PONDICHERRY INSTITUTE OF MEDICAL SCIENCES	**INSTITUTE RESEARCH COMMITTEE** **PONDICHERRY INSTITUTE OF MEDICAL SCIENCES**

STANDARD OPERATING PROCEDURE

For

INSTITUTE RESEARCH COMMITTEE

Pondicherry Institute of Medical Sciences

Ganapathichettikulam,

Kalapet, Puducherry 605014

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HOLDER'S NAME & DESIGNATION	**Dr. Reba Kanungo** **Dean Research** **PIMS**

Prepared by	Reviewed and approved by	Issued by
Dr. Reba Kanungo	Dr. Renu G' Boy Varghese	Dr. Reba Kanungo

1. Objective:

The objective of this standard operative procedure is to contribute to the effective functioning of the Research Committee of Pondicherry Institute of Medical Sciences so that a quality and consistent review mechanism for health and biomedical research is put in place for all proposals dealt by the Committee. The purpose of this document is to outline the process for authorizing, reviewing, archiving, and amending SOP of PIMS

2. Role of Research Committee

The committee will review and approve all types of proposals for biomedical research and related fields involving human subjects and animals with a view to conduct responsible research safeguard the dignity, rights, safety and well being of all actual and potential research participants. The goals of research, however important, should never be permitted to override the health and well being of the research subjects.

The RC will take care 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

3. Composition of RC

RC should be multidisciplinary and multisectorial in composition. Independence and competence are the two hallmarks of an RC. The number of persons in a research committee should be kept fairly small (7-9 members). It is generally accepted that a minimum of five persons is required to compose a quorum. There is no specific recommendation for a widely acceptable maximum number of persons but it should be kept in mind that too large a Committee will make it difficult in reaching consensus opinions. 12-15 is the maximum recommended number.

The Chairperson of the Research Committee and the Member Secretary who generally belongs to the same Institution should conduct the business of the committee should be nominated by the Head of the

Institute. Other members should be a mix of medical / non-medical faculty from within and outside the Institute.

The composition may be as follows:-

1. Chairperson
2. 2-3 basic medical scientists.
3. 3-4 clinicians from the institute
4. Biostatistician
5. Epidemiologist

The research committee can have as its members, individuals from other institutions or communities if required. If required, other subject experts could be invited to offer their views, for example for drug trials a pharmacologist, preferably a clinical pharmacologist, should be included. Similarly, based on the requirement of research area, for example HIV, genetic disorders etc. specific patient groups may also be represented in the Committee. They should be appointed by the Head of the Institute based on their competencies and integrity.

4. Authority under which RC is constituted:

The Institutional Head constitutes the RC.

5. Purpose

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

6. Mandate

The mandate of the PIMS RC is to review and approve all types of research proposals including basic and applied research, clinical trials involving human participants and animals to be conducted at the Institute. The goals of research, however important, will never be permitted to override the health and well-being of the research subjects. Autonomy, Beneficence, Non- maleficence and Justice are taken

care of in planning, conduct and reporting of the proposed research. It reviews the proposals before start of the study through appropriate well-documented procedures; for example, annual reports, final report etc.

7. Scope

This SOP pertains to the formation of the RC.

8. Responsibility

The RC is responsible for achieving the following objectives:

- To ensure that all aspects of research are compliant of methods based on sound scientific and ethical bases.
- To educate and train RC members and other staff on scientific research.
- To monitor periodically the research undertaken by members of faculty, PGs & UGs
- To scrutinize and review all research and publication related matters in PIMS
- To review and recommend proposals submitted for intramural funding through designated committees
- To review project submitted for extramural funding and ensuring equitable involvement of investigators in such projects
- To review the budget allocation of the studies submitted by postgraduate, undergraduate and faculty and to suggest means for financial feasibility.

9. Membership requirements:

a. The duration of appointment is initially for a period of 2-3 years

b. At the end of 2-3 years, as the case may be, the committee is reconstituted, and 50% of the members will be replaced by a defined procedure.

c. A member can be replaced in the event of death or long-term nonavailability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.

d. A member can tender resignation from the committee with proper reasons to do so.

e. All members should maintain absolute confidentiality of all discussions during the meeting

f. Conflict of interest should be declared by members of the RC

10. Quorum requirements:

The minimum 50% of members are required to compose a quorum. All decisions should be taken in meetings and not by circulation of project proposals.

11. Offices

The Chairperson will conduct all meetings of the RC. If for reasons beyond control, the Chairperson is not available, the Deputy Chairperson or an alternate Chairperson will be elected from the members by the Chairperson with prior approval from Director-Principal, who will conduct the meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairman before communicating to the researchers with the approval of the appropriate authority.

12. Independent consultants

RC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases 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 do not take part in the decision making process which will be made by the members of the IEC.

13. Application Procedures:

a. All proposals should be submitted in the prescribed application form

b. All relevant documents should be enclosed with application form

c. Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators should be forwarded by the Head of the Departments / Institution to the research committee.

d. The date of meeting will be intimated to the researcher, to be present, if necessary to offer clarifications.

e. The decision will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

14. Documentation:

For a thorough and complete review, all research proposals should be submitted with the following documents:

1. Name of the applicant with designation
2. Name of the Institute/ Hospital / Field area where research will be conducted.
3. Approval of the Head of the Department / Institution
4. Protocol of the proposed research
5. Ethical issues in the study and plans to address these issues.
6. Proposal should be submitted with all relevant enclosures like proforma, case report forms, questionnaires, follow - up cards, etc.
7. Informed consent process, including patient information sheet and informed consent form in local language(s).
8. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centres within the country if available.
9. Any regulatory clearances required.
10 Source of funding and financial requirements for the project.
11. Other financial issues including those related to insurance
12. An agreement to report only Serious Adverse Events (SAE) to RC/ IEC.

13. Statement of conflicts of interest, if any.

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

15. 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 a 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 that account. The reasons for negative decisions should be provided.

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

17. Any other information relevant to the study

15. Review procedures:

a. The meeting of the RC should be held on scheduled intervals as prescribed and additional meetings may be held as and when the proposals are received for review.

b. The proposals will be sent to members at least 2 weeks in advance.

c. Decisions will be taken by consensus after discussions, and whenever needed voting will be done.

d. Researchers will be invited to offer clarifications if need be.

e. Independent consultants/Experts will be invited to offer their opinion on specific research proposals if needed.

f. The decisions will be minuted and Chairperson's approval taken in writing.

16. Element of review

The study design shall be reviewed with a view of evaluating the need for human participants and animals for study, objectives of the study, and adequacy in literature review, appropriateness of the methodology proposed, assumptions on sample size estimation, inclusion/exclusion criteria, control

arms (placebo, if any) and withdrawal or discontinuation criteria. Information on where to report a participant with unexpected disease(s) and state clearly how the PI should handle that case

1. Scientific design and conduct of the study.
2. Examination of predictable risks/harms.
3. Examination of potential benefits.
4. Procedure for selection of subjects in methodology including inclusion/ exclusion, withdrawal criteria and other issues like advertisement details.
5. Management of research related injuries, adverse events.
6. Compensation provisions.
7. Justification for placebo in control arm, if any.
8. Availability of products after the study, if applicable.
9. Patient information sheet and informed consent form in local language.
10. Protection of privacy and confidentiality.
11. Involvement of the community, wherever necessary.
12. Plans for data analysis and reporting
13. Adherence to all regulatory requirements and applicable guidelines
14. Competence of investigators, research and supporting staff
15. Facilities and infrastructure of study sites
16. Criteria for withdrawal of patients, suspending or terminating the study

ASSESSMENT OF STUDY PROTOCOLS:

1. Check List for Assessment

Reviews and assessment of the protocol submitted for approval of the study. The Check list for assessment is designed to structure the protocol review process and to facilitate reporting recommendation and comments. The specific questions in the Check list must be adequately addressed in the protocol itself and/or protocol-related documents under review. Relevant points made during

discussion and deliberation about a specific protocol shall be recorded on the form. The decision reached by the committee and the reasons for its decision shall be recorded on the check list. It is the responsibility of the member secretary to record and file the decision, relevant points and deliberation about a specific protocol, including the reasons for that decision on the check list such as title of the protocol, protocol number and date, principal investigators and co-investigators, funding agency and project status whether new/revised/rejected version.

2. Qualification of investigators and study sites

Qualification of investigators shall be examined to see whether study and training background of the participating investigators relate to the study. The study sites shall also be examined for suitability of the study in terms of geographical distribution of the problem of under study and facility and infrastructure accessibility and availability at study sites to accommodate the study. Disclosure of potential conflicts of interest shall also be examined.

3. Review Study Participation

Under this item the assessment shall be done with a view of evaluating voluntary, non-coercive recruitment of participation. The following aspects shall be assessed to see if they have been adequately considered in the protocol:

1. Procedures for obtaining informed consent
2. Contents of the patient information sheet
3. Risks -physical/mental/social
4. Benefits -to participants and to others
5. Compensation -reasonable/ unreasonable
6. Involvement of vulnerable participants
7. Provisions for medical/psychosocial support
8. Treatment for study related injuries
9. Use of biological materials
10. The issue of insurance of health research participants, indemnity

17. Decision-making

1. Members will discuss the various issues before arriving at a consensus decision.
2. A member should withdraw from the meeting during the decision 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.
3. Decisions will be made only in meetings where quorum is complete.
4. Only members can make the decision. The expert consultants will only offer their opinions.
5. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
6. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.
7. Modified proposals may be reviewed by an expedited review through identified members.
8. Procedures for appeal by the researchers should be clearly defined.

18. Communicating the decision

1. Decision will be communicated by the Member Secretary in writing.
2. Suggestions for modifications, if any, should be sent by RC
3. Reasons for rejection should be informed to the researchers.
4. The schedule / plan of ongoing review by the IEC should be communicated to the PI.

19. Follow up procedures

The review and follow-up reports of adverse experience and unexpected events for any active study approved by the committee Unanticipated risks are sometimes discovered during the course of a study. Information that may impact on the risk/benefit ratio must be promptly reported to, and reviewed by, the Committee to ensure adequate protection of the welfare of the study participants.

1. All SAEs and the interventions undertaken should be intimated.
2. Protocol deviation, if any, should be informed with adequate justifications.
3. Any amendment to the protocol should be resubmitted for renewed approval.

4. Any new information related to the study should be communicated.
5. Premature termination of study should be notified with reasons along with summary of the data obtained so far.
6. Change of investigators / sites should be informed.

20. Record keeping and Archiving

1. Curriculum Vitae (CV) of all members of RC
2. Copy of all study protocols with enclosed documents, progress reports, and SAEs.
3. Minutes of all meetings duly signed by the Chairperson.
4. Copy of relevant national guidelines on research, ethics and laws along with amendments.
5. Copy of all correspondence with members, researchers and other regulatory bodies.
6. Final report of the approved projects.
7. All documents should be archived for prescribed period of 5 years

21. Updating RC members:

1. All relevant new guidelines should be brought to the attention of the members.
2. Members should be encouraged to attend national and international training programs in research methodology and research ethics for maintaining quality in scientific and ethical review and be aware of the latest developments in this area.

22. Protocol Format for submission

- Protocol in the PIMS format for all faculty proposals and PIMS fellowship
- ICMR format for all ICMR STS projects
- Any other format or protocols for clinical trial or multi centric studies to be modified as per PIMS faculty proposals
- CONSORT statement to be included in all protocols those who are doing clinical trial

1. Submission of CRF/ Proforma as per the protocol
2. Budget details (unit cost, justification and source)

3. Questionnaire (English & Tamil version), to mention validated or not and source of questionnaire
4. PIS in Layman's language with details of procedure
    - Participants role
    - Reimbursement or compensation
    - Clause for withdrawal
    - Confidentiality
    - Data protection
    - Permission for publication
    - Contact number of PI and ethics (IEC)
5. Consent form
    - Signature of participants
    - Signature of witness / LAR (legally authorized representative)
    - Assent form (children between 7 to 17)
    - Consent of parents in case of minor children
6. Permission letters from regulatory / administrative bodies were necessary

23. Details of circular for submission of proposals from research office

1. To submit completed protocol with check list (2 hard copies with all signatures) and 1 soft copy of the protocol with all the details as mentioned above. Secretary to check for all the above details after that the proposal will be accepted (before the last date).
2. To circulate the soft copy to all members of RC atleast 10 days before the meeting.
3. Making the list for RC should include the current title on the protocol and Name of PI, Co-PI, department and RC. No.
4. After research committee meeting, minutes to be written in detail including suggestions/ correction on the following
    - Title
    - Study design
    - Sample size
    - Feasibility
    - Ethical contents
    - Budget etc.
5. Minutes to be circulated to all RC members within specified time (draft copy) for their inputs.
6. The signed final copy of the minutes to be circulated to RC members.

- Comments to be forwarded to the investigators
- Two hard copies and soft copy along with the checklist of corrections done must be submitted before the last date.

7. Following submission of the corrected version a detailed scrutiny has to be done by the office of the Dean Research for compliance
   - If corrections are not satisfactory the protocol will be sent back for compliance
8. The final protocol (1 hard copy) and the soft copy to be forwarded to the ethics committee

List of Research Committee Members

SI.No.	NAME	DESIGNATION
1.	Dr. Renu G'Boy Varghese	Director-Principal
2.	Dr. Kurien Thomas	HOD and Professor, General Medicine
3.	Dr. Anita Ramdas	HOD and Professor, Pathology
4.	Dr. Udit B Das	Addl.MS
5.	Dr. Subhasis Das	Dean MEU
6.	Dr. Sheela Devi C	Dean PG
7.	Dr. Mary Daniel	HOD and Professor, OBG
8.	Dr.Sheela Kuruvila	HOD and Professor, Dermatology
9.	Dr.Renuka Srinivasan	Professor, Ophthalmology
10.	Dr. Ranjan	Professor, Anesthesiology
11.	Dr.Sunil Kumar Nanda	HOD and Professor, Biochemistry
12.	Dr.Susan Solomon	Professor, Psychiatry
13.	Dr. Ravichandran	Lecturer, Biostatistics
14.	Dr.Reba Kanungo	Dean Research- Chairperson

Dr.Reba Kanungo
Dean Research
PIMS

Dr.Renu G' Boy Varghese
Director-Principal
PIMS