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: