.5 of this SOP.

The following qualities are sought in IEC members:

- Interest and motivation
- Time and effort
- Commitment and availability
- Experience and education
- Respect for divergent opinions
- Integrity

2.5 Terms of appointment

2.5.1 Duration and renewal

- The IEC Members will be appointed by the Vice Chancellor/Director, UHS/PGIMS, Rohtak for a duration of 5 years. The Head of the Institute will issue letters of appointment to the Chairman, and Member Secretary and Director/Member Secretary can issue appointment letters to IEC members as per office order.
- The appointment procedure for membership will be followed so that it allows for continuity, the development and maintenance of expertise within the IEC, and the regular input of fresh ideas and approaches.
- The members can be continued and there is no limit on the number of times the membership is extended. Extension of membership will be decided by the Vice Chancellor/ Director, Pt. B.D. Sharma Post Graduate Institute of Medical Sciences/ Pt. B. D. Sharma University of Health sciences, (PGIMS/UHS) Rohtak
- Chairperson, Member Secretary and an IEC member may be appointed before the completion of the tenure of the existing appointed committee.

2.5.2 Conditions of appointment

- Name, gender, profession, and affiliation of IEC members will be publicized.
- Members must accept the appointment in writing.
- Submit CV (AN7-V3/IEC-PGIMS SOP V3/02).
- Members must apprise themselves of the relevant documents, codes, GCP, ICH guidelines and the ICMR code & IEC, PGIMS/UHS SOPs. Copies of these documents will be provided by the IEC office on written request.
- An investigator can be a member of the IEC; however, the investigator-as-member cannot participate in the review and approval process for any project in which the member is PI, Co-PI or has any other potential conflict of interest.
- The designated member of the IEC who accepts the membership should sign the Conflict of interest, if any, must be disclosed (AN5-V3/IEC-PGIMS SOP V3/02) and the Confidentiality Document (AN1-V5/IEC-PGIMS SOP V3/02).

2.5.3 Resignation/replacement procedure

- If a regular member resigns, or ceases to be a member due to disqualification, or death, a new member will be appointed for the remaining term as per the Conditions of appointment stated above.
- IEC member who decides to resign should send a written notification of resignation to the Vice Chancellor/Director, UHS/PGIMS Rohtak.
- Vice Chancellor/Director, UHS/PGIMS, Rohtak would appoint a new member, falling in the same category of membership (ex. NGO representative with NGO representative).

- Similarly, if internal faculty member proceeds on leave for more than 6 months, the Vice Chancellor/Director, UHS/PGIMS Rohtak may replace with another faculty member.

2.5.4 Termination/Disqualification procedure

A member may be relieved or terminated of membership in case of:

- Conduct unbecoming for a member of the Ethics Committee.
- If a member fails to attend more than 3 consecutive meetings of IEC, the matter shall be reviewed by the IEC. If deemed necessary, the IEC may decide to terminate the membership and recommend to the Vice Chancellor/Director, UHS/PGIMS Rohtak through the Chairperson IEC for necessary replacement.
- In all such situations/circumstances, Vice Chancellor/Director, UHS/PGIMS Rohtak/Member Secretary, IEC, will send a letter of termination to the member. Documentation of the termination will be recorded in the meeting minutes of the next IEC meeting and IEC membership circular will be revised.

2.6 Independent consultants

- The IEC may call upon, or establish a standing list of, independent consultants/ experts
- who may provide special expertise to the IEC on proposed research protocols, when the
- Chairperson or the IEC members determine that a study will involve procedures or information that is not within the area of expertise of the IEC members.
- These consultants may be specialists in ethical or legal aspects, specific diseases or methodologies, (e.g. genetic disorders, stem cell research etc.) or they may be representatives of communities, patients, or special interest groups.
- These consultants must sign the Confidentiality Document (AN2-V3/IEC-PGIMS SOP V3/02) regarding meeting, deliberations, and related matters.
- These consultants or subject experts cannot vote for decision. They may attend the IEC meeting as special invitee as per the requirement for the research protocol only.

2.7 Office bearers

The IEC will have the following office bearers who have the expertise and professional qualifications to review the submitted documents.

2.7.1 Chairperson

The IEC Chairperson should be from outside the institution, capable of managing the IEC and the matters brought before it with fairness and impartiality. He/she should not be a former faculty member of PGIMS, Rohtak. The task of making the IEC a respected part of the institutional community will fall primarily on the shoulders of this individual. The IEC must be perceived to be fair and impartial, immune from pressure either by the institution's administration, the investigators whose protocols are brought before it, or other professional and nonprofessional sources.

The Chairperson will conduct all meetings of the IEC. If the chairperson is not available for reasons beyond control, then his/her designee will act as alternate Chairperson. In case, designee is not available, then an alternate Chairperson will be elected by the members present from among themselves.

2.7.2 Member Secretary (MS)

The Member Secretary will be a staff member of institute, responsible for coordinating and managing the activities of the committee including scheduling the meetings, describing the agenda and ensuring that the function of the committee is conducted as per the norms and policies described in this SOP.

In absence of Member Secretary of IEC, a PGIMS member of IEC may perform the function of the Member Secretary if necessary. In case of conflict of interest of MS, a PGIMS member of IEC may act as acting member secretary.

2.7.3 IEC office

IEC office is composed of In-charge IEC office (Member Secretary, IEC) and the administrative supporting staff. The supporting staff consists of staff members of the PGIMS appointed by the Vice Chancellor/Director, UHS/PGIMS Rohtak or contractual staff approved by the Vice Chancellor/Director, UHS/PGIMS Rohtak.

The IEC office shall have the following functions:

- SOP operations.
- Organizing an effective and efficient tracking procedure for each proposal received.
- Preparation, maintenance and distribution of study files.
- Organizing IEC meetings.
- Preparation of agenda and minutes of the meetings.
- Maintaining IEC documentation and archive.
- To receive IEC processing fees as prescribed by the institute time to time and issue official receipts for the same.
- Communicating with IEC members and principal investigators (PIs).
- Providing necessary administrative support for IEC related activities to the Member Secretary, IEC.
- Arrangement of training for personnel and IEC members.
- The IEC may conduct workshops from time to time for institutional faculty members.

2.8 Roles and responsibilities of the IEC members

The Committee's primary responsibilities will be protection of safety, rights, dignity and confidentiality of the research participants.

- Review and discuss research proposals submitted for evaluation.
- Review progress reports and monitor ongoing studies.
- Monitor SAEs and recommend appropriate action(s).
- Maintain confidentiality of the documents and deliberations of the IEC meetings.
- Declare conflict of interest, if any.
- To carry out work delegated by Chairperson and Member Secretary.
- To participate in continuing education activities in biomedical ethics and research.

- To provide information and documents related to training obtained in biomedical ethics and research to the IEC office.

2.9 Quorum requirements

For review of each protocol the quorum of Ethics Committee shall be at least five members with the following representation:

1. Basic medical scientist (preferably one pharmacologist)
2. Clinician
3. Legal expert.
4. Social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person
5. Lay person from community

2.10 Decision making

- Decision is arrived at by consensus. In exceptional case, if consensus not possible, voting is carried out.
- Opinions of absent members that are transmitted by email or telephone or fax may be considered by the attending members during discussion but may not be counted as votes or quorum for formally convened full board meetings.
- Any committee member with a conflicting interest in a proposal will abstain from deliberations and in decision making process on that proposal, except to provide information as requested by the committee. Such abstentions will be recorded in the minutes.
- In case of a tie the chairperson will have a casting vote.

2.11 Education and training for IEC members

- IEC members should become conversant with all national and international ethics guidelines like, Indian GCP Guidelines by CDSCO, National Ethical Guideline for Biomedical and Health Research Involving Human Participants and National Ethical
- Guideline for Biomedical Research Involving Children by ICMR, Standard and Operational Guidance for Ethics Review of Health-Related Research with Human Participants by WHO, ICH-GCP guidelines.
- The institute shall support participation of IEC members in bioethics workshop/conference once a year, for capacity building. The request should be recommended by Chairperson, IEC.

2.12 IEC subcommittees

Subcommittees of IEC may be formed as when required for expedited review of new or revised proposal where major changes are not required and SAE reporting. The decisions of all the subcommittees will be reported to the next meeting of IEC by the Member Secretary.

2.12.1 Expedite review committee

It will consist of the Member secretary and two/three members designated by the chairperson. The subcommittees should report to the main IEC. The approval granted through expedited review must be ratified at the next Full committee meeting.

2.12.2 SAE subcommittee

The subcommittee will consist of the Member Secretary, one senior faculty member of the Institute (Chairman of SAE subcommittee) and 1-2 other members of the IEC. At least one member should be from outside the Institute.

The SAE subcommittee will review SAE reports with assessment of causality, compensation and regulatory compliance. The decisions of the SAE subcommittee must be approved at the next Full committee meeting.

AN1/IEC-PGIMS SOP V3/02

Confidentiality and Conflict of Interest Document for IEC Members

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

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

Whereas, the IEC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects; the undersigned, as a member of the IEC is expected to meet the same high standards of ethical behavior to carry out its mandate.

That, the Undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. All Confidential information (and any copies and notes thereof) shall not be copied and retained by member, and remain the sole property of the IEC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement.

Conflict of Interest

It has been recognized that the potential for conflict of interest will always exist but I have faith in the IEC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human participants.

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

I will disclose to the Chairperson of the IEC any actual or potential conflict of interest that I may have in relation to any particular proposal submitted for review by the committee, and abstain from participation in discussions or recommendations in respect of such proposals.

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

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment.

- If an applicant submitting a protocol identifies a potential conflict of interest with the undersigned, then the investigator may request in writing to the Chairman; and the undersigned may be excluded from the review of the project.

In the course of my activities as a member of the IEC, I may be provided with confidential information and documentation ("Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the access to it, as per the right to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any agenda items) to the IEC office upon termination of my functions as a Committee member.
Whenever I have a conflict of interest, I shall immediately inform the committee not to count me toward a quorum for consensus or voting.
I, …….... have read and I accept the aforementioned terms and conditions as explained in this Agreement.

Signature: _____

Name:_____

Date: _____

AN2-V3/IEC-PGIMS SOP V3/02

Confidentiality Document Form for Independent Consultants

I,……
……...(name and designation) as a non-member of IEC understand that the copy (ies) given to me by the IEC is (are) confidential. I shall use the information only for the indicated purpose as described to the IEC and shall not duplicate, give or distribute these documents to any person(s) without permission from the IEC.
Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as confidential.

Signature_____

Name_____

Date: _____

AN3-V3/IEC-PGIMS SOP V3/02
Invitation to Attend a Meeting as Independent Consultant

To,

_____
_____
_____

Sub: Invitation to attend Institutional Ethics Committee meeting

Sir/Madam,

The Chairman IEC has nominated you as an independent consultant/observer to evaluate a research protocol submitted to the Institutional Ethics Committee for approval.
You are requested to attend the meeting of IEC on …….at…….and to provide written opinion regarding the assigned research proposal (IEC code no ……. and title of project…….). You will not have any voting right during the meeting and you will have to sign confidentiality document, which is enclosed for your kind perusal.

Kindly note that all the documents submitted to you are confidential. These should not be disclosed to anyone and should be returned to the IEC office, PGIMS/UHS, Rohtak after the meeting.

Yours faithfully,

Signature of the Member Secretary _____ Date _____

Name of the Member Secretary _____

Enclosures:
1. Research protocol
2. Confidentiality document

AN4-V3/IEC-PGIMS SOP V3/02
Invitation to Attend a Meeting as Observer

To,
_____
_____
_____

Sub: Invitation to attend Institutional Ethics Committee meeting

Sir/Madam,

The Chairman IEC has invited you as an independent observer to see functioning of the Institutional Ethics Committee meeting.
You are requested to attend the meeting of IEC on …….at…….
You will not have any voting right during the meeting and you will have to sign confidentiality document, which is enclosed for your kind perusal.

Yours faithfully,

Signature of the Member Secretary _____ Date _____

Name of the Member Secretary _____

Enclosures:
1. Confidentiality document

AN5-V3/IEC-PGIMS SOP V3/02
Confidentiality Document Form for Observer Attendees to IEC, PGIMS Meetings

I,…… (name and designation) understand that I am invited to attend the IEC meeting scheduled on…….at……..am/pm as an Observer. In the course of the meeting of the IEC some confidential information may be disclosed or discussed. Upon signing this form, I ensure to take reasonable measures to keep the information and discussion as confidential.

Signature_____

Name_____

Date: _____

AN6-V3/IEC-PGIMS SOP V3/02

Confidentiality Document Form for Non-members Requesting Copies of IEC/Documents

I,……,..,., as a non-member of IEC, understand that the copy (ies) given to me by the IEC is (are) confidential. I shall use the information only for the indicated purpose as described to the IEC and shall not duplicate, give or distribute these documents to any person(s) without permission from the IEC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential. I have received copies of the following IEC documents:

……
……
……
……

_____

Signature of the recipient

Name……

Designation and address

Date…….

AN7-V3/IEC-PGIMS SOP V3/02
List of Members of Institutional Ethics Committee

Sr. No.	Name	Affiliation	Roles
1	Dr. Yatish Agarwal	Not Affiliated with Institution	Chairman
2	Dr. Savita Verma	Affiliated with Institution	Member Secretary/ Basic Medical Scientist
3	Dr. Sunita Siwach	Not Affiliated with Institution	Scientific Member
4	Dr. Alpana Raizada	Not Affiliated with Institution	Scientific Member
5	Mr. Yogender Rathee	Not Affiliated with Institution	Legal Expert
6	Prof. K.S. Sangwan	Not Affiliated with Institution	Social Scientist
7.	Dr. Pradeep Garg	Affiliated with Institution	Scientific Member
8.	Dr. Harpreet Singh	Affiliated with Institution	Scientific Member
9.	Dr. Sumit Sachdeva	Affiliated with Institution	Scientific Member
10.	Dr. Reetu Hooda	Affiliated with Institution	Scientific Member
11.	Dr. Raj Singh	Affiliated with Institution	Scientific Member
12.	Dr. Kapil Bhalla	Affiliated with Institution	Scientific Member
13.	Dr. Aarti	Affiliated with Institution	Scientific Member
14.	Mrs N Sankareswari	Not Affiliated with Institution	Lay Person

AN8-V3/IEC-PGIMS SOP V3/02
Conflict of Interest Declaration for IEC Members

(During IEC meeting)

To,

The Chairperson
Institutional Ethics Committee
PGIMS, Rohtak
IEC Meeting Number: _____

Conflict of Interest

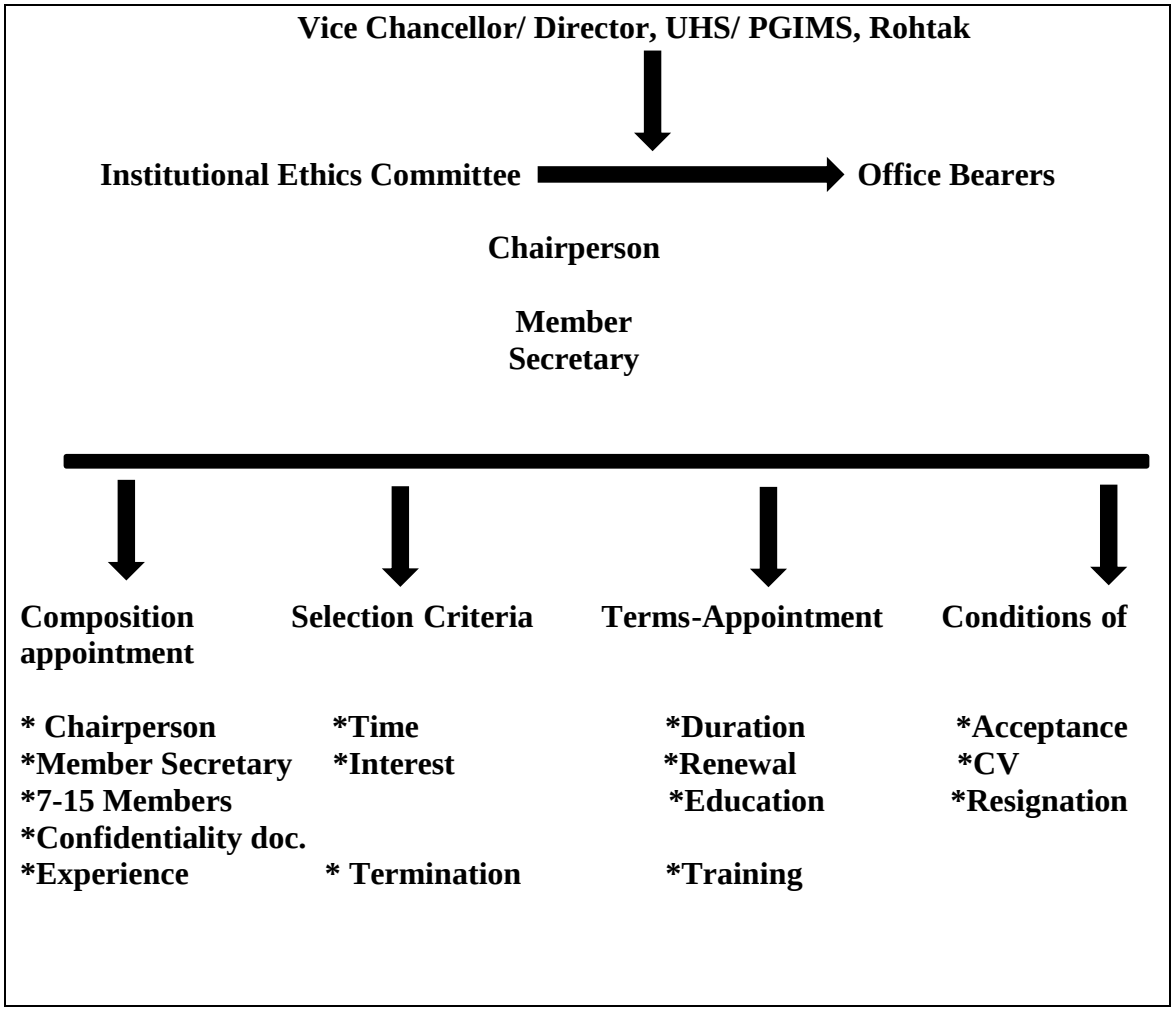
I hereby declare that I have conflict of interest in the following Agenda:
1.
2.
3.
4.

_____
Signature of member

Name_____

Date_____

Flow Chart


Vice Chancellor/ Director, UHS/ PGIMS, Rohtak
Institutional Ethics Committee
Office Bearers
Chairperson
Member Secretary
Composition appointment
Selection Criteria
Terms-Appointment
Conditions of
* Chairperson
*Member Secretary
*7-15 Members
*Confidentiality doc.
*Experience
*Time
*Interest
* Termination
*Duration
*Renewal
*Education
*Training
*Acceptance
*CV
*Resignation

Chapter 3: Management of Protocol Submissions

This SOP is designed to describe and act as a guideline for the IEC office of the IEC to manage research protocol submissions.

3.1 Type of Protocols

The type of protocols includes:

I. Submission of protocols for initial review.
II. Resubmission of protocols with modifications.
III. Protocol amendments and any other amendments.
IV. Continuing review of approved protocols.
V. Protocol completion/termination.

3.2 Detailed Process

It is the responsibility of the IEC office to receive, record and distribute the protocols for review by the IEC and communicate the decisions to PI in a prescribed format.

3.2.1 Receiving protocols

The PI can submit research proposal to the IEC for review and approval under any of the 5 sections mentioned above (see section 3.1).

3.2.2 IEC office

The IEC office will:

- Check the application documents to ensure that all required forms and documents are submitted as per checklist (AN5-V3/IEC-PGIMS SOP V3/03). Refer to **Table 3.1 (section 3.2.3)** which should include**:**
    - Original Application form/Project submission form (AN1-V3/ IEC-PGIMS SOP V3/03)
    - Study protocol
    - Case Record Form
    - Other documents necessary for initial review (AN2 to5-V3/IEC-PGIMS SOP V3/03)
- Check completeness of necessary information and signature at all appropriate places in the application form submitted for initial review.
- Notify the applicants, if incomplete.
- State clearly the missing documents in the document receipt Form (AN5-V3/IEC-PGIMS SOP V3/03).
- Stamp, sign and put date of receipt on the cover letter confirming receipt of the documents.

- Return one copy of the document receipt form (AN5-V3/IEC-PGIMS SOP V3/03) to the applicant for their records
- Count number of copies (Initially 2 hard copies and one soft copy accepted by email/CD/pen drive).
- Store the hard copies and soft copy of the research project. The hard copies will be archived in the office of the IEC office and soft copy will be saved on IEC office computer and external hard disc drive/CD.
- The project file is uniquely numbered as "A-x-y-z" where "A" will indicate years, e.g. 2012 "x" is abbreviation for serial no. of project, "y" will be type of project such as EMP for extramural, IM for intramural, IP for independent, MD for MD thesis, DT for drug trial and so on, "z" will denote IEC meeting number.
- All correspondence for the project, should quote the complete project number assigned to it.

3.2.3 Table 3.1 Documents to be submitted for Initial review

Sr. No.	Document	Annexure	Remarks
1	Original Application form/Project submission form	AN1-V3/IEC-PGIMS SOP 03/V3	Attach copy of protocol and case report form
2	Undertaking by PI		
3	Conflict of Interest Declaration by PI	AN4-V3/ IEC-PGIMS SOP 03/V3	
4	Recent signed and dated curriculum vitae (CV) of Investigator or student		
5	Participant/volunteer/control/child information documents, consent forms [legally accepted guardian in case of patient incapable of giving consent e.g. unconscious, mentally deranged and parent consent forms if participant is a child/ adolescent between 7–18 years of age] and assent form (child 7-18 yrs)		English and Hindi and any other language if necessary
6	Investigator Brochure and advertisement /information brochure for drug/device trials		
7	CTRI (Clinical Trial Registry of India) registration		Prerequisite for sponsored clinical trials. In other trials,

			it can be done after IEC approval
8	DCGI approval letter with list of approved Institutes		For sponsored drug/device trials.
9	Details of funding agency/sponsors and fund allocation (patient care/staff /contingency /travel etc.)		In project submission form and CTA
10	Clinical Trial Agreement (CTA)		For drug/device trials
11	Insurance policy and certificate		For drug/device trials
12	For international export/import of Biological materials: Material Transfer Agreement (MTA) and Health Ministry's screening committee (HMSC) clearance		In collaborative projects. Copy of HMSC clearance should be submitted to IEC before start of study
13	For export of study samples: Director General Foreign and Trade (DGFAT) approval		In clinical trials
14	Clinical trials with stem cells*		
15	Recombinant DNA/Gene therapy: DST-GEAC (Genetic Engineering Advisory Committee) approval		
16	Study involving radioisotopes/ionizing radiations: Bhabha Atomic Research Centre (BARC) approval		
17	Decision of other concerned Ethics Committees		In collaborative studies
18	IEC Processing Fees		As per IEC SOP
19	Any other MOU/Agreement in International collaboration		
20	Any other document		

• Please see guidelines for device based studies in Appendices (AP17/V5).

In investigator initiated drug trials for academic purposes: the trial can be approved by the IEC and information sent to DCGI (as per recent guidelines)

* All clinical trials with any stem cells shall have prior approval of Institutional Committee for Stem Cell Research and Therapy (IC-SCRT).

3.3 Informed consent process

For biomedical and health research involving human participants, the investigator must obtain voluntary written informed consent of the prospective participant. It is based on the principle that competent individuals are entitled to choose freely whether to participate in research or not. Informed consent is a process that provides opportunity to the individual to accept or refuse to participate in the study. It protects the individual's freedom of choice and respects the individual's autonomy.

Table 3.2 Essential elements of an informed consent document

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 clinical trial, free medical management shall be given as long as required or 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 rule 39, 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 can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled.
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 without his 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 continue participation will be provided.

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

(f) Approximate number of Subjects enrolled in the study.

2. Format of informed consent form for Subjects participating in a clinical trial –

Informed Consent form to participate in a clinical trial
Study Title:
Study Number:
Subject's Initials: _____ Subject's Name: _____
Date of Birth/Age: _____
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 my medical care or legal rights being affected.

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

IV. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific 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.

3.4 Information of change in funding agency/status of approved project:

If there is change in funding status/agency of approved project; PI should inform same to IEC through the IEC office stating the title of project, IEC code and date of approval and PI should also state that there are no changes in title, design, methodology. The IEC office will notify to the IEC and PI will be given fresh approval letter for administrative purpose (if requested by PI).

3.5 Resubmission of protocols with corrections as per IEC suggestions

- For minor corrections as per the suggestions of the IEC, the PI will submit cover letter stating the changes along with one copy of the amended Protocol and related documents with clearly highlighted/demarcated sections which have undergone correction.
- For resubmitted/major changes in the protocol, the PI will submit 3 copies of the amended
- Protocol and related documents along with justification for amendment, and clearly highlighted/demarcated sections which have undergone amendment.
- When the protocol has been revised and is being submitted for review as a new study, the PI will submit 6 copies with related documents as per the checklist for initial review.
- The IEC office will verify the completeness and confirm that the copy contains the modification highlighted with respect to the earlier protocol.
- The IEC office will perform the steps 3.2.2 as mentioned in initial review application.

3.6 Research protocol amendments and other study related documents

- The PI will submit 6 copies of the protocol amendments or any other study related documents to the IEC office.
- DCGI approval letter is required for amended protocol in drug/device trials.
- The PI must highlight the modification/s in the amendment, along with a summary of changes and whether these changes would entail changes in the ICF. If yes, details of changes should be summarized.
- The Member Secretary in consultation with Chairperson will decide whether to:

a) Carry out an expedited review
b) Table for discussion at the full board meeting

This process is further elaborated in IEC-PGIMS SOP V3/06.

3.7 Annual continuing reviews of approved protocols

The IEC office will:

- Send reminders for annual report to Individual PI, 15 days prior to the expiry date of approval, which usually is one year from the date of approval letter
- The IEC office will receive 6 copies of Annual Study/Continuing Review Report/ progress report/request letter for extension of approval and related documents of the project in the prescribed format (as per IEC-PGIMS SOP V3/08) for each approved protocol.
- The IEC office will verify for completeness of the documents and sign and date the documents. These will be tabled in the next full board meeting of IEC.

3.8 Project completion

- It is the responsibility of the PI to submit the final report within 6 months of completion of the project along with a copy of abstract/publication.
- The IEC office will receive 6 copies of Study Completion Report in the prescribed format (as per IEC-PGIMS SOP V3/11).
- The IEC office will send reminders for completion report to PI, 15 days prior to the date of completion.
- The IEC office will verify the completeness of the Study Completion Report Form (IEC-PGIMS SOP V3/11) filled by the PI and the study completion report will be tabled in the next full board meeting of IEC.

3.9 Clinical Trial Agreement (CTA) or Other Agreement for Sponsored Drug/ Device/ Collaborative Trials/ Study

After the approval from IEC, the sponsor/ principal investigator (PI) will submit the duly signed copies by the sponsor/ CRO of CTA/ other agreement on Rs. 100 quasi-judicial stamp papers (three copies) to the institute with counter signature by PI, for signature of the Director, PGIMS.

CTA/ other agreement and indemnity will safeguard the interest and right of the research participant, investigator and institute.
The drug trial shall be started by the PI after the agreement is signed by all the parties. Also, DCGI and other required regulatory approvals should be obtained for the concerned trial, and copy of the same should be submitted to IEC office before starting the trial.
After signature of the CTA, a copy of the duly signed CTA should be submitted to the IEC office before starting the trial.

Material transfer agreement (MTA): For any study, where there is exchange of biological samples, by import or export from abroad, there has to be an MTA as per ICMR format; and it should be submitted along with the study protocol to the IEC. After the approval from IEC, PI has to obtain endorsement from HSMC, ICMR before starting the study.

3.10 Charges

Ethics Committee will charge fee for review of applications, documents & safety review. The non-refundable fees for reviewing various categories of research study proposals in INR (Indian National Rupees) are mentioned below.

Sr. No.	Category of Review	Pharma industry sponsored Research	Govt. sponsored/ NGO Research
1.	New study protocol	50,000 INR	10,000 INR
2.	Protocol Amendment (per amendment review) (if applicable)	10,000 INR	-
3.	Archival Charges	50,000 INR	-

(Note: Charges may be revised in every 3 years after discussion in the full board Ethics Committee meeting)

3.11 Reporting of SAE/protocol violation/protocol amendment is detailed in chapter 7, 9 And 10.

3.12 Site Monitoring procedures are detailed in Chapter 17 (IEC-PGIMS SOP V3/17).

AN1-V3/IEC-PGIMS SOP V3/03
Project Submission Form for Review by IEC
(02 copies and 01 softcopy required**)**

To be filled by IEC Office:

Project ID: _____ Date of Submission of completed form: _____

A. Identification:

Project Title:				
Principal Investigator (PI)		**Department and designation**	**Tel. no./E-mail**	**Signature**
Co-I/ Collaborator*/Student*				
1				
2				
3				
Project funded	**☐No** **☐Yes**	**Funding Agency:** **☐Intramural** **☐Extramural** **☐Clinical Trial**	**Sponsor/CRO/Funding agency:** **…….** **Budget:** **…….**	
Student project	**☐No** **☐Yes**	**MD ☐ DM ☐ MCh ☐ PhD ☐ SRF ☐**		
Collaborative	**☐No**	**☐National**	**Name of Institute/'s:**	

	☐**Yes**	☐**International**	
Study Duration			

B. Project Details

I. Study Design	☐Interventional ☐ Others …….. ☐Observational		☐Single Centre ☐Multicentre
II. Participants			
1. From AHI* Controls Patients	Numbers ……..... …….....	Source …… ……	Total (if multicentre) …… …… …… ……
2. Gender	☐Both ☐Males only ☐Females only		
3. Clearly defined inclusion/ exclusion criteria:☐Yes ☐No			
4. Vulnerable subjects	☐No ☐Yes	☐Pregnancy ☐Children ☐Elderly ☐Illiterate ☐Handicapped ☐Terminally/seriously ill ☐Mentally challenged ☐Economically/socially backward ☐Others	
5. Special group subjects:	☐No ☐Yes	☐Captives ☐Employees ☐Students ☐Nurses ☐Armed Forces ☐Healthcare workers ☐Any other	
6. Advertising for recruitment of subjects	☐No ☐Yes	If yes, please attach copies of posters, flyers, brochures, websites etc.	
III. Specimen collection	☐No ☐Yes	If yes, complete AN2-V3/IEC-PGIMS SOP V3/03	
IV. Interventional Study	☐No	If yes, complete AN3-V3/IEC-PGIMS SOP V3/03	

<table>
<tr><td></td><td colspan="2">☐Yes</td></tr>
<tr><td>V. Risk and Benefits</td><td colspan="2">a. Does this study qualify for;☐ Minimal risk'*
☐ More than minimum risk
☐ High risk

b. Is there benefit a) to the subject? ☐Yes ☐No; ☐Direct ☐Indirect
b) to the society? ☐Yes ☐No

c. Is the risk commensurate to the benefits to be accrued by the subjects/ community/country? ☐Yes ☐No</td></tr>
<tr><td>VI. Privacy and Confidentiality</td><td colspan="2">Study Involves: ☐Direct Identifier (Subject identified by name/ Cr. No) ☐ Indirect identifiers (Patient identified by study ID) ☐ Completely Anonymized (Subject cannot be identified)

Confidential handling of data by staff:☐Yes ☐No</td></tr>
<tr><td rowspan="5">VII. Informed Consent Documents:a. Participant Information Document (PID)*
b. Informed Consent Forms (ICF's)</td><td colspan="2">☐ None (Waiver of consent form)</td></tr>
<tr><td>☐Written
☐Verbal
☐Audiovisual</td><td>Language: ☐Hindi ☐English ☐Others
-Study includes children: ☐Yes ☐No
If yes, Age group …….</td></tr>
<tr><td colspan="2">PID and ICF for: ☐Patient ☐Controls/volunteers ☐Parents/LAR
LAR-Legally acceptable/authorized representative/guardian</td></tr>
<tr><td colspan="2">PID and Assent form (children 7-18yrs): ☐Child</td></tr>
<tr><td colspan="2">Consent will be taken by: ☐PI/Co-PI ☐Nurse ☐Counselor
☐Research Staff ☐Student ☐Any Other</td></tr>
<tr><td colspan="3">VIII. Archival of records by EC office for more than 3years (5years for clinical trials) after termination/completion of study: ☐Yes ☐No

If yes, for how many years……
Reasons for Archival ……</td></tr>
</table>

C. Identify the ethical Issues (if any) related with the study:

……
……
……
……

D. Brief proposal summary

Aim(s) and objectives, methodology describing the potential risks and benefits, outcome measures (maximum 500 words).

_____

Signature of PI
Name_____ Date_____

AN2-V3/IEC-PGIMS SOP V3/03
Specimen collection

1. Type	Nature	Amount	Frequency	Total amount	Comment

2. Collection of fetal tissue or abortus: ☐No ☐Yes
Specify……

3**. Use of pre-existing/stored/left over samples: ☐No ☐Yes**
Provide details……
……
……

4. Proper disposal of material: ☐Yes ☐No

5. Storage for banking/future research: ☐Yes ☐No

6. Will any sample collected from the patients be sent abroad? ☐Yes ☐No
If yes, give details and address of collaborators:
_____
_____

Sample will be sent abroad because: ☐Facility not available in India
☐Facility in India is inaccessible
☐Facility available but not being accessed
If so, reasons_____
Has necessary clearance been obtained: ☐Yes ☐No

AN3-V3/IEC-PGIMS SOP V3/03
For Interventional studies only

1. Study involves use of: ☐Drugs* ☐Devices* ☐Vaccines* ☐Radiopharmaceutical ☐Recombinant DNA/Gene therapy ☐Stem cell ☐Indian/Alternate system of Medicine ☐Any other …….

*(need approval from *DCGI; BARC for radioactive substances and from DBT for gene therapy. Research in alternate system of medicine in accordance to AYUSH-GCP guidelines)*

2. Is it approved and marketed in: ☐India ☐UK & Europe ☐USA ☐Other Countries

Approved Indication, specify…….

3. Is it an Investigational New Drug? ☐Yes ☐No.

If yes:

a. Investigator's Brochure enclosed ☐Yes ☐No

b. Preclinical studies data available (If yes, provide summary ☐Yes ☐No

c. Clinical studies data available (If yes, provide summary ☐Yes ☐No

d. Clinical study in Phase: ☐I ☐II ☐III ☐IV☐NA

e. DCGI's permission obtained: ☐Yes ☐No, **if yes,** copy of letter enclosed ☐Yes ☐No

4. If phase I-III will the drug/device provided free? ☐Yes ☐No

If phase IV will drug/device provided at cost less than Hospital pharmacy? ☐Yes ☐No

5. Data monitoring

a. Is there plan for reporting of adverse events? ☐Yes ☐No

If yes, reporting will be done to: ☐Sponsor ☐IEC ☐DCGI

b. Is there a plan for interim analysis of data? ☐Yes ☐No

Mention Date Monitoring Plan

……

…….

6. **Provision for travel/treatment due to injury from study funds:** ☐Yes ☐No

If yes, by: ☐Sponsor ☐Investigator ☐Insurance Company ☐Any Other

7. Registered with Clinical Trial Registry – India: ☐Yes ☐No

If yes, copy of certificate enclosed: ☐Yes ☐No

Instructions/ Notes:

1. Submit six copies and one C.D of form and all documents as per checklist.
2. Submit detailed Study/Project Protocol (Short review of literature, justification for study, aim, methodology, inclusion, exclusion criteria, statistical analysis).
3. Submit case report form
4. Submit a page of recent, signed and dated curriculum vitae for **PI or investigator outside PGIMS** or of the **student (MD/MS/DM/MCh/PhD)** who has submitted thesis/project.
5. Mention sample size calculation in protocol
6. Mention source of controls/healthy volunteers.
7. PID should be in simple language avoiding technical terms
8. 'More than minimal risk': *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than

those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (US-FDA 2014).

9. Consider the following while framing Participant Information Sheet/Document (PIS/PID):

• Understandable language • Purpose and procedures
• Alternatives to participation• Risks & discomforts
• Statement that study involves • Consent for future use of biological research sample
• Confidentiality of records • Benefits if any in future
• Sponsor of study • Right to withdraw
• Contact information • Free supply of drug, as applicable
• Statement that consent is voluntary • Compensation for study related injury

AN4-V3/IEC-PGIMS SOP V3/03

Conflict of Interest Declaration by PI

To,
The Member Secretary
Institutional Ethics Committee
PGIMS, Rohtak.

Project entitled: …….

Name of PI:

Conflict of Interest

[ ] I hereby declare that I have no conflict of interest in my project.
[ ] I have following conflict of interest:

_____
Signature of PI
Name_____ Date_____

AN5-V3/IEC-PGIMS SOP V3/03

Receipt and Checklist of Submitted Documents to IEC office for Review (02 copies and a softcopy of all documents listed below)

(Non-Interventional trial require documents listed in Item no. 1 to 11,22,23 and 24)

Please give page no. to all documents (start from 1, 2, 3…….40 and so on,)
****Please provide version no. and date of each document* (for drug/device trial*)***

Type of Submission: New ( ) **Revised ( )**
Protocol Title:
Principal Investigator:
Type of document: Intramural/extramural/student project/investigator initiated/drug trial

As per **Table 3.1, Section 3.2.3** in SOP

Item No.	Mandatory Documents (*with version and date)	Yes	No	NA	PageNo.
1	Project Submission Form (AN1-V3/IEC-PGIMS SOP V3/03)				
2	Study Protocol				
3	Case Report Form (form to enter data)				
4	Undertaking by the PI				
5	Conflict of Interest Statement by PI (AN4-V3/IEC-PGIMS SOP V3/03)				
6	CV of investigator outside PGIMS or of the student				
7	Participant Information document (PID) and consentforms CF) in English and Hindi (and if required in anyother language)				

8	Child Information Document and assent form in English and Hindi (and if required in any other language				
9	Ethics Committee clearance of other centers				
10	Clinical Trials Registry- India(CTRI)				
11	Investigator Brochure				
12	Advertisement/Information brochure				
13	Insurance policy and certificate				
14	DCGI approval letter				
15	Director General of Foreign Trade (DGFAT) approval				
16	Genetic Engineering Advisory Committee (GEAC)approval				
17	Bhabha Atomic Research Centre (BARC) approval				
18	Stem cell (NAC-SCRT) registration and approval				
19	DCGI marketing/manufacturing license for herbal formulations/nutraceutics				
20	Clinical Trial Agreement (CTA)				
21	Material Transfer Agreement (MTA)/MOU/Health Ministry Screening Committee (HMSC) approval				
22	IEC processing fee (applicable for sponsored trials)				
23	Any other Agreements/documents				
24	Document Receipt Form (AN15-V5/IEC-PGIMS SOP V5/03, in duplicate)				

Note: Please provide version no. and date of each document (for drug/device trial)

Documents submitted: ( ) Complete ( ) Incomplete; will submit on……..
Comments:
Receiver Name, Sign & Date: **_** **(IEC office)** **Project submitted by Name & sign**: **_** **(Project or study team member)**

Flow Chart

Research protocol & related documents

• Initial Review Application
• Resubmission of Protocols with Corrections
• Protocol Amendment and any other amendments
• Continuing Review of Approved Protocols

Receive & verify as per document checklist

Stamp the receipt of documents

Complete document receipt form

Store hard copies and soft copy of project

Numbering the project

Chapter 4: Initial Review of Submitted Protocol

4.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the IEC members will review an initially submitted protocol for approval.

The IEC must review every research proposal on human participants and approve it before the research is initiated. The committee should evaluate the possible risks to the participants with proper justification, the expected benefits to participants/community and adequacy of documentation for ensuring privacy &confidentiality.

4.2 Scope

This SOP applies to the review and assessment of all protocols submitted for initial review and approval from the IEC. The specific points in the guidelines attached to the assessment form for initial review must be adequately addressed in the protocol itself and/or protocol related documents under review. Relevant comments made during discussion and deliberation about a specific protocol should be recorded in the minutes of the meeting. The decision reached by the IEC will be communicated to the PI.

4.3 Categorization of protocols

The Member Secretary, IEC or IEC office shall screen the proposals for their completeness before putting at the IEC meeting for review. It is categorized as exempt, full review or expedited. In case of an emergency proposal needing immediate approval; an adhoc meeting will be called by the Chairperson.

Types of Review

4.3.1 Exemption from review

Proposals that can be exempt from review include those with less than minimal risk where there are no linked identifiers, e.g.

- Research conducted on data that is in the public domain for systematic reviews or meta analyses.
- Observation of public behavior when information is recorded without linked identifiers and disclosure would not harm the interests of the observed person.
- Quality control and quality assurance audits in the institution.
- Comparison among instructional techniques, curricula, or classroom management methods.
- Consumer acceptance studies related to taste and food quality.
- Public health programmes including programme evaluation where the sole purpose of the exercise is refinement and improvement of the program or monitoring.

4.3.2. Expedited review

Proposals that pose no more than minimal risk may undergo expedited review, e.g.

- Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks, left over clinical samples.

- Research involving clinical documentation materials which are non-identifiable (data, documents, records)
- Modifications or amendment to approved protocol including administrative changes or correction of typographical errors and change in investigator(s).
- Revised proposals previously approved through expedited review, full review or continuing review of approved proposals.
- Minor deviations from originally approved research causing no risk or minimal risk.
- Progress/ Annual reports where there is no additional risk e.g. activity limited to data analysis.
- Expedited Review will be conducted by Chairperson, Member Secretary and 1-2 designated members.
- Expedited review of SAEs/ unexpected AEs will be conducted by SAE subcommittee.
- The approval granted through expedited review and the decisions of the SAE subcommittee must be ratified at the next Full committee meeting.
- Research during emergencies and disasters.

4.3.3. Full Committee Review

All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review, e.g.

- Studies involving vulnerable population even if the risk is minimal.
- Studies involving deception of participants (Refer Informed Consent Process for further detail).
- Research proposals that have received exemption from review, or have undergone expedited review/ undergone subcommittee review should be ratified by the full committee. Full committee has a right to reverse/or modify any decision taken by the subcommittee or expedited committee.
- Amendments of proposals/related documents (including but not limited to informed consent documents, Investigators Brochure, advertisements, recruitment methods etc.) involving an increase in risk.
- Major deviations and violations.
- Any new information that has emerged during the course of the research must also be reviewed and decisions taken if necessary to terminate the study or not in view of altered benefit–risk assessment.
- Research during emergencies and disasters through unscheduled meetings.
- Program evaluation research activities other than those mentioned in the exempt category.

4.4 Elements of review

The primary task of the IEC is review of research proposals and their supporting documents with special attention given to the informed consent process, documentation, and the suitability and feasibility of the protocol. IEC will consider the prior scientific review by the Research committee/department/funding agency/doctoral committee/scientific committee, and the requirements of applicable laws and regulations. Primary reviewer assigned by the Member Secretary will review and present the project in the meeting.

The IEC Member receives the letter for review (AN1-V3/IEC-PGIMS SOP V3/04) and assessment Form (AN2-V3/IEC-PGIMS SOP V3/04). The assessment form is designed to standardize the review process and to facilitate reporting, recommendations, and comments offered on each individual protocol.

The following will be considered (as applicable):

4.4.1 Scientific design and conduct of the study

- The appropriateness of the study design in relation to the objectives of the study.
- The statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest number of research participants.
- The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities.
- The justification for the use of control arms; criteria for prematurely withdrawing research participants.
- Criteria for suspending or terminating the research as a whole.
- The adequacy of provisions made for monitoring and auditing the conduct of the research, the adequacy of the site, including the supporting staff, available facilities, and emergency procedures.
- The way the results of the research will be reported and published.

4.4.2 Care and protection of research participants

- Suitability of the investigators' qualifications and experience for the proposed study.
- Any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action.
- Medical care to be provided to research participants during and after the course of the research.
- Adequacy of medical supervision and psycho-social support for the research participants
- Steps to be taken if research participants voluntarily withdraw during the course of the research.
- Criteria for extended access to, the emergency use of, and/or the compassionate use of study products.
- Arrangements, if appropriate, for informing the research participant's general practitioner or family doctor, including procedures for seeking the participant's consent to do so.
- Description of any plans to make the study product available to the research participants following the research; a description of any financial costs to research participants.
- Rewards and compensations for research participants (including money, services, and/or gifts).
- Provisions for compensation/treatment in the case of the injury/disability/death of a research participant attributable to participation in the research as per Gazette of India (2013).
- Valid Insurance policy for the participant and indemnity arrangements.

4.4.3 Protection of research participant confidentiality

- A description of the persons who will have access to personal data of the research
- participants, including medical records and biological samples.
- The measures taken to ensure the confidentiality and security of personal information
- concerning research participants.

4.4.4 Participant information document and consent process

- A full description of the process for obtaining consent, including the identification of those responsible for obtaining consent.
- Adequacy, completeness, and comprehension of written and oral information to be given to the research participants, and, when appropriate, their Legally Acceptable Representative(s).
- Clear justification for the intention to include research participants who cannot consent, and a full account of arrangements made to obtain their consent /authorization.
- Assurances that research participants will receive information that becomes available during the research relevant to their participation including their rights, safety, and wellbeing.
- Provisions made for receiving and responding to queries and complaints from research participants or their representatives during a research project.
- In clinical trials of new chemical entity or new molecular entity, audio-visual recording of informed consent process is required when vulnerable participants are enrolled.

4.4.5 Community considerations

- Impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn.
- Steps taken to consult with the concerned communities during designing the research.
- Influence of the community on the consent of individuals.
- Proposed community consultation during the research.
- Extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research, and the ability to respond to public health needs.
- A description of the availability and affordability of any successful study product to the concerned communities following the research.
- The way the results of the research will be made available to the research participants and the concerned communities.

4.4.6 Recruitment of research participants

- The characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status, and ethnicity) (Refer AP1/V3).
- The means by which initial contact and recruitment is to be conducted.
- The means by which full information is to be conveyed to potential research participants or their representatives.
- Inclusion criteria for research participants.
- Exclusion criteria for research participants.
- Students or staff recruitment in research (Ref. AP1/V3).

4.4.7 Risk-Benefit Analysis

While reviewing the research protocols, the following points should be carefully assessed for risk/benefit analysis:

a. Collection of blood samples by finger prick, heel prick, ear prick, or venipuncture (Refer AP5/V3).
b. Prospective collection of biological specimens for research purposes by noninvasive means. E.g. skin, saliva, sputum, other body fluids etc.
c. Collection of data through noninvasive procedures routinely employed in clinical practice. E.g. Magnetic Resonance Imaging, sensory acuity, Electrocardiography,
d. Echocardiography, Electroencephalography, Ultrasound, Doppler Blood Flow and other similar procedures.
e. Research involving clinical materials (data, documents, records, or specimens) that will be collected solely for non-research (clinical) purposes.
f. Collection of data from voice, video, digital, or image recordings made for research purposes.
g. Research on individual or group characteristics or behavior not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, focus group, or quality assurance methodologies
h. Research involving collection and storage of genetic materials (Refer AP9/V3)
i. Research involving gene therapy and gene transfer protocols (Refer AP10/V3)

Where medical devices are employed, they must be cleared/ approved for marketing (Refer for detailed guidelines, Medical Device Rules 2016&2017: www.cdsco.nic.in/)

4.5 Responsibility

The IEC office is responsible for receiving, verifying, and managing the hard/soft copies of the received protocols and documents. In addition, the IEC office should create a protocol specific file, distribute the protocols to the IEC members for review by IEC and communicate the review results to the investigators. IEC members are responsible for receiving and reviewing the research protocols.

4.6 Detailed instructions

Distribution of the project documents

- The distribution of the project documents for IEC review will be as follows: Chairperson,
- Member Secretary and all members will get complete project proposal as hard/soft copy.

Assigning Primary reviewer

- Member Secretary, IEC assigns 1 or 2 Primary reviewers for each research protocol. A Primary reviewer is the member of IEC responsible for an initial detailed review of the assigned protocol.

- The Primary reviewer is informed preferably 10 days prior to the meeting through the agenda. A project evaluation form will also be sent along with the necessary document for each project assigned to the IEC Member. In case, the lead discussant is not in a position to review due to some reason including conflict of interest; he/she should inform the
- Member Secretary, IEC at the earliest, so that the research protocols can be assigned to other member.
- In the event of his/her absence, a Primary reviewer can send written comments on the research protocols to the Member Secretary, which will be tabled and discussed during meeting. However, a final decision on the research protocol will be arrived at, by a consensus at the end of discussion among attending members and not solely based on written comments.
- The assigned lead discussant/s shall review the assigned research protocols offer their Observations, comments, and decisions to the IEC during the meeting and return all the documents including a completed evaluation form to the IEC office on the day of the meeting.

Responsibilities of IEC members

- Check the contents of the documents received and acknowledge receipt.
- Return the acknowledgement form/receipt back to the delivery person /IEC office.
- Check the meeting date and inform the IEC office immediately if unable to attend the meeting.
- Identify the project assigned for review.
- Notify the IEC office immediately regarding the missing documents, if any.
- The members must return the documents to the IEC office on the day of the scheduled meeting. In case, IEC member is not able to attend the scheduled meeting, the proposals should be returned at the next meeting.

4.7 Review of protocol

Review all elements as per section 4.4. The Chairperson will invite comments from IEC members following the presentation of Primary reviewer covering the element mentioned in AN1-V3/IEC-PGIMS SOP V3/04.

4.8 Study assessment forms

The primary reviewer for a particular project should use assessment form as a checklist while reviewing each research protocol. The duly filled, signed and dated assessment forms should be returned along with the research protocols to the IEC office at the end of the meeting. The assessment form is designed to standardize the review process. The study assessment form helps to ensure that all elements of research protocol are reviewed and are accordingly documented during the discussion/meeting Study Assessment Form template (AN1-V3/IEC-PGIMS SOP V3/04).

Note: **The completed assessment form is part of the official record of the decision reached by the IEC for the specific protocol**

4.9 Collection of assessment reports

The IEC office will collect the Study Assessment Forms AN1-V3/IEC-PGIMS SOP V3/04, the Comments from each reviewer and file in the original set of the study file.

4.10 At IEC meeting

The details of review procedures and communication of decision is described in detail in IEC-PGIMS SOP V3/04.

AN1-V3/IEC-PGIMS SOP V3/04

Study Assessment Form

IEC Code:	**Date of IEC meeting:**	**Date (DD/MM/YY):**
Protocol Title:		
Principal Investigators:		
Primary reviewer's name:		

Mark and comment on whatever items applicable to the study

Items	**Comments**
1 Objectives of the Study ( ) Clear ( ) Unclear	
2 Need for Human Participants ( )Yes ( ) No	
3 Methodology: ( ) Clear ( ) Need changes	
4 Background Information and Data ( ) Sufficient ( ) Insufficient	
5 Risks and Benefits Assessment ( ) Acceptable ( ) Unacceptable	
6 Inclusion Criteria: ( ) Appropriate ( ) Inappropriate	
7 Exclusion Criteria ( ) Appropriate ( ) Inappropriate	
8 Discontinuation and Withdrawal Criteria ( ) Appropriate ( ) Inappropriate	
9 Involvement of Vulnerable Participants ( ) Yes ( ) No	

10 Voluntary, Non-Coercive Recruitment of Participants ( ) Yes ( ) No	
11 Sufficient number of participants? ( )Yes ( ) No	
12 Control Arms (placebo, if any) ( ) Yes ( ) No	
13 Are qualification and experience of the Investigators appropriate? ( ) Yes ( ) No	
14 Disclosure or Declaration of Potential conflicts of Interest ( ) Yes ( ) No	
15 Facilities and infrastructure of Participating Sites ( ) Appropriate ( ) Inappropriate	
16 Community Consultation ( ) Yes ( ) No	
17 Involvement of Researchers and Institution in the Protocol Design, Analysis and Publication of Results ( ) Yes ( ) No	
18 Contribution to Development of Local Capacity for Research and Treatment ( ) Yes ( ) No	
19 Benefit to Local Communities ( ) Yes ( ) No	
20 Are blood/tissue samples being sent abroad? ( ) Yes ( ) No	
21 Are procedures for obtaining Informed Consent appropriate? ( ) Yes ( ) No	
22 Contents of the Informed Consent Document ( ) Clear ( ) Unclear	
23 Language of the Informed Consent Document ( ) Clear ( ) Unclear	
24 Contact Persons for Participants ( ) Yes ( ) No	
25 Privacy & Confidentiality ( ) Yes ( ) No	

26 Provision for Medical / Psychosocial Support ( ) Appropriate ( ) Inappropriate	
27 Provision for Treatment of Study-Related Injuries ( ) Appropriate ( ) Inappropriate	
28 Provision for Compensation ( ) Appropriate ( ) Inappropriate	

Comments:_____
_____
_____
_____

If revision/rejection of project is recommended Yes [ ] No [ ]

Signature of Primary reviewer
Date: _____

Flow Chart

Protocols

Exemption from Review Full Review Expedited Review

↓

Responsibilities: IEC office Receive, verify and distribute
Verify the contents of the package

↓

Responsibilities: IEC Members Review of protocol
Fill assessment form and submit during meeting

↓

Responsibilities: IEC office IEC meeting - Record the IEC discussion
Decision is communicated to the PI

↓

Storage of original documents with relevant correspondence

Chapter 5: Exemption from Ethical Review for Research Projects

5.1 Purpose and scope

This SOP applies to the all protocols submitted for exemption from review by the IEC. The purpose of this SOP is to describe which research projects can be exempted from ethics review and do not require the approval of the IEC. The Exemption Form AN1-V3/IEC-PGIMS SOP V3/05is designed to standardize the process of exemption.

5.2 Type of Protocol for Exemption from review

The exemption from review may be seen in following situations:

1. Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exceptions:

a. When research on use of educational tests, survey or interview procedures, or observation of public behavior can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.
b. When interviews involve direct approach or access to private papers.

2. Proposals which do not involve live human participants or data derived from them are exempt from ethics review.

For example:

- Audits of educational practices
- Research on microbes cultured in the laboratory
- Research on immortalized cell lines
- Research on cadavers or death certificates provided such research reveals no identifying personal data
- Analysis of data freely available in public domain

In some circumstances research which meets above criteria may need to be reviewed by the IEC.
This might be because of requirements of:

- The publisher of the research
- An organization which is providing funding resources, existing data, access to participants etc.

5.3 Responsibility

The Member Secretary will record the decision in the Exemption Form with reasons. The IEC office is responsible for recording and filing the decision including the reasons for that decision (AN2-V3/ IEC-PGIMS SOP V3/05).

5.4 Detailed instructions for IEC office

5.4.1 Receive the submitted documents

- The IEC office will receive the Exemption from Review Application Form AN1-V/IEC-PGIMS SOP V3/05, Project Submission Form for Review by IEC (AN1-V3/IEC-PGIMS SOP V3/03)
- Protocol and other documents submitted by the investigators.
- Acknowledge the submitted documents
- Put it at the full board meeting of the IEC.

5.4.2 Exemption process

IEC may exempt a proposal from ethical review.

- The Member Secretary records the decision on the Exemption Form.

AN1-V3/IEC-PGIMS SOP V3/05
Review Exemption Application Form

IEC Code no.: _____ (To be filled by the IEC office)

1 **Principal Investigator's Name:** _____

2 Department: _____

3. Title of Project: _____
_____

4 **Names of other participating staff and students:**

5 **Brief description of the project:**

- Please give a brief summary (approx. 300 words) of the nature of the proposal, including the aims/objectives/hypotheses of the project, rationale, participants' description, and procedures/ methods to be used in the project [Please fill Project Submission Form for Review (AN1-V3/IEC-PGIMS SOP V3/03].

6 **State reasons why exemption from ethics review is requested?**

□Audits of educational practices.
□Research on microbes cultured in the laboratory.
□Research on immortalized cell lines.
□Research on cadavers or death certificates provided such research reveals no identifying personal data.
□Analysis of data freely available in public domain.
□Any other.

(This should include justification for exemption e.g. study does not involve human participants. If exemption is being requested on the basis of low risk involved in the study, please refer to AP15/V3).

Principal Investigator's signature: _____ Date _____

AN2-V3/IEC-PGIMS SOP V3/05

Decision of IEC Regarding Exemption from the Ethical Review

To,
Dr._____
Principal Investigator,
PGIMS, Rohtak.

Ref: IEC code.
Title of project:

Dear Dr.
Institutional Ethics Committee reviewed and discussed your application (dated) for waiver to exemption from the ethical review during the IEC (number of meeting) meeting held on (date).

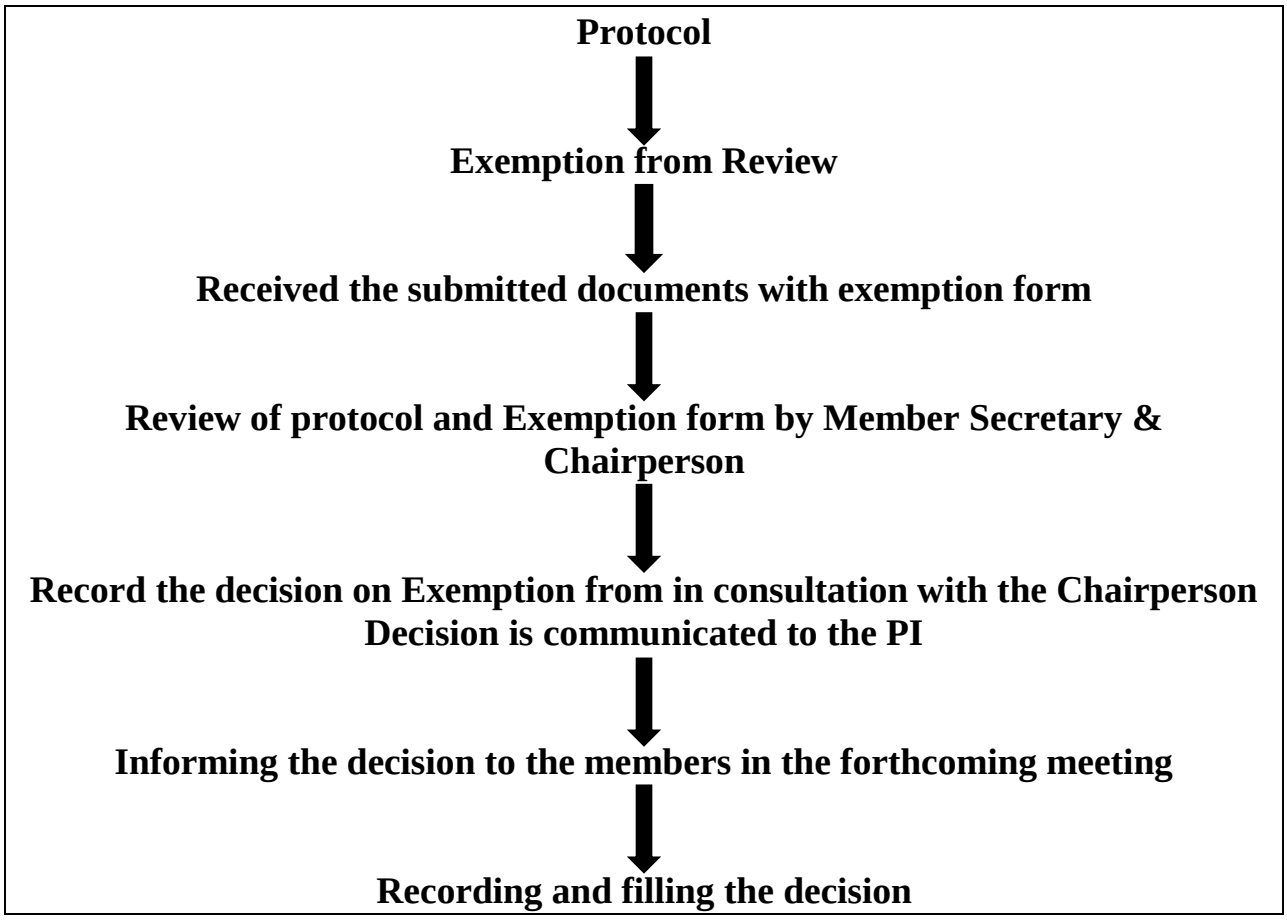
Exemption granted: Yes [ ] No [ ]

Cannot be exempted, Reasons, reasons
_____
_____

Thanking You,
Yours Sincerely,
Signature of the Member Secretary _____ Date _____

Name of the Member Secretary _____

Flow Chart


Protocol
Exemption from Review
Received the submitted documents with exemption form
Review of protocol and Exemption form by Member Secretary & Chairperson
Record the decision on Exemption from in consultation with the Chairperson
Decision is communicated to the PI
Informing the decision to the members in the forthcoming meeting
Recording and filling the decision

Chapter 6: Agenda Preparation, IEC Meeting Procedures and Recording of Minutes

This SOP applies to administrative processes concerning the conduct of the meeting. The purpose of this procedure is to elaborate administrative process and provide instructions for preparation, review, approval, and distribution of meeting agenda, minutes, and notification letters of IEC, PGIMS/UHS meetings. The day, time, and venue of IEC meetings will be communicated at least 10-14 days' in advance in routine circumstances.

6.1 Responsibility

It is the responsibility of the IEC office to prepare for the respective IEC meeting.

6.2 Detailed instructions

6.2.1 Agenda for full board IEC meeting

- Prepare the agenda of the IEC meeting
- Schedule protocols on the agenda on a first come first serve basis.

6.2.2 Distribution of Protocol/Documents to the IEC Members

- Circulate meeting agenda with date, time, venue, and submitted documents to the IEC members preferably 10-14 days in advance of the scheduled meeting.
- Verify (verbally, by e-mail, or by phone) with the members whether all relevant documents are received.
- It is the responsibility of the IEC member to verify items on receipt and in the event of any missing items, intimate the IEC office immediately so that the relevant documents could be made available to the members before the meeting.

6.2.3 Preparation for the meeting

- Circulate meeting notice with agenda to investigators by email/circular, with request to be available on meeting date.
- All relevant guidelines and SOPs should be available at venue on the day of meeting.

6.2.4 Conduct of meeting

- Administrative Health related scenario as guided by Chairperson of Ethics Committee for such pandemic situation. When physical presence of all member is not possible, virtual presence by email/video calling should be done.
- Electronic documents may be accepted for review and timelines shortened for accelerated procedures.
- Emails or virtual or Tele/Video conferences should be attempted to ensure social distancing as face-to face meetings may not be suitable. Use suitable virtual software platform,

preferably a video conference to enable face to face discussion or teleconference if connectivity is an issue.

- Agenda of virtual meetings should be kept short, however, EC may meet more frequently for fast track review within in 24-48 hrs.
- The EC may plan a prior review by subject experts/obtain clarifications from researchers before the meeting or/ invite independent consultants (non-voting) or representative from a specific patient group as special invitee. The special invitees invited for the web-meeting may be asked to leave the meeting before final decision making.
- During the review process, the Ethics Committees should consider the following: If written consent is not possible (e.g., physical isolation/severe COVID-19 patients), consent could be given orally/ use electronic methods to document and record. Due to inability of the participant to attend the site (for e.g., social distancing), the contact/communication can be made via phone, to enquire and identify adverse events, serious adverse events and ensure medical care and oversight with documentation. In an ongoing study, if the designated principal investigator (PI) is indisposed for a period, she/he may need delegate parts of her/his duties temporarily to others/ co-investigator and the same should be documented and reported to EC at the earliest.
- Withholding information in Public Health emergencies may be a threat to national security, and therefore the right balance must be maintained to protect individual privacy and confidentiality, and relevant disclosure to public health authorities.
- Suggest steps to protect participants of researchers from possible stigma or discrimination.
- EC members present during the virtual meeting should decide through consensus or cast online vote or via email expressing their decision. Any disagreement to be recorded with reasons.
- Secretariat is responsible to note the attendance/ participation in the virtual meeting.
- The members should reach IEC meeting room on scheduled time
- The Chairperson should determine that the quorum
    - requirements are met.
- The Chairperson should ask for declaration of conflict of interest either verbal or written
    - on any protocol for discussion.
- If an IEC member has conflict of interest involving a project, then he/she should declare the same, before the meeting commences and leave the meeting room before the discussion on the same. This should be recorded in the minutes.
- The Member Secretary should table the minutes of the previous meeting and which should be confirmed.
- The IEC may invite investigators to attend the full board meeting related to their studies, and clarify doubts, if any.
- The meeting proceeds in the sequential order of the agenda; however, the Chairperson may change the order, if the situation so demands.
- The Member Secretary will request the lead discussant (primary reviewer) to discuss the research protocol. The primary reviewer will submit the duly filled study assessment form at the end of the discussion or at the conclusion of IEC meeting.

- In case the primary reviewer cannot attend the meeting, Member Secretary, IEC or any other IEC member may brief the IEC about the research protocol and also discuss the written comments/duly filled study assessment form, if provided by the primary reviewer.
- The Member Secretary, IEC/the IEC office staff minutes/records the proceeding of the IEC meeting.

6.2.5 Decision Making Process

IEC shall provide complete and adequate review of the research proposals submitted to them. The committee will review new project proposals, amendments, annual progress of ongoing projects, SAE reports, protocol violations and assess final reports of all research activities through a scheduled agenda.

- If IEC member has her/his own proposal for IEC review he/she will not participate in the IEC discussion on that particular project.
- The documents required for a full review of the application should be complete and the relevant elements considered before a decision is made.
- Decisions will only be made at meetings where a quorum is present.
- Decisions will be arrived at through consensus. When a consensus is not possible, the IEC will vote. In case of tie the Chairperson can have a casting vote.
- If the full board approves a research proposal in principle subject to minor modifications, the revised project proposal submitted by the PI will be reviewed and approved by the
- Member Secretary, IEC or subcommittee of IEC on behalf of the full board, Member Secretary will report the decisions to the next IEC meeting. Such revised proposals will not be taken up for the full board review. However, in case of major changes, the revised documents will be discussed by 3-member subcommittee or in full board meeting.
- An IEC may decide to reverse its positive decision on a study if it receives information that may adversely affect the risk/ benefit ratio.
- Any advice that is non-binding will be appended to the decision.
- In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed will be specified.
- A negative decision on an application will be supported by clearly stated reasons. If the investigator wishes to appeal against the decision, he/she may do so.
- The discontinuation of a trial will be recommended if the IEC finds that the goals of the trial have already been achieved midway, unequivocal results are obtained or SAE have been observed.
- If necessary, the investigator may be invited to present the protocol or offer clarifications in the meeting. Representative of the patient groups or community can be invited during deliberations to offer their viewpoint.
- Subject expert/s may be invited as consultant to offer their views, but should not participate in the decision-making process. However, his/her opinion must be recorded.
- The proceedings of the IEC meetings will be documented and signed by the Member Secretary and the Chairperson.

6.2.6After the IEC meeting

A Preparing the minutes and the decision letters

- The Member Secretary will compile the proceedings of IEC meeting in a concise and easy-to-read style and will check spelling, grammar and context of the written minutes.
- The minutes of the meeting will be compiled.

B Approval of the minutes and the decision

- The minutes of the IEC meeting will be signed by Member Secretary, IEC.
- The minutes of the IEC meeting will be ratified in the subsequent IEC meeting.
- The IEC decisions will be communicated to the PIs by the Member Secretary.

C Filing of the minutes of the meeting

- Place the original version of the minutes in the minutes' file and copy of the minutes are filed in the corresponding research protocol file.

6.2.7 Communicating decisions

The decision will be communicated in writing by the Member Secretary to the PI, preferably within a period of 2 weeks of the IEC meeting at which the decision was made.
The communication of the decision will include, but is not limited to, the following,

- IEC code of project and title of the research proposal reviewed.
- The clear identification of the protocol of the proposed research or amendment, date and version number (if applicable).
- The names and specific identification number version numbers/dates of the documents reviewed, including the potential research participant information sheet/material and informed consent form.
- The name and title of the Principal Investigator.
- The date and place of the decision.
- A clear statement of the decision reached.
- Validity of approval usually will be yearly; for multiyear projects, however changing on case to case basis.
- Any suggestions by the IEC.
- A dead line of 4 weeks will be given to PI. If Clarification is received after dead line, the project may not be put up in next meeting for approval. Conditional approval pending clarification will not be given. If PI fails to provide clarification, reminder will be send by
- IEC office stating that failure to respond will lead to closure of the file.
- In the case of a positive decision, the PI is notified of the following requirements through an approval letter.
    - A statement of the responsibilities of the PI; for example, confirmation of the acceptance of any requirements recommended by the IEC.
    - Registration with CTRI if applicable.
    - Communicate date of start of study to IEC
    - Submission of annual progress report.

- The need to notify the IEC in cases of protocol amendments (other than amendments involving only logistical or administrative aspects of the study).
- The need to notify the IEC in the case of amendments to the recruitments like the potential research participant information, the informed consent form or participant numbers.
- The need to report serious and unexpected adverse events related to the conduct of the study
- The need to report unforeseen circumstances, the withdrawn/ termination of the study, or significant decisions by another IEC.
- The information the IEC expects to receive in order to perform ongoing review.
- The final summary or final report.
- The schedule/plan of ongoing review of sponsored trials.

- In the case of a negative decision, the reasons should be clearly stated in the communication to the PI.
- The PI will also be notified of the duration of the approval, which normally will not exceed one year or duration of project whichever is later.
- All decision and approval letters will be signed by the Member Secretary, IEC
- The Member Secretary, IEC, will sign and date the approval letter and approval certificate in the original research protocol.

AN1-V6/IEC-PGIMS SOP V3/06

Agenda Format

I) Minutes

II) New Projects for Review

III) Report of approved clarification/revision by of 3 Member Committee/Member Secretary

IV) Amendments/Addendum

V) SAEs

VI) Letters/General notification

VII) Protocol violation

VIII) Progress report

IX) Closed out notification

X) Any other matter

AN2-V6/IEC-PGIMS SOP V3/06

Format for Approval Letter of Ethics Committee

To,
Dr._____
Principal Investigator,

Ref: IEC code & Project title:
Study/Protocol No.

Dear Dr.
Institutional Ethics Committee reviewed and discussed your application (dated) to conduct the research study entitled "_____" during the IEC meeting held on (date).
The following members of the Institutional Ethics committee (IEC) were present at the meeting held on Date _____ Place _____
Name of member/Position on IEC/Affiliation/Gender
_____ Chairman of the Ethics committee
_____ Member secretary of the Ethics committee
_____ Name of each member with designation

The following documents were reviewed and approved:

1. Project Submission form (IEC Proforma).
2. Study protocol (including protocol amendments), dated_____, version no(s)_____.
3. Research committee/department/funding agency/doctoral committee/scientific committee approval
4. Patient information document and consent form (including updates if any) in English and/Vernacular language.
5. Investigator's brochure, dated_____, version no._____
6. Proposed methods for patient accrual including advertisement(s) etc. proposed to be used for the purpose.
7. Insurance policy/compensation for participation and for serious adverse events occurring during the study participation.
8. Investigator's Agreement with the sponsor
9. Investigator's undertaking
10. DCGI/DGFT approval
11. Clinical Trial Agreement (CTA)/Memorandum of Understanding (MOU)/Material Transfer Agreement (MTA), if applicable
12. Clinical Trials Registry-India (CTRI), in case of drug trial require at time of submission but in other case this must be done after approval of the study but before initiation.

The trial is approved in its presented form.

It is to be noted that neither you nor any of your study team members were present during the decision making procedures of this Institutional Ethics Committee.

The IEC functions in accordance with the ICH-GCP/ICMR/ New Drugs and Clinical Trial Rules-2019.

Following points must be noted: -

1) IEC should be informed of the yearly progress of the study.
2) PI and other investigators should co-operate fully with Monitor of the IEC, who will monitor the trial from time to time, if required.
3) At the time of PI's retirement/intention to leave the institute, study responsibility should be transferred to colleague after obtaining clearance from HOD. Status report, including accounts detail should be submitted to HOD and extramural sponsors and same may be communicated to IEC.
4) In case of any new information which could affect the study or any **SAE**, must be informed to IEC and sponsors. The PI should report SAEs occurring during the trial within 24 hrs. of the knowledge of occurrence to IEC, sponsor and licensing authority. The detailed report of SAE's, after due analysis should be forwarded by PI and sponsor to IEC, licensing authority and Head of Institution within 14 days of the knowledge of occurrence of SAE's failing which the IEC approval will be withdrawn.
5) In the event of any protocol amendments, IEC must be informed and the amendments should be highlighted in clear terms as follows: -
    a) The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project (Page No. Clause No. etc.)
    b) Alteration in the budgetary status should be clearly indicated and the revised budget form should be submitted.
    c) If the amendments require a change in the consent from, the copy of revised consent form should be submitted to Ethics Committee for approval.
    d) If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented.
    e) If there are any amendments in the trial design, these must be incorporated in the protocol, and other study documents. These revised documents should be submitted for approval of IEC, only then they be implemented.
    f) Approval for amendment changes must be obtained prior to implementation of changes.
    g) Without including all the above points, the amendment is unlikely to be approved by the Ethics Committee.
6) Any deviation/violation/waiver in the protocol must be informed to the IEC.
7) **Closure report** must be submitted to the IEC after completion of the project.

a) If project/drug/device trial initiation not done in next 6 months from date of approval from IEC, further extension will not be granted and it will require resubmission to IEC.

Thanking You,
Yours Sincerely,

Signature of the Member Secretary _____ Date _____

Name of the Member Secretary _____

AN3-V6/IEC-PGIMS SOP V3/06

Format for Communication of IEC decisions project/trials

To,
Dr._____
Principal Investigator,
AADHAR HEALTH INSTITUTE.

IEC code and Project title:
Study/Protocol No.:

Dear Dr.
The above referenced project was tabled, reviewed and discussed during the Institutional Ethics Committee meeting held on (date)_____
List of documents reviewed.
The following members attended the meeting.
The committee suggested the following changes or additional information in project proposal:
a.
b.
c.
The approval will be granted subject to the compliance with all the above suggestions of the IEC. PI advised to submit above clarifications within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.
Kindly resubmit the 1 copy of revised proposal or documents within 4 weeks for re-review by the Member Secretary/three Member Sub-committee.

Thanking you,
Yours Sincerely,

Signature of the Member Secretary _____ Date _____
Name of the Member Secretary_____

AN4-V6/IEC-PGIMS SOP V3/06

Format for Three-Member Subcommittee of IEC Approval for Project

Deliberation by the 3 members' committee for the review of the clarification made by the PI regarding the objections raised about the research protocol presented during IEC meeting held, on_____

IEC code:
Title of projects:

The clarification made by the Principal Investigator was reviewed by the 3 Members Committee comprising of:
1
2.
3.
After due deliberation the committee made the following decisions regarding the clarifications presented by the PI.

Signature and date
(Member)

Signature and date
(Member)

Signature and date
(Member Secretary)

AN5-V6/IEC-PGIMS SOP V3/06

Intimation of Start of Study

1. **IEC code Number:**

2. **Study/Protocol No. (For drug/device trials/any other):**

3. **Title of the drug/multicentre trial:**

4. **Principal Investigator (Name & Department):**

5. **Sponsor:**

6. **Contract Research Organization (CRO) if any:**

7. **Date of approval by IEC:**

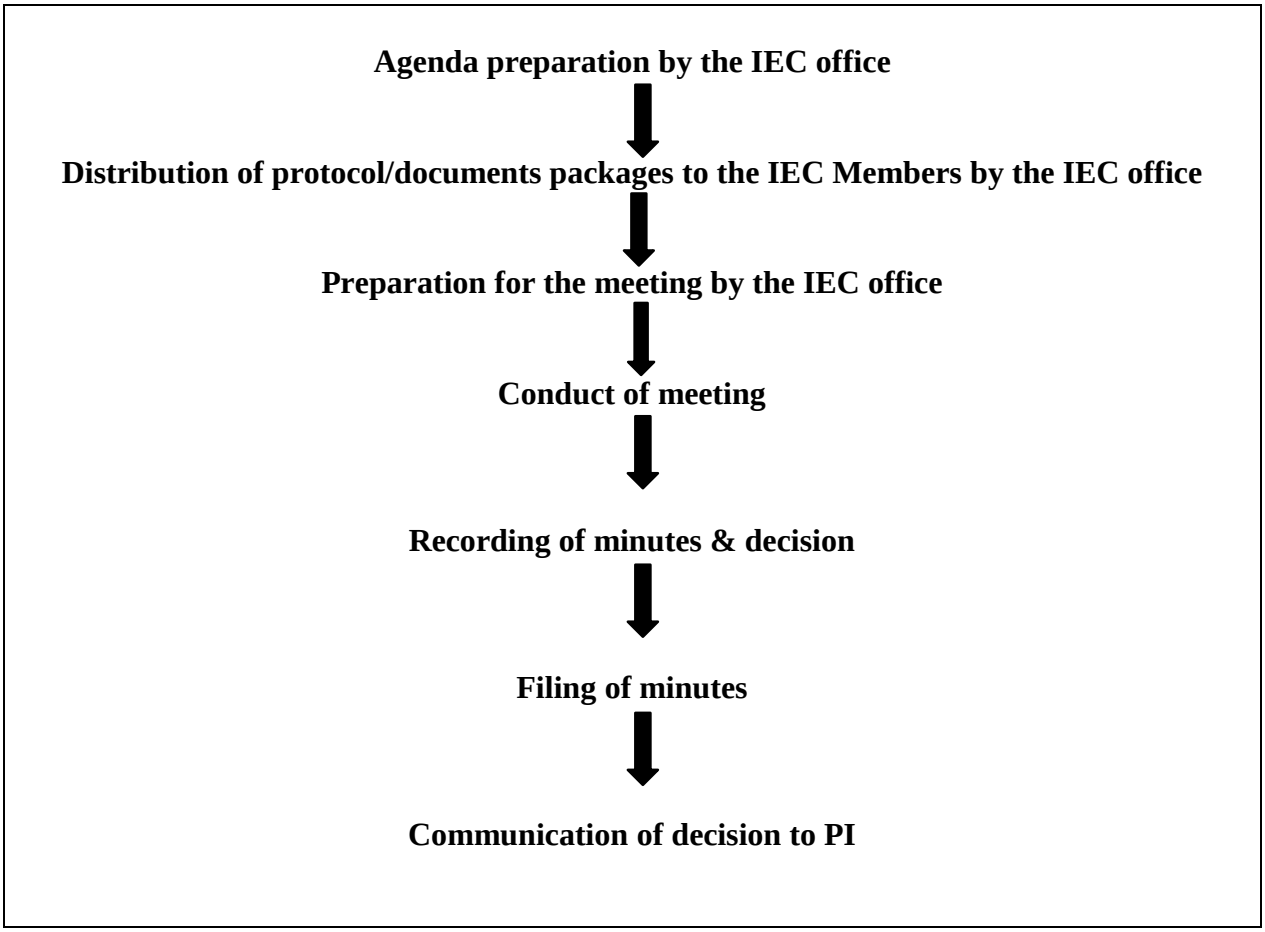
8. **Date of start**:

_____
Signature of PI

Name_____

Date_____

Flow Chart


Agenda preparation by the IEC office
Distribution of protocol/documents packages to the IEC Members by the IEC office
Preparation for the meeting by the IEC office
Conduct of meeting
Recording of minutes & decision
Filing of minutes
Communication of decision to PI

Chapter 7: Review of Amendments/Notifications

Purpose & Scope:

The purpose of this procedure is to describe how protocol amendments or any other amendments/letters are reviewed by the IEC. This SOP applies to amended study protocols/ documents and letters that are submitted for IEC approval. Amendments made to protocols or any other amendments related to the study may not be implemented until reviewed and approved by the IEC.

7.1 Procedures

7.1.1 Receipt of the amended protocol

- The amendment forwarded by the PI is received by the IEC office. The amendment along with the covering letter should be accompanied by Amendment Reporting Form
- It is the responsibility of the Bioethics cell to manage protocol amendments, documents and letters.
- The IEC office should follow the procedures as in IEC-PGIMS SOP V3/03 (Procedures for Management of protocol submission).

7.1.2 Review of amended protocols/documents/letters: Review as per IEC-PGIMS SOP V3/04

7.1.3 Minor amendments and notifications

Minor amendments (those that do not increase the risk or decrease the potential benefit to subjects) may be approved in the 3-member subcommittee meeting.

Minor notifications may be noted by the Member Secretary, IEC and reported in IEC meeting. This may include but may not restrict to: Renewed insurance policy, DCGI and DGFT approvals, Administrative notes, etc.

7.2 Decision

- If the IEC approves the amendments, the IEC staff communicates this decision to the PI

- If the IEC does not approve the amendments, the Member Secretary should notify the investigator in writing of the decision and the reason for not approving the amendment.
- If the IEC recommends or suggests modifications to any of the documents, or the amendments, the Bioethics cell sends a written communication to the investigator about the specific changes asking him or her to make the necessary changes and resubmit the documents to IEC.

7.3 Storage of documents

File the amendments in the corresponding research protocol file.

AN1-V3/IEC-PGIMS SOPV3/07

Amendment Reporting Form

1. IEC Code No.	
2. Study/ Protocol No. (For drug/device trials/any other):	
3. Protocol Title	
4. Principal Investigator:	
5. Please mention version no. and date of amended Protocol/Investigators brochure/Addendum	
6. Have you highlighted the amended portion in the document or tabulated details of changes?	
7. Have you highlighted the amended portion in the document or tabulated details of changes?	**Yes/No**
8. Does this amendment lead to any change in trial protocol? If yes: please specify the changes	**Yes/No**
9. Does this amendment entail any changes in Participant information documents (PID)?	**Yes/No**
10. If yes, is the amended PIDs is enclosed	**Yes/No** **If No, reasons for not submitting**
11. Does it require signing of new consent form by participant already on trial	**Yes/No**
12. No. of active trial participants	**Yes/No**

13. Any other additional comment including changes to budgetary or staff requirement:	**Yes/No**

Signature of PI

Name: _____ **Date_____**

AN2-V3/IEC-PGIMS SOPV3/07

Format for Project Amendment/Document Amendment Approval letter

To,

Dr._____
Principal Investigator,
Pt. B. D. Sharma PGIMS/UHS Rohtak

IEC code no.
project title:
Study/Protocol No. (For drug/device trials/any other):

Dear Dr.,

We have received the following document/s on (date)_____

1.
2.

At the IEC meeting held on (date)_____, the above-mentioned documents were reviewed. After deliberation, the committee has decided to approve the aforementioned study-related documents.

The members who attended this meeting held on _____date and place of meeting_____ at which the above-mentioned document was discussed, are listed below.

1.
2.
3.

Yours Sincerely,

Signature of the Member Secretary _____ **Date _____**

Name of the Member Secretary _____

AN3-V3/IEC-PGIMS SOPV3/07

Format for Project Amendment/Approval letter

To,
Dr._____
Principal Investigator,
Pt. B. D. Sharma PGIMS/UHS Rohtak

IEC code no. & Project Title:
Study/Protocol No. (For drug/device trials/any other):

Dear Dr.,
We have received the following document/s on (date)_____

1.
2.

At the IEC meeting held on (date)_____, the above-mentioned documents were reviewed. After deliberation, the committee has decided to approve the aforementioned study-related documents.
The members who attended this meeting held on _____date and place of meeting_____ at which the above-mentioned document was discussed, are listed below.

1.
2.
3.

The committee suggested the following:

a.
b.
c.

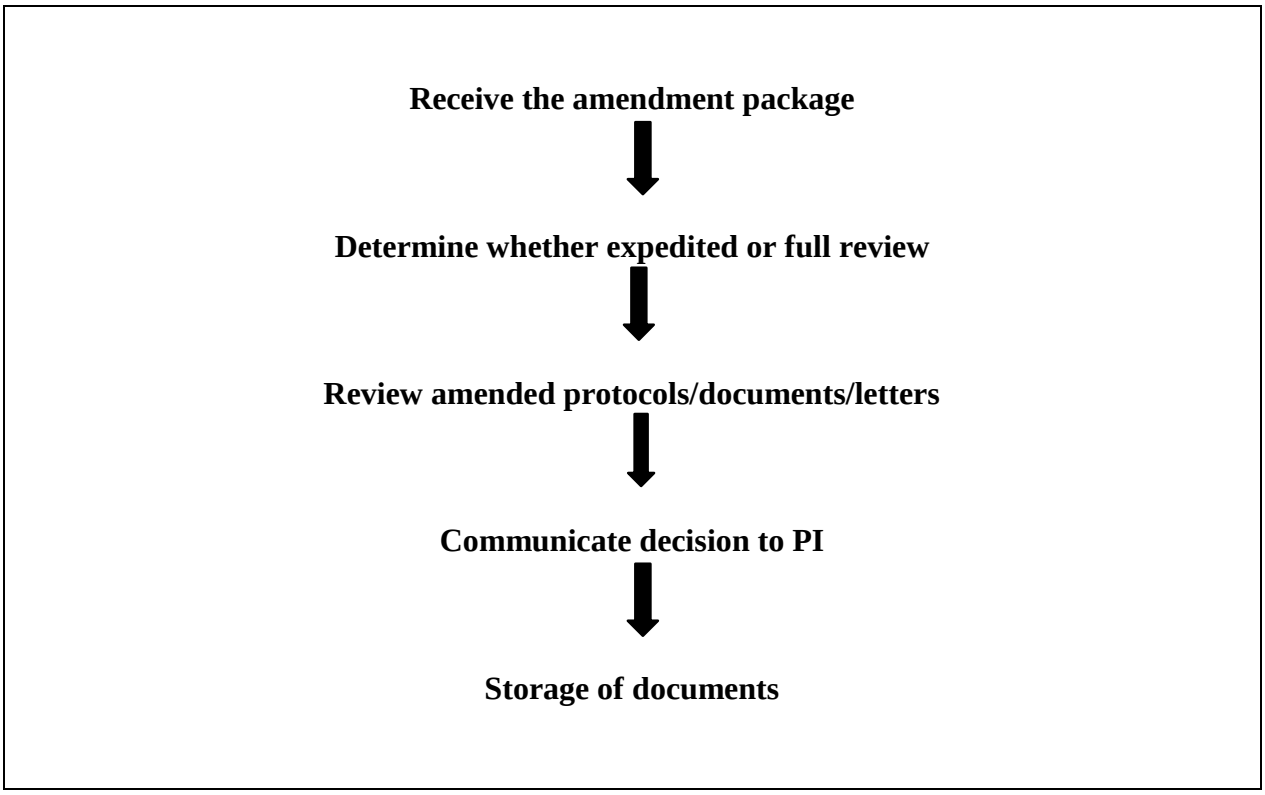
The approval will be granted subject to the compliance with all the above suggestions of the IEC. Kindly resubmit one of revised proposal or documents within 4 weeks for re-review by the Member Secretary/three Member Sub-committee/IEC.

Yours Sincerely,

Signature of the Member Secretary _____ **Date _____**

Name of the Member Secretary _____

Flow Chart


Receive the amendment package
Determine whether expedited or full review
Review amended protocols/documents/letters
Communicate decision to PI
Storage of documents

Chapter 8: Continuing Review of Study Protocols

Purpose & Scope:

The purpose of continuing review is to monitor the progress of the study which was previously approved; not just the changes in it to ensure continued protection of the right and welfare of research participants.

This SOP applies to continuing review of study protocols involving human participants, at intervals appropriate to the degree of risk but not less than once a year. Depending upon the degree of risk to the participants, the nature of the studies and the vulnerability of the study participants and duration of the study, the IEC may choose to review a study more frequently.

8.1 Responsibility

- It is the responsibility of principal investigator (PI) to submit the periodic/annual progress report of the approved ongoing studies.
- The Chairperson is responsible for determining the date of continuing review if the project will be reviewed more frequently. This decision is taken during the IEC meeting wherein the project is finally approved.
- The IEC is responsible for reviewing the progress made in the protocol, the occurrence of unexpected events or problems, and the rate of accrual of participants. The protocol, informed consent documents and assent documents are examined to ensure that the information remains accurate.
- PI will also apply for extension of approval of the project if necessary, along with the submission of the annual project progress report.
- Any PI who fails to submit the report for review within the stipulated time, will have to clarify the delay in writing, this will be forwarded to the Chairperson, IEC.

8.2 Procedures

The IEC Office will:

- Check the master file of projects approved by the IEC for the due date of continuing reviews.
- It will inform the PI well in advance (one to two months) before the due date for the continuing review in writing, (AN3-V3/IEC-PGIMS SOPV3) requesting for 6 copies of the annual/periodic progress report to allow the study team sufficient time to collate the information and to prepare a report required for the continuing review.
- It will verify that the following documents are submitted:
    1. Continuing Review Application Form (AN1-V3/IEC-PGIMS SOPV3/08 or AN2-V3/IEC-PGIMS SOPV3/08 with signature of PI.
    2. The Progress Report with information about the number of participants enrolled to date and since the time of the last review, an explanation for any "yes" (ticked on the Continuing Review Application Form AN1-V3/IEC-PGIMS SOPV3/08 or AN2-V3/IEC-PGIMS SOPV3/08 answers on the application form and a discussion of scientific development, either through the result of this study or similar research elsewhere that may alter risks to research participants.
    3. Summary of the progress since the time of the last review.
    4. Request letter for extension of approval of the project, if requested by PI.
- The IEC follows the procedure for review and decision making same as for an initial review.
- The Member Secretary will consult the Chairperson whether to include the annual project report/s in the forthcoming IEC meeting for discussion. After consultation with Chairperson, it can be reviewed by Member Secretary/Chairperson and informed in the full board meeting or sent to two more IEC members nominated by Chairperson for review.

8.3 Decision making

The IEC members could arrive at any one of the following decisions at the IEC meeting:

1. Noted and the project can be continued without any modifications.

2. Modifications recommended - Protocols for which modifications have been suggested by the IEC may not proceed until the conditions set by the IEC in the decision have been met. Protocols should be amended and submitted to the IEC within one four weeks for rereview.
3. Disapproved further continuation.

- This decision is recorded by the Member Secretary on AN4-V3/IEC-PGIMS SOPV3/08.
- The IEC Chairperson will sign and date the IEC decision on Continuing Review Report after a decision has been reached.
- The IEC Office will maintain and keep the IEC decision forms and minutes of the meeting relevant to the continuing review as part of the official record of the review process.

8.4 Communicate the IEC decision to the PI

The Member Secretary IEC will notify the PI of the decision (AN5-V3/IEC-PGIMS SOPV3/08) within 14 working days.

AN1-V3/IEC-PGIMS SOPV3/08

Continuing Review Application Form/Annual status Report form

(For Interventional Study, 6 copies required)

IEC Code No. **Study/ Protocol No. (For drug/device trials/any other):**
Protocol Title
PI: **Institute:** **Date of IEC approval:** **Start Date of study:** **Duration of study:**

1. **Project Status**

[ ] Ongoing

[ ] Completed

[ ]Accrual completed

[ ] Follow-up

[ ] Suspended

[ ] Terminated

[ ] Closed

[ ] Not started/Not initiated

If 'Not started' state reasons:

2. Provide the date of last status review report submitted to IEC for this project

3. Have there been any amendments since the last status report?

   [ ] YES

   [ ] NO

   If 'Yes', Were these Protocol amendments approved by IEC

   YES, if 'YES', please provide date of approval_____

   No

   Note: Kindly attach a sheet with the list of amendments to be approved / approved by the IEC in a tabular column with details of amendment no. with date, date of submission to IEC and date of approval by IEC.

4. Have there been any Participant Information Document (PID) amendments since the last status report?

   [ ] YES

   [ ] NO

   If 'Yes', Were these PID amendment approved by IEC

   - YES, if 'YES', please provide date of approval_____
   - No

   Note: Kindly attach a sheet with the list of amendments to be approved / approved by the IEC in a tabular column with details of amendment no. with date, date of submission to IEC and date of approval by IEC.

5. **Summary of protocol Participants:**

- Accrual ceiling set by IEC_____

- New participants accrued since last review_____
- Total participants accrued since protocol began_____
- Number of active patients_____
- Number of patients who have completed the study_____
- Impaired participants:
  - None_____
  - Physically_____
  - Cognitively_____
  - Both_____

6. Is the recruitment on schedule?

[ ] YES

[ ] NO

(If 'NO', please attaché a sheet giving reason and your plans to improve accrual)

7. Have there been any changes in the participant population, recruitment or selection criteria since the last status report was submitted to IEC review?

[ ] YES (If 'YES', kindly attach a sheet explaining the changes)

[ ] NO

8. Have any participants withdrawn from this study during the last one year?

[ ] YES (If 'YES', kindly attach a sheet stating reasons for drop-outs)

[ ] NO

9. **Have any participating Investigators been added or deleted since last status report was submitted to IEC?**

   [ ] YES (If 'YES', kindly attach a sheet with details regarding the changes)

   [ ] NO

10. **Have any new collaborating sites (institutions) been added or deleted since the last status report was submitted to IEC?**

    [ ] YES (If 'YES', kindly attach a sheet with details)

    [ ] NO

11. **Does the Protocol have an inbuilt monitoring plan?**

    [ ] YES

    [ ] NO

12. **Is interim data analysis report available?**

    [ ] YES (If 'YES', kindly submit as an attachment)

    [ ] NO

13. **Has any information appeared in the literature, or evolved from this or similar research that might affect the IEC evaluation of the Risk/Benefit analysis of human subjects involved in this protocol?**

    [ ] YES (If 'YES', kindly attach a sheet with details)

    [ ] NO

14. **Have any unexpected complications, AEs or SAE been noted since last status report?**

[ ] YES

[ ] NO

(If 'YES', please attach a sheet giving complete details regarding number of SAEs occurred, whether reports of SAEs have been submitted to IEC, type of adverse events in a tabular format.)

15. When was study last monitored?

Date of monitoring_____

Monitored by_____

Number of subjects monitored_____

16. Is report of the data safety and monitoring board report available?

[ ] YES (If 'YES', submit as an attachment)

[ ] NO

17. Did the monitoring team have any adverse comments regarding the study?

[ ] YES (If 'YES', please attach a copy of their comments)

[ ] NO

18. Has there been any presentation/publication related to the data generated in this trial?

[ ] YES (If 'YES', kindly attach a sheet with details)

[ ] NO

19. **Have any investigators developed an equity or consultative relationship with a source related to this protocol which might be considered as conflict of interest?**

[ ] YES (If 'YES', kindly append a statement of disclosure for the same)

[ ] NO

Signature of PI

Name: _____ **Date_____**

AN2-V3/IEC-PGIMS SOPV3/08

Continuing Review Application Form/Annual status Report form

(For Non-Interventional Study)

1. **IEC code no.**
2. **Title of the project:**
3. **Principal Investigator (Name & Department):**
4. **Sponsor:**
5. **Date of sanction by IEC**
6. **Date of start:**
7. **Duration of project:**
8. **Objectives of the study:**
9. **Total number of patients to be recruited for the study:**
10. **Progress report as per objectives (summary in 250 word):**

    _____

    _____

    _____

11. **Protocol deviation if any with reasons/justifications:**

    _____

    Signature of PI

    Name_____ Date_____

AN3-V3/IEC-PGIMS SOPV3/08

Reminder Letter by the IEC to PI

Name of Principal Investigator: -

Address of Principal Investigator: -

IEC code no. & Project Title:

Study/Protocol No. (For drug/device trials/any other):

The above referenced project was approved by the IEC on…….and is due for continuing annual review by the IEC. You are requested to submit an annual status report in the prescribed format **AN1-V3/IEC-PGIMS SOPV3/08** or **AN2-V3/IEC-PGIMS SOPV3/08** on or before……

Signature of the Member Secretary _____ Date _____

Name of the Member Secretary _____

AN4-V3/IEC-PGIMS SOPV3/08

IEC Decision on Continuing Review Report

IEC code no:

Project Title:

PI:

Review: Annual Progress Report

Date of IEC meeting:

Further the review and approval of resubmitted protocol is subjected to:

- Reviewed in Full Board

Decision:

- Noted and the project can be continued without any modifications
- Modifications recommended, requiring protocol resubmission
- Protocol discontinued
- Extension of project (if extension necessary, Yes/No, if Yes, period of extension)

State the recommendations:

Signature of the Member Secretary _____ Date _____

Name of the Member Secretary _____

AN5-V3/IEC-PGIMS SOPV3/08

Project Annual Report Approval Letter

PI Name:

PI address:

Project Title:

IEC code no.

Study/Protocol No. (For drug/device trials/any other):

This is with reference to your letter regarding the annual status report of the above-mentioned project. The Annual Study Status Report was discussed and noted in the IEC meeting held on _____ The IEC has noted the progress report. The following recommendations are suggested (wherever applicable);

Signature of the Member Secretary _____ **Date _____**

Name of the Member Secretary _____

Flow Chart

Determine the date of continuing review

↓

Notifying the PI or study team

↓

Manage continuing review package upon receipt

↓

Verify the contents of the package

↓

Prepare meeting agenda

↓

Protocol review process

↓

Storage of original documents

↓

Communicate the IEC decision to the PI

Chapter 9: Reporting of Protocol Deviation/Non-Compliance/Violation/Waiver

Purpose & Scope:

These SOPs provide instructions for taking action and maintaining records, when investigators/ trial sites, fail to:

- Follow the procedures written in the approved protocol.
- Comply with national/international guidelines for the conduct of human research.
- Respond to the IEC requests.

This SOP applies to all IEC approved research protocols involving human subjects.

9.1 Responsibility

- The PI should forward protocol deviation/non-compliance/violation/waiver reports to the IEC. Protocol Waiver is analogous to a Protocol Deviation, except that prior IEC approval must be obtained before implementing the necessary departures from the protocol. Therefore, Protocol Waivers are anticipatory, while Protocol Deviations are not. e.g. Protocol Waiver means a prospective decision by a sponsor or investigator to permit accrual of a subject who does not satisfy the approved inclusion/exclusion criteria for enrolment.
- The IEC office will receive deviations /violations/waiver reports submitted by the PI. Reporting of deviation/ noncompliance/ violation/ waiver in any other reporting format will not be accepted. It will be placed in the meeting agenda.
- IEC members should review and take action on such reports.

9.2 Detailed instructions

9.2.1 Detection of protocol deviation/non-compliance/violation/waiver

A. The IEC members performing monitoring of the project at trial site can detect protocol deviation/non-compliance/violation, if the project is:

- Not conducted as per protocol/national/international regulations

- When scrutinizing annual/periodic reports/SAE reports
- Any other communication received from the Investigator/trial site/sponsor/study monitor/ CRO

B. IEC office can detect protocol deviation/non-compliance/violation from failure to

- Comply with statutory requirements
- Respond to requests from IEC within reasonable time limit
- Respond to communication made by IEC

C. Communication/complaint/information received from research participant who has been enrolled or any individual who has been approached for enrollment

D. Any report/communication brought to the notice of the Member Secretary/Chairperson of IEC

E. Communication received from the Director, Pt. B. D. Sharma, PGIMS, Rohtak informing IEC about an alleged protocol violation/non-compliance/protocol deviation.

9.2.2 Noting protocol deviation/non-compliance/violation/waiver by the IEC office

- The members of site monitoring committee who have performed monitoring of a particular trial site and detect protocol deviation/non-compliance/violation will inform the IEC office in writing within 24 hours [one working day].
- Whenever protocol deviation/non-compliance/violation have been observed, the IEC office will ensure that the issues as well as the details of non-compliance involving research investigators are included in the agenda of the IEC meeting.

9.2.3 Board Discussion, Decision and Action

- If the protocol deviation/non-compliance/violation is detected by IEC member during monitoring visit he/she will present the protocol deviation/noncompliance/violation information.
- If detected by the IEC office forwarded by PI, the Member Secretary will present the protocol deviation/non-compliance/violation/waiver information.

- The deviations/violations will be scrutinized for gravity and implications in the formal full board IEC meeting. The IEC members will review the information available and take a decision depending on the seriousness of the violation.
- The decision will be taken to ensure that the safety and rights of the research participants are safeguarded. The decision will be taken by consensus and if no consensus is arrived at, voting will be conducted.
- The IEC decision will be communicated to PI.

The actions taken by IEC could include one or more of the following:

- Inform the PI that IEC has noted the violation/noncompliance/deviation and inform the PI to ensure that deviations/noncompliance/violations do not occur in future and follow IEC recommendations.
- Enlist measures that the PI would undertake to ensure that deviations/noncompliance /violations do not occur in future.
- Reprimand the PI.
- Call for additional information.
- Suspend the study till additional information is made available and is scrutinized.
- Suspend the study till recommendations made by the IEC are implemented by the PI and found to be satisfactory by the IEC.
- Suspend the study for a fixed duration of time.
- Inform the Director, Pt. B. D. Sharma PGIMS, Rohtak for suitable action.
- Revoke approval of the current study
- Keep other research proposals from the PI/ Co-PI under abeyance.
- Review and / or inspect other studies undertaken by PI/Co-PI.

9.3 Notifying the investigator

- The IEC office records the IEC decision and prepares a notification letter.

- The Member Secretary signs and dates the letter.
- The IEC office sends a copy of the notification to the investigator.
- The IEC office sends a copy of the notification to the relevant national authorities, the sponsor or the CRO of the study and other trial sites, in case of multi-centric trial, if so, recommended by IEC.

9.4 Records and follow up by IEC office.

- Keeps the original copy of the notification letter in the "non-compliance' file.
- Stores the file on the shelf with an appropriate label.
- Follows up the action after a reasonable time.
- Maintains a file that identifies investigators who are found to be non-compliant with national/international regulations or who fail to follow protocol approval stipulations or fail to respond to the IEC request for information/action.

AN1-V3/IEC-PGIMS SOPV3/09

Deviation (D)/Waiver (W)/Violation (V) Reporting Form)

1. IEC Code No. **2. Study/ Protocol No. (For drug/device trials/any other):** **3. Protocol Title** **4. Principal Investigator:**
5. Specify if D/W/V
6. Date of occurrence: dd/mm/yyyy (Not applicable in case of Waiver)
7. No of similar D/W/V occurred the same trial:
8. Patient No. and name: **9. Complete Details of D/W/V (attach separate sheet if necessary):**
10. Action taken by PI/Co-PI/guide: (Not applicable in case of Waiver)
11. Impact on trial subject (if any): (Not applicable in case of Waiver)
12. Whether D/W/V informed to sponsor/CRO:

Signature of PI

Name: _____ **Date_____**

AN2-V3/IEC-PGIMS SOPV3/09

Form for communicating decision of Deviation (D)/Waiver (W)/Violation (V) to PI
IEC Code No.

Study/ Protocol No. (For drug/device trials/any other):

Protocol Title

Principal Investigator:

Subject:

Reviewed by the IEC

Final decision at the full board meeting held on _____

Action taken:

[ ] Noted

[ ] Request the Principal Investigator to take immediate action to prevent such deviations/non compliances/violations in future

[ ] Specific recommendations stated below to be followed

_____

_____

[ ] Suspend the study till the IEC recommendations are implemented

[ ] Suspend the study till information available

[ ] Terminate approval of the current study

Reasons for termination:

_____

_____

Any other comment _____

Signature of the Member Secretary _____ **Date _____**

Name of the Member Secretary _____

Flow Chart

Detection of Protocol/noncompliance/Violation, Request for waiver by PI

Noting protocol deviation/non- compliance/waiver

Board discussion, decision and action

Notify the PI of IEC action

Maintain record

Chapter 10: Review of Adverse Events (AE) Reports

10.1 Purpose:

The purpose of this SOP is to provide instructions on the review and follow-up reports of serious adverse events (SAEs) and unexpected events for study approved by the IEC. The reporting is in accordance to the Gazette, Govt. of India. Unanticipated risks are sometimes discovered during the course of studies. Information that may impact on the risk/benefit ratio should be promptly reported to and reviewed by the IEC or SAE monitoring sub-committee (formed by IEC) to ensure adequate protection of the welfare of the study participants. The unanticipated risks may as well include any event that in the investigator's opinion, may adversely affect the rights, welfare or safety of participants in the study.

10.2 Scope:

This SOP applies to the IEC and SAE monitoring sub-committee review of SAE and unexpected events reports, both on site and off site, including follow up reports submitted by investigators.

10.3 Responsibility

It is the responsibility of the PI to report any AE/SAE (onsite or offsite) in the enrolled participants as per rules of Govt. of India.

The primary responsibility of the IEC or SAE monitoring sub-committee is to review and address SAE and unexpected events involving risks to research participants. IEC should also make sure that researchers are made aware of the policies and procedures concerning reporting and continuing review requirements for SAE.

In case, the investigator fails to report any SAE within the stipulated period, he shall have to furnish the reason for the delay to the satisfaction of DCGI along with the report of the SAE.

10.4. Detailed instructions

A. On site SAEs

10.4.1 SAE related activities before IEC meeting

- The IEC office will verify that the reports are complete, signed and dated by the PI. In case the IEC office notes that the report is incomplete, it will be forwarded to Member Secretary, IEC for decision and also revert back to PI.
- The IEC office should receive the reports of SAEs occurred for IEC approved studies within the stipulated time of the occurrence of the SAE.
- If the SAE is 'Death', the IEC office should receive the SAE reporting form (AN1-V3/IEC-PGIMS SOPV3/10) within the stipulated time of its occurrence.
- If the PI has not adhered to the above stipulated time period, the IEC office will notify the discrepancies in the reporting time and time of occurrence of SAE to the PI.

10.4.2 Actions to be taken by Member Secretary, IEC

- If the SAE reported is 'death', the Member Secretary will send to SAE monitoring subcommittee, and it will report to the Chairperson, IEC for further action.
- The Member Secretary will table SAE report (as submitted by SAE monitoring subcommittee) at the next scheduled IEC full board meeting

10.4.3 Actions to be taken by SAE Subcommittee

The SAE subcommittee will look at the report of SAEs submitted by PI (on site) and will report to the Chairperson, IEC.

Decision of subcommittee will be reported in the next IEC meeting (AN2-V3/IEC-PGIMS SOPV3/10).

10.4.4 Actions to be taken by Chairperson

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

- Suspending enrolment of new research participants till further review by the IEC.
- Suspending all trial related procedures (except those intended for safety and wellbeing of the participant) till further review by the IEC.

- Suspend some trial-related procedures (to be listed).
- Calling for an emergency review by full board.
  - This review should be initiated within 48 working hours (2 working days) of receipt of information.
  - This review could be done through a meeting, teleconference, email or telephonic conversation.
  - The IEC office will take appropriate steps to ensure that IEC members are informed about this full board emergency review.
  - The chairperson could direct the Member Secretary, IEC, to invite one or more experts if necessary. These experts could participate after they agree to the confidentiality clause and abide by the rules and regulations of IEC.
  - Soliciting opinion of one or more expert in writing. The information can be provided to expert after he/ she/ they agree(s) to the confidentiality clause and abide by the mandate of IEC. The expert would be requested to provide an opinion in writing within 14 working days, depending upon the gravity and seriousness of the matter.
  - Report at the next IEC meeting for discussion**.**

B. Off-site SAEs

- Off Site SAEs where adverse event reports that are serious, unexpected and related (definitely, probably and possibly) to the drug need prompt reporting to the IEC with reporting of center-wise SAE's.
- The SAEs that are expected (if listed in the informed consent) or unexpected but unrelated to the drug (classified as per the Offsite Safety Report Classification form (AN3-V3/IEC-PGIMS SOPV3/10) have to be logged (AN4-V3/IEC-PGIMS SOPV3/10) by the PI and to be submitted every 3 months and/or submitted along with continuing review report. The log has to be maintained continuously until the end of the study.

- Those off site SAEs which qualify for prompt reporting, (classified as per the Offsite Safety Report Classification form AN3-V3/IEC-PGIMS SOPV3/10) will be reported to the IEC office, and forwarded to Member Secretary, IEC for further action.
- If a trend is observed in SAEs by PI, such a trend will be reported to the IEC office, action on such reports will be taken by the Member Secretary, IEC as per 10.3-10.4.
- The IEC office will require complete set of "Off-site Safety Reports" and/or the log. The IEC will review the log of (AN4-V3/IEC-PGIMS SOPV3/10) the SAEs every 3 months and at the time of continuing review/submission of annual status report.
- **The PI must comment possible effect of previously reported and current SAE reports on ongoing study while submitting the documents.**

10.5 During the IEC meeting (On site or off-site SAEs)

- If appropriate, specific action or combination of actions will be taken, based on the consensus decision of the IEC discussion. Some of these are listed below:
  - Terminate the study.
  - Suspend the study till review is completed.
  - Suspend the study till additional information is obtained. o Suspend the study for a fixed duration of time.
  - Suspend the study till amendments requested for by the IEC are accepted.
  - Suspend enrolment of new research participants.
  - Suspend certain activities under the protocol (while going on with activities intended to protect the safety, well-being of participants who have already been enrolled).
  - Recommend an amendment to the protocol, the ICD, Participant information sheet, investigator brochure and/ or any other document.
  - Request additional details. o Request further follow up information.
  - Direct the PI to inform participants already enrolled in the study about the SAE and obtain their consent regarding continuation in the research trial, if necessary.

- Direct the PI to inform participants already enrolled in the study about the SAE and request them to undertake additional visits, additional procedures, additional investigations, etc. as prescribed in the amendment.
- Note the SAE report in the IEC.
- Recommend for compensation and send to DCGI.
- Any other action (as per schedule Y).

10.6 After the review of SAE

- The IEC office will send a formal letter signed by the Member Secretary to the investigator/s with instructions for specific actions as per the IEC decision and compliance to actions recommended by the IEC within 14 days of receipt of the IEC letter.
- The IEC will instruct the PI to forward follow-up reports of the SAE to the IEC.
- The IEC office keeps a copy of the letter in the master file of the research protocol.
- In case a PI fails to respond to the IEC letter, the matter will be discussed at the next full board meeting and a decision will be taken for specific action.
- Inform the DCGI (within 30 days) of IEC decision in case of drug trials.
- IEC will decide if it is necessary to suspend recruitment/modify protocol/PID.

10.7 Time line for reporting of SAE('s)/SAE for 'death' (as per Gazette, Govt. of India)

Responsibility of PI

- The researcher is responsible for reporting all SAEs to the IEC within 24 hours of knowledge. Reporting of SAE may be done through email or fax communication (including on nonworking days)
- A report (after due analysis) has to be submitted by the PI to DCGI, Chairman of IEC and the Head of Institution where the trial is being conducted, ***within 14 days of the occurrence of SAE.***

Responsibility of IEC

- The IEC shall forward its report on the SAE, after due analysis, along with opinion on the financial compensation, if any to be paid by the sponsor, to DCGI ***within 30 days of the occurrence of the SAE***

Responsibility of DCGI

- DCGI shall forward the report of the Investigator, sponsor and the IEC to the chairman of the independent Expert Committee of DCGI. The Expert Committee of DCGI shall examine the report of SAE and give its recommendations to DCGI for the purpose of arriving at the cause of SAE ***within 105 days of occurrence of the SAE***. In case of clinical trial related death, the Expert Committee shall also recommend the quantum of compensation to be paid by the sponsor/representative.
- DCGI, after considering the recommendations of Expert committee, shall decide the quantum of compensation to be paid by the sponsor/representative and pass orders ***within 150 days of occurrence of the SAE.***

Responsibility of sponsor/PI

- The sponsor/representative, shall pay the compensation in case of clinical trial related injury or death as per the order of the DCGI ***within 30 days of the receipt of such order.***

AN1-V3/IEC-PGIMS SOPV3/10

Onsite Adverse Drug Event Reporting Form

1. IEC Code No.
2. Study/ Protocol No. (For drug/device trials/any other):
3. Protocol Title
4. Principal Investigator:
5. Suspected Adverse Reaction (diagnosis): **6. Report date:** **7. Date of onset of SAE:**
8. Report type: a. Initial: b. Follow up---------- If Follow-up report, state date of Initial report---------- **c.** Final:
9. Patient information: a. Patient Initial and Case No./Subject ID. b. Age: c. Gender: d. Height: e. Weight:
10. Information related to no. of recruitment/prior SAE and death

	Total number of recruitments at	**Total number of SAE (prior) occurred at**	**Number of similar SAEs (prior) occurred for same study at**	**Total number of deaths at**
This site				
Other site (s)				

11. Tick whichever is applicable for serious adverse event

A. Expected event [ ] Unexpected event [ ]

B. Hospitalization [ ] Increased hospital stay [ ] Death [ ] Others [ ]

C. In case of Death, state probable cause of death…….

D. (If other, please specify: …….

E. No permanent significant functional/cosmetic impairment [ ]

Permanent significant functional/cosmetic impairment [ ]

Not applicable [ ]

12. If there was a research related injury/hospitalization, the cost of treatment/ hospitalization was borne by:

Patient [ ] Institute [ ] Sponsor/CRO [ ]

13. Suspect drug information

a) Suspect drug (include generic name) device/intervention:

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

c) Daily dose and regimen:

d) Route(s) of administration:

e) Dosage Form and Strength:

f) Therapy dates (start and stopped date):

14. Did the reaction decline after stopping the drug/procedure (Dechallenge & Rechallenge information):

YES [ ] NO [ ] NA [ ]

15. Concomitant drugs history and lab investigations:

a) Concomitant drug (s) and date of administration:

b) Relevant test/laboratory data with dates:

c) Patient relevant history (e.g. diagnosis, allergies):

16. Description of adverse event

a) Start date (and time) of onset of reaction:

b) Stop date (and time) or duration of reaction:

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

d) Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious.

e) In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction, indicate if this is follow-up report and if so, include follow-up information only:

17. Describe the medical treatment provided for adverse reaction (if any) to the research subject. This is an update on treatment given during hospitalization:

18. Outcome:

Resolved [ ] Ongoing [ ] Death [ ]

19. Was the research subject continued on the research protocol?

Yes [ ] No [ ] NA (Mark 'NA' in case of death) [ ]

20. Has this information been communicated to sponsor/CRO/regulatory agencies?

Yes [ ] No [ ]

Provide details if communicated (including date):

21. In your opinion, does this reaction require any alteration in trial protocol?

Yes [ ] No [ ]

If yes then please specify:

22. Causality Assessment:

23. Details about the Investigator

- Name:
- Address:
- Telephone number/email:
- Profession (specialty)

Signature of PI

Date_____

Upon receipt of this report, the IEC will decide whether additional information is needed or whether further investigation of the reaction is required.

AN2-V3/IEC-PGIMS SOPV3/10

Form to Record Recommendations by IEC

Noted and follow up report requested (if applicable) No [ ] Yes [ ]

Changes to the protocol recommended? No [ ] Yes [ ]

If yes then recommendations:

_____

_____

Changes to the informed consent form recommended? No [ ] Yes [ ]

If yes then recommendations:

_____

_____

Request for additional information [ ]

Additional Information needed:

_____

_____

(Till additional information is received, new recruitment should be withheld)

Terminate the project [ ]

Reasons for termination:

_____

_____

Any other including communicated of information to sponsor/CRO/regulatory agencies

_____

_____

Signature of the Member Secretary _____ Date _____

Name of the Member Secretary _____

AN3-V3/IEC-PGIMS SOPV3/10

Off-site Safety Reports Classification Form

Note to PI:

The following questions will act as a guide for submission of the "Safety Reports". This form is merely providing guidance for reporting / logging of Offsite Safety Reports.

If the answer to initial three questions (1-3) is ***"Yes", prompt reporting is required and such off-site Safety Reports need to be reported to IEC along with the log.***

If any one answer is "No", it needs to be logged as prescribed format (AN4-V3/IEC-PGIMS SOPV3/10). This log should be submitted to the IEC office every 3 months and/or along with Continuing Review report.

IEC Code No.:

Project No.

Project Title:

Subject ID.:

Type of SAE (initial/follow up/any other):

Sr. No.	Questions	
1.	**Is adverse event serious? Yes/No**	
2.	**Is adverse event related to the trial medication/procedure? Yes/No**	
3.	**Is adverse event unexpected? Yes/No**	
4.	**Does warrant any change in protocol, PID? Yes/No**	**If yes, please provide details**

Date of Reporting:

Signature of the PI _____ **Date _____**

Name of the PI _____

AN4-V3/IEC-PGIMS SOPV3/10

Off-site Safety Reports Log

Note to PI:

1. Please log in details of Off-Site Safety Report.
2. The following log has to be maintained continuously until the end of the study.
3. This log should be submitted to the IEC office every 3 months and/or along with Continuing Review report.
4. The log must be submitted to the IEC office immediately, if prompt reporting is required and/or if a trend related to the occurrence of SAE is observed.
5. Please note the complete sets of Offsite Safety Reports need to be sent to IEC office as and when received.

IEC Code No.:
Study/Protocol No. (For drug/device trials/any other):
Project Title:
PI:

No. of Participants enrolled in Pt. B. D. Sharma PGIMS/UHS, Rohtak: _____

No. of Participants enrolled globally: _____

No. of subjects on trials at Pt. B. D. Sharma PGIMS/UHS, Rohtak: _____

No. of SAE at Pt. B. D. Sharma PGIMS/UHS, Rohtak: _____

No. of deaths at Pt. B. D. Sharma PGIMS/UHS, Rohtak: _____

No. of deaths globally: _____

S. No.	Subject ID/ SAE No.	Country	Date of Onset	Adverse event	Out Come	Remarks

Is any change in protocol, PID required on the basis these and of previously reported SAE? Yes/No, if yes, please provide details.

Signature of the PI _____ **Date _____**

Name of the PI _____

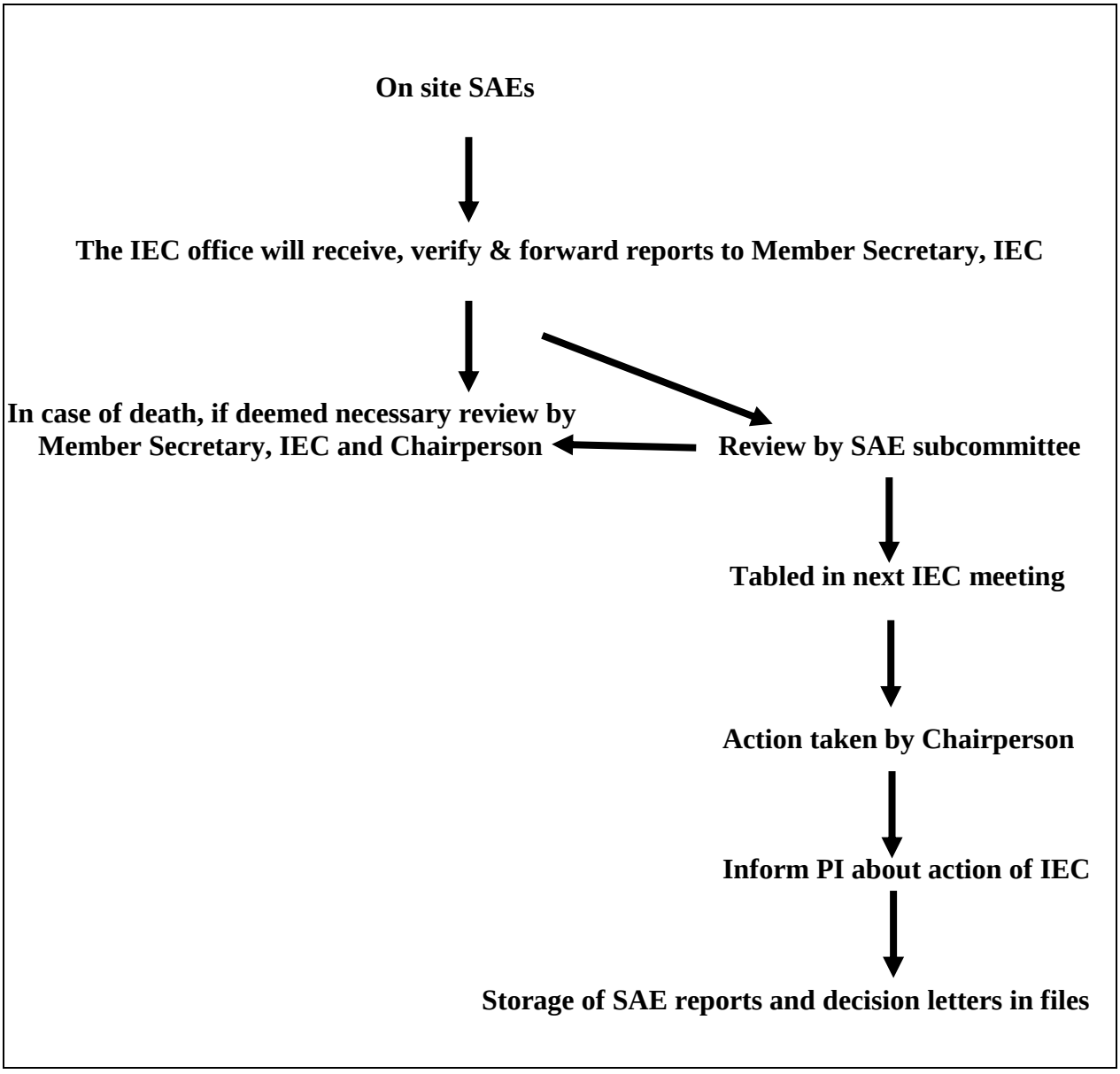
AN5-V3/IEC-PGIMS SOPV3/10

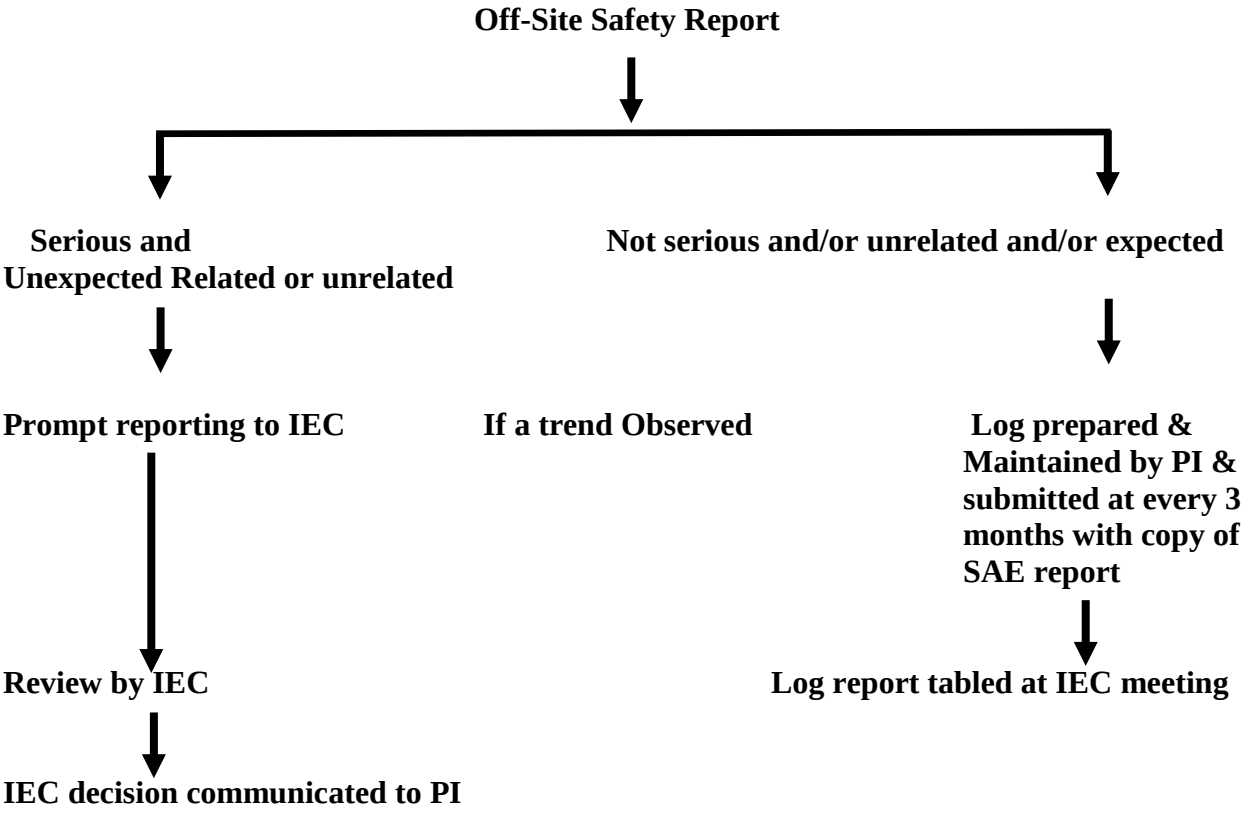
Form to Record SAE assessment by SAE monitoring subcommittee

1. Details of the communication between you & Investigator along with other details etc. with regard to the event.
2. Details of examination of event by the SAE monitoring subcommittee, minutes of meeting including cause of death & recommendation on compensation, if any.
3. Details of the documents considered during the assessment of the SAE.
4. Indicate with justification and documentary evidence to as whether the SAE (death) is related/no related to each of the following criteria mentioned under GSR 53 (E) dated 30.01.2013 and rule 122 DAB of the Drugs and Cosmetics Rules.
   a) Adverse effects of investigational product(S);
   b) Violation of the approved protocol, scientific misconduct or negligence by the sponsor or his representative or the investigator;
   c) Failure of investigational product to provide intended therapeutic effect;
   d) Use of placebo in a placebo-controlled trial;
   e) Adverse effect due to concomitant medication excluding standard care necessitated as part of approved protocol;
   f) For injury to a child in-utero because of the participation of parent in clinical trial;
   g) Any clinical trial procedures involved in the study.
5. Inform the risk Factor depending on the Seriousness and severity of disease, presence of co-morbidity and duration of disease the subject at the time of enrolment in the clinical trial between a scale of 0.5 to 4 as per the compensation formula decided by IEC (available on website: cdsco.nic.in).

a) 0.50 terminally ill patients (expected survival not more than (NMT) 6 month).
b) Patient with high (expected survival between 6 to 27 months)
c) Patient with moderate risk.
d) Patient with mild risk.
e) Healthy Volunteers or subject of no risk

Flow Chart


On site SAEs
The IEC office will receive, verify & forward reports to Member Secretary, IEC
In case of death, if deemed necessary review by Member Secretary, IEC and Chairperson
Review by SAE subcommittee
Tabled in next IEC meeting
Action taken by Chairperson
Inform PI about action of IEC
Storage of SAE reports and decision letters in files


Off-Site Safety Report
Serious and Unexpected Related or unrelated
Not serious and/or unrelated and/or expected
Prompt reporting to IEC
If a trend Observed
Log prepared & Maintained by PI & submitted at every 3 months with copy of SAE report
Review by IEC
Log report tabled at IEC meeting
IEC decision communicated to PI

Chapter 11: Review of Study Completion Reports

Purpose & Scope:

The purpose of this SOP is to provide instructions on the review of Study Completion Report for every study previously approved by the IEC. Review of the Study Completion Report which is an obligatory review of each investigator's activities presented to the IEC as a written report of study completed.

11.1 Responsibility

- It is the responsibility of the PI to submit Study Completion Report for the concerning project to the IEC office within 6 weeks of completion of the study as per the Study Completion Report form (AN1-V3/IEC-PGIMS SOPV3/11) or AN2-V3/IEC-PGIMS SOPV3/11). Any alternate form for Pharma company driven trials (provided by the Sponsor, etc.) may be used, provided that the information submitted covers all the points mentioned in Study Completion Report forms. Site closure information Pharma company driven trials should also be submitted.
- It is the responsibility of the IEC members to review the study completion report and notify its approval or request for further information, if necessary.

11.2 Detailed Instructions

11.2.1 Before Board Meeting

- The IEC office will receive Study Completion Reports from the PI and check for completeness before submission for the Board meeting

11.2.2 During Board Meeting

- IEC member(s) should review and discuss the Final Report in the IEC meeting.
- If appropriate to the discussions, the Chairperson may call for consensus to accept it or request further information or take any other action as suggested by IEC.

11.2.3 After Board Meeting

- The IEC office will note the decision in the meeting minutes and the study will be considered as closed if the document is accepted.
- The IEC decision is communicated to the investigator. In case further information/action are requested, the same should be followed by the PI and communicated to the IEC office within 4 weeks. This update will be tabled in the full board meeting of IEC (AN3-V3/IEC-PGIMS SOPV3/11).
- The IEC office will archive the entire study protocol and the report for a period of 5 years or longer as per the requirement of the study.

AN1-V3/IEC-PGIMS SOPV3/11

Study Completion Report form
(For Interventional Study)

(To be Filled by PI and submit 6 copies)	
1. IEC Code No. **2. Study/ Protocol No. (For drug/device trials/any other):** **3. Protocol Title:**	
4. Principal Investigator: **5. Phone number, email ID:**	
6. Sponsor: **7. Address:** **8. Phone, E mail:**	
9. Study Initiation Date:	
10. Study Completion Date:	
11. Number Screened: **12. Number Enrolled:** **13. Target Number:**	
14. Date of first Subject enrolled: **15. Date of last Subject enrolled:** **16. Date of first Subject completed study:** **17. Date of last Subject completed study:**	
18. No. of study arms:	
19. Duration of the study:	
20. Objectives:	
21. SAEs at the center: **(Total number and type)**	

22. Whether all SAEs intimated to the IEC (Yes/No):	
23. No. of patients withdrawn/lost to follow up (drop out):	
24. Reasons for withdrawal: **25. Protocol deviations/violations: (Number and nature)**	
26. Storage of document for more than 5 years, Yes [ ] No [ ] **If yes, for how many years? _____**	
27. Results (please attach a separate sheet if necessary):	
28. Conclusion:	
Signature of PI **Date_____**	

Please submit thesis summary/manuscript (if applicable)

AN2-V3/IEC-PGIMS SOPV3/11

Study Completion Report form
(For Non-Interventional Study)

IEC code no.

Title of the project:

Principal Investigator (Name & Department):

Sponsor:

Date of sanction by IEC: _____Date of start: _____

Date of termination: _____

Duration of project:

Objectives of the study:

Total number of patients to be recruited for the study: _____

Number actually recruited: _____

Protocol deviation/violation (number):

Result:

_____

_____

Conclusion:

Storage of document for more than 5 years, Yes [ ] No [ ]

If yes, for how many years? _____

Signature of the PI _____ Date _____

Name of the PI _____

Please submit thesis summary/manuscript (if applicable)

AN3-V3/IEC-PGIMS SOPV3/11

Notification for Acceptance of Study Completion Reports

Reviewed by the IEC

Full Board meeting held on (date)_____

Comments (if any):

_____

_____

Action taken:

Noted [ ]

Requires more information/ action as follows [ ]:

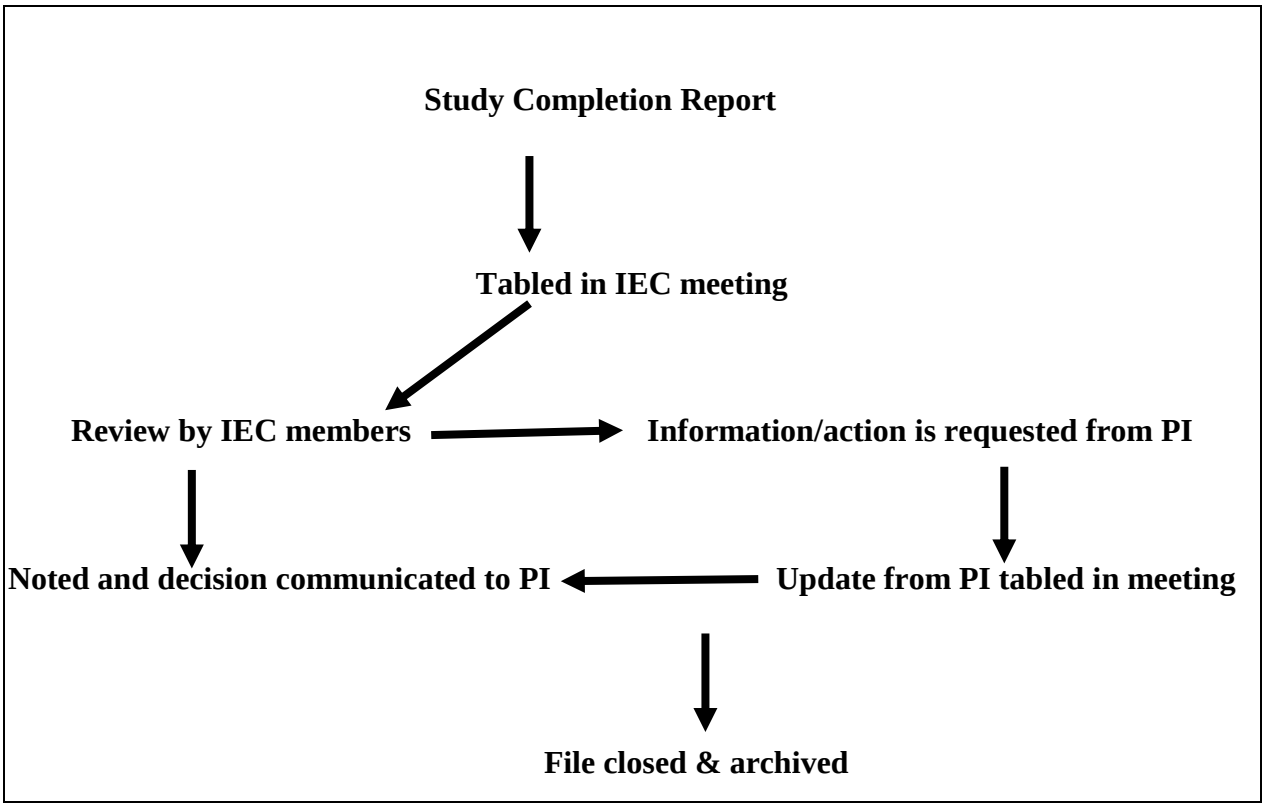
_____

_____

Signature of the Member Secretary _____ **Date _____**

Name of the Member Secretary_____

Flow Chart


Study Completion Report
Tabled in IEC meeting
Review by IEC members
Information/action is requested from PI
Noted and decision communicated to PI
Update from PI tabled in meeting
File closed & archived

Chapter 12: Management of Premature Termination/Suspension/ Discontinuation of the Study

Purpose & Scope:

The purpose of this SOP is to describe how the IEC proceeds and manages the premature termination/suspension/discontinuation of a research study. Protocols are usually terminated at the recommendation of the IEC, PI, sponsor or other authorized bodies wherein subject enrollment and subject follow-up are discontinued before the scheduled end of the study. This SOP applies to any study approved by IEC that is being recommended for termination/ suspension/discontinuation before its scheduled completion.

12.1 Responsibility

It is the responsibility of the IEC to terminate any study that it has previously approved when the safety or benefit of the study participants is doubtful or at risk. The IEC office is responsible for management of the premature termination/suspension/discontinuation process.

12.2 Detailed instructions

12.2.1 Receiving recommendation for study termination/suspension/discontinuation

- The IEC office will receive recommendation and comments from PI, sponsor or other authorized bodies for premature termination of study protocol and place them before the board.
- The IEC members/ Chairperson can prematurely terminate study if protocol noncompliance/ violation is detected and IEC decision is to terminate the study.
- SAE occurring at trial site may require the study to be prematurely terminated for the safety of the patients.
- The IEC office will inform the PI to prepare and submit a protocol termination report.

- The IEC office will receive the Premature Termination Report (AN1-V3/IEC-PGIMS SOPV3/12) submitted by the PI and check for completeness. It should contain a brief written summary of the protocol, its results, and accrual data. The IEC office will initial and date it upon receipt.

12.2.2 Review and decision on termination/suspension/discontinuation report

- IEC will review the Premature Termination Report (AN1-V3/IEC-PGIMS SOPV3/12) at regular full board meeting and make appropriate recommendation(s).
- If the report is unclear, a query can be sent to the PI for more information.

12.2.3 Notifying the PI

- The IEC office will make notification letter acknowledging the approval of termination or query letter to request additional information regarding the premature termination within 14 days after the meeting (AN2-V3/IEC-PGIMS SOPV3/12).
- If a query is sent to PI, the reply letter will be reviewed in the next full board meeting and steps in 12.4.2 will be performed by the IEC office.

AN1-V3/IEC-PGIMS SOPV3/12

Premature Termination/Suspension/Discontinuation Report

1. IEC Code No. **2. Study/ Protocol No. (For drug/device trials/any other):** **3. Protocol Title:**	
4. Principal Investigator:	
5. Sponsor:	
6. IEC Approval Date:	**Date of Last Progress Report Submitted to IEC:**
7. Starting Date:	**Termination Date:**
8. No. of Participants Enrolled:	**No. of Participants Completed:**
9. No. of Ongoing Participants:	**No. of Drop Outs:**
10. SAE (Total No.):	**SAE Event:**
11. Summary of Results (please attach a separate sheet if necessary):	
12. Reason for Termination/Suspension/Discontinuation: ▪ **Safety concern** ▪ **Lack of efficacy** ▪ **Others**	
13. Storage of document for more than 5 years, Yes [ ] No [ ] **If yes, for how many years? _____**	
Signature of PI **Date_____**	

AN2-V3/IEC-PGIMS SOPV3/12

Notification from IEC for Premature Termination/Suspension/ Discontinuation of the Study

IEC code no.

Study/Protocol No. (For drug/device trials/any other):

Title of the project:

Principal Investigator (Name & Department):

Reviewed by the IEC

Full Board meeting held on (date)_____

Action taken:

Approval of the Premature Termination of the project [ ]

Requires more information/ action as follows [ ]

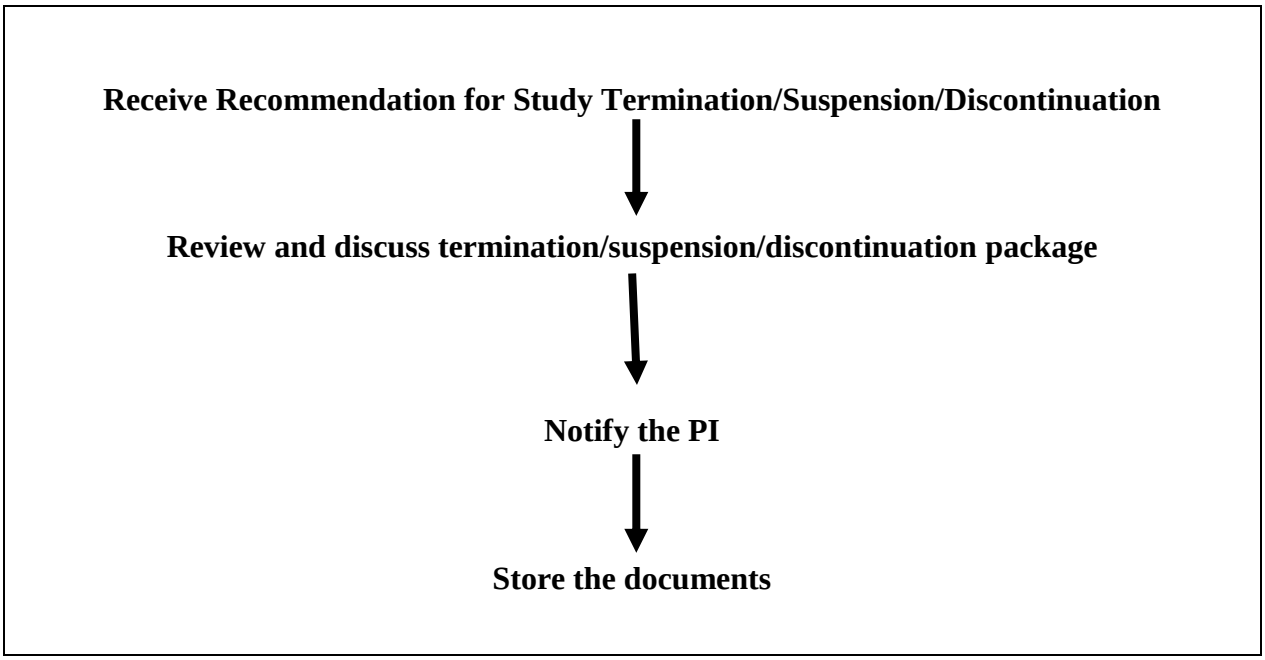
_____

_____

Signature of the Member Secretary _____ Date _____

Name of the Member Secretary _____

Flow Chart


Receive Recommendation for Study Termination/Suspension/Discontinuation
Review and discuss termination/suspension/discontinuation package
Notify the PI
Store the documents

Chapter 13: Request for Waiver of Written Informed Consent

Purpose:
The purpose of this SOP is to describe the type of research projects for which the IEC may grant waiver for requirement of obtaining written informed consent and the format of the application form to be used by the investigators for requesting waiver of consent.

Scope:
This SOP applies to the all protocols with a request of granting consent waiver submitted for review by the IEC. The decision should be taken by the IEC members at the expedited subcommittee/full board meeting.

13.1 Type of research projects which may qualify for consent waiver

The investigator can apply to the EC for waiver of consent if the ***proposed research should present no more than minimal risk to the participants and the waiver will not adversely affect the rights and welfare of the participants***. A request to waive written informed consent must be accompanied by a detailed explanation. The investigator is also required to provide assurance regarding protection of identity of research participants and maintenance of confidentiality about the data of the research participants. As per the ICMR 2017guidelines (http://ncdirindia.org/Ethics/Download/ICMR_Ethical_Guidelines_2017.pdf)in the following conditions consent waiver may be granted by IEC:

1	Research cannot practically be carried out without the waiver and the waiver is scientifically justified (e.g. disease burden estimation in HIV, genetic studies etc.).
2	Retrospective studies, where the participants are de-identified or cannot be contacted. e.g. a retrospective review of patient case records
3	Research on anonymized biological samples/ data.
4	Surveillance programmes/ programme evaluation studies.
5	Research on data available in public domain.
6	Research on humanitarian emergencies and disasters, when the participant may not be in a position to give consent. However, information about the study should be given to the patients whenever he/she gains consciousness, or to relative/ legal guardian when available later.

The requirement for obtaining consent can be waived of by the IEC, if there is a possible legal, social or economic risk to the participant entailed in signing the consent form as they might be identified as such by signing the consent form, In case of telephonic interviews, waiver of written informed consent may be requested but this does not mean that verbal consent cannot be utilized.

For verbal consent/telephonic interviews, the following documents need to be submitted by the PI:

- A script for verbal consent - a verbal consent script provides all of the elements of consent in a more informal style. In addition, each subject should be provided with an information sheet that describes the study and gives contact names and numbers.
- The interview schedule will confirm that the interview is a simple 5-minute call and that no questions are asked that compromise a person's confidentiality or position.
- Normally, investigators will be asked to keep a log of those who were approached about the study, and offered verbal consent. A simple chart can indicate the subjects as participant 1,2,3. A column can indicate that verbal consent was given and a date.
- Since a specific number of study participants are to be recruited. It is important that investigators keep some record to indicate that they are not enrolling more subjects than they originally requested.

13.2 Detailed instructions

- The PI will submit request for waiver of consent along with the study documents to the IEC office, in the given format AN1-V3/IEC-PGIMS V3/13 stating the reasons for the consent waiver
- The IEC members will review the request taking into consideration the types of studies for which waiver of consent may be granted.
- The IEC will ensure that there are adequate mechanisms described in the protocol for protection of the identity of the research participants and maintaining confidentiality of the study data.
- The decision regarding approval/disapproval of waiver is informed to the PI in writing. If the waiver is not granted, the IEC will provide reasons for the same in the given format AN2-V3/IEC-PGIMS V3/13.

AN1-V3/IEC-PGIMS V3/13

Application Form for requesting Waiver of Consent

1. **Principal Investigator's name**: _____

2. **Department**: _____

3. **Title of project**: _____
_____
_____

4. **Names of other participating staff and students:**
_____
_____

5. **Request for waiver of informed consent:**
Please check the reason(s) for requesting waiver (Please refer the back of this annexure for criteria that will be used by IEC to consider waiver of consent).

1. Research involves 'not more than minimal risk'
2. There is no direct contact between the researcher and participant
3. Emergency situations as described in ICMR Guidelines (ICMR 2006 Guidelineshttp:// www.icmr.nic.in/ethical_guidelines.pdf)
4. Any other (please specify)

_____
Statement assuring that the rights of the participants is not violated

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

_____

_____
Signature of PI

Name_____ Date_____

AN2-V3/IEC-PGIMS V3/13

Decision of IEC Regarding Waiver of Consent

To,

Dr._____
Principal Investigator,
PGIMS.

Ref: IEC code.
Title of project:

Dear Dr.
Institutional Ethics Committee reviewed and discussed your application (dated) for waiver to written informed consent during the IEC (number of meeting) meeting held on (date).

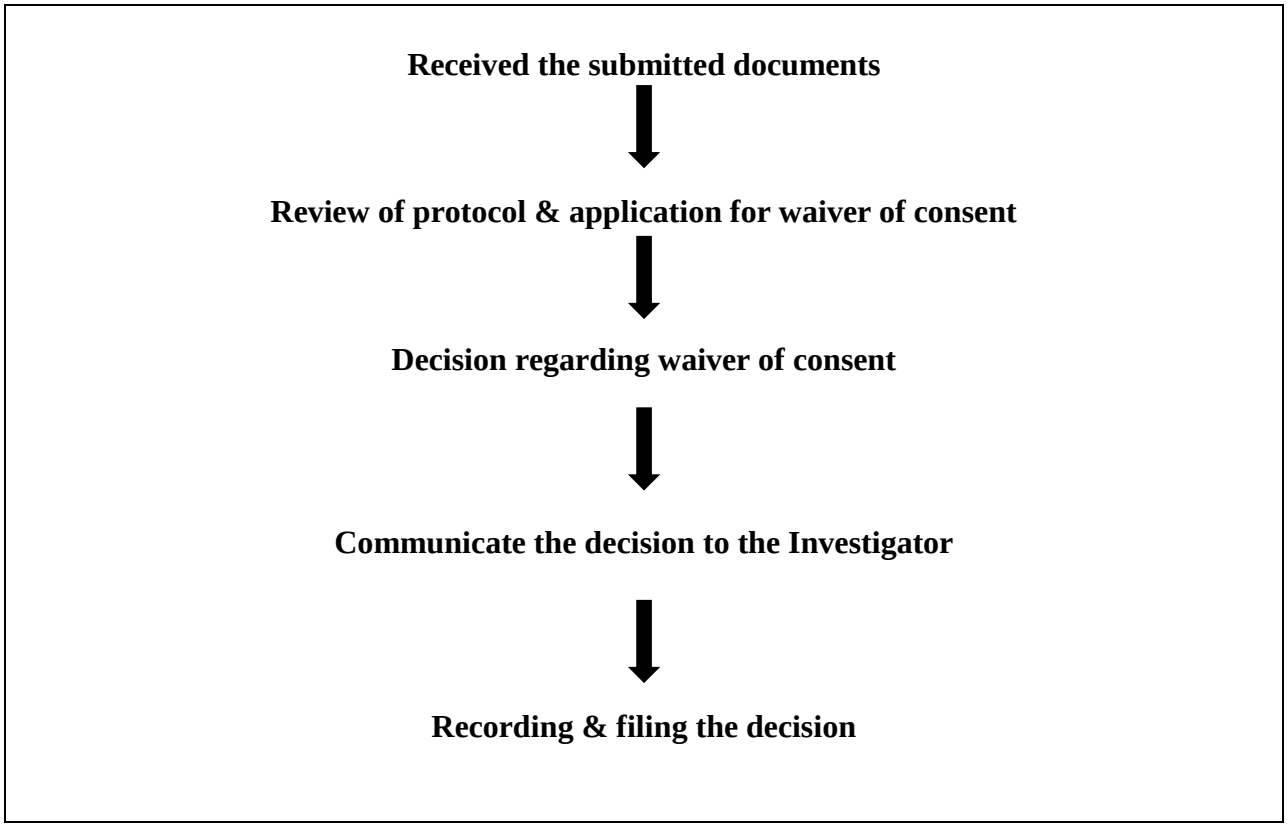
Waiver granted: Yes [ ] No [ ]
If not granted, reasons

_____
_____

Thanking You,
Yours Sincerely,
Signature of the Member Secretary _____ Date _____

Name of the Member Secretary _____

Flow Chart


Received the submitted documents
Review of protocol & application for waiver of consent
Decision regarding waiver of consent
Communicate the decision to the Investigator
Recording & filing the decision

Chapter 14: Maintenance of Active Project Files, Archival of Closed Files and Retrieval of Documents

This SOP provides instructions for maintenance of active study files and other related documents approved by the IEC, PGIMS ROHTAK, and storing of closed files and retrieval of documents.

14.1 Responsibility

It is the responsibility of IEC office staff to ensure that all study files are prepared, maintained, and kept securely for a period of five years after the closure of the project (under a proper system that ensures confidentiality and facilitates retrieval at any time) or till the time stipulated in the project whichever is later.

14.2 Maintenance of the active study files

- Master file is the file comprising of all essential documents and correspondence related to the study/protocol. Trial master files shall be established at the beginning of the trial, in the IEC office.
- The approved study files will assign unique identifiers (serial IEC code no.).
- All related documents together of the approved study files appropriately should be collected together.
- All active files will be kept in a secured file cabinet with controlled access. A log book of authorized individuals accessing the files will be maintained.
- All closed study files will be separately archived.
- Final disposal of study/master files, on completion of archival period, will be done by a committee constituted by Chairperson, IEC.

14.3 Accessibility/retrieval

Master files will be made available for inspection and copying by authorized representatives of regulatory authorities after receiving the request in writing. In case, any investigator needs a copy of any document from the master file, he/she should make a written request (AN1-V3/IEC-PGIMS SOP V3/14). The staff of the IEC office will furnish a copy of the required document within a week with IEC Member Secretary's approval.

14.4 Disposal of closed files and copies of protocols and documents

The records for any study in master file will be maintained in the IEC office for a period of 5 years or longer if required in the protocol following closure of the study. After completion of archival period, the records for closed files will be shredded by the Bioethics cell and disposed off, without any notification to PI. This will be done preferably within 1 year of completion of archival period. A log book of disposed documents will be maintained (AN2-V3/IEC-PGIMS SOP V3/14).

AN1-V3/IEC-PGIMS SOP V3/14

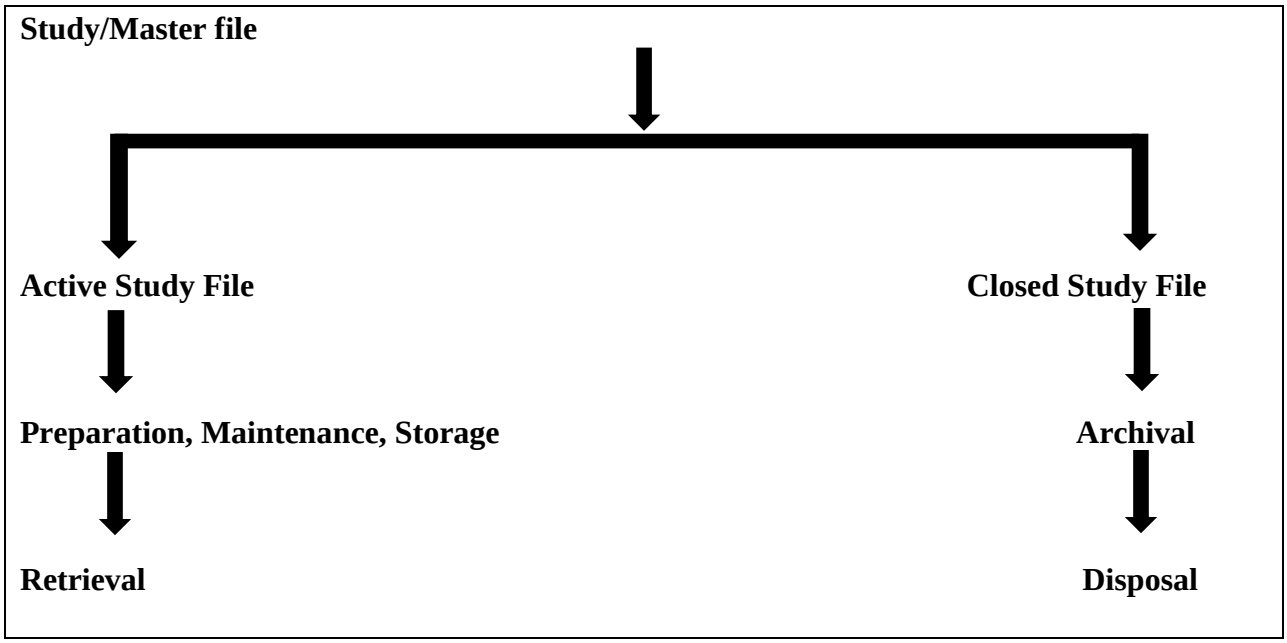
Document Request Form

IEC code no.:	**Project Title:**
Name of PI:	**Requested by:**
Documents requested:	
Purpose of the request:	
Principal Investigator's Signature:	
Signature of the requesting person:	
Permission of Member Secretary, IEC YES/NO **Signature of the Member Secretary _____ Date _____** **Name of the Member Secretary _____**	

AN2-V3/IEC-PGIMS SOP V3/14
Format of Written Online/Off log

Project No.	Title	PI	No of files	EC approval	Study Initiation Date	Study Closure Date	Name & Sign of Authorized Individual

Flow Chart


Study/Master file
Active Study File
Closed Study File
Preparation, Maintenance, Storage
Archival
Retrieval
Disposal

Chapter 15: Documentation of the IEC Activities

This SOP describe the procedures for documenting all IEC activities.

15.1 Responsibility

It is the responsibility of the IEC office staff to maintain all records.

15.2 Detailed instructions

15.2.1 IEC records. It will include the following:

1. IEC member's records.
    a. Acceptance letters of each member.
    b. Signed and dated recent Curriculum vitae and confidentiality agreement letters of each member.
    c. Records for each IEC member's participation in National/International Bioethics related activities
    d. Documentation of resignation/termination.
2. IEC members list
3. IEC attendance roster.
4. IEC meeting agenda and minutes.
5. Standard Operating Procedures.
6. Archival of current and completed/terminate study files.
7. Annual/ continuing/ completion reports.

15.2.2 Access to IEC records

IEC records will be made available for inspection by authorized representatives of regulatory authorities'/funding agency after receiving the request (AN1-V3/IEC-PGIMS SOP V3/15) in writing and log will be maintained (AN2-V3/IEC-PGIMS SOP V3/15).

AN1-V3/IEC-PGIMS SOP V3/15
Request/Compliance Form

To,

The Member Secretary,
IEC, PGIMS ROHTAK,

Dear Sir,
I would like to inform you that I want to take documents for following purpose. I will ensure you I will not divulge any information from the documents to anyone without your written authorization.

Purpose_____

List of documents,
_____
_____
_____
_____

You're faithfully,

Signature: _____

Date: _____

Name and designation_____

Address_____

AN2-V3/IEC-PGIMS SOP V3/15
Log of Requests for Copies of IEC Documents

No./ date of request	Documents requested (including file number if relevant)	No. of Copies	Name address of the individual requesting copies	Reason for request	Signature of the individual receiving the copy and date	Name and Signature of the IEC staff providing the copy and date

Flow Chart

IEC records

IEC member's records

IEC members list

IEC attendance roster **IEC office Staff**

IEC meeting agenda and minutes

Standard Operating Procedure

Annual/Completion reports **Access to Records**

Chapter 16: Dealing with Research Participant's Requests and Complaints

This SOP applies to all requests concerning the rights and well-being of subjects participating in studies approved by the IEC. This procedure provides guidelines for dealing with and accommodating requests by participants/patients regarding their rights as a participant or to resolve their complaints in any approved research study.

The IEC considers protection of the rights and welfare of the human subjects participating in a clinical research approved by the IEC as its primary responsibility. Informed Consent documents reviewed by the IEC contain the statement, "The queries related to the study and rights of participants may be addressed to the IEC, Member secretary (with the IEC address and phone number)".

16.1 Responsibility

It is the responsibility of the IEC office for providing required information to the research participants in case of queries received from research participants as per the guidelines/regulation of Right to Information (RTI) Act.

It is the responsibility of the IEC to initiate a process to give information to the participants or to identify and address any injustice that has occurred, if complaints are received from research participants.

16.2 Detailed instructions

- The Member Secretary/the IEC office receive an inquiry or request from research participant /patient.
- The request and information are recorded in the request record form (AN1-V3/IEC-PGIMS SOP V3/16)
- The IEC office will inform the Chairperson about the query /complaint received from the research participant.
- The Chairperson/Members designated by the Chairperson will provide information required by the research participant as per RTI Act.
- In case of complaint received from a research participant, the Chairperson initiates a process to identify and address any injustice that may have occurred.
- The Chairperson will direct the Member Secretary to consider the matter for discussion at a full board meeting or to call an emergency meeting of 2 or more IEC members for discussion or enquiry in order to resolve the matter.
- The Chairperson/Member Secretary/designated IEC members will assess the situation and mediate a dialogue between the research participant and the investigator to resolve the matter.

- The IEC will insist on factual details to determine reality between truth and individual perception.
- The final decision will be informed to the research participant by the IEC office. The information including any action taken or follow-up will be recorded in the form AN1-V3/IEC-PGIMS SOP V3/16 and the form is signed and dated.
- The IEC members shall be informed about the action taken and the outcomes in the forthcoming IEC meeting.

16.3 Filing the request document

The request details and copy of response by IEC office will be kept in the study file.

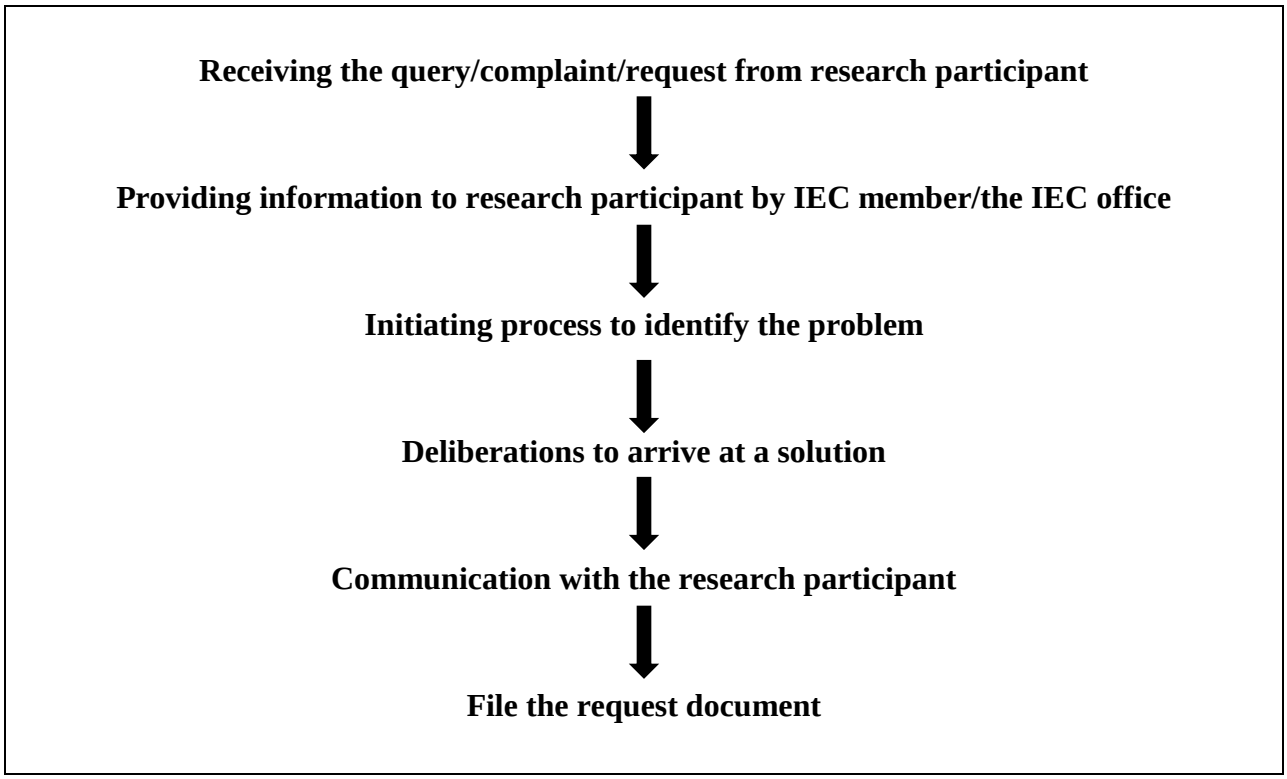
AN1-V3/IEC-PGIMS SOP V3/16
Request Record Form

Date Received:	
Received by:	
Request from:	o Telephone call No o Fax No o letter / Date o E-mail / Date o Walk-in: Date / Time o Other, specify
Participant's Name:	
Contact Address: **Phone:**	
Title of the Participating Study:	
Starting date of participation:	
What is requested?	
Action taken:	
Outcome:	

Signature of the Member Secretary _____ Date _____

Name of the Member Secretary _____

Flow Chart


Receiving the query/complaint/request from research participant
Providing information to research participant by IEC member/the IEC office
Initiating process to identify the problem
Deliberations to arrive at a solution
Communication with the research participant
File the request document

Chapter 17: Site Monitoring and Post-Monitoring Activities

17.1 Purpose

The purpose of this standard operating procedure (SOP) is to describe the procedures for site monitoring of an Institutional Ethics Committees (IEC) approved protocol to ensure participant rights, safety and wellbeing.

17.2 Scope

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

17.3 Responsibility

It is the responsibility of the IEC to decide for conduct on-site monitoring. It is further the responsibility of the designated IEC member(s) to perform on-site monitoring of selected study site(s).

17.4 Detailed instructions

17.4.1 Selection of study sites

- Routine monitoring for a site may be decided at the time of approval of the project by the Full Board.
- This is recorded in the IEC minutes.
- *"For-cause monitoring"* will be performed at sites for reasons identified by any member of the IEC, after approval by the Chairperson.
- The reasons for identifying a particular site for "*for-cause monitoring*" could include any one or more of the following:
- High number of protocol violations,
- Large number of studies carried out at the study site or by the investigator,
- Large number of Serious Adverse Events (SAE) reports,
- High recruitment rate,
- Large number of Protocol deviations,
- Complaints received from participants or any other person,
- Frequent failure to submit the required documents
- Any other cause as decided by IEC.

17.4.2 Before the visit

Irrespective of the cause for conducting monitoring the following procedure will be followed

- The IEC will identify and select one or more IEC members (henceforth referred to as monitors) to conduct monitoring of a site.

- The selected member/members will be given a letter in this regard.
- The agenda of monitoring will be decided by the identified monitors in consultation with the Member Secretary and Chairperson.
- The Bio-Ethics Cell will decide the date of the monitoring in consultation with the monitors and the PI.
- The final date will be communicated to the PI (with a request to be available) and monitors.
- The monitor/monitors will receive documents from Bio-Ethics Cell and review the relevant project documents and make appropriate notes.
- Monitors will carry with them Site Monitoring Visit Report Forms- AN-1/ IEC-PGIMS SOP V3/17 and AN-2/IEC-PGIMS SOP V3/17 (if applicable) collected from the Bio-Ethics Cell.

17.4.3 During the visit

- The Monitor will follow the check list and:
- check the log of delegation of responsibilities of study team.
- check if the site is using latest IEC approved current versions of the protocol,
- informed consent documents, case record forms, diaries, advertisements, etc. observe the informed consent process, if possible. review randomly selected participant's files to ensure that participants are signing the correct informed consent. check investigational product accountability is adequately controlled and documented throughout the product flow at the study site (arrival, dispensing, use, return from the subject and return/destruction after the study).
- check for storage times, conditions and expiry dates to be acceptable and sufficient supplies available, wherever applicable.
- verify that the investigator follows the approved protocol and all approved amendment(s), if any.
- ensure that the investigator and the investigator's trial staff are adequately
- informed about the trial.
- verify that the investigator and the investigator's trial staff are performing the
    - specified study functions, in accordance with the approved protocol and any
    - other written agreement between the sponsor and the investigator/institution,
    - and have not delegated these functions to unauthorized individuals.
- verify that the investigator is enrolling only eligible subjects.
- determine whether all SAEs are appropriately reported within the time as per
    - the applicable regulatory requirement(s). Case record forms would be checked

- to review the safety data i.e. Adverse Events (AEs) and SAEs for the volume
- or severity of adverse events.

- review the project files of the study to ensure that documentation is filed
- appropriately.
- review the source documents for their completeness.
- collect views of the study participants, if possible.
- The Monitor will fill the Site Monitoring Visit Report Form- AN-1/IEC-PGIMS SOP V3/17and
- AN-2/IEC-PGIMS SOP V3/17(if applicable), sign and date it.

17.4.4 After the visit

- The Monitor will submit the completed Site Monitoring Visit Report Form- AN-
- 01/SOP 17/V3 and AN-02/SOP 17/V3 (if applicable) to the IEC Bio-Ethics Cell within 7
- working days of conducting a site monitoring visit or at the time of full board meeting
- (whichever is earlier).
- The report should describe the findings of the monitoring visit.
- The Member-Secretary will present the monitoring report at the next full board IEC
- meeting and the concerned Monitor will provide additional details/ clarifications to
- members, as required.
- The IEC will discuss the findings of the monitoring process and take appropriate
- specific action by voting or combination of actions, some of which are listed below:
  - Continuation of the project with or without changes,
  - Restrictions on enrollment,
  - Recommendations for additional training,
  - Recruiting additional members in the study team,
  - Revising/ providing qualifications/ experience criteria for members of the
  - study team, termination of the study,
  - Suspension of the study, etc.
- If the Monitor has findings that impact on safety of the participant the Monitor will inform the Member Secretary on the same day. The Member Secretary will discuss with the Chairperson and any one of the actions described above will be taken.
- The final decision taken at the full board IEC meeting by the Chairperson will be recorded in the Site Monitoring Visit Report Form- AN-01/SOP V3/17.
- The Bio-Ethics Cell will convey the decision to the Principal Investigator in writing within 14 working days of the meeting.
- The Bio-Ethics Cell will place the copy of the report in the protocol file.

IEC-PGIMS SOP V3/17
Site Monitoring Visit Report
(Please tick the box corresponding to the answer)

Date of Inspection:	
Inspection Team Members:	1.
Name and address of Clinical Trial Site:	
Name, address & Contact details of Principle Investigator:	
Sponsor:	
Protocol Title	
Protocol Study Number	
Investigational Product	
Date of Study Started	
Qualification and Experience of the study staff	
Personal present during Inspection (with name and role/designation)	

Protocol approval status **i. CDSCO approvals** **ii. Ethics Committee (EC) approval** **iii. CTRI Reg. No.**	
Regulatory Inspectional History (if any)	
Whether valid financial agreement between the Sponsor, Investigator & Institution available.	
Is the valid clinical trial Insurance available?	
Whether SOP for various activities are established and documented.	
Assure that signed & dated, Curriculum Vitae is available for the Investigator, Sub Investigator /Co-Investigator	
Confirm the educational qualification of the Investigator with registration by Medical Council of State/India.	
Confirm the GCP, Schedule Y and protocol specific training of Investigator, Sub- Investigator/Co-Investigator and its team.	
Determine whether authority for conducting various clinical trial activities were delegated properly by Investigator to competent personnel (obtain the list of personnel and duty delegation log).	

Check and review the informed consent for the screening of the subjects.	
Check site screening log & enrolment log	
Whether ICF have all the elements enlisted in Appendix V of Schedule Y.	
Whether ICF is approved by Ethics Committee prior to consent process.	
Whether IC has been obtained from each subject prior to participation of the subject in the study.	
Whether signature/thumb impression of the subjects/legal representative have been affixed with date.	
Is the completed ICF signed and dated by the investigator?	
Check whether re-consenting is done for changes in ICF, if any.	
Audio-Visual recording of Informed Consent Process	

Verify condition, completeness, legibility, accessibility of the investigators source data file. (source data includes study subject's files, recording from automated instruments, tracings, X-ray and other films, laboratory notes, photograph negatives, magnetic media, hospital records, clinical and office charts, subject's diaries, evaluation checklists and pharmacy dispensing records)	
Whether subject received the test drug with respect to dose and frequency according to the protocol	
Determine whether safety/ efficacy end point data(Clinical, laboratory examination results) were collected and reported in accordance with the protocol	
Verify whether SOP for all procedures conducted at site are available i.e. have a copy of Site Specific and Trial specific SOPs	
Is adequate space available for document retention?	
Recruitment Status:	
I. Screened:	
II. Screen failure:	
III. Enrolled:	

IV. Withdrawn: Reason:	
V. Discontinued: Reason:	
VI. Completed:	
VII. Active:	
Are the present study team members (PI and CO-PI) as per the list approved by the IEC?	**Yes:** **No:**
Are site facilities appropriate?	**Yes:** **No:**
Is the recent version of informed consent document (ICD), after IEC approval, used:	**Yes:** **No:**
Whether appropriate vernacular consent has been taken from all patients?	**Yes:** **No:**
Any others findings noted about the ICDs?	**Yes:** **No:**
Is recent IEC approved version of protocol used?	**Yes:** **No:**
Has the eligibility, inclusion exclusion criteria been adhering to?	**Yes:** **No:**
Any Adverse Event found?	**Yes:** **No:**

Any SAEs found?	**Yes:**	**No:**	
Were the SAEs informed to IEC within timelines specified by CDSCO?	**Yes:**	**No:**	**NA:**
No. of deaths reported: **I. Death unrelated to participation in the trial:** **II. Death related to participation in the trial:** **III. Any other non-death related injury:**	**Yes:**	**No:**	**NA:**
Compensation paid for study related injury or death	**Yes:**	**No:**	**NA:**
Are there any protocol non-compliance deviations/ violations?	Yes		
Have the protocol non-compliance deviations/ violations been informed to IEC?	Yes, duly notified to IEC		
Are all case record forms up to date?	**Yes**		
Are storage of data and investigating products locked?	**Yes**		

Final Decision at the IEC meeting held on _____

_____

Signature of Chairperson, IEC with date: **_____**

IEC-PGIMS SOP V3/17
Monitoring of Audiovisual recording of AV consent Process

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

2. The consent is taken in language the participant/LAR understands best and is literate in.
• Yes _____ No_____
• Remarks: _____

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

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

5. Information to the participant/ LAR and impartial witness (as applicable) that the confidentiality of information and privacy of participants is assured.
• Yes _____ No_____
• Remarks: _____

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

7. Explanation or narration by the person conducting the informed consent discussion.
• Yes _____ No_____
• Remarks: _____

8. Questions asked by the potential participant/LAR are answered satisfactorily.
• Yes _____ No_____
• Remarks: _____

9. Allowing ample time and opportunity to read/understand the information in the informed consent document or discuss the same with family members.
• Yes _____ No_____
• Remarks: _____

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

11. Documentation of signatures of all those involved in the Informed Consent Process.
• Yes _____ No_____
• Remarks: _____

12. Clarity and completeness of AV recording
• Yes _____ No_____
• Remarks: _____

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

Flow chart

Activity		**Responsibility**
1. Selection of Study Sites	→	IEC Member Secretary/Chairperson
2. Identification of IEC Members for Monitoring during meeting	→	Chairperson
3. Inform Principal Investigator in Writing	→	IEC office
4. Review of IEC Protocol file prior to Visit and collect site Monitoring Visit report from IEC office	→	IEC Member
5. Review of monitoring site	→	IEC Member (Monitor)
6. Complete the monitoring	→	IEC Member (Monitor)
7. Communication of IEC decision to PI	→	IEC office

Chapter 18 Handling of Pandemic/Epidemic Condition (Like Covid-19)

18.1 Purpose:

The purpose of this standard operating procedure (SOP) is to describe the procedures for Handling of Pandemic/Epidemic Condition (Like Covid-19) to ensure safety of research participants.

18.2 Scope:

This SOP applies to all IEC approved studies for the safety of research participants.

18.3 Responsibility:

IEC is following ethical review procedure as per the National Guidelines for Ethics Committees Reviewing Biomedical & Health Research during Pandemic/Epidemic Condition (Like Covid-19) Site has directional flow chart to avoid contamination of such pandemic condition (like Covid-19). Site has provision to provide additional safety measures to subjects during pandemic/epidemic condition. (like Covid-19)

18.4 Decision:

1. **Telephonic/video conference or virtual IEC meeting and approval for study.**
2. **If the patient has any symptom of such disease/pandemic condition (Like Covid-19)**

✓ Home care guidance
✓ Call clinic to determine if reevaluation is needed
✓ Home isolation guidance
✓ If reevaluation is needed call ahead and wear face mask

3. **The Site Have Procedure in Place to Screen the Subjects During Pandemic Condition (Like Covid-19)**

✓ Thermal scanning
✓ Hand Gloves
✓ Disinfectant of site
✓ Mask
✓ Sanitizer
✓ Social Distancing

Note:-Above mentioned conditions can be change according to:-

✓ The type of agent (influencing the normal activity of human being),
✓ National Guidelines for Ethics Committees regarding the situation,
✓ DCGI regulation,
✓ WHO guidelines

Flow Chart

Call to patient

Fix appointment

Screening of patient

Travel history **Red zone**

Proper address **Inform to Govt/Nodal Agency**

Medical history **Like Covid-19 positive**

Symptoms of (like Covid-19) **If any**

Institutional Ethics Committee

PGIMS/UHS, Rohtak

Standard Operating Procedures

(IEC-PGIMS SOPs)

Version 3.0

Dr. Savita Verma,

Department of Pharmacology,

PGIMS, Rohtak