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

FORMAT OF RESEARCH PROPOSAL FOR PG DISSERTATION

PART A – GENERAL INFORMATION

1. **Title of the dissertation:**
2. **Name of the Post Graduate Student**
   Mobile number:
   Email:

3. **Name of the course:**
4. **Month and year of appearing for final examination:**
5. **Name (s), Designation (s) of the**
   Guide
   Co-guide
   (with mobile numbers and email ID)

6. **A. State whether it is intradepartmental or interdepartmental :**
   B. If the study is interdepartmental
      i. **State the names of collaborating departments:**
      ii. **State whether consent has been obtained from the Heads of the collaborating departments:**

Certification by the HOD:

The protocol has been presented, reviewed and approved in the department.

Signature of the HOD

CHECK LIST ***(To be filled and duly signed by the post graduate student)***

S. No	Items	Yes/No
1	Exact title	
2	Name & Signatures of post graduate and guides	
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	Soft copy of the proposal is attached	

Date: **Signature of the student:**

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

PART B – TECHNICAL DETAILS

1. **Title of the dissertation:**
2. **Introduction**
    a. **Problem statement**
    b. **Rationale**
    c. **Novelty**
    d. **Expected outcome and application**
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. 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

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

12. References (Vancouver's style):

13. Estimated Budget in words (Rs):

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

Appendices:

i. Participant Information Sheet (PIS) and Informed Consent Form (Both Tamil & English)

ii. Questionnaire/Case Report Form (CRF)/Data Extraction Sheet

Signature of the Post Graduate Student: .....
Signature of Guide: .....
Signature of Co-guide: .....
Signature of Head of the Department: .....
Signature of Co-guide (Collaborating Dept.): .....
Signature of Head of the Collaborating Department: .....