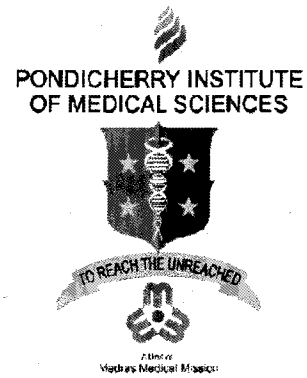
PONDICHERRY INSTITUE OF MEDICAL SCIENCES
(A UNIT OF MADRAS MEDICAL MISSION)



Institute Ethics Committee, PIMS

Standard Operating Procedures

Prepared by	Verified by	Approved and Issued by
Dr. Rema Devi	Dr. Reba Kanungo	Dr. Manikandan S

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Chapter 1.Preparation of Standard Operating Procedures for Institutional Ethics Committee

1.

PONDICHERRY INSTITUTE OF MEDICAL SCIENCES

TO REACH THE UNREACHED

A Unit of Madras Medical Mission

PREPARATION OF STANDARD OPERATING PROCEDURES FOR INSTITUTIONAL ETHICS COMMITTEE

Prepared by	**Verified by**	**Approved and Issued by**
Dr. Rema Devi	Dr. Reba Kanungo	Dr. Manikandan S

1. Purpose

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

2. Scope

It covers the procedures of writing, reviewing, distributing and amending the SOPs of the IEC.

3. Responsibility

It is the responsibility of the Chairperson of the IEC to appoint an SOP team to formulate a new SOP or to revise existing SOP. The SOP team shall do this by following the standard procedures, format and coding system that is used while drafting or editing any SOP of the IEC.

3.1 Secretariat of the IEC

Function of the Secretariat:

- Assist Chairperson to formulate an SOP Team
- Co-ordinate activities of writing, reviewing, distributing and amending SOPs
- Ensure that all the IEC members and involved administrative staff have access to the SOPs
- Ensure that all the IEC members and involved staff are working according to current version of SOPs
- Maintain an up-to-date distribution list for each SOP distributed to the IEC members.
- Maintain a register to record the names of investigators to whom SOPs are distributed
- Maintain a file of all current SOPs and the list of SOPs
- Maintain a file of all past SOPs of the IEC

3.2 Preparation of SOP

- A team will be identified for the preparation of a particular SOP.
- Function of the identified SOP team:
  - Assess the request(s) for SOP/s revision in consultation with the Secretariat, Member Secretary and Chairperson
  - Propose new / modified SOP/s as needed
  - Draft the SOPs in consultation with the IEC members and involved administrative staff
  - Review the draft SOP

  - Submit the draft for approval to Chairperson
- Chairperson of the IEC will sign and date the approved SOPs
- IEC members and involved administrative staff receive a soft copy of the SOP.
- Only secretariat of the IEC will maintain a hard copy of all SOPs prepared and archive the previous one, marking it as 'Obsolete'.

4. Detailed instructions

4.1 Identify the need for new or amendment of current SOP

- Any member of the IEC or Secretariat who feels the requirement of a revision or notices an inconsistency/ discrepancy / has any suggestions on how to improve the existing SOPs or requests to design an entirely new SOP can put forth his / her request by writing to the IEC Chairperson either through an email/letteror as a verbal request.
- The Chairperson will inform all the IEC members about this request at a regular full-board IEC meeting. If the IEC members agree to the request, an appropriate SOP team(s) will be appointed by the Chairperson and designated the task to proceed with the revision / formulation process of the SOP.
- If the IEC members do not agree, no further action will be taken. The Chairperson will inform the member of the IEC or Secretariat accordingly.

4.2 Appoint the SOP Team(s)

- The Chairperson will constitute an SOP Team(s) consisting of the member-secretary and two or more members of the IEC who have a thorough understanding of the ethical review process.
- The SOP writing team will carry out the subsequent steps as described in sections 4.3-4.7.

4.3 Write and review a new SOP

- Initially, a draft will be written by one the SOP team, appointed by the Chairperson.
- Each SOP should be given a number and a title that is self-explanatory and easily understood. A unique code number with the format SOP xxwill be assigned to each SOP item by the Secretariat. "xx" will be a two-digit number assigned specifically to each activity based SOP. The first SOP of the current version would be designated as SOP 01.
- Each SOP may have annexure which are forms to be filled in by various stakeholders (IEC or Principal Investigator). Each annexure will be given a unique code number with the format AX No./SOP xx. AX refers to annexure form, No. is a two-digit number identifying the number of the annexure, while xx refers to the SOP number. For example AX 01/SOP01 means annexure form number 1 belonging to SOP 01.

- Each SOP will be prepared according to the standard template in AX 01/SOP01. Each page of the SOP will have the face (first) page, header and the footer.
- The face page will have the following contents:

Prepared by:	Name of person / persons /team -Signature with date	
Verified & approved by	Name of person / persons - Signature with date	
Clause	Contents	Page no.
1.		

- The header will bear the following contents:
  - The IEC name and the Institution name in the center.
  - The effective date (dd/mm/year) i.e. the date of approval of the SOP by the Chairperson and the Version Number on the right side.

  -The SOP number on the left hand corner along with the title of the SOP.

SOP No: PIMS-IEC /SOP NO.	**PONDICHERRY INSTITUTE OF MEDICAL SCIENCES**	Effective date:
Title: **XXX**	**INSTITUTE ETHICS COMMITTEE**	Version:

- The footer will bear the page number as page p of q (total) pages along with the name of the team which formulated the SOP.

Prepared by: PIMS-IEC Team for Formulation of SOP	Page No: p

- The draft SOP written by one or more members of the SOP team will be reviewed by the remaining members of the SOP team.
- After incorporating the suggestions put forth by the SOP team members; a copy of the revised draft SOP will be sent to the Member-Secretary, who will circulate it to all the IEC members.

4.4Write and review a revised SOP

- If an SOP supersedes a previous version, the previous SOP version will be indicated in the Document History Form (AX 02/SOP01) along with description of the main change/s.
- The rest of the *steps are as described in* Section 4.3.

4.5Prepare and submit the final draft

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

4.6Approve the new / revised SOP

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

4.7 Implement, distribute and file SOPs

- The approved SOP will be implemented from the effective date.
- The Member Secretary will discuss the approved SOP with the administrative staff and instruct them to implement it accordingly.
- The soft copy of the approved SOP will be distributed to the IEC members and a distribution list will be maintained in the IEC Secretariat.
- One complete original set of current SOP will be filed in the SOP Master file, by the IEC Secretariat in the IEC office.
- When the revised version is distributed, all the IEC members will be requested to destroy their earlier version. Only one copy of the earlier version will be filed in the file entitled 'OBSOLETE Copy SOPs of the IEC' by the IEC Secretariat in the IEC office.
- The IEC members and Secretariat will review the SOPs at least once in every 3 years.

5. Work Flow chart

No.	Activity	Responsibility
1	Identify the need for new or amending SOP	IEC members
2	Appoint an SOP Teams	Chairperson
3	List all relevant SOPs	SOP Team
4	Design a format and layout	SOP Team
5	Write and review a new/revised SOP	SOP Team
6	Preparation and submission of final draft	SOP Team
7	Approve a new/revised SOP	Chairperson
8	Ensure implementation, distribute and file allSOPs	IEC members and Secretariat
9	Manage current and archive superseded SOPs	Office secretary

6. Glossary

SOP (Standard Operating Procedure): Detailed, written instructions, in a certain format, describing activitiesand actions undertaken by the IEC to achieve uniformity of theperformance of a specific function.The aim of the SOPs and their accompanying checklists and forms is tosimplify the functioning, whilst maintaining high standards of GoodClinical Practice.

SOP Team:A team of members selected from the IEC, including the Member Secretary and at least two
more members, who oversee the creation, preparation, review andperiodic revision of the SOPs.

Effective date: The date of implementation of the SOPs which has been approved and signed by the Chairperson.

7. References

1. WHO Operational Guidelines for Ethical Review Committee that Review BiomedicalResearch (Geneva 2000) - www.who.int/tdr/publications/publications/ (last accessed 24March 2008)
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICHGCP) 1996. http://www.ich.org/LOB/media/MEDIA482.pdf (last accessed 26 December 2020)
3. ICMR's Ethical Guidelines for Biomedical research on Human Participants, ICMR (2017)-http://www.icmr.nic.in/ethical_guidelines.pdf
4.Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005)https://www.kem.edu/wp-content/uploads/2019/12/Regulations_Dr.Bangaruranjan-Well-drfine-Drug-ministry.pdf(last accessed 28th December 2020)

8. Annexure:

1. **AX 01/SOP01:**Template for SOPs
2. **AX 02/SOP 01:**Documentation of History of the SOPs

AX 01/SOP01

TEMPLATE FOR STANDARD OPERATING PROCEDURES

Header on all pages	
FACE SHEET	PIMS logo
	Self explanatory title of the SOP
	Details on preparation of SOP
	Contents
Footer on all pages	

Main Text:

1. **Purpose**: Summarizes and explains the objectives of the SOP.
2. **Scope:** States the range of activities that the SOP applies to.
3. **Responsibility**: Refers to person(s) assigned to perform the activities involved in the SOP.
4. **Detailed instructions**: Describes procedures step by step in short and clear sentences
5. **Flow chart:** Simplifies the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity.
6. **Glossary:** Clarifies uncommon or ambiguous words or phases by explanation.
7. **References:** The relevant sources of the information used for preparing the document.
8. **Annexure**: Documents to capture information pertaining to the SOP instructions.

AX 02/SOP02

DOCUMENTATION OF HISTORY OF THE SOPS

Details of superseded SOP:

Name of the team of authors	Version	Effective date (dd-mm-yyyy)	Description of the main change/s

PONDICHERRY INSTITUTE OF MEDICAL SCIENCES

Institute Ethics Committee, PIMS

Constitution of Institute Ethics Committee

Prepared by	**Verified by**	**Approved and Issued by**
Dr. Rema Devi	Dr. Reba Kanungo	Dr. Manikandan S

1. Purpose

The Institute Ethics Committee (IEC) has been constituted by the Director-Principal, PIMS. The IEC was established in 2006with the intent to specify and formalise the Institute's commitment to high ethical standards in professional education, patient care, clinical research, and their interaction with the community.

The IEC is guided in its reflection, advice and decision by the ethical principles expressed in Declaration of Helsinki (Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, and amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975; 35thWorld Medical Assembly, Venice, Italy, October 1983; 41stWorld Medical Assembly, Hong Kong, September 1989; 48thWorld Medical Assembly, Somerset West, Republic of South Africa, October 1996; and the 52ndWorld Medical Assembly, Edinburgh, Scotland, October 2000; Note of Clarification on Paragraph 29added by the World Medical Assembly, Washington 2002; Note of Clarification on Paragraph 30 added by the World Medical Assembly, Tokyo 2004, 59thWMA General Assembly, Seoul, October 2008) and by the most recent- 68thWorld Medical Assembly, Chicago 2017, where quality assurance in medical education was one of the main objectives.

It makes further reference to the International Ethical Guidelines for e.g.: The Nuremberg Code (1945), Belmont Report (1979), The Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects (Geneva 2002), and the European Convention on Human Rights and Biomedicine (1997).

The IEC will work according to its established Standard Operating Procedures based on the Operational Guidelines for Ethics Committees that review Biomedical Research(WHO, 2000), International Conference on Harmonization- Good Clinical Practices (ICHGCP)Guidelines (1996), Schedule Y (Drugs and Cosmetic Act 1940; amendment 20thJanuary 2005) and Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2017).

2. Mandate

The mandate of the PIMS IEC is to review and approve all types of research proposals involving human participants to be conducted at the Institute with a view to safeguard the dignity, rights, safety and well-being of all actual and potential research participants, irrespective of the funding agency. The goals of research, however important, will never be permitted to override the health and well-being of the research subjects. The PIMS IEC ensures that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non-maleficence and Justice are taken care of in planning, conduct and reporting of the proposed research. For this purpose, it looks into the

aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensation wherever required. It reviews the proposals before start of the study through appropriate well-documented procedures; and follows up the approved studies through annual reports, final report, site visits if necessary etc. The committee also examines compliance with all regulatory requirements, applicable guidelines and laws.

3. Scope

This SOP pertains to the formation of the IEC.

4. Responsibility and duty:

The IEC is responsible for achieving the following objectives:

- To protect the safety, rights and confidentiality of the research subjects.
- To ensure that all aspects of research are compliant with the appropriate laws and conducted according to the ethical guidelines.
- To provide consultation for clinical ethics
- To educate and train IEC members and other staff on ethical issues
- To create, revise, and implement SOPs

It is the responsibility of IEC to

- Keep all information submitted to them confidential, especially the proprietary information.
- Maintain concise but clear documentations of its views on there search proposal.
- Review the progress of each research project at appropriate and specified intervals, but not less than once a year and will also review the final report of the studies approved by them.
- Participate in activities that promote ethical research in the institution and community.
- Participate in and organize programs aimed at educating and training community members, members of the public, investigators, ethics committee members in ethical research.

5. Ethical Basis

The PIMS IEC is constituted of members who together, have the qualifications and experience needed to review and evaluate the scientific, medical, and ethical aspects of a research proposal. Being cognizant of the diverse laws, cultures, and practices governing research and medical practices in various countries around the world, the committee is also guided by the ethical principles expressed in the Declaration of Helsinki and the International Ethical Guidelines.

The PIMS IEC has established their Standard Operating Procedures based on guidelines given by organisations like ICMR and WHO.

6. Composition

PIMS IEC is multidisciplinary and multi-sectorial in composition with independence and competence as the two hallmarks. The number of persons in an ethical committee is kept fairly small (9-11 members). A minimum of seven persons is required to compose a quorum.

The Chairperson of the Committee is a senior person appointed from outside the Institution, who is well versed in ethics, to maintain the independence of the Committee. The Member Secretary, who is a staff of PIMS, conducts the business of the Committee. Other members are a mix of medical/non-medical, scientific and non-scientific persons including lay public to reflect the differed viewpoints. Both genders are adequately represented. To ensure independent activity, at least 50% of the members are non-affiliated.

The composition is as follows:

1. Chairperson- Non affiliated
2. Member-Secretary - PIMS staff
3. 1–2 Basic Medical Scientists, including pharmacologist
4. 1–2 Clinicians
5. One Legal Expert
6. One representative of NGO/community
7. One Theologian
8. One Lay person - Non affiliated

An acting chairperson, from outside the institution is selected from the IEC members, for conducting the meeting or signing the documents, in the absence of the chairperson. If required, subject experts are invited to offer their views as independent consultants, for example, for drug trials a pharmacologist, preferably a clinical pharmacologist, will be included. Similarly, based on the requirements of research area, for example HIV, genetic disorders etc, a specialist in that particular area will be invited which may include any of the following, an Epidemiologist, Sociologist, Lawyer, Theologian, Statistician, Clinician, Basic scientist, Pharmacist or a Clinical Pharmacologist. However, they have no right in decision making.

6.1 Membership

All members are appointed by the Director – Principal, PIMS, in consultation with the Chairperson, IEC. While selecting members, care is taken to ensure that transparency is maintained in the whole process. Members will be selected in their personal capacities based on

their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IEC work.

New members will be appointed when a regular member completes his/ her tenure; when a regular member resigns before the tenure is completed; so as to fulfill the membership requirements as per the regulatory guidelines.

6.2 Terms and conditions of appointment

The duration of appointment is initially **for a period of 3 years**. At the end of 3 years, the committee is reconstituted as the case may be, and **50% of the members are replaced by a defined procedure.** There is no restriction to the number of terms of appointment.

a. A member should be willing to publicize his/her full name, profession and affiliation.
b. A member can be replaced in the event of death or long-term non-availability or for any action not commensurate with the responsibilities deemed unfit for a member.
c. A member can tender resignation from the committee with proper reasons.
d. All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form in which they also declare Conflict of Interest, if any (Annexure: PIMS-IEC/SOP01/AX01).

6.3 Independent Consultants

The PIMS-IEC may call upon subject experts as independent consultants who will provide special review of selected research protocols, if need be. These experts are specialists in ethical or legal aspects, specific disease or methodologies, or represent specific communities; patient groups or special interest groups e.g. Cancer patients, HIV/AIDS positive persons or ethnic minorities. They are required to give their specialized views but not take part in the decision-making process, which will be made by the members of the IEC. Independent consultants are also required to sign a Confidentiality Agreement (Annexure:PIMS-IEC /SOP01/AX02).

6.4 Roles and responsibilities of office bearers

The Chairperson conducts all meetings of the PIMS-IEC. If for reasons beyond control, the Chairperson is not available, he/she can nominate, an alternate member of the committee to chair the meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she prepares the minutes of the meetings and gets it approved by the Chairperson before communicating to the researchers with the approval of the appropriate authority.

Chairperson

- The Chairperson will be responsible for conducting committee meetings, and will lead all discussions and deliberations pertinent to the review of research proposals.
- The Chairperson will sign documents and communications related to IEC functioning.
- The Chairperson will delegate his/ her responsibilities to appropriate individuals in accordance with IEC SOPs.

Member secretary

- To receive research proposals, maintain and distribute the same.
- To organize an effective and efficient tracking procedure for each proposal received.
- To schedule and organize IEC meetings.
- To prepare and maintain meeting, agenda and minutes.
- To communicate with the IEC members and investigators.
- To notify the Principal Investigator regarding IEC decisions related to the submitted research proposal.
- To maintain IEC documents and to archive them.
- To organize the preparations, review, revision and distribution of SOPs and guidelines and to ensure adherence of IEC functioning as per SOPs.
- To arrange for training of IEC members.
- To provide updates on relevant and contemporary issues to ethics in health research as well as relevant contemporary literature to the committee members.
- To provide necessary administrative support for IEC related activities to the Chairperson.
- To monitor the function of the office secretary, with regard to the activities of the IEC.

IEC members

- To review, discuss and consider research proposals submitted for evaluation.
- To monitor Serious Adverse Event reports and recommend appropriate action(s).
- To review the progress reports and monitor ongoing studies as appropriate.
- To evaluate final reports and outcomes.
- To participate in continuing education activities in biomedical ethics and biomedical research.
- To carry out the work delegated by Chairperson / Member-secretary.
- To assist Chairperson / Member-secretary in carrying out IEC work as per SOPs.

6.5 Quorum requirements

Minimum of seven members is required to compose a quorum. It is ensured that the lay person is available for the meeting. All decisions are taken in meetings and not by circulation of project proposals. Online meetings with the member being available during the discussions can be considered as part of the quorum requirement.

6.6 Decision Making

The following factors are taken into consideration towards the process of decision making.

a. Members will discuss the various issues before arriving at a consensus decision.
b. A member will withdraw from the meeting during the decision-making procedure concerning an application where a conflict of interest arises and this should be indicated to the Chairperson prior to the review of the application and recorded in the minutes.
c. Decisions will be made only in meetings where quorum is complete.
d. Only members can make the decision. The expert consultants will only offer their opinions.
e. Decision may be to approve, reject or revise the proposals. Specific suggestions for modification and reasons for rejection will be given.
f. In cases of conditional decisions, clear suggestion for revision and the procedure for having the application re-reviewed will be specified.
g. Modified proposals will be reviewed by an expedited review through identified members.

6.7 Education of IEC members

IEC members have a need for initial and continued education regarding the ethics and science of biomedical research. All IEC members must be conversant with ICMR Guidelines for Research involving Human Subjects 2017, Schedule Y of Drugs and Cosmetics Act and ICH-GCP guidelines.

IEC members receive introductory training material in research bioethics and functioning of IEC and are exposed to ongoing opportunities for enhancing their capacity for ethical review.

Training of the IEC members in Research Bioethics:

- A new member is inducted 1 month prior and is requested to be an 'observer' for the first board meeting. An introductory training is imparted by the Member Secretary.
- The IEC members are encouraged to receive ongoing training by attending workshops at least once a year. The IEC conducts workshops from time to time to impart training to the IEC members and institutional faculty members. The training programs are scheduled and spread over the year.

6.8 Preparing an annual activity report

This report contains a qualitative evaluation of the activities of the committee during the past year. It also includes a list of the research proposals reviewed during that time and also informs the status of each research proposal.

6.9 Conflict of Interest

If an applicant submitting a protocol believes that an IEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the IEC member(s) in question. The committee may elect to investigate the applicant's claim of the potential conflict.

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

Examples of conflict of interest 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 bias may interfere with his / her impartial judgment.

7. References

1. CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects. Retrieved from – http://www.cioms.ch/frameguidelines Nov 2002.htm(as on March, 2018)

2. ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2017). Retrieved from - http://www.icmr.nic.in/ethical guidelines.pdf(as on March, 2018)

3. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000. (Geneva 2000) Retrieved from- www.who.int/tdr/publications(as on March, 2018)

8. Glossary

Confidentiality: Prevention of disclosure, to other than authorized individuals, of information and documents related to IEC.

Independent Consultants: Professionals with advanced training and expertise in the medical or non-medical areas related to the protocol being reviewed by the Institute Ethics Committee, PIMS.

9. Annexure

1. **AX 01/SOP 02:** Confidentiality and Conflict of Interest Agreement form for IEC Members
2. **AX 02/SOP 02:** Confidentiality Agreement Form for Independent Consultants

AX 01/SOP02

Confidentiality and Conflict of Interest Agreement form for IEC Members

In recognition of the fact, that I, Dr..... herein referred to as the "Undersigned", has been appointed as a member of the Institute 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 fundamental duty of an IEC member is to independently review research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the 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.

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

As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets ('information') in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the 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. Furthermore, the Undersigned confirms that my performance of this agreement is consistent with the Institute's policies and any contractual obligations they may have to third parties.

Conflict of Interest

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.

The Undersigned will immediately 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 to abstain from any participation in discussions or recommendations in respect of such proposals.

Agreement on Confidentiality and Conflict of Interest

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

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

I, Dr. ..... have read and I accept the aforementioned terms and conditions as explained in this Agreement.

Undersigned Signature Date

Director, PIMS Date

AX 02/SOP02

Confidentiality Agreement 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.

Undersigned Signature Date

Chairperson of IEC Date

I, _____ (Enter name) acknowledge that I have received a copy of this Agreement signed by Chairperson, IEC and me.

Signature of the recipient Date

PONDICHERRY INSTITUTE OF MEDICAL SCIENCES

TO REACH THE UNREACHED

A Unit of Madras Medical Mission

INSTITUTE ETHICS COMMITTEE, PIMS

Management of Protocol Submissions

Prepared by	Verified by	Approved and Issued by
Dr. Rema Devi	Dr. Reba Kanungo	Dr. Manikandan S

1. Purpose

This SOP is meant to serve as a guideline for the PIMS IEC to manage research protocol submissions.

2. Scope

The scope includes the processes involved in managing a submission beginning with an initial review, resubmission of protocol with suggested modifications, continuing review of protocols until the completion / termination of the project, protocol amendments

3. Responsibility

It is the responsibility of the IEC Secretary to receive, record, and distribute the protocols for review by the IEC and communicate the decisions to the Principal Investigator (PI).

4. Detailed Process

a. The last date for submission of proposals would be intimated through notice from the IEC office and any proposal submitted thereafter would be considered only in the subsequent convened meeting.

b. All proposals should be submitted in the prescribed application form, the details of which are given below under the heading Documentation (Annexure IEC/SOP 03/AX 01& AX 02)

c. All relevant documents should be enclosed with the application form.

d. The proposal should be submitted in the PDF format.

e. The proposal should be submitted with the covering letter showing the table of comments given by the Research committee, and the corrections done by the researcher (with page number and the highlights in the concerned sections).

f. Required number of copies of the proposal along with the application and documents in the prescribed format, duly signed by the PI and Co-investigators / Collaborators and forwarded by the Head of the Department / Institution (in case of collaborators) to be submitted to the ethics committee. (Template given in Annexure IEC/SOP02/AX 02 & AX 03)

g. If the researcher has to attend the meeting and present the proposal, the date of meeting will be intimated to the researcher in advance. Failure to attend the meeting for presentation, the proposal will be considered for the next convened meeting. In case the review is done by an expedited process, the researcher need not present in the meeting, unless specifically asked.

h. It is mandatory that the PG proposal is presented by the student, along with the presence of the guide or co-guide, in the meeting

i. The final decision of the ethics committee will be communicated to the PI in writing. If revision is to be made, the revised document (usually two copies) should be submitted within one week's time or as specified in the comments sent to the PI following the meeting.

j. Reports on the progress of the approved protocol have to be sent to the IEC annually or at intervals suggested by the IEC, in the IEC prescribed format.

k. All documents submitted to the IEC, should be in the IEC prescribed format. (E.g. Annual report, extension of approval, amendments in the previously approved documents)

l. The Study Completion Report also should be sent to the IEC.

5. Documentation

For a thorough and complete review, all research proposals should be submitted with the following documents: (Annexure IEC/SOP 03/AX 01& AX 02)

a. Name of the applicant with designation

b. Name of the Institute / Hospital / Field area where research will be conducted.

c. Approval of the Head of the Department / Institution

d. Protocol of the proposed research.

e. Ethical issues in the study and plans to address these issues.

f. Proposal should be submitted with all relevant enclosures like proforma / case report forms, questionnaires, follow-up cards, etc.

g. Patient information sheet and informed consent form in English and local language(s)

h. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centres within the country or countries, if available.

i. Curriculum vitae of all the investigators with GCP training certificate, relevant publications in the last five years.

j. Any regulatory clearances required: (DCGI / Investigator's Undertaking to DCGI / FDA marketing / manufacturing license for herbal drugs / Health Ministry Screening Committee (HMSC) approval / Bhabha Atomic Research Centre (BARC) approval / Genetic Engineering Advisory Committee (GEAC) approval / Director General of Foreign Trade (DGFT) approval / Administrative sanction from the Dean in case of studies involving collaboration with other institutions)

k. Source of funding and financial requirements for the project.

l. Other financial issues including those related to insurance

m. An agreement to report all Seriously Adverse Events (SAE) to IEC.

n. Statement of conflicts of interest, if any.

o. Agreement to comply with the relevant national and applicable international guidelines.

p. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the arrangements for indemnity, if applicable (in study-related injuries); a description of the arrangements for insurance coverage for research participants, if applicable; all significant previous decisions (e.g., those leading to negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on the account. The reasons for negative decisions should be provided.

q. Plans for publication of results-positive or negative while maintaining the privacy and confidentiality of the study participants.

6. Categorisation of Protocols

The Secretary of the IEC screens the proposals for their completeness and depending on the nature of the proposals categorises them into three types; namely, initial review, expedited review and exemption from review. This SOP describes the process of initial review.

7. Follow-up procedures

a. Reports should be submitted at prescribed intervals for review.
b. Final report should be submitted at the end of study.
c. All Serious Adverse Events (SAEs) and the interventions undertaken should be intimated.
d. Protocol deviation, if any, should be informed with adequate justifications.
e. Any amendment to the protocol should be resubmitted for renewed approval.
f. Any new information related to the study should be resubmitted for renewed approval.
g. Premature termination of study should be notified with reasons along with summary of the data obtained so far.
h. Change of investigators/sites should be informed

8. Processing fees:

For all extramural sponsored studies, a processing fess is levied and proof of payment has to be submitted. Payment is in the form of a crossed cheque / DD in the name of Pondicherry Institute of Medical Sciences.

For Pharma sponsored clinical trials

- Initial processing fees- Rs.40,000/- + GST
- Amendment (Protocol / ICF)- Rs.5,000/- + GST
- Extension of approval – Rs.20,000/- + GST
- Extension of approval with late fees – Rs.25,000/- + GST

9. Work Flow chart

	Activity	**Responsibility**
1	Receive submitted proposals	IEC office secretary
2	Check for the completeness of the documents	IEC office secretary
3	Categorise the documents for expedited review / full board meeting	IEC Member Secretary
4	Arrangement for the review meeting	IEC Member Secretary

9. Reference

1. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996 Retrieved from - http://www.ich.org/LOB/media/MEDIA482.pdf

10. Glossary

Study Protocol: A document that describes the objective(s), design, methodology, statistical considerations and organization of a trial.

11. Annexure

1. **AX 01/SOP 03:** Protocol format for faculty proposals
2. **AX 02/SOP 03:** Protocol format for PG studies
3. **AX 03/SOP 03:** Template for Participant Information Sheet
4. **AX 04/SOP 03:** Template for Consent form

AX 01/SOP 03

Pondicherry Institute of Medical Sciences

PROTOCOL FOR RESEARCH PROPOSAL FOR FACULTY

Research title:

Research/Project Number:

Team	Name	Position	Department	Telephone	Email
Principal Investigator					
Co I					
Co I					
Co I					

Duration of study in months: **Proposed date of start:**

Total Budget:

Users of Research Results:

I agree to submit the final report of this project to the Research and Institute Ethics committee.

Signature of P.I: ..... Date:

Signature of Co.I: ..... Date:

Signature of Co.I: .....Date:

Signature of Co.I: ..... Date:

Planned Contribution of Research team members

Title of study:

[e.g. Conception of idea, Research design, Data collection/field work, data management, analysis, report writing ,interpretation of results ,critical reviewing with intellectual input]

S.N.	Name of Researcher	Job Title	Contribution of Researcher	Signature

Principal Investigator

Name and signature

Date

Chairman

Research Committee

Date

CHECK LIST

(To be filled and duly signed by the principal investigator)

Title:

Name of the Principal Investigator:

Designation & Department:

S.No	Items	Yes/No
1	Exact title	
2	Name & Signatures of PI and Co-I/s	
3	Name, Designation and Signature of HOD or other sanctioning authority	
4	Primary and Secondary Objectives specified	
5	Sample Size and Sample Size justification	
6	Permission from DCGI (if applicable).	

7	Adequate justification for exemption from obtaining informed consent given (if applicable).	
8	Consent form - in both English and Tamil attached	
9	Consent form - (information to the participant/ parent/guardian) in simple layman language attached.	
10	Separate consent (assent) form for subjects < 18 yrs attached (if applicable)	
11	Consent form from parents/LAR, where assent form is included	
12	Separate consent form for cases and controls attached (if applicable)	
13	Ethical issues explained in detail with level of risk	
14	Validated questionnaire both in Tamil and English attached (if study involves interview/ questioning)	
15	Budget with Justification provided	
16	Case Report Form (CRF)	
17	Work Plan and Time lines provided	
18	CV of PI and CO-I Attached	
19	GCP training certificate of investigators	
20	Comments from the Research Society with the corrections (tabulated) attached	
21	Highlighted corrections of the research society, in the different sections	
22	Soft copy with all enclosures attached- in PDF format	

Date: Signature of principal investigator

Research Proposal Summary

(It is mandatory to submit this form along with protocol)

Detailed Research Plan

1. **Research Title:**
2. **Introduction:**
3. **Problem Statement / Rational and justification of the research:**
4. **Literature Review:**
5. **Objectives:**

   - Primary objectives
   - Secondary objectives

6. **Research Hypothesis:**

7. **Research Questions**:
8. **Methodology**

8.1 Summary of Research strategy (study design/type):
Retrospective study, cross-sectional, Experimental etc

8.2 Characteristics of study area & target population:
Inclusion / Exclusion criteria

8.3 Period of study:
8.4 Sample Size:
8.5 Method of Recruitment and Allocation:
8.6 Data collection, Issues on Measurements and tools used (Brief procedure):

9. **Case Report Form (CRF):**
(Attach CRF as appendix if more than one page)

10. **Pre-test / Pilot study:**
11. **Data Management**:
    11.1 Quality Control of Data:
12. **Limitations and constraints of the study:**
13. **Expected Results and Relevance to Action and Policy Change:**
    13.1 Beneficiaries of the Research Results:
    13.2 Dissemination of findings, conclusions and recommendations:
    13.3 Priority and importance of the research topic:

14. **Ethical considerations:**

I undertake to ensure the following as per the ICMR 2017 and other applicable guidelines: *(Tick whatever is applicable)*

- That the rights and welfare of the study subjects will be protected.
- All participants will be explained in the language comprehensible to them, the details of the study and level of risk/ benefit associated with it.
- Voluntariness to participate and Consent/Assent to be obtained
- Privacy and confidentiality will be strictly maintained.
- The study will be performed as per the approved protocol only.
- If any deviation is warranted, the same will be presented to the ethical committee and permission will be sought.
- No reimbursement and compensation as per PIMS rules.
- We assure that the study will be terminated immediately, if there is such a decision

- In case of any unforeseen adverse consequences, it will be informed to the ethical committee immediately.
- Follow up in case of opting out of study (referral for appropriate treatment)
- Freedom to withdraw at any time, without giving any explanation

15. Resources & facilities and budget/budget justification:

16. Administration and monitoring of the research activities:

17. References:

Appendices:

I. List of Abbreviations (if applicable)
II. Curriculum Vitae of the P.I. and Co-I/s
III. Participant Information Sheet (PIS) and Informed Consent of Research (Both Tamil & English)
IV. Declaration for acceptance of responsibility
V. Case Report Form (CRF)
VI. Other Information Relating to the Study

" To be signed by the Principal Investigator"

Research title:

.....
.....

.....
.....

Name of P.I: .....

Dept.:.....

If the application is accepted, I (we) declare that I (we) shall be actively engaged in, control the project and agree to provide progress reports and final report to the committee for revision before final dissemination of it.

I (we) confirm that the details of this proposal are a true representation of the research to be undertaken. I (we) will ensure that the research does not deviate from the protocol described. If significant protocol amendments are required as the research progresses, I (we) shall submit these to the Research and Institute Ethics Committee for approval.

I (we) confirm to follow the ICMR research guidelines 2017.

Signature:..... Date:

BUDGET FORM

Budget (in rupees)

Consumables

Items	Justification	Unit Cost	Total

Contingency

Items	Justification	Unit cost	Total
Grand total			

Signature of PI: Date:

Signature of Co I:

Head of the Department:

Head of the collaborating department: (if any)

AX 02/SOP 03:

FORMAT OF RESEARCH PROPOSAL FOR PG DISSERTATION

SECTION- 1
PART A – GENERAL INFORMATION

1. Title of the dissertation:

2. Name of the Post Graduate Student:
Mobile number:
Email id:
3. Name of the course studying:
4. Month and year of appearing for final examination:
5. Name of the Guide -
Designation of the Guide -
Mobile number -
Email id -
*Name of the Co-guideI /II/III-
Designation of the Co-guide I /II/III -
Mobile number -
Email id -
6. A. State whether it is intradepartmental or interdepartmental:
If the study is interdepartmental
   i. State the names of collaborating departments:
   ii. State whether consent has been obtained from the collaborating departments:

Certification by the HOD:

The protocol has been presented in the department and reviewed:

Signature of the HOD

PART B – TECHNICAL DETAILS

1. Title of the dissertation:
2. Introduction/Background
3. Problem statement:
4. Rationale
5. Expected outcome and application
6. Research question:
7. Research hypothesis, if any:
8. **Objectives:**
   - (i)Primary objective:
   - (ii)Secondary objectives:
9. Brief review of literature: *Current literature (atleast 5-6, published within the last 5 years)*
10. **Methodology:**

A. Study design:

B. Study participants:

a. **Inclusion criteria:**

b. **Exclusion criteria:**

c. **Withdrawal criteria**, if any (trial-related therapy, follow-up and documentation areterminated prematurely as it is indicated to ensure safety of the participants)

d. **Rescue criteria**, if applicable (starting symptomatic therapy either to control symptoms of disease or to overcome lack of adequate efficacy of the study drug or placebo).

C. Sampling

a. **Sample size calculation**:(reference of previously published study)

b. **Sampling technique:**

D. Randomization details:

a. Selection of groups

b.Allocation to groups

E.Studyprocedure: Intervention details with standardization techniques (drugs/devices/invasive procedures /non-invasive procedures /others

Details of how the study will be carried out.

- Work flow chart & time line (CONSORT for clinical trial & FLOW CHART for observational study)
- *Include parameters to be studied*

F. Data collection methods

- Settings – Hospital setting (Pondicherry Institute of Medical Sciences)
- Periodicity – One - time data collection

G. If it is a clinical trial, whether registration with CTRI will be done:.

H. Are the drugs/devices to be used approved for these indications by Drug Controller General of India (DCG-I)?

I. Method of Result Analysis:

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

11. List risks and benefits of the study:

Risks:

Benefits:

12. Ethical considerations: (Tick what is applicable)

While carrying out the study, to ensure the following:

- That the rights and welfare of the study subjects will be protected.
- All participants will be explained in the language comprehensible to them, the details of the study and level of risk/ benefit associated with it.
- Voluntariness to participate and Consent/Assent will be obtained from all participants.
- Privacy and confidentiality of participants and their data will be strictly maintained.
- The study will be performed as per the approved protocol only.
- If any deviation is warranted, the same will be presented to the ethical committee and permission will be sought.
- Reimbursement and compensation rules will be followed as per PIMS policy.
- In case of any unforeseen adverse consequences, it will be informed to the ethical committee immediately.
- Ensure that the study will be terminated immediately following any adverse consequences.
- Participants are free to withdraw at any time, without giving any explanation
- In case of participants opting out of study they will continue to receive referral for appropriate treatment.

13. Relevant current **references** (numbering 5-6) for the study:

14. CONSORT Chart for clinical trials and flow chart for other types of studies

15. Budget

16. Enclosures

A. Case Report Form

B. Validated questionnaires (English & Tamil) (if applicable) and reference of questionnaire adopted from published articles and whether permission has been taken from the author

C. Participant Information Sheet & Consent form (English and Tamil versions)

Signature of the Post Graduate Student: .....
Signature of Guide: .....
Signature of Co-guide:I/II/III .....
Signature of Head of the Department:I/II/III .....

CHECK LIST

(To be filled and duly signed by the student)

Title:

Name of the Student:

Name of the course:

S.No	Items	Yes/No
1	Exact title	
2	Name & Signatures of Student and Guide, co-guide	
3	Name and Signature of HOD	
4	Primary and Secondary Objectives specified	
5	Sample Size and Sample Size justification	
6	If it is a clinical trial, whether mentioned, that registration with CTRI will be done	
7	Adequate justification for exemption from obtaining informed consent given (if applicable).	
8	Consent form - both English and Tamil attached	
9	Consent form part 1 (information to the participant/ parent/guardian) in simple layman language attached	
10	Separate consent (assent) form for subjects < 18 yrs attached (if applicable)	
11	Consent form from parents/LAR, where assent form is included	
12	Separate consent form for cases and controls attached (if applicable)	
13	Ethical issues explained in detail with level of risk	
14	Validated questionnaire both in Tamil and English attached (if study involves interview/ questioning)	
15	Budget with justification provided	
16	Case Report Form (CRF)	
17	Work Plan and Time lines provided	
18	CV of PI and CO-I attached	
19	GCP training certificate of the candidate	
Undertaking by Principal Investigator		
20	Comments from the Research Committee with the corrections (tabulated) attached	
21	Highlighted corrections of the research committee, in the different sections	
22	Soft copy with all enclosures attached- in PDF format	

Department:

Date: Signature of Student:

DECLARATION

"To be signed by the Principal Investigator"

Research title:
Name of P.I:
Dept.:

If the application is accepted, I (we) declare that I (we) shall be actively engaged in, control the project and agree to provide progress reports and final report to the committee for revision before final dissemination of it.

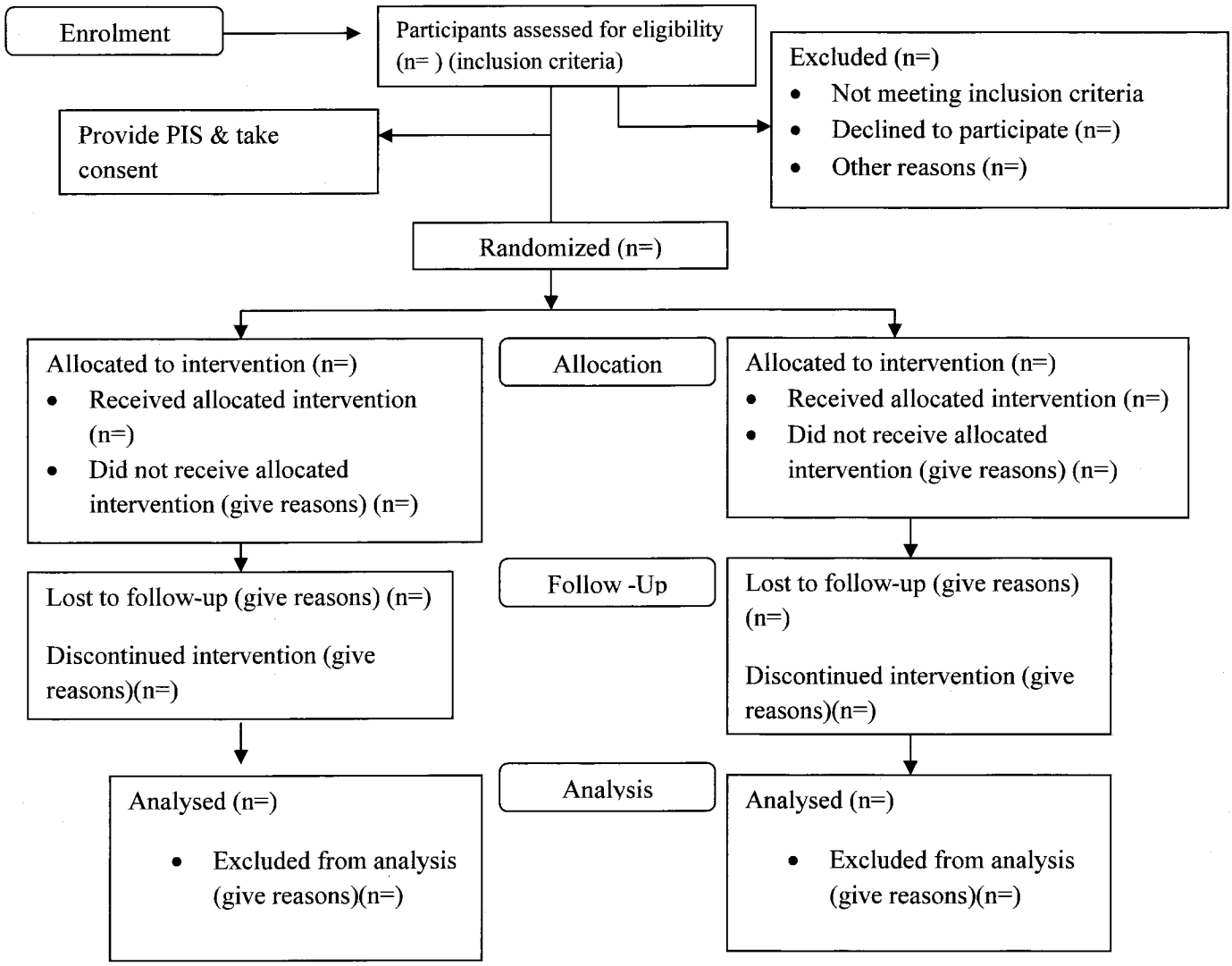
I (we) confirm that the details of this proposal are a true representation of the research to be undertaken. I (we) will ensure that the research does not deviate from the protocol described. If significant protocol amendments are required as the research progresses, I (we) shall submit these to the Research and Institute Ethics Committee for approval. I (we) will abide by the ICMR guidelines 2017.

Signature:..... Date:

CONSORT

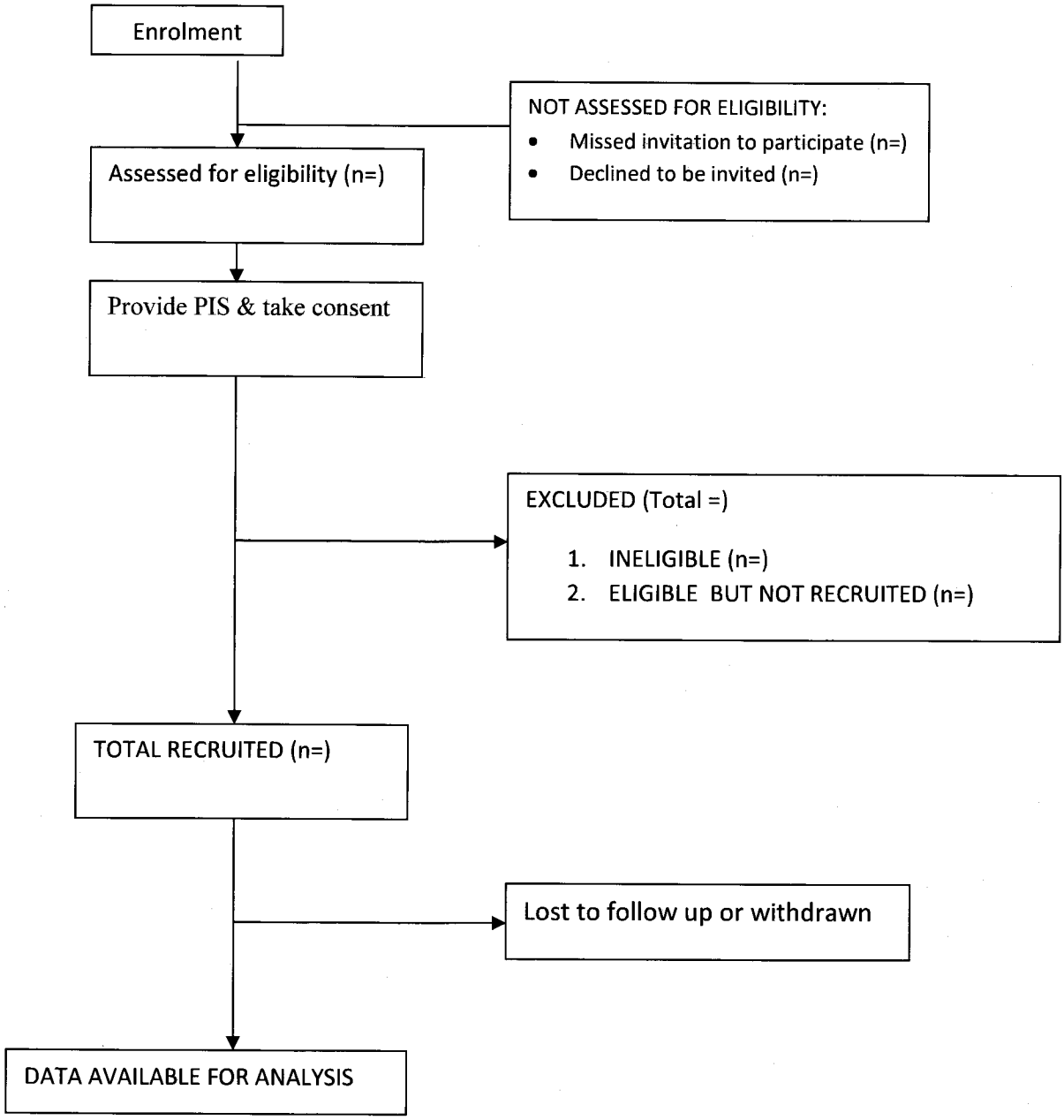
TRANSPARENT REPORTING of TRIALS

CONSORT 2010 FLOW DIAGRAM



FLOW CHART

TRANSPARENT REPORTING of OBSERVATIONAL STUDIES



AX 03/SOP 03:

PROTOTYPE

Informed Consent Form (ICF) Part-I

Sample Format for Participant Information Sheet (PIS)

(This template should be customized according to the requirement of individual research project)

Project title:

Introduction:

You are invited to participate in a research study conducted by

Name of the student:..... under the guidance of

Name of the Guide: .....Department:.....

It is important that you read the description of this study and understand your role in it including the nature and risks of participation. Please give your consent to participate in this clinical study only if you have completely understood the nature and course of this study and if you are aware of your rights as a participant.

Purpose of the study:

I am doing the study to understand .....

Expected duration of the study and number of subjects:

You will be one of approximately ..... people who will participate in this study. You will be in the study for about ..... days.

Study procedures to be followed:

If you agree to participate in this study you will have to give a written consent.

- **In case of randomized control trial**: you will be randomly assigned by a computer generated number to a study group / a control group to receive one of the two study treatments / procedures (in randomized trials).
- **In other types of studies** explain method of selection to participate.
- Mention the study procedure in detail in layman's language including the following

a) Previous medical problems, current health and medications

b) Physical examination (to give details)

c) Need to undergo baseline investigation (give details if required).

d) Expected duration of participation in the study

e) Details of the procedure / methodology of the study in layman's language. **Do not use technical terms**

f) Explain in detail risks and discomforts of participating

g) The benefits to be expected from the research to the participant or to others

Confidentiality:

- All study records will be kept confidential at all times. Your identity will not be revealed except as required by law. The results of your treatment (details: laboratory tests, photographs, x-rays etc.) may be published for scientific reasons. Your identity will not be revealed in these publications.
- Possible current and future uses of the biological material to be generated from the research will not be used for any other purpose without taking your consent
- Possible current and future uses of the data to be generated from the research and if the data is likely to be used for secondary purposes
- Data will be maintained for a period of 3 years.

Treatment for study related injury: You will be provided medical care in this institute for any physical injury or illness that occurs as a direct result of your participation in this study.

Risks and Benefits of participation: The level of risk involved to be mentioned. What is the benefit of participating has to be highlighted.

Compensation / Reimbursement: There is no reimbursement and/or compensation for participating in this study. These rules will be followed as per PIMS policy.

Right to withdraw from the study: Your participation in this study is entirely voluntary. You may choose not to take part or you may leave the study at any time. Your decision will not affect your further treatment at this institute. If you decide to leave the study. You are encouraged to seek further clarification if unable to understand any component of the PIS.

Contact for further information:

Before you sign this document, you should ask questions about anything that you do not understand.

Contact details of the investigator (PI):

For other queries/ complaints, contact Member Secretary, PIMS IEC

Signature of the investigator with date:

AX 04/SOP 03:

PROTOTYPE

Informed Consent Form (ICF)

Part-II

Date:

I, ----------(Age----), have been informed of the need for the study titled ....., and the process involved, in my own language. I am also aware of that the personal and family details that I disclose will be kept confidential.

I am willing to be a participant of the study (and have my photograph taken-*include if applicable*). I have been assured that my privacy will be maintained. Adequate opportunity has been provided for me to clear my doubts. I am also aware that my participation is voluntary and I may withdraw at any time during the course of the study. I give my consent to use my data and report for academic purpose.

Signature of the Parent:

Signature of the Witness (third party):

Signature of the Doctor:

PROTOTYPE

Informed Consent Form (ICF)

Part-II

Consent form of parent / Legally Authorized Representative (LAR)

Date:

I, ---------- (Father/Mother/LAR) of ----------, Age---- (of minor), have been informed of the need for the study titled ....., and the process involved, in my own language. I am also aware of that the personal and family details of the minor that I disclose will be kept confidential.

I am willing for my ward to be a participant of the study (and have my ward's photograph taken-*include if applicable*). I have been assured that my ward's privacy will be maintained. Adequate opportunity has been provided for me to clear my doubts. I am also aware that my ward's participation is voluntary and that I may withdraw my ward at any time during the course of the study. I give my consent to use my ward's data and report for academic purpose.

Signature of the Parent:

Signature of the Witness (third party):

Signature of the Doctor:

PROTOTYPE

Informed Consent Form (ICF)

Part-II

Assent Form (Minors between ≥7 to ≤18 years)

Date:

I, ----------(Age----), have been informed of the need for the study titled ....., and the process involved, in my own language. I am also aware of that the personal and family details that I disclose will be kept confidential.

I am willing to be a participant of the study (and have my photograph taken-*include if applicable*). I have been assured that my privacy will be maintained. Adequate opportunity has been provided for me to clear my doubts. I am also aware that my participation is voluntary and I may withdraw at any time during the course of the study. I give my consent to use my data and report for academic purpose.

Signature of the Parent:

Signature of the Witness (third party):

Signature of the Doctor:

PONDICHERRY INSTITUTE OF MEDICAL SCIENCES

INSTITUTE ETHICS COMMITTEE, PIMS

Initial Review of Submitted Protocol

Prepared by	Verified by	Approved and Issued by
Dr. Rema Devi	Dr. Reba Kanungo	Dr. Manikandan S

1. Purpose

The purpose of this SOP is to describe the steps taken by the IEC members when reviewing for approval an initially submitted protocol.

2. Scope

This SOP refers to the process of review and assessment of all protocols submitted to the IEC for initial review and approval.

3. Responsibility

It is the responsibility of all the IEC members to fill the Assessment Form (Annexure: SOP 04 / AX 01)along with decision and comments they might have after reviewing each study protocol. The IEC Secretariat is responsible for recording and filing the decision, relevant points and deliberation about a specific protocol, including the reasons for that decision. The Chairperson and Member Secretary must sign and date to approve the decision in the IEC Approval letter(Annexure: AX 02/SOP 07).

4. Detailed procedure

4.1 Review procedure

a. The meeting of the IEC is held in the first week of (alternate) months as given in the IEC calendar of events and additional meetings may be held depending upon the need of the proposals submitted.

b. The proposals are sent as soft copy to members at least 1week in advance.
c. The proposals are distributed amongst to all members, after being allotted as primary and secondary reviewers for the identified proposals by the Member Secretary.
d. Decisions are taken by consensus after discussions.
e. Researchers are invited to offer clarifications, if need be.
f. Independent consultants/experts are invited to offer their opinion on specific research proposals, if needed.
g. The completed Reviewer Study Assessment Form (Annexure 1:AX 01/SOP 04) is the official record of the review done by the IEC for the specific protocol.

The decisions are entered in the minutes of the meeting and an assessment report with comments is handed to the PI with the signature of the Member Secretary. The final approval form signed by the Member secretary and the Chairperson is issued to the PI, when the suggested modifications are satisfactorily rectified. (*Annexure 3: IEC/SOP07/AX03*)

4.2 Elements of initial review

The following elements are considered at the time of initial review.

a. Scientific design and conduct of the study.
b. Approval of the corrections made, as suggested by the scientific review committee.
c. Examination of predictable risks/harms.
d. Examination of potential benefits.
e. Procedures of selection of subjects in methodology including inclusion/exclusion, withdrawal criteria and other issues like advertisement details.
f. Use of placebo, if applicable (To check with the guidelines - Annexure 2: IEC/SOP 04/ AX02)
g. Management of research related injuries, adverse events.
h. Compensation provisions.
i. Justification for placebo in control arm, if any*.
j. Availability of products after the study, if applicable.(Benefits provided)
k. Patient information sheet and informed consent form in local language.
l. Protection of privacy and confidentiality.
m. Involvement of the community, wherever necessary.
n. Plans for data analysis and reporting, if deemed necessary.
o. Adherence to all regulatory requirements and applicable guidelines.
p. Competence of investigators, research and supporting staff.
q. Facilities and infrastructure of study sites.
r. Criteria for withdrawal of patients, suspending or terminating the study.
s. Proposals of studies on vulnerable groups:
   - A vulnerable category of subjects includes children, prisoners, pregnant women, handicapped or mentally disabled persons, refugees, displaced persons and economically or educationally disadvantaged persons, who are likely to be vulnerable to coercion or undue influence.
   - Proposal is subjected to full review by all the members.
   - An expedited review cannot be done for clinical trials involving drugs and medical devices on vulnerable groups
t. Conflict of interest:
   - Conflict of interest includes those researchers who are also teachers, treatment-providers, colleagues or employers of the research participants, or there is any other power relationship between the researcher and the research participants.
   - The Chairperson asks for declaration of conflict of interest either verbally or written on any protocol for discussion.

- 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 he or she has presence as a PI, Co-PI or CI or potential conflict of interest of any sort.
- 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.
- The IEC ensures that the investigators state that they do not stand to gain financially from the commercial sponsor and don't have conflict of interest in the drug or product by way of consultations, shareholding, etc
- Prospective participants in research are informed of the sponsorship of research, so that they can be aware of the potential for conflicts of interest and commercial aspects of the research.

4.3. Review Outcome

- Review outcome can either be
- **Approved** implies the approval of the study as it is presented, with no modifications; and the study can be initiated.
- **Provisionally Approved** implies that the items noted at the convened meeting require modifications which may be of a minor nature and the proposal should be re-submitted to the IEC. This is then subjected to expedited review by the Member Secretary or any other member designated by the chairperson; and the study can be initiated only after the modifications are approved.
- **Resubmit** implies that the proposal has to be reviewed in a full board IEC meeting after the suggested corrections.
- **Rejected** implies that the submitted proposal has not been approved for various reasons – be it the objective / methodology.
- The review outcome is conveyed to the Principal Investigator in a written format, signed by the Member Secretary.

5. Work Flow chart

	Activity	**Responsibility**
1	Classify the received protocols for primary and secondary reviewers	Member Secretary
2	Distribute the agenda, protocol with the assessment form and guidelines as soft copy to the IEC members	IEC office Secretary
3	Review the Protocol using the guidelines and the enter the comments in the assessment form	IEC members

4	Compilation of the assessment forms	IEC office Secretary
5	Presentation of the study protocol at the IEC meeting	Principal Investigator
6	Review of the meeting and summarizing the comments after the meeting	Member Secretary
7	Final communication of the IEC decision taken on the project to the Principal Investigator	Member Secretary
8	Review of the proposals after the suggested corrections	Member Secretary / IEC members
9	Storage of documents	IEC office Secretary

6. References

1. World Health Organization. Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000). Retrieved from www.who.int/tdr/publications.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996 Retrieved from- http://www.ich.org/LOB/media/MEDIA482.pdf
3. Cavazos N., Forster D., and Bowen A.J., Ethical Concerns in Placebo-controlled studies: An Analytical Approach, Drug Information Journal 36(2) 2002: pgs 249- 259, via WIRB documents
4. Draft Guidelines for Compensation to Participants for Research Related Injury in India. http://icmr.nic.in/guidelines.htm
5. Maureen H. Fitzgerald, Paul A. Phillips, and Elisa Yule, The Research Ethics Review Process and Ethics Review Narratives, Ethics & Behavior, 16(4), 2006: 377–395

7. Glossary

Expedited review/meeting: An expedited review is an accelerated review for minor changes to the approved protocol, for research proposal with minimal risk and documents of minor nature.

Full Board/ Regular Review: Review of initial, resubmitted, continuing review, amendments of protocols and / or ICFs and any other documents which are tabled in a formally convened meeting of the full IEC committee for detailed discussion and decisions.

Initial Review: The first time review of the protocol done by one or two individual reviewers/ lead discussants (IEC members) during the formally convened full board IEC meeting.

Vulnerable subjects: A vulnerable category of subjects includes children, prisoners, pregnant women, handicapped or mentally disabled persons, refugees, displaced persons and economically

or educationally disadvantaged persons, who are likely to be vulnerable to coercion or undue influence.

Primary reviewer: The member who would do an in-depth review of the submitted protocol and accompanying documents, and submit the comments on the Reviewer assessment form.

Secondary reviewer: The member who would do a detailed review of the submitted protocol, and concentrate mainly on the Patient Information Sheet and the Consent forms.

8. Annexures

1. **AX 01/SOP 04:** Reviewer Study Assessment Form
2. **AX 02/SOP 04:** Guidelines to members to review a study protocol

AX 01/SOP 04

Reviewer Study Assessment Form

Protocol Number :Date (DD/MM/YY)
Protocol Title :

SL.NO	CRITERIA	COMMENTS
1	**Study title** – matching the objectives	Yes /No
2	**Investigators** (PI /Co-I) Qualification / experience / affiliation / responsibilities delineated Disclosure or Declaration of Potential Conflicts of Interest	 Yes /No Yes /No
3	**Funding** agency / sponsor If yes, agreement / contract / regulatory documents /	Yes /No Yes /No
4	**Description of the Study** in brief: Randomized / Stratified Randomized Open-labeled Double blinded / Placebo controlled / Treatment controlled Cross-over/ Parallel / Interim Analysis Multicenter study / Alternative medicine use Screening / Descriptive Use of Tissue samples/ Use of Blood samples/	(Tick relevant)

	Use of genetic materials	
5	**Statistics** Sufficient number of participants Result analysis	 Yes / No Yes / No
6	**Study design** clear Use of placebo Use of placebo justification acceptable Community Consultation Maintenance of anonymity Delinking identifiable data	Yes / No Yes / No Yes / No Yes / No / NA Yes / No Yes / No
7	Objectives	Clear / Unclear / Suggestions
8	Methodology	Clear / Unclear / Suggestions
9	Need for Human Participants justified	Yes / No
10	Involvement of Vulnerable Participants	Yes / No
11	Inclusion Criteria	Appropriate/ inappropriate
12	Exclusion Criteria	Appropriate/ inappropriate
13	Discontinuation & Withdrawal Criteria	Appropriate/ inappropriate
14	Voluntary, Non-Coercive Recruitment of Participants	Yes / No
15	Background Information and Data (Review of literature) Availability of similar Study	Sufficient/ insufficient Yes / No
16	Risks and Benefits Assessment	Acceptable/ unacceptable
17	Benefit to Local Communities	Yes / No
18	Contribution to development of local capacity for research and treatment	Yes / No
19	**Informed Consent** Appropriate procedures for obtaining consent Contents and language of the ICF Maintenance of privacy & confidentiality Inducement for Participation Provision for Compensation for Participation Provision for Treatment for Study Related Injuries Provision for compensation for Study Related Injuries Provision for Medical / Psychosocial Support Provision for post-trial access to new drug or treatment regime Extra expenses involved due to participation	 Yes / No Clear / Not clear Yes / No Yes / No Yes / No Yes / No Yes / No Yes / No Yes / No Yes / No

20	Facilities and infrastructure of Participating Sites	Appropriate/ Inappropriate

Nature of the reviewer: Primary / Secondary
Name of reviewer:
Signature with date:

AX 02/SOP 04

Guidelines to members to review a study protocol

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

1. How will the knowledge, result or outcome of the study contribute to human well-being?
   - Knowledge from the basic research may possibly benefit.
   - A new choice of method, drug or device that benefits the research participants during the study and others in the future.
   - Provide safety data or more competitive choices
2. Does the study design will be able to give answers to the objectives? Whether
   - The endpoints are appropriately selected.
   - The participating duration of a study participant is adequate to allow sufficient change in the endpoints.
   - The control arm is appropriately selected for best comparison.
   - The placebo is justified.
   - The number of study participants in non-treatment (or placebo) arm is minimized.
   - Unbiased assignment (e.g. randomization, etc.) is in practice.
   - Inclusion and exclusion criteria are carefully selected to eliminate confounding factors as much as possible.
   - The sample group size appropriate with the given statistical assumptions.
   - Predictable risks are minimized.
   - The tests and procedures that are more than minimal risk are cautiously used.
   - Research participants deception is avoid.
   - Instruction and counseling for study participants are included (if needed) when deception is integral to the study design.
   - The study participants are adequately assessed and provided follow-up care, if needed.
3. Who will be the participants in the study? Whether
   - The described population is appropriate for the study.
   - Predictable vulnerabilities are considered.

- It is completely necessary to conduct the study in a vulnerable population. If not, is there any other way to get the study answers?
- There will be secondary participants.

4. Do the inclusion and exclusion criteria
   - Selectively include participants most likely to serve the objective of the study?
   - Equitably include participants?
   - Properly exclude participants who can predictably confound the results?
   - Properly exclude participants who may predictably be at increased risk in the study due to coexisting conditions or circumstances?
5. Does the study design have adequate built-in safeguards for risks?
   - Appropriate screening of potential participants?
   - Use of a stepwise dose escalation with analysis of the results before proceeding?
   - Does the frequency of visits and biological samplings reasonably monitor the expected effects?
   - Are there defined stopping (discontinuation) / withdrawal criteria for participants with worsening condition?
   - Is there minimized use of medication withdrawal and placebo whenever possible?
   - Will rescue medications and procedures be allowed when appropriate?
   - Is there a defined safety committee to perform interim assessments, when appropriate?
   - Is appropriate follow-up designed into the study? For e.g., gene transfer research may require following the participants for years or for their entire lifetime after they receive the gene transfer agent.
6. Is pre-clinical and/or early clinical studies sufficiently performed before this study?
   - The animal study and *in vitro* testing results?
   - Previous clinical results, if done?
   - Whether the proposed study is appropriately built on the pre-clinical and/or early clinical results.
   - The selected dose based on adequate prior results?
   - Monitoring tests designed to detect expected possible risks and side effects?
7. Do the study and the informed consent process include issues of special concern, such as:
   - Waiver or alteration of consent?
   - Delayed consent (e.g., emergency treatment, etc.)?
   - Deception?
   - Sensitive information of participants that may require a confidentiality statement?

Guidelines to review Informed Consent Document/Patient Information Sheet

The actual process of informed consent should:

- Give the participants significant information about the study.
- Make sure the participants have enough time to carefully read and consider all options.

- Answer all questions of the participants before making decision to participate.
- Explain risks or concerns to the participants.
- Make sure that all information is understood and satisfied by the participants.
- Make sure the participants understand the study and the consent process.
- Obtain voluntary informed consent to participate.
- Make sure the participants can freely consent without coercion, pressure or other undue influences.
- Consent should be informally verified on a continuing basis.
- Continue to inform the participants throughout the study.
- Continue to re-affirm the consent to participate throughout the study.

Guidelines to Placebo Justification

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

I. Benefits of standard treatment

- Is there a standard treatment?
- Is the standard treatment widely accepted?
- Has efficacy of the treatment been consistently proven?
- Are all newly diagnosed patients with this condition put in standard treatment (versus observed or other)?
- Does the treatment act on the basic mechanism of the disease (vs. symptoms)?
- Are most (>85%) of the patients with this condition responsive to standard treatment alternatives (vs. resistant or refractory)?

  If the answers to above are "yes", placebo is not recommended.

  If any one or more answers are "no", placebo may be possible.
- Are the side effects of the standard treatment severe?
- Does standard treatment have many uncomfortable side effects?
- Does standard treatment have contraindications that prevent some research participants from being treated?
- Is there substantial (<25%) placebo response in this disease or symptom?

  If the answer to the above are "no", placebo is not recommended.

  If any one or more answers are "yes", placebo may be possible.

2. Risks of placebo

- Is the risk of using placebo instead of treatment life threatening?

If yes, placebo is not acceptable.

- Is the use of placebo instead of treatment likely to lead to permanent damage?

If yes, placebo is not acceptable.

- Is the risk of using placebo instead of treatment likely to cause irreversible disease progression?

If yes, placebo is not acceptable.

- Can the use of placebo instead of treatment lead to an acute emergency?
- Is the risk of using placebo instead of treatment lead to the persistence of distressing symptoms?
- Is the risk of using placebo instead of treatment lead to severe physical discomfort or pain?

If answers of the above clauses are "yes", placebo is not acceptable unless risk management is adequate.

3. Risk management

- Is there benefit in the overall management of the subject?
  If Yes, consider placebo. *If No, placebo not recommended.*
- Will the discontinuation of previous treatment put the participant in danger of acute relapse when transferred to placebo?
  If No, consider placebo *If Yes, placebo not recommended.*
- Are subjects at high risk for the use of placebo, excluded?
  If Yes, consider placebo. If No, placebo not recommended.
- Is the duration of the study the minimum necessary in relation to the action of the drug?
  If Yes, consider placebo. If No, placebo not recommended.
- Are there clearly defined stopping rules to withdraw the subject in case he/she does not improve?
  If Yes, consider placebo. If No, placebo not recommended.
- Is risk monitoring adequate to identify progression of the disease before the subject experience severe consequences?
  Applicable or not.
  If Yes, consider placebo. If No, placebo not recommended.
- Are there clearly defined stopping rules to withdraw the subject before the advent of severe disease progression?
  If Yes, consider placebo. If No, placebo not recommended.
- If the risk of placebo is an acute emergency, are rescue medication and emergency treatment available?
  Applicable or not.
  If Yes, consider placebo. If No, placebo not recommended.
- If the risk of placebo is the persistence of distressing symptoms, is concurrent medication to control them allowed?
  Applicable or not.
  If Yes, consider placebo. If No, placebo not recommended.
- If the risk of placebo is severely physical discomfort or pain, is there rescue medication?
  Applicable or not.
  If Yes, consider placebo. If No, placebo not recommended.

4. Risk disclosure in the consent form

- Are the risks of getting placebo instead of active treatment fully disclosed?
- Are the risks of the test drug disclosed?
- Are the advantages of alternative treatments explained?

If answers of the above clauses are "yes", consider placebo.

Conclusion:

The use of placebo is ethically acceptable because:

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

Guidelines to review advertisements

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

- The name and address of the researcher or research facility.
- The purpose of the research or the condition under study.
- In summary form, the criteria that will be used to determine eligibility for the study.
- A brief list of benefits to participants, if any.
- The time or other commitment required of the participants.
- The location of the research and the person or office to contact for further information

The IEC reviews advertising to ensure that advertisements **DO NOT**:

- State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
- Include exculpatory language.
- Emphasize the payment or the amount to be paid, by such means as larger or bold type.
- Promise "free treatment" when the intent is only to say participants will not be charged for taking part in the investigation.

INSTITUTE ETHICS COMMITTEE, PIMS

Expedited Review of Submitted Protocol

Prepared by	**Verified by**	**Approved and Issued by**
Dr. Rema Devi	Dr. Reba Kanungo	Dr. Manikandan S

1. Purpose

The purpose of this SOP is to provide details of the criteria under which research protocols are eligible to be reviewed under an expedited process. This also outlines the procedure involved in the decision making regarding a protocol under the expedited process.

2. Scope

This SOP applies to the review and approval of research protocols and documents under the expedited process.

3. Responsibility

- Member Secretaryis responsible to identify the fresh proposals that can be considered for expedited review, after categorization of the projects.
- The IEC Office Secretary is responsible for creation of the study file, their distribution along with study assessment forms to the designated IEC members for review (if the study is categorized for expedited review) and communicate the review results to the investigators.
- Designated IEC members (including Member Secretary and/or Chairperson) will be responsible for reviewing the research protocols and related documents within the given time frames.
- Member Secretary is responsible to collate the review opinion, and present it in the forthcoming full board review meeting.
- The Chairperson is responsible to sign and date the decision in the IEC Approval Form.

4. Detailed instructions

Expedited review may be undertaken under the following circumstances:

- Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples
- Research involving clinical documentation materials that are non-identifiable (data, documents, records)
- Modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s)
- New proposals that pose no more than minimal risk, and when vulnerable subjects are not involved as the study group.
- Research during emergencies and disasters

- 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, for example activity limited to data analysis
- Review of SAEs/unexpected AEs
- For multicentre research, if a designated main EC among the participating sites has reviewed and approved the study; for looking at site specific requirements

Procedure

- Member Secretary, identifies the studies, that can go for expedited review.
- Fresh proposal, when undergoing expedited review, is sent to at least three independent reviewers (as soft copy).
- The Member Secretary compiles the comments and sends to the principal investigator within 3 days.
- Once the sought clarifications are satisfactory, approval is sought from the chair person.
- The IEC Office Secretary will send the Study approval letter to the PI.
- The outcome of such expedited review is ratified in the subsequent full board meeting.

5. Work Flow chart

	Activity	**Responsibility**
1	Receive the submitted study documents	IEC office Secretary
2	Determine protocols for expedited review	Member Secretary
3	Expedited process	IEC Members
4	Presentation of the study protocol at the IEC meeting	Principal Investigator
5	Decision of IEC	Chairperson
6	Communicate with the IEC and the Investigator	Member Secretary/ IEC office Secretary

6. References

1. ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2017) - http://ncdirindia.org/Ethics/Download/ICMR_Ethical_Guidelines_2017.pdf
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICHGCP) 1996- http://www.ich.org/LOB/media/MEDIA482.pdf
3. WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) - www.who.int/tdr/publications/

7. Glossary

Expedited review: An expedited review is an accelerated review for minor changes to the approved protocol, for research proposal with minimal risk and documents of minor nature.

PONDICHERRY INSTITUTE OF MEDICAL SCIENCES

TO REACH THE UNREACHED

INSTITUTE ETHICS COMMITTEE, PIMS

Exemption from the Ethical Review

Prepared by	**Verified by**	**Approved and Issued by**
Dr. Rema Devi	Dr. Reba Kanungo	Dr. Manikandan S

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to outline the process which governs projects which the IEC considers to be exempted from ethics review.

2. Scope

This SOP applies to all protocols submitted for exemption from review by the IEC. The decision is taken by the Member Secretary in consultation with the Chairperson and is informed to the members at the next full board meeting of the IEC.

3. Responsibility

- It is the responsibility of the Member Secretary in consultation with the Chairperson to record the decision in the Exemption Form with reasons.
- The IEC office Secretary is responsible for recording and filing the decision.
- The Chairperson signsthe letter conveying the decision.

4. Detailed instructions

The following proposals may qualify from exempted review:

- Proposals with less than minimal risk where there are no linked identifiers.
- Research conducted on data available in the public domain for systematic reviews or meta-analysis.
- Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person.
- Quality control and quality assurance audits in the institution.
- Comparison ofinstructional techniques, curricula, or classroom management methods.
- Consumer acceptance studies related to taste and food quality.
- Public health programmes by Government agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring and where there are no individual identifiers.

Procedure

- On receipt of the request for exemption,the Member Secretary, in consultation with the Chairperson, takes a decision on whether the proposal deserves exemption from the ethical review.
- Once the decision is taken, all the members are informed of the same at the next full board meeting of the IEC and the Member Secretary minutes it in the meeting notes.

- It is also the Secretary's responsibility to communicate the decision to the PI, within 2 weeks of submission.

5. Work Flow chart

	Activity	**Responsibility**
1	Receive the submitted study documents	IEC office Secretary
2	Review and determine protocols for exemption of review	Member Secretary and Chairperson
3	Communicate the decision with the Investigator	IEC office Secretary
4	Informing the decision to the members in the forthcoming meeting	Member Secretary
5	Filing the documents	IEC office Secretary

6. References

1. ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2017) - http://ncdirindia.org/Ethics/Download/ICMR_Ethical_Guidelines_2017.pdf
2. WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) - www.who.int/tdr/publications/publications/

7. Glossary

Exemption from review: A research study is said to be exempt from review when it does not require the Ethics Committee approval for its conduct.

8. Annexure

1. **IEC/ SOP 06/ AX 01:** Review exemption application form

IEC/SOP06/AX01

Review Exemption Application Form

Project No. :

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

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

Principal Investigator's signature: Date:

Forwarded by the Head of the department:

Approved by the Scientific Committee: Date:

Recommendations by the IEC Member Secretary:

Exemption Granted / Rejected

If rejected, Reasons

Discussion at full board, held on

Signature of the Member Secretary: Date:

Final Decision: Granted / Rejected

If rejected, Reasons

Signature of the Chairperson: Date:

NOTE:

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

(i) Invasive physical procedures or potential for physical harm

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

(iii) Personal or sensitive issues

(iv) Vulnerable groups

(v) Cross cultural research
(vi) Investigation of illegal behavior(s)
(vii) Invasion of privacy
(viii) Collection of information that might be disadvantageous to the participant
(ix) Use of information already collected that is not in the public arena, which might bed is advantageous to the participant
(x) Use of information already collected which was collected under agreement of confidentiality
(xi) Participants who are unable to give informed consent
(xii) Conflict of interest e.g. the researcher is also the lecturer, teacher, treatment-provider, colleague or employer of the research participants, or there is any other power relationship between the researcher and the research participants.
(xiii) Deception
(xiv) Audio or visual recording without consent
(xv) Withholding benefits from "control" groups
(xvi) Inducements
(xvii) Risks to the researcher

PONDICHERRY INSTITUTE OF MEDICAL SCIENCES

TO REACH THE UNREACHED

A Unit of Madras Medical Mission

INSTITUTE ETHICS COMMITTEE, PIMS

Agenda Preparation, Meeting Procedures and Recording of Minutes

Prepared by	Verified by	Approved and Issued by
Dr. Rema Devi	Dr. Reba Kanungo	Dr. Manikandan S

1. Purpose

The purpose of this SOP is to describe the process of preparation, review, approval and distribution of meeting agenda, minutes and notification of IEC meetings.

2. Scope

This SOP applies to administrative processes concerning the conduct of the meeting.

3. Responsibility

It is the responsibility of the Member Secretary to prepare for the IEC meetings.

4. Detailed process

a. The last date for the receipt of the IEC proposals, after the approval from the scientific committee, is announced much in advance (as per the IEC calendar of meetings).
b. Prepare the agenda (Annexure IEC/SOP07/AX01) of the upcoming meeting.
c. Distribute soft copies of the protocol to all members at least 7 days ahead of the proposed meeting and make sure that the members have received them.
d. The IEC members are categorised into Primary or secondary reviewers, and the proposals are allotted to the IEC members by the IEC Member Secretary.
e. Depending on the protocols, meeting may be arranged as on-line or on-site. In case it is an on-line meeting, the link would be sent to all the IEC members within 24 hours of the scheduled meeting. There is a provision to have a hybrid meeting as well.
f. All those members who attend the meeting are expected to sign the attendance sheet, which will be filed along with the minutes of the meeting.
g. Investigators may be invited to attend the meeting to clarify doubts, if any.
h. The proceedings of the meeting are to be recorded by the Secretary, or someone appointed by the Chairperson.

5. Decision Making process

a. Members discuss the various issues before arriving at a consensus decision.
b. Where a conflict of interest arises in an application under review, the concerned member withdraws from the meeting during the decision procedure and this is indicated to the Chairperson prior to the review of the application and recorded in the minutes.
c. Decisions are made only in meetings where quorum is complete. Provision to have a complete quorum is ensured by facilitating an on-line meeting facility.
d. Only members can make the decision. The expert consultants only offer their opinions.

e. Decision may be to approve, reject or revise the proposals. Specific suggestions for modification and reasons for rejection are also given (as per format given in IEC/SOP07/AX02 and IEC/SOP07/AX03).
f. In cases of conditional decisions, clear suggestion for revision and the procedure for having the application re-reviewed are specified.
g. Modified proposals are reviewed in an expedited manner through identified members and ratified in the subsequent full board meeting.

6. Post-Meeting

a. After the meeting, the Member Secretary compiles the proceedings of the meetings as the minutes of the meeting, and after it is approved by the Chairperson, it is filed.
b. The decision is conveyed to the investigators.
c. A copy of the minutes is circulated to the IEC members.
d. A maximum period of three months time is given to the investigators to respond to the IEC decisions.

7. Communicating the decision

a. Decision is communicated by the Member Secretary in writing.
b. Suggestions for modifications if any, or reasons for rejection are informed to the researchers from the IEC office.

8. Work Flow chart

	Activity	**Responsibility**
1	Announce the last date for receipt of proposals	IEC office secretary
2	Announce the date of the meeting	IEC Member Secretary
3	Prepare the agenda for the meeting	IEC Member Secretary
4	Distribute the proposals to the IEC members	IEC office secretary
5	Provide the on-line link for the meeting	IEC office secretary
6	Minute the meeting	IEC Member Secretary
7	Communicate the decisions to the PI, IEC members	IEC office secretary

9. References

1. International Conference on Harmonization, Guidance on Good Clinical Practice (ICHGCP) 1996 Retrieved from- http://www.ich.org/LOB/media/MEDIA482.pdf
2. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research (Geneva 2000)- Retrieved from www.who.int/tdr/publications/publications/

10. Glossary

Agenda: A list of things to be done; a program of business for the meeting
Minutes: An official record of proceedings at a meeting
Quorum: Number of IEC members required to act on any proposal presented to the committee for action.

11. Annexure

1. **IEC/SOP07/AX01** - Agenda format
2. **IEC/SOP07/AX02** - Format for approval letter of ethics committee
3. **IEC/SOP07/AX03** – Format for the conditioned approval for projects / amendments

IEC/SOP07/AX01

AGENDA FORMAT

I) Minutes of the previous meeting – Ratification
II) Projects for Initial Review – Discussion
III) Presentation of Expedited review documents
IV) Outcome of continuing monitoring
V)Letters and clarifications
VI) Any others, permitted by the Chairperson

IEC/SOP07/AX02

FORMAT FOR APPROVAL LETTER OF ETHICS COMMITTEE

Date: _____ **REF NO:**

Protocol Title	
Principal Investigator	
Co-Investigator(s)	
Name of the Department(s) & Institution(s)	
New Review / Old Review	
Date of Review (DD/MM/YY)	
Decision of the IEC (Approved / Approved with suggested modifications / Pending / Revision / Rejected)	
Remarks	-

Please note*

- Inform IEC immediately in case of any adverse events and serious adverse event.
- Inform IEC in case of any amendments to the protocol, change of study procedure, site and investigator and premature termination of study with reasons along with summary.
- Final & yearly reports to be submitted to IEC.
- Members of IEC have right to monitor the trial with prior intimation.
- A copy of the consent document to be given to the study participant giving consent.

Name
Member Secretary
Address
PIMS, Puducherry

Name
Chairperson
Address

IEC/SOP07/AX03

FORMAT FOR CONDITIONAL APPROVAL FOR PROJECT/AMENDMENTS

To
The Principal Investigator

Ref: Project No.------

Dear Dr.

The above referenced project was tabled, reviewed and discussed during the Institutional Ethics Committee meeting held on date/time/place
List of documents reviewed: -------

The following members attended the meeting.--------

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 two copies of revised proposal or documents within three months for re-review.
This conditional approval is valid only for six months from the date of issue of letter.
Thanking you,

Yours sincerely,

Member Secretary, IEC

PONDICHERRY INSTITUTE OF MEDICAL SCIENCES

TO REACH THE UNREACHED

INSTITUTE ETHICS COMMITTEE, PIMS

Review of Amended protocol/ Protocol related documents

Prepared by	Verified by	Approved and Issued by
Dr. Rema Devi	Dr. Reba Kanungo	Dr. Manikandan S

1. Purpose

The purpose of this SOP is to outline how amendments to protocol and other protocol related documents are reviewed by the IEC.

2. Scope

The scope of this SOP applies to amended protocols, documents and letters which are submitted for IEC approval. It should be noted that any amendments made may not be implemented until approved by the IEC.

3. Details

a. The Secretary of the IEC is responsible for managing all protocol related work.
b. Once the amended protocols are presented at the committee, the Secretary informs the decision, either approval or otherwise, to the investigator in writing.
c. In case further modifications are called for, the investigator is informed in writing as to the changes to be made, and asked to resubmit the documents to the IEC.
d. All amendments are properly documented and archived

4. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research (Geneva 2000) Retrieved from-www.who.int/tdr/publications/
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICHGCP) 1996 Retrieved from-http://www.ich.org/LOB/media/MEDIA482.pdf
3. Code of Federal Regulation (CFR), 21 §56.110, The United States of America, 1998

PONDICHERRY INSTITUTE OF MEDICAL SCIENCES

INSTITUTE ETHICS COMMITTEE, PIMS

Review of Serious Adverse Events (SAE) Reports

Prepared by	Verified by	Approved and Issued by
Dr. Rema Devi	Dr. Reba Kanungo	Dr. Manikandan S

1. Purpose

The purpose of this SOP is to outline the steps involved when any serious adverse events (SAEs) or unexpected events are reported for any active study approved by the IEC.

2. Scope

This SOP applies to the IEC review of SAE and other unexpected event reports including follow-up reports submitted by the investigators.

3. Details

A- CLINICAL TRIALS

a. It is the responsibility of the IEC to review and deal with reports of SAE and unexpected events. They will also ensure that researchers are made aware of all the policies and procedures concerning reporting such events and the continuing review requirements.

b. On receiving a report of SAE in the prescribed format (Annexure IEC/SOP08/AX01), the Chairperson on the basis of the comments and information provided by the Secretary, gives instructions on the action to be taken, depending on the gravity and seriousness of the matter.

c. In case of regulatory clinical trials, the PI is expected to report the SAEs within the stipulated time, according to the current regulation notifications.

Report to the Sponsor- within 24 hours

Report to the Ethics Committee- within 24 hours in the event of death.

- within 7 working days of their occurrence

d. All decisions by IEC are informed to all the IEC members as well as the PI; minutes of the meeting and a copy of which is filed for archival purposes.

e. The PI is also instructed to forward follow-up reports of the SAE to the IEC.

B- ACADEMIC STUDIES

a. In case of academic studies, the PI is expected to inform the IEC, forwarded by the concerned Head of the Department

b. Following review by the IEC, if any modification to the study is opined, the same is conveyed to the Head of the Department and Head of the institution

4. Work Flow chart

No.	Activity	Responsibility
1	Receiving the SAE report from the PI	Office secretary
2	Reviewing the report, informing the IEC members	Member Secretary
3	Alternate decisions regarding conduct of approved study	Chairperson
4	Correspondence with regulatory authorities for CT	Member Secretary

5. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)- www.who.int/tdr/publications/
2. International Conference on Harmonization, Guidance on Good Clinical Practice, (ICH GCP)1996 - http://www.ich.org/LOB/media/MEDIA482.pdf
3. Nationwide Children's Hospital, Standard Operating Procedure: SAE Reporting and Reviewhttp://etrac.ccri.net/CRI/Doc/0/2137HUSRMVKKFBHAT542EHDME8/011%20Adverse%20Event.pdf

6. Glossary

Adverse Event: Any untoward medical occurrence in a patient or clinical investigation participant administered an investigational product and which does not necessarily have a causal relationship with this treatment. The adverse event can therefore be any unfavorable or unintended sign or experience associated with the use of the investigational product, whether or not related to the product.

Adverse Drug Reaction: In the pre-clinical experience with a new medicinal product or itsnew usages, particularly as the therapeutic dose(s) may not have been established all noxious or unintended responses to the product related to any dose should be considered adverse drug reactions. The phrase "responses to a medicinal product" means that a causal relationship between the productand the adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruledout. Regarding marketed products, a response to a product which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of diseases or for modification of physiological function.

Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR):

Any untoward medical occurrence (due to the participation in the concerned trial) thatat any dose:

- results in death
- is life-threatening
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability / incapacity
- is a congenital anomaly/birth defect

7. Annexure

1. IEC/SOP 09/AX 01: Serious Adverse Event Review Report form

IEC/SOP09/AX01

SERIOUS ADVERSE EVENT REVIEW REPORT FORM

1. Title of project and Project No:
2. Principal Investigator:
3. Report date:
4. Report type: Initial Follow up
5. Patient case no:

5a. Age ---------- 5b. Gender M / F

6. Mention the total number of SAE (prior) occurred at our site----------; other site(s)----------
7. Mention number of similar SAEs (prior) occurred for same study at our site----------; other site(s)----------

Suspect drug /device/intervention information

8. Suspect drug (include generic name)/device/intervention
9. Dose:
10. Route(s) of administration:
11. Therapy dates (from/to)
12. Therapy duration:
13. Did the reaction decline after stopping the drug/procedure: YES/ NO / NA

Concomitant drugs and history

14. Concomitant drug(s) and date of administration
15. Patient relevant history (e.g. diagnosis, allergies)

Reaction information

16. Description of adverse event (indicate if this is follow-up report and if so, include follow-up information only) Underline the adverse event

17.Tick whichever is applicable for specific adverse event

A] expected event / unexpected event (this refers to trial being conducted and notdisease process)

B] hospitalization /prolonged hospital stay / death/ others (If others, please specify)

C] No permanent significant functional/ cosmetic impairment

Permanent significant functional/ cosmetic impairment /Not applicable

18. Describe the medical treatment provided(if any) to the research subject:
19. Outcome wasresolved / ongoing / death
20. Was the research subject continued on the research protocol?Yes /No
21. In your opinion, does this report require any alteration in trial protocol?Yes / No

If yes, then please specify.

22. Does the Principal Investigator feel this SAE is related to participation in the trial?Yes / No/ Possible
23. Does the protocol have an inbuilt data monitoring plan?Yes / No

Reporting

24. Have the sponsors been notified? Yes / Noon ----------
25. Reported to DCGI: Yes / No on----------

Signature of Principal Investigator ----------Date: ----------

Received in IEC Office on----------

INSTITUTE ETHICS COMMITTEE, PIMS

Documentation of the IEC activities

Prepared by	Verified by	Approved and Issued by
Dr. Rema Devi	Dr. Reba Kanungo	Dr. Manikandan S

1. Purpose

The purpose of this SOP is to describe the procedures for documenting the IEC activities.

2. Scope

This SOP will apply to all research activity approved by the IEC, regardless of the source or type of funding.

3. Responsibility

It is the responsibility of the IEC staff to maintain all the files pertaining to IEC activities and ensure that they be archived for the prescribed period.

4. Details

The IEC records include the following:

a. IEC members' records, including their Curriculum vitae and records of training undergone by each member
b. IEC membership and attendance rosters
c. Standard Operating Procedures
d. Copy of all study protocols with enclosed documents, progress reports, and SAEs.
e. Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.
f. Copy of all correspondence with members, researchers and other regulatory bodies.
g. Final report of the approved projects.
h. IEC meeting agenda and minutes
i. Annual Reports

5. Access to records

All records are confidential and are made available for inspection by authorized personnel after receiving a request for the same in writing.

6. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research (Geneva 2000) Retrieved from-www.who.int/tdr/publications/

INSTITUTE ETHICS COMMITTEE, PIMS

Review of study completion reports

Prepared by	Verified by	Approved and Issued by
Dr. Rema Devi	Dr. Reba Kanungo	Dr. Manikandan S

1. Purpose

The purpose of this SOP is to outline the steps involved in the review of Study Completion Report for all studies which have been approved by the IEC.

2. Scope

The scope of this SOP covers the review of the Study Completion Report which every investigator is obliged to present to the IEC as a written report of his or her activities connected with the study.

3. Details

a) The Study Completion Reports is presented at the full meeting of the IEC, and it is the responsibility of the IEC members to review the Study Completion Report and notify it or request for further information, if necessary.
b) Depending on the discussions, the Chairperson may ask for its acceptance by a consensus decision or request for further information, or take any other action as suggested by the IEC.
c) The decisions are minuted, and if the document is accepted, the study is considered closed.
d) All reports are filed and archived for a stipulated period of time.

4. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research (Geneva 2000) Retrieved from-www.who.int/tdr/publications/
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- http://www.ich.org/LOB/media/MEDIA482.pdf

INSTITUTE ETHICS COMMITTEE, PIMS

Request for Waiver of Written Informed Consent

Documentation of the IEC activities

Prepared by	Verified by	Approved and Issued by
Dr. Rema Devi	Dr. Reba Kanungo	Dr. Manikandan S

1. Purpose

The purpose of this SOP is to outline the process whereby the IEC may grant a waiver for requirement of obtaining written or video informed consent.

2. Scope

The scope of this SOP applies to all protocols submitted for review to the IEC wherein a request has been made for granting a waiver of obtaining consent.

3. Responsibility

It is the responsibility of the IEC to grant the waiver for informed consent. However, a request should be provided by the researcher along with the application.

3. Details of procedure

The IEC may grant consent waiver in the following situations:

- Research cannot practically be carried out without the waiver and the waiver is scientifically justified
- Retrospective studies, where the participants are de-identified or cannot be contacted
- Research on anonymized biological samples/data
- Certain types of public health studies/surveillance programs/program evaluation studies
- Research on data available in the public domain
- Research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent. (Attempt should be made to obtain the participant's consent at theearliest subsequently)

a. All requests made for waiver of consent should be accompanied by a detailed explanation for making such a request in the prescribed application form (Annexure PIMS-IEC /SOP12/AX01).
b. These requests are tabled and a decision arrived at, either during an expedited meeting or at the regular full board meeting.
c. The request for waiver is granted only after the members are assured that adequate mechanisms have been included in the protocol to ensure the identity protection of the research participants and to maintain confidentiality of the study data.
d. The decision of the committee is conveyed to the PI in writing, with reasons given in case of denial of request.
e. All decisions made are recorded and filed for archival purposes.

4. References

1. Ethical Guidelines for Biomedical research on Human Participants, ICMR (2017)
2. 45CFR Title 45 Public Welfare (45 CFR 46) Protection of human subjects, Department of Health and Human Services, revised June 23, 2005.
Retrieved From: http://www.hhs.gov/ohrp/humansubjects/guidance/45 CFR 46.htm

5. Annexure

1. **PIMS-IEC /SOP12/AX01 -** Application form for requesting waiver of consent

PIMS-IEC /SOP12/AX01

APPLICATION FORM FOR REQUESTING WAIVER OF CONSENT

1. Title of project:
2. Principal Investigator's name:Department:
3. Co- investigators (Faculty /Department ; Student / Semester)
4 . Request for waiver of informed consent:
(Please check the reason(s) for requesting waiver)
    a. Research involves 'not more than minimal risk'
    b. There is no direct contact between the researcher and participant
    c. Emergency situations as described in ICMR Guidelines (ICMR 2017 Guidelines)
    d. Any other (please specify)
5. Statement assuring that the rights of the participants are not violated
6. State the measures described in the Protocol for protecting confidentiality of data and privacy of research participant

Principal Investigator's signature with date:

PONDICHERRY INSTITUTE OF MEDICAL SCIENCES

TO REACH THE UNREACHED

INSTITUTE ETHICS COMMITTEE, PIMS

Dealing with complaintson an IEC approved study

Prepared by	Verified by	Approved and Issued by
Dr. Rema Devi	Dr. Reba Kanungo	Dr. Manikandan S

1. Purpose

The purpose of this SOP is to provide guidelines for dealing with complaints made by participants or any others in an IEC approved research study, regarding the rights of participantsor any complaints pertaining to the rightful conduct of the study.

2. Scope

This SOP applies to all complaints that may be made which concern the rights and well-being of the research participants in studies approved by the PIMS-IEC.

3. Responsibility

It is the primary responsibility of the IEC to act on a complaint, received from a participant or any other individual, on any study approved by the IEC.

4. Details

a. Any PIMS-IEC member or administrative staff receiving an enquiry or a request from a research participant or any other individual (viz. researches, staff) in the prescribed request form (Annexure PIMS-IEC /SOP13/AX01) informs the Chairperson of the same.
b. It is the responsibility of the Chairperson to initiate the process of giving information or providing justice in case of a complaint.
c. In case of a complaint, an inquiry is conducted to resolve the matter and if necessary, members are designated to mediate a negotiation to resolve the issue between the complainant and the investigator.
d. Any complaint that cannot be dealt by the chairperson will be handed over to the Head of the Institution
e. The complainant is informed of the final decision by the Member Secretary, and the PIMS-IEC members are informed of the outcome at the next full meeting.
f. All documents pertaining to the issue are kept confidential and filed.

5. References

1. Kathleen J. Motil, Janet Allen and Addison Taylor, "When a Research Subject Calls with a Complaint, What Will the Institutional Review Board do?" IRB: Ethics and Human Research 26, no.1(January –February 2004):9-13

2. *https://www.boltonclarke.com.au/globalassets/about-us/innovation/x-researchcomplaintsprocedure*(accessed in Dec 2020)

6. Annexures

1.PIMS-IEC /SOP13/AX01- Complaint Record Form

PIMS-IEC /SOP13/AX01

COMPLAINT RECORD FORM

COMPLAINT	Received on:	Received by:	
Received through	Telephone call No	Letter / Date	E-mail / Date
	Fax No	Walk-in: Date / Time	Other, specify
Participant's Name:			
Contact details	Address		
	Phone No:		
Title of the participating study:			
Details of complaint			
Action taken			
Outcome			
Member secretary: Name /sign/ date		**Chair person: Name /sign/ date**	

INSTITUTE ETHICS COMMITTEE, PIMS

Continuing review of submitted protocols

Prepared by	Verified by	Approved and Issued by
Dr. Rema Devi	Dr. Reba Kanungo	Dr. Manikandan S

1. Purpose

The purpose of this SOP is to describe how continuing review of previously approved protocols should be managed by the IEC. The purpose of the continuing review is to periodically monitor the progress of the study, to ensure continuous protection of the rights and welfare of research participants and that there is no deviation from the submitted and approved protocol.

2. Scope

This SOP applies to conducting any continuing review of already approved study protocols at pre-specified intervals. All the projects approved by the IEC will be reviewed at least once a year, and annual reports are to be submitted by the PI.

This is mainly intended for regulatory clinical trials. Depending upon the degree of risk to the participants, the nature of the study, the vulnerability of the study participants and duration of the study, the use of placebo, the IEC may choose to review or monitor the protocols, other than those included in regulatory clinical trials more frequently.

3. Responsibility

It is the responsibility of the IEC Secretary to remind the PIs and Member Secretary regarding continued review of protocols at the specified interval. All the approved protocols will be reviewed annually. It is the responsibility of the Member Secretary to ensure that a decision regarding whether the project needs to be reviewed more frequently is taken during the IEC meeting, in which the project is finally approved. If so, the same must be recorded in the minutes of the concerned meeting and conveyed to the researcher through the approval letter. A fresh decision to increase the review may be taken based on the SAE reports, monitoring reports, or safety concerns, or through any new information.

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

4. Detailed procedure

4.1 Determining the date of continuing review

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

- The Office Secretary will inspect the minutes of meeting to set a timetable for continuing review.
- The Office Secretary will identify and record the due dates for each project and inform the PI.

4.2 Notifying the PI or the study team

The Office Secretary will send a reminder to the PI as per the format AX 01/SOP 14two months prior (for an annual review) or less as appropriate (if any special additional reviews are required) to the due date of continuing review.

4.3 Managing the continuing review package upon receipt

The Office Secretary will receive ONE set of soft and hard copy submitted by the PI for continuing review of each approved protocol. Only one set of continuing review report has to be submitted by the PI to the IEC as per the format Continuing Review Application Form (AX 02/SOP 14; AX 03/SOP 14).The Office Secretary will check the documents for completion, as and when received.

4.4Review process

The Continuing review submission may undergo expedited review or full board review as opined by the Member Secretary.

- The IEC Chairperson/ Member Secretary/ Member/s will use the Continuing Review Application Form (AX 02/ 03/SOP 14)to guide the review and deliberation process.
- The Office Secretary will send the Continuing Review Application Form (AX 02/03/SOP 14)to the designated IEC members.
- The IEC Chairperson/ Member Secretary/ Member/s could reach one of the following decisions after review:

  1. *Noted* - The IEC approves the continuation of the project without any modifications.

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

  3.*To be discontinued*: The reasons for discontinuation of the project should be mentioned in the letter notifying the decision to the Principal Investigator. This decision shall be recorded by the Member Secretary.
- The IEC Chairperson will sign and date the IEC decision on Continuing Review Report after a decision has been reached.
- The decision on continuing review taken by the Chairperson/ Member Secretary/ Member/s will be informed to all IEC members at the next full board meeting

- The continuing review report may be discussed at full board, if deemed necessary by Chairperson/Member Secretary.
- The IEC Office Secretary will maintain and keep the IEC Decision forms and minutes of the meeting relevant to the continuing review as part of the official record of the review process in the project file.
- The Office Secretary will notify the PI of the decision within 14 days of the meeting at which the report was discussed or of the date of review by the Chairperson/ Member Secretary/ IEC Member(s).

4.5 To grant a continuation of the approval of the research:

The IEC, while reviewing, must determine that

- No material changes to the research protocol / informed consent, that has not been previously approved
- No new Conflict of interest or new information that has emerged which might affect the well being of the participants
- Risks are minimized and reasonable in relation to the anticipated benefits
- Selection of participants is equitable
- Informed consent process is appropriate and documented
- Adequate provisions are in place for monitoring and data protection which will ensure safety and privacy of the participants
- Any complaints from research participants have been followed up appropriately

The IEC may also recommend

- Changes to the ICF
- Changes to the periodicity of continuing review (based on risks)
- Impose special precautions like increasing frequency of monitoring, requirement of interim reports
- Require modifications of research

4.6Non-submission of continuing review report by principal investigator before due date

- If a PI fails to submit the continuing review report within one month of the due date (i.e. 11th month from the date of approval, or earlier on the dates, as specified), the Office Secretary will send a telephonic and /or email reminder at least 15 days prior to due date of review. If there is no response, the IEC Member Secretary will put up the matter for discussion at the forthcoming full board meeting for appropriate action which may consist of but not limited to sending:

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

5. Work Flow chart

	Activity	**Responsibility**
1	Determine the date of continuing review	IEC office Secretary
2	Notify the Principal Investigator or study team	IEC office Secretary
3	Manage continuing review documents upon receipt and verifying its contents	IEC office Secretary
4	Notify the members of the IEC	IEC office Secretary
5	Review of Continuing review documents	IEC Member Secretary
6	Communicate the IEC decision to the Principal Investigator	IEC Member Secretary IEC office Secretary
7	Present in the subsequent convened full board meeting	IEC Member Secretary

6. References

1. WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) - www.who.int/tdr/publications/publications/ (last accessed 24 March 2008)
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996. http://www.ich.org/LOB/media/MEDIA482.pdf (last accessed 24 March 2008)
3. ICMR's Ethical Guidelines for Biomedical research on Human Participants, ICMR (2017)- http://www.icmr.nic.in/ethical_guidelines.pdf (last accessed March, 2018)
4.https://hopitalmontfort.com/sites/default/files/PDF/sop_405.002_continuing_review.pdf(last accessed December 2020)

7. Glossary

Continuing review: is a re-evaluation of an approved study that is required to be conducted at least once a year.

8. Annexures

1. **AX 01/SOP 14:** Reminder letter by the IEC to principal investigator
2. **AX 02/SOP 14:** Extension of approval application form (non regulatory CT)
3. **AX 03/SOP 14:** Submission of interim / status report for non-clinical trials /student thesis

AX 01/SOP 14

TEMPLATE FOR REMINDER LETTER BY THE IEC TO PRINCIPAL INVESTIGATOR

Date:-

Project No.:	Date of last IEC approval:
Project Title:	
Principal Investigator :	
Department :	

The above referenced project was approved by the IEC on (DATE)and is due for Continuing Annual/ Periodic Review by the IEC. You are requested to submit an Annual/ Periodic status report in the prescribed format which is enclosed (Continuing Review Application Form *AX 02/SOP 14*) at the earliest, on or before DATE. (A 1month period), failing to submit will warrant an action from IEC.

Signature with date _____

Member Secretary/ Chairperson _____

AX 02/SOP 14

EXTENSION OF APPROVAL APPLICATION FORM

(to be filled by the PI)

IEC Study Ref No: Study title : PI. Name : Initial Approval by EC(date): Subject: Submission of study progress report (for the period from----------to----------) Study initiated (date) : Participant Recruitment: ongoing/ completed Sample collection: ongoing/ completed Data entry: ongoing/ completed **Expected completion (date)**: Mention if there are changes in the current versions (other than approved) being used: - Informed consent document (Eng/ regional) - Investigator's Brochure - Protocol - PI / Co PI change: details....	**Report:** 1. Participant recruitment: • Total number of Participants screened: ---- • Randomized ----- • Recruitment: continuing / closed on..... If closed, mention no subjects are ongoing in the study. 2. Protocol Amendment, if any: Yes /no 3. Any new and relevant information: Yes /no 4. A summary of any unanticipated problems: 5. Any complaints about the research from subjects: Yes /no 6. Reason for seeking extension:
Signature of the PI: Forwarded by: Guide /HOD	

AX 03 /SOP 14-Submission of interim / status report for non-clinical trials / student thesis

1	**IEC reference No**	
	Study title	
	PI Name	
	Designation & Department	
	Mobile No & email ID	
	IEC approval date	
	Date of Initiation of study	
	Duration of the study:	
	Details of previous extensions taken	
2	**Study team details:**	
	To be listed: (PI/Co-I, Co-ord) with Affiliations	
	Are the Present study Team members as per the list approved by IEC?	
	If no, was the relevant communications sent to IEC?*(give the reference)*	
3	**Status of study** *(Tick the relevant response)*	
	Ongoing / Completed / Enrolling / Recruitment completed / Follow up / Data analysis	
	Expected completion date	
	Suspended / Terminated *(provide reason)*	
4	**Recruitment details**	
	Eligibility criteria adhered to?	Yes /No
	Total participants planned to be enrolled	
	Screened – No.	
	Screen Failure- No.	
	Enrolled/ Randomized- No.	
	Withdrawn- No.	
	Discontinued- No.	
5	**DOCUMENTS**	
	Use of recent version of protocol with IEC approval	Yes / No
	Amendment, if any, with summary	
	A summary of any unanticipated problems	Yes / No
	Any complaints about the research from subjects	Yes / No
	Signature of PI : ..... Date:	

INSTITUTE ETHICS COMMITTEE, PIMS

Monitoring clinical trials

Prepared by	**Verified by**	**Approved and Issued by**
Dr. Rema Devi	Dr. Reba Kanungo	Dr. Manikandan S

1. Purpose

The purpose of this SOP is to describe how clinical trials registered with the Clinical Trials Registry of India (CTRI) are to be managed by the IEC. The purpose is to protection of the rights and welfare of research participants; verifying that the reported trial data are accurate, complete and verifiable from source documents and that the conduct of the trial is incompliance with the currently approved protocol/amendment(s), GCP and the applicable regulatory requirements (CDSCO & ICMR).

2. Scope

This SOP applies to IEC monitoring the regulatory clinical trials, registered with CTRI, having a sponsor and being conducted with the permission of CDSCO. All the projects approved by the IEC will be monitored, based on the documents submitted by the PI, which includes updates, reports of adverse events, and annual reports.
Depending upon the degree of risk to the participants, the nature of the studies, the vulnerability of the study participants and duration of the study, the IEC may choose to review or monitor the protocols at a periodicity which deems fit for that particular study.

3. Responsibility

It is the responsibility of the

- PI to submit all documents and updates on the study to the IEC: reports, notifications, submissions which are accurate, complete, timely, version controlled and all are to be legible.
- IEC Office Secretaryis to collect all documents, inform the IEC Member Secretary and file the documents in the study file after review.
- IEC Member Secretary makes arrangements to review the documents (either expedited or full board) as appropriate.

4. Detailed procedure

4.1 Extent of monitoring

Monitoring will be proportional to the objective, purpose, design, size, complexity, binding, endpoints and risks of the CT. It is the responsibility of the IEC team, during evaluation of the proposal, to determine the appropriate nature and level of monitoring required for CT by risk assessment.

4.2 Personnel involved in monitoring

Monitoring is a two stage program done from the sponsors and by the IEC at the site.

4.3 Monitoring process

- Done through

i. Checking the documents submitted(either through expedited review or full board meeting): SAE / Death / Protocol deviation and corrective action taken / Protocol violation and corrective action taken / Premature termination notification / Complaints received regarding study by participants or public.

ii. Internal audits (conducted by two IEC members, preferably one non affiliated member): All required documents available at the site –ISF / CRF / PIS / ICF / SAE notifications / functioning equipment / adequate storage space for documents, records & medicines / confidentiality maintenance of documents / participants recruited, withdrawn, dropouts, lost on follow up / compensation phenomenon. During audits, it is endured that all documents are submitted to IEC and approved by IEC before being put into use.

iii. For-cause audit (conducted by two IEC members, identified by the chair person): A complete checking of all available documents, depending on the nature of a complaint received (Ref: SOP16)

- In case there is any deviation / violation of the protocol, the PI is expected to submit a statement which includes Root cause analysis (RCA) and Corrective and preventive action (CAPA).
- In case of SAEs, it is to be checked if they have been reported timely to the sponsor, IEC and DCGI. The follow up of the same also has to be maintained.
- The documents / audit findings are discussed in Full board meeting and the IEC decides the course of action which may either be continual of study / modify the study protocol / suspension of the study /termination of the study. The same is minutes by the Member secretary and thereafter conveyed to the PI.

5 Work Flow chart

	Activity	**Responsibility**
1	Determine the nature of monitoring	IEC members
2	Notify the PI or study team, if an audit is planned	IEC office Secretary
3	Review of documents Conduct of an audit	IEC members

4	Notify the members of the IEC	IEC Member Secretary
5	Review of the IEC approval	IEC members
6	Communicate the IEC decision to the PI	IEC Member Secretary

6 References

1. https://khpcto.co.uk/SOPs/03_MonitoringSOP.php (last accessed on October 2019)
2. National Ethical Guidelines for Biomedical and Health Research involving human participants -ICMR guidelines 2017

7 Glossary

- **Adverse Event (AE):** Any untoward medical occurrence in a subject to whom a medicinal product has been administered, including occurrences which are not necessarily caused by or related to the product
- **Corrective Action Preventive Action (CAPA):** Is a process which investigates and solves problems, identifies causes, takes corrective action and prevents recurrence of the root causes.
- **Case Record Form (CRF):** A printed, optical or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.
- **Clinical Trial (CT):** Any investigation in human subjects, other than a non interventional trial intended to discover or verify the clinical, pharmacological or other pharmaco-dynamic effects of one or more medicinal products or to identify any adverse reactions to one or more such products and to study absorption, distribution mechanism and excretion in more of such products with the object of ascertaining the safety or efficacy of those products.
- **Clinical monitoring** is to observe each trial site to ensure that the standardized operation procedures for the trial are being followed, reporting and managing any deviations from the investigation plan as they occur.
- **Informed Consent Form (ICF):**The document which is signed by the participant / legal representative as well the person who conducted the informed consent discussion (most often the PI) confirming the willingness of the participant to take part in the trial, after having been informed of all aspects of the trial that are relevant to their decision.
- **Investigator Site File (ISF):** A standard filling system which allows the effective storage and location of essential documents related to an individual trial site.
- **Participant Information Sheet (PIS):** Explains all relevant trial information, in a very simple layman's language without medical jargon, to assist the participant in understanding the expectations and requirements of participating in a CT.

- **Root cause analysis (RCA):** Is a systematic process for identifying "**root causes**" of problems or events and an approach for responding to them.
- **Serious Adverse Event or Reaction (SAE/SAR):** Is defined as an adverse experience that results in any one of the following outcomes:
  i. Death
  ii. A life threatening adverse experience (According to the PI, any adverse experience that places the participant at immediate risk of death from the reaction as it occurred)
  iii. Inpatient hospitalization or prolongation of existing hospitalization
  iv. A persistent or significant disability/incapacity (disruption to conduct normal life functions)
  v. A congenital anomaly / birth defect
- **Source documentation:** Original documents, data and records (E.g. hospital records; clinical and office charts; laboratory notes; memoranda; subjects' diaries or evaluation checklists; pharmacy dispensing records; recorded data from automated instruments; copies or transcriptions certified after verification as being accurate copies; photographic negatives, microfilm or magnetic media; X rays; subject files at the Medical Records Department(MRD)

8 Annexures

1. AX 01/SOP 15- Detailed interim / status report for sponsored clinical trials
2.AX 02/SOP 15- Report on protocol deviation / violations in CT.
3.AX 03/SOP 15- Submission of other study related documents in CT
4.AX 04/SOP15- Report of onsite Serious Adverse Events (SAE)

AX 01/SOP15

Detailed interim / status report for sponsored clinical trials

1. Details of Principal Investigator

IEC Study Ref. No	
Name:	
Designation & Department: Contact details (if there is any change):	
Mobile No & email ID	

2. Registration

Is the CT registered on a publicly accessible database?	Yes / No
If yes, please provide the name of the database and the registration number Database: Registration number:	
If NO: What is the reason for non-registration? What are your future intentions for registration?	

3. Details of study

Full title of study:	
Date of favorable ethical opinion:	
IEC approval validity expiring on:	
Details of the extensions taken	
Sponsor:	

4. Commencement and termination dates

Has the study started in the India	Yes / No
If yes, what was the actual start date in the India?	
If no, what are the reasons for the study not commencing in the India? What is the expected starting date?	
Is the study over?	Yes / No
If no, what is the expected completion date? *If you expect the study to overrun the planned completion date this should be notified to the main IEC for information.*	
If you do not expect the study to be completed, give reason(s)	

5. Recruitment of participants

* Number of participants recruited:	*Proposed in original application:* *Actual number recruited to date:*
* Number of participants completing trial:	*Actual number completed to date:*
* Number of withdrawals from trial to date due to: (a) withdrawal of consent	

(b) loss to follow-up (c) death (where not the primary outcome) Total study withdrawals:
*Number of treatment failures to date (prior to reaching primary outcome) due to: (a) adverse events (b) lack of efficacy Total treatment failures:

Have there been any serious difficulties in recruiting participants?	Yes / No
If yes, give details:	
Do you plan to increase the planned recruitment of participants into the study? *Any increase in planned recruitment should be notified to the EC as a substantial amendment for ethical review.*	Yes / No

6. Safety of participants

Have there been any serious adverse events (SAEs) in this study?	Yes / No
Have these SAEs been notified to the IEC? *If no, please submit details with this report and give reasons for late notification.*	Yes / No /Not applicable
Have any concerns arisen about the safety of participants in this study? *If yes, give details and say how the concerns have been addressed.*	*Yes / No*

7. Safety reports

Have there been any Suspected Unexpected Serious Adverse Reactions (SUSARs) in this trial in the India?	*Yes / No*
Have these SUSARs been notified to the Ethics Committee within 7 days as per Schedule-Y? *If no, please arrange urgently and give reasons for late notification.*	Yes / No
What is the reporting date for periodic safety reports to the EC during this trial?	

Has a 6 monthly safety report been submitted?	Yes / No / Not applicable
Has the Annual Safety Report been submitted?	Yes / No / Not yet due
When is the next ASR due?	

8. Amendments

Have any substantial amendments been made to the trial during the year?	Yes / No
If yes, please give the date and amendment number for each substantial amendment made.	

9. Serious breaches of the protocol or Good Clinical Practice

Have any serious breaches of the protocol or GCP occurred in relation to this trial during the year?	Yes / No
If yes, please give the date of each notification to the EC. *Please provide the EC with a copy of each notification for information (unless previously notified).*	

10. Other issues

Are there any other developments in the trial that you wish to report to the Committee? Are there any ethical issues on which further advice is required? *If yes to either, please attach separate statement with details.*	*Yes / No* *Yes / No*

11. Declaration

Signature of PI:	
Date of submission:	

AX 02-S0P 15

Report on protocol deviation / violations in CT

IEC Ref No	
Study / protocol No (For drug / device trials / any other)	

Study title	
Principal Investigator	
Designation & Department	
Mobile No & email ID	
Date of initial approval by IEC	
Date of study initiation	
Dates of extension of approvals taken previously	
Current IEC approval validity expiring on	
Details of Deviation / Violation Date of occurrence *dd/mm/yyyy (Add extra sheet if needed)*	
Participant ID No.	
Root Cause analysis	
Corrective and Preventive action taken by the researcher	
Impact on the trial subject (if any)	
No of similar D/ V occurred in the same trial	
Whether D/V informed to sponsor / CRO	
Signature of PI :	Date : .....

AX 03/ SOP 15

Submission of other study related documents in CT

(DCGI Approval / DCGI Correspondence / CTA / Insurance Policy / Investigator's Undertaking / CRF / PIS / any other)

IEC Ref No	
Study / protocol No (For drug / device trials / any other)	
Study title	
Principal Investigator	
Designation & Department	

Mobile No & email ID	
Date of initial approval by IEC	
Date of study initiation	
Extension of approvals taken previously	
Current IEC approval validity expiring on	

List of Documents (Approval / Notification)

No.	List of new documents submitted	Current Version No	Version date

Any other changes:

Signature of PI : ..... Date : .....

AX04/SOP 14

Report of onsite Serious Adverse Events (SAE)

1. IEC **Study** No.	
2. Study / Protocol No. (For drug/ device trials/ any other)	
3. Title of project	
4. **Principal Investigator**	
Name	
Designation and Department	
Mobile No & email ID	
5. **Suspected Adverse Reaction** (diagnosis)	
6. Report date:	
7. Date of onset of SAE:	
8. Report type Initial / Follow up / Final	
If Follow-up report, state date of Initial report & SAE No	
9. Participant Information	
a. Subject ID.	

b. Age	
c. Gender	

10. Information related to no. of recruitment/prior SAE and death :

	Total number of Recruitment at	Total number of (prior) SAE occurred at	Number of similar SAEs (prior) occurred for same study at	Total number of death 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 [ ]

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

(If other, please specify: .....

C] 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 [ ]

Concomitant drugs history and lab investigations	
15. Concomitant drug (s) and date of administration	
16. Relevant test/ laboratory data with dates:	
17. Patient relevant history (e.g. diagnosis, allergies)	

Reaction information

18. 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. In addition to 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]:	
19. Describe the medical treatment provided for adverse reaction (if any) to research subject. This is an update on treatment given during hospitalization:	
20. Outcome: Resolved [ ] Ongoing [ ] Death [ ]	
21. Was the research continued on the research participant? Yes [ ] No [ ] NA (Mark 'NA' in case of death) [ ]	
22. Has this information been communicated to sponsor/ CRO/ regulatory agencies? Yes [ ] No [ ] Provide details if communicated (including date) :	
23. In your opinion, does this reaction require any alteration in trial protocol? Yes [ ] No [ ] **If yes then please specify:**	
24. Causality Assessment:	
Signature : ..... Date :	
IEC RESPONSE: *Upon receipt of this report, the IEC will decide whether additional information is needed or whether further investigation of the reaction is required.*	

INSTITUTE ETHICS COMMITTEE, PIMS

Internal audit

Prepared by	**Verified by**	**Approved and Issued by**
Dr. Rema Devi	Dr. Reba Kanungo	Dr. Manikandan S

1. Purpose

The purpose of this SOP is to provide guidelines for conduct of an internal audit in compliance with ICH Good Clinical Practice, ensuring ethical principles are followed and quality Assurance mechanisms are in place when IEC approved studies are conducted.

2. Scope

This SOP applies to the audit of IEC approved studies, both funded and non-funded, conducted by the staff of PIMS, so as to ensure that ethical principles are followed and research participants are protected.

3. Responsibility

It is the responsibility of

- Designated IEC members to ensure that good practices are followed in the IEC approved studies
- PI is ultimately responsible accountable for all clinical research activities and is responsible for the appropriate delegation of tasks to individuals with adequate training and education to perform such tasks

4. Detailed process

4.1 Pre-audit

Internal audit can be a planned one, as part of monitoring process or can be a for-cause audit. In a fully convened IEC meeting, a study approved within the last one year is randomly selected for being audited. Minimum of two auditors are also identified for auditing each study. If it is a CT, at least one clinician is chosen as the auditor. The IEC office informs the PI about 2 weeks prior to the scheduled audit date and lists the documents that need to be made available. In case the date is not convenient for the PI, a mutually acceptable date would be considered.

4.2 Auditing process

At the site, the auditors have an opening meeting with the PI and the study coordinators and proceed to check the documents, as per the checklist. With the permission of the study subject, an interview with the study subject is also attempted. Attempts are also made to witness an informed consent procedure. The findings are discussed with the study team.

4.3 Post auditing

Following the audit, the auditors submit the report to the IEC office sin a week's time and in two days time if there is violation of a major protocol. A report is sent to the PI within 2 weeks time and asking for compliance of the noted non-conformities. The PI is expected to respond to the observed comments within a month's time. The same is discussed in the forthcoming IEC meeting where the final outcome measures are discussed.

4.4 Outcome

The audit procedure is discussed in a fully convened IEC meeting. If the response is found satisfactory, the audit procedure is closed. If the response is not found to be satisfactory, a re-audit is done within the next3 months. Still, if the response is not found to be satisfactory, the following measures can be undertaken: a. The institutional authorities are informed
b. The study may be suspended
c. The study may be handed over to one of the co-investigators, barring the PI
d. If the study is a CT, the regulatory authorities and the sponsor are informed of the decisions made.

5. Work Flow chart

	Activity	**Responsibility**
1	Random selection of an IEC approved study and the auditors	IEC Chairperson
2	Notify the PI or study team of the planned audit	IEC office Secretary
3	Conduct of the audit	IEC members (auditors)
4	Follow up with the comments and the observations	IEC auditors
5	Review of the IEC approval in a full board meeting	IEC members
6	Communicate the IEC decision to the PI	IEC Member Secretary

6. References

1. National Ethical Guidelines for Biomedical and Health Research involving human participants -ICMR guidelines 2017
2. https://ccts.osu.edu/sites/default/files/inlinefiles/SOP%2018%20Clinical%20Research%20Audits.pdf (assessed on Dec 2020)

7. Glossary

Auditing is defined as the on-site verification activity, such as inspection or examination, of a process or quality system, to ensure compliance to requirements

8. Annexure

AX 01/SOP 16: Study Monitoring visit: checklist and report

AX 01/SOP 16

Study Monitoring visit: checklist and report

DATE OF VISIT:

1	a. IEC reference No: b. Study title: c. IEC approval date:	
2	Department (s):	
3	Study team members to be listed: (PI/Co-I, Co-ord):	
4	Sponsor:	
5	CRO:	
6	Status of study: Enrolling / Follow up / Data analysis:	
7	SUBJECT DETAILS: • Total enrolled: • No. ongoing: • No. completed: • No. of dropouts:	**SUBJECT INTERVIEW:** Awareness of study: Y/N Awareness of Rights: Y/N Awareness of responsibilities: Y/N Satisfaction: Y/N
8	APPROPRIATE SITE FACILITIES: as is specified by the sponsor	Availability : Y/N
9	INFORMED CONSENT: • ICF – Use of IEC approved version (check MS sign/date) • Assent forms • Appropriate vernacular consent taken	**WITNESS OF AN ICF PROCESS:** Oral / written / with AV aids Assent taken

	• Approval taken from all subjects • Reconsent taken where applicable • Witness signature • AV aids used for ICF documentation • Waiver of consent	Cleared Subject's doubts Witness signature taken
10	DOCUMENTS: • IEC approval letter • Use of recent version of protocol with IEC approval • Report of protocol deviations • Report of serious adverse events (in a week's time) • Report of deaths (in 24hrs) • Up-to-date Case Record Forms • Safe storage • Easy retrieval • Site SOP	
11	CONDUCT OF AUDIT: • Any SAEs detected during visit? • Any Non compliance noticed during visit? • Any complaints obtained regarding the study?	
12	INVESTIGATING IND PRODUCT • Is IND well preserved? • Is it kept under safe custody? • Are there any expired products? • Is there accountability of the IND?	
13	Is Participant protection adequate?	Yes / No
14	IEC VISIT / AUDIT DETAILS • Starting time: • Finishing time: • Total duration:	
15	SIGNATURE: • IEC member • Site representative	
<u>Observation / Suggestion of IEC Audit</u>		