RESEARCH PROPOSAL FORMAT FOR AIIMS MADURAI RESEARCH CELL

Section 1 (For Research Cell)

Part A: Investigator Details

1.	**Project title**		
2.	**Principal investigator** (Name, Designation & Department)		
	Email ID (PI)		
	Mobile (PI)		
	Ongoing projects with the PI (either PI or Co-investigator)		
	Ongoing funded projects as PI		
3.	**Coinvestigators** (Name, Designation, Department) (Add rows if needed) (Please attach a one-page CV for PI. Number mentioned here are illustrative only. Use single row for each Co-Investigators)	Name, designation, email id and contact number	Department (and institution name, if not JIPMER)
		Co-investigators from AIIMS Madurai	
		Investigator 1	Department
		Investigator 1	Department
		Co-investigators from AIIMS Madurai	
		Investigator 1	Department
		Investigator 1	Department

4.	**Responsibilities of the collaborating institutions (national and international) [Applicable for multicentric projects]** (Please include letter of support and one-page CV of investigators outside the institute)	*Oversight:* *Lead coordination:* *Data collection and data entry:* *Data analysis:* *Source of Funding:*	
	Name of two external experts with whom this protocol can be shared for technical evaluation (Name of the expert, affiliation, contact number and email id)		
5.	**Details in case of inter-institutional projects**		
	Name of the coordinating institution		
	Is a copy of the protocol submitted to the coordinating center enclosed?		
6.	**Duration of study**		
7.	**Type of Study**	☐ International	☐ National ☐ Inter-institutional ☐ Intra-institutional
8.	**Funding Agency (name)**		
	Overall project amount		
	Funding approved?	☐ Yes (attach sanction letter) ☐ Submitted ☐ No	
9.	**Detailed budget** (Under different Heads as it is submitted to funding agency with justification)		

Part B: Project details for technical evaluation

Project title		
Project Summary (Not a layman summary) **Should be confined to one single page**		
1.	**Introduction** (may contain background, rationale, novelty and implications, as applicable)	
2.	**Research question (s)**	1. (a) 2. (b) 3. (c) 4. (d)
3.	**Aims and objectives**	
	Primary	1.
	Secondary	2.
4.	**Brief review of literature: (organize in different section if it caters to different objectives)**	
5.	**Study design / type** (Choose more than one option if applicable)	☐ Basic Sciences ☐ Epidemiological ☐ Public Health ☐ Clinical ☐ Socio-behavioral ☐ Implementation Research
		☐ Descriptive ☐ Longitudinal ☐ Cross-sectional ☐ Cross-sectional analytical ☐ Case control ☐ Cohort ☐ RCT ☐ Diagnostic validity ☐ Systematic review ☐ Meta-analysis
		☐ Qualitative ☐ Quantitative ☐ Mixed Method ☐ Any other (please specify)

6.	Study methods (this template applicable only to human studies)		
7.	**Study participants**		
	a.	Number of Study groups (Number, names and definitions)	One group
	b.	Study participants (Inclusion and exclusion criteria– for each group)	
	c.	Source of subjects / Study setting	
	d.	Is sampling involved? If yes, please indicate the population, sample size and sampling method	
	e.	Is randomization involved? If yes, details of procedure	NA
	f.	Is allocation concealment involved? If yes, details?	NA
	g.	Is blinding involved? If yes, methods.	NA
8.	**Details of interventions (only for interventional studies [randomized/cluster trials)**		
	a. Details of drugs, devices, or invasive /non-invasive procedures for interventional studies		NA
	b. Are the drugs or devices to be used approved for these indications by Drug Controller General of India (DCGI)? (Attach evidence, approval letter for the study or give undertaking – see below -- to get the approval before starting study)		NA
9.	Data safety monitoring plan (if it is a clinical trial)		

10.	**Procedures** (Please provide details of variables to be collected, frequency (if it is a follow up study) study tools, operational definitions and equipment to be used). We encourage you to provide a flow diagram of the study to get better idea.		
	Withdrawal criteria (Circumstances that could lead to a decision to withdraw the participant from the study)		
11.	**Ethical considerations (Please fill the separate Ethics forms in the prescribed template for submission to ethics committee)**		
	a.	Are all the proposed procedures considered acceptable in routine practice? If not, please provide details.	
	b.	Important ethical issues involved that you can identify	
12.	**Variables** (for a, b, list only those that you wish to analyses)		
	a.	Study variables	
	b.	Confounding/interacting	-
	c.	Any other comments	Nil
13.	Plan for statistical analysis, including tests to be used if any. [be specific according to the stated objective]		
14.	**Sample Size**		
	a.	Assumptions	

	b.	Method used (Manual or software give details of it)	
	c.	Initial estimate	
	d.	Corrected estimate (After considering losses)	
15.	**Relevant references** (Use Vancouver style)		

16. Enclosures

a.	Data collection proforma / Case Record Form	Attached
b.	Questionnaire (s)	Attached
c.	Copy of signed original protocol (only for multicentric studies) (Please refer to item 7 above)	Not applicable
d.	Copy of signed consent letter from coordinator (only for multicentric studies) (Please refer to item 7 above)	Not applicable
e.	Each external collaborators' consent and one-page CV (Please refer to item 3 above)	Not applicable
f.	Others (please specify)	Not applicable

17. Undertaking

PI gives undertaking for submission of annual progress report and publications or conference proceedings coming out of the approved study

Signature of the Investigator and Head of the concerned Department

Name of the investigator	**Head of the Department**
Investigator 1 Details Signature	Name & Department Signature
Investigator 2 Details Signature	Name & Department Signature