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

(A Unit of The Madras Medical Mission)

Ganapathichettikulam,

Kalapet, Puducherry 605014

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HOLDER'S NAME & DESIGNATION	**Dr. P. Stalin** **Vice-Principal (PG & Research)** **PIMS**

Prepared by	Reviewed and approved by	Issued by
Dr. P. Stalin	Dr. Anil J Purty	Dr. P. Stalin

1. Scope of the SOP:

This SOP pertains to the formation and functioning of the Research Committee of Pondicherry Institute of Medical Sciences.

2. 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 biomedical research is put in place for all proposals on human & animal studies. The purpose of this document is to outline the process for reviewing, approving, archiving, and amending the research proposals.

3. Composition of Research Committee

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 (10-12 members). It is generally accepted that a minimum of 50% of members is required to compose a quorum.

The Chairperson and the Member Secretary of the Research Committee should conduct the business of the committee. They should be nominated by the Head of the Institute. Other members should be a mix of basic sciences, medical, surgical and faculty from statistics department within the Institute.

The composition may preferably as follows:-

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

The research committee may have as its members, individuals from other institutions or communities if required. Subject experts may be invited to offer their views, for example for drug trials a pharmacologist, preferably a clinical pharmacologist. 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 for reviewing the concerned protocol only. However they will not have any voting rights, but provide only scientific input.

4. Authority under which Research Committee is constituted:

The Research Committee is constituted under the authority of Institutional Head.

5. Purpose for which the Committee is constituted:

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

6. Mandate

- The mandate of the RC is to review and approve all types of research proposals including basic research, applied research, animal studies and clinical trials involving human participants.
- The goals of research, however important, will not be permitted to override the health and well-being of the research subjects.
- The Committee shall ensure that 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; and follows up through interim report and final report etc.

7. Roles & Responsibility of Research Committee (RC):

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, faculty and students on scientific research.
- The committee will review and approve all types of proposals for biomedical research and related fields involving human subjects with a view to conduct responsible research, safeguard the dignity, rights, safety and well being of all actual and potential research participants.
- All protocols must be revised following review by the committee and ensure that changes & modifications suggested have been incorporated. This is to be verified by the member secretary.
- To review the budget allocation of the studies submitted by postgraduate, undergraduate and faculty and to suggest means for financial feasibility.
- To review and recommend approved human studies for submission to the Institute Ethics Committee.
- To review and recommend approved animal studies for submission to the Institute Animal Ethics Committee.
- The committee must ensure that all clinical trials are registered with CTRI (clinical trial registry of ICMR) and other regulatory bodies.
- All trials involving drugs and biological material must be verified for clearance from DCGI.
- The committee must ensure that all academic clinical trials adhere to stipulated regulatory mechanism.
- To review and recommend proposals submitted for intramural funding through designated committees.
- To review proposals submitted for extramural funding and ensuring equitable involvement of investigators in such projects.
- To monitor periodically the research undertaken by members of faculty and students.

- Issues related to implementation of research projects must be addressed by the research committee and decision taken unanimously.
- Issues related to publications arising out of research must also be reviewed by a subcommittee (which will be formed by the Director-Principal) and action taken thereof.

8. Membership requirements:

- The duration of appointment is initially for a period of 2-3 years.
- 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.
- A member can be replaced in the event of death or long-term non availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.
- A member can tender resignation from the committee with proper reasons to do so.
- All members should maintain absolute confidentiality of all discussions during the meeting.
- Conflict of interest should be declared by members of the RC.

9. 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.

10. Offices

The Vice-Principal (Research) will be nominated as the chairperson and the Deputy Vice-Principal (Research) shall be the member secretary appointed by the Director-Principal. The Chairperson will conduct all meetings of the RC. If for reasons beyond control, the Chairperson is not available, an alternate Chairperson will be elected from the members by the Chairperson who will conduct the meeting, with prior approval from Director-Principal. 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 Chairperson before communicating to the researchers with the approval of the appropriate authority. If the Member Secretary is not available, an alternate Member Secretary will be elected from the members by the Chairperson with prior approval from Director-Principal.

11. Independent consultants

RC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if required. 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 RC.

12. Application Procedures:

- All proposals should be submitted in the prescribed format.
- All relevant documents should be enclosed with the proposal.
- Required number of hard copies of the proposal and a soft copy (to be mailed to the office of the Vice-Principal (Research) at pimsresearch@gmail.com) along with the necessary documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators should be forwarded by the Heads of the main and collaborating Departments / Institution to the research committee.
- The date of meeting will be intimated to the researcher.
- The researcher has to present the protocol to the research committee along with other co-investigators.

- 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, before the next meeting.

13. 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) must be submitted with all protocols involving research studies on human subjects.

8. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data (of the previous phase study) from other centers or regulatory bodies, within the country if available must be submitted.

9. Any regulatory clearances required must be mentioned, and supporting document should be provided.

10 Source of funding and financial requirements for the project must be clearly stated.

11. Other financial issues including those related to insurance must accompany the protocol.

12. An agreement to report Serious Adverse Events (SAE) to RC / IEC is mandatory.

13. Statement of conflicts of interest, if any must be clearly stated.

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

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

14. Review procedures:

- 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.
- The proposals will be sent to members for review at least one week in advance.
- Decisions will be taken by consensus after discussions, and whenever needed voting will be done.

- Researchers will be invited to present the proposal and address the queries raised by the research committee members.
- Independent consultants / Experts will be invited to offer their opinion on specific research proposals if needed.
- The decisions will be minuted by the member secretary and approved by the Chairperson.

15. 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 and ethical considerations. The following points have to be checked during the review process:

1. Scientific design and conduct of the study.
2. Procedure for selection of subjects in methodology including inclusion / exclusion and other issues like advertisement details.
3. Criteria for withdrawal of patients.
4. Sample size calculation and sampling technique.
5. Study tools – questionnaire / case report form / data extraction sheet
6. Procedures for data collection and measurements
7. Plans for data analysis and reporting.
8. Patient information sheet and informed consent form in local language.
9. Protection of privacy and confidentiality.
10. Involvement of vulnerable participants.
11. Use of biological materials
12. Examination of potential benefits.
13. Justification for placebo in control arm, if any.
14. Availability of products after the study, if applicable.

15. Examination of predictable risks / harms.
16. Management of research related injuries, adverse events.
17. Management of unexpected diseases if any
18. Compensation provisions.
19. Competence of investigators, research and supporting staff.
20. Disclosure of potential conflicts of interest.
21. Adherence to all regulatory requirements and applicable guidelines.
22. Facilities and infrastructure of study sites.
23. Involvement of the community, wherever necessary.
24. Source of funding and budget details.
25. Criteria for suspending or terminating the study.

16. Decision-making

1. Members will discuss the various issues before arriving at a decision.
2. A member should withdraw from the meeting during the decision making process 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. Revised proposal will be re-reviewed by an expedited review through identified members and decision will be taken.
7. If researchers are not satisfied with the decision taken by the committee, they may appeal to the research committee with proper justification / explanation which will be discussed by the research committee and appropriate decision will be taken.

17. Communicating the decision

1. Decision will be communicated by the Chairperson in writing.
2. Specific suggestions for modifications should be given.
3. Reasons for rejection should be informed to the researchers.
4. Instructions for submitting the approved proposal to Institute Ethics Committee should be shared to the PI.

18. Follow up procedures

1. Protocol deviation, if any, should be informed with adequate justifications.
2. Any amendment to the protocol should be resubmitted for renewed approval.
3. Any new information related to the study should be communicated.
4. Change of investigators / sites should be informed.
5. All SAEs and the interventions undertaken should be intimated.
6. Premature termination of study should be notified with reasons along with summary of the data obtained so far.
7. Researcher should update the progress of their projects by submitting interim and final report.
8. Publications arising out of the research projects should be submitted.

19. 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 and the Member Secretary.
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

20. 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 to be aware of the latest developments in this area.

21. Protocol Format for submission

- PIMS format for faculty proposals (attached as annexure) and postgraduate dissertation.
- ICMR format for all ICMR STS and PIMS STS fellowship proposals.
- Any other format recommended by the funding agencies for extramural research proposal. There is no need for submitting extramural research proposals in PIMS format.
- For animal studies, the format recommended by Institute Animal Ethics Committee to be followed.

22. Details of procedures to be followed from submission to approval of research proposal.

1. To submit completed protocol with check list (1 hard copy with all signatures and 1 soft copy). Secretary will receive the proposal, if it is in correct format with all relevant documents (before the last date).
2. To circulate the soft copy to all members of RC atleast 7 days before the meeting.
3. Making the list of proposals for RC meeting 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
    - Methodology
    - 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.
7. Decision with comments and suggestions to be communicated to the investigators in writing
8. Two hard copies and soft copy along with the checklist of corrections done must be submitted by the investigator before the prescribed last date.
9. Following submission of the corrected version a detailed scrutiny has to be done by the office of the Vice-Principal (Research) for compliance
    - If corrections are not satisfactory the protocol will be sent back for compliance
10. The final approved 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. Anil J Purty	Director-Principal
2.	Dr. Peter Manoharan	Medical Superintendent
3.	Dr. R. P. Swaminathan	Professor and Head, General Medicine
4.	Dr. Shashikala Nair	Professor and Head, Microbiology
5.	Dr. Sivakumar S	Professor and Head, Anaesthesiology
6.	Dr. Padma A	Professor of OBG
7.	Dr. Moses Ambroise	Professor of Pathology
8.	Dr. Sithananda Kumar	Professor of ENT
9.	Dr. Sathya G R	Associate Professor of Physiology
10.	Dr. Manikandan M	Biostatistician
11.	Dr. Aparna Muraleedharan	Dy. Vice-Principal (PG & Research) - Member Secretary
12.	Dr. P. Stalin	Vice-Principal (PG & Research) - Chairperson

Dr. P. Stalin
Vice-Principal (PG & Research)
PIMS

Dr. Anil J Purty
Director-Principal
PIMS

Annexure:

Pondicherry Institute of Medical Sciences
(A Unit of The Madras Medical Mission)

Protocol for faculty research project

Research title:

Research/Project Number:

Role (PI/ CoI)	Name	Designation & Department	Telephone	Email	Contribution*

[*conception of idea, research design, data collection/field work, data management, analysis, report writing, interpretation of results, critical reviewing with intellectual input]

Proposed date of start: **Total Budget:**

I have read the full document including appendices. I agree to submit the final report of this project to the Research and Institute Ethics committee.

Signature of Principal Investigator ..... Date:

Signature of Co-Investigator ..... Date:

Signature of Co-Investigator ..... Date:

Signature of Co-Investigator ..... Date:

Signature of Co-Investigator ..... Date:

Signature of HOD (Main department) ..... Date:

Signature of HOD (Collaborating departments) ..... Date:

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

S. No	Items	Yes/No
1	Exact title	
2	Name & Signatures of PI and Co-I/s	
3	Name, Designation and Signature of HOD/HODs or other sanctioning authority	
4	Primary and Secondary Objectives specified	
5	Sample Size and Sample Size justification	
6	Permission from DCGI (if applicable)	
7	Will register with CTRI after IEC approval for clinical trials (if applicable)	
8	Adequate justification for exemption from obtaining informed consent given (if applicable).	
9	Consent form part 1 and 2 in both English and Tamil attached	
10	Consent form part 1 (information to the participant/ parent/guardian) in layman (simple) language.	
11	Separate consent form for subjects < 18 yrs attached (if applicable)	
12	Separate consent form for cases and controls attached (if applicable)	
13	Ethical issues explained in detail in PIS and level of risk indicated	
15	Validated questionnaire both in Tamil and English attached	

	(if study involves interview/ questioning)	
16	Budget with justification provided	
17	Case Report Form (CRF)	
18	Work Plan and Time lines provided	
19	CV of PI an d CO-I Attached	
	Soft copy of the proposal is attached	

Date: **Signature of principal investigator:**

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

Research Proposal Summary (Max 500 words):

Detailed Research Plan

1. **Research Title:**
2. **Rationale and justification of the research (Max 500 words):** (what is already known from previous literatures? what are the gaps? what is the need for the study?)
3. **Literature review (Max 500 words):**
4. **Research Questions:**
5. **Objectives:**
   - **Primary objectives**
   - **Secondary objectives**
6. **Research Hypothesis:**
7. **Materials and Methods**

   7.1 Study settings: (Hospital/Community)

   7.2 Study design: (Eg: Cross-sectional, cohort study, randomized controlled trial (RCT) etc)

7.3 Study period and duration:

7.4 Study participants:

Inclusion criteria:

Exclusion criteria:

7.5 Description of study groups (for comparative/analytical studies only):
[Cohort study - Exposed and Non-exposed groups; Case control study - Cases and Controls; Experimental study - Intervention and Control groups]

7.6 Sample size and method of calculation with reference to study on which it is based:

7.7 Sampling technique and method of recruitment: (Eg: simple random sampling, convenient sampling etc)

7.8 Method of randomization (for RCT only):

7.9 Study tools: (questionnaire, case report form, data extraction sheet, instruments, laboratory equipments etc)

7.10 Study variables: (socio-demography, exposure, outcome, confounding etc)

7.11 Data collection and measurements: (by whom, when, where and how? Any training, standardization etc)

7.12 Interventions (For experimental studies only): (what, who, when, where, how?)

7.13 Criteria for withdrawal, rescue etc (For experimental studies only):

7.14 Description of study procedure:

7.15 CONSORT diagram (For RCT) or Flow Chart for other types of study:

8. Pre-test / Pilot study:

9. Statistical analysis plan: (Data entry, descriptive statistics, inferential statistics, statistical tests, softwares used etc)

9.1 Quality Control of Data:

10. Limitations and constraints of the study:

11. Expected Results and Relevance to Action and Policy Change:

11.1 Beneficiaries of the Research Results:

11.2 Dissemination of findings, conclusions and recommendations:

11.3 Priority and importance of the research topic:

12. Ethical considerations:

- I undertake to ensure the following as per the ICMR and other applicable guidelines:
- 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
- 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.

1	Level of risk <Minimal / Minimal / Minor increase over Minimal / >Minimal / High	
2	Conflict of interest (Financial / Non financial)	Yes/ No
3	Involvement of Legally Accepted Representative (LAR)	Yes/ No
4	Inclusion of Vulnerable population as participants	Yes/ No
5	Maintenance of confidentiality of collected data	Yes/ No
6	Anonymization of collected data	Yes/ No
7	Provision of extra medical care, if needed	Yes/ No
8	Plan for compensation for any injury	Yes/ No
9	Extra financial burden to participant	Yes/ No
10	Financial transaction between PI and participant	Yes/ No
11	Anticipated adverse events due to participation	Yes/ No
12	Reuse of collected biological samples	Yes/ No
13	Request for waiver of informed consent	Yes/ No

13. Resources & facilities available for carrying out the project:

14. Administration and monitoring of the research activities:

15. References (Vancouver's style):

16. Estimated Budget in words (Rs):

Items	Units	Unit cost	Total	Justification
Consumables				
Reagents				
Kits				
Stationery				
Printing/photocopy				
Local travel				
Staff remuneration				
Total				

(Signatures on this page are mandatory for intra and extramural funds, not required for self funded proposals)

Signature of Principal Investigator ..... Date:

Signature of Co-Investigator ..... Date:

Signature of Co-Investigator ..... Date:

Signature of Co-Investigator ..... Date:

Signature of Co-Investigator ..... Date:

Signature of HOD (Main department) ..... Date:

Signature of HOD (Collaborating departments) ..... Date:

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 Form (Both Tamil & English)
iv. Declaration for acceptance of responsibility
v. Questionnaire/Case Report Form (CRF)/Data Extraction Sheet
vi. Other Information Relating to the Study

DECLARATION FOR ACCEPTANCE OF RESPONSIBILITY

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.

Signature of Principal Investigator: ..... Date: