TAGORE MEDICAL COLLEGE & HOSPITAL
Rathinamangalam, Melakkottaiyur Post, Chennai - 600127.
Phone : 044-30101111, Fax : 044-222 5555, Email: tagoremch@gmail.com
(Affiliated to the Tamil Nadu Dr.MGR Medical University & Recognized by the Ministry of Health & Family welfare. Govt. of India New Delhi)

PROFORMA FOR IRC SUBMISSION (July 2025 Version)

1.	Title of project	
2.	Name of the investigators/co-investigators with Designation & Department	
3.	Objectives of the study	
4.	Justification for conducting the study	
5.	Novelty of the study	
6.	Benefits used in the study	
7.	Total cost involved (Approximate sum in Rupees)	
8.	Source of funding (Tick the appropriate box)	☐ Self-Funding ☐ Institutional Funding / Internal Funding ☐ External funding
9.	Investigations	
10.	Disposables	
11.	Implants/Devices	
12.	Drugs	
13.	Who will bear the cost of requirements? (Give accurate details along with actual cost)	☐ Self ☐ Patient ☐ Part-self and part-patient

14.	Ethical issues involved in the study (in detail with levels of risk with justifications)	
15.	Permissions from DCGI	
16.	Permissions from HODs, collaborating Department HODs, Medical Superintendent, etc.	
17.	Conflict of interest	
18.	Consent Forms part 1 and part 2 (English and Tamil)	
19.	List of enclosures	a. Letter from Principal Investigator to IEC for accepting submission of proposal to IEC, TMCH b. Detailed Research Protocol c. Procedure of the study d. CV of investigators e. Informed consent in English and Tamil (Part1 and part 2) f. Others: Brochures, Advertisements, Compensation, Confidentiality, Special Consents, Questionnaires, Any exemptions etc. g. Detailed Budget h. Consenting letter from the eligible guide/co-guides accepting to guide the research project i. Permission letter from Department HOD j. Permission letter from collaborating Department(s) HODs (If applicable) k. Permission of TMCH Medical Superintendent (if the study is conducted at TMCH Hospital) l. Permission from Dean **(for all studies)**

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CHECKLIST

The principal investigators are requested to fill in the table, if the details mentioned have been addressed in the submission by marking yes/no in the relevant column. If the concerned detail is not applicable, it can be mentioned as NA. If the detail is missing in the submitted proposal, the same needs to submitted as annexures in hard/ soft copy

Sno	Detail	Whether enclosed / mentioned in proposal Yes/ No
1.	Letter from Principal Investigator to IEC for accepting submission of proposal to IEC, TMCH	
2.	Consenting letter from the eligible guide/co-guides accepting to guide the research project	
3.	Permission letter from Department HOD	
4.	Permission letter from collaborating Department(s) HODs (If applicable)	
5.	Permission of TMCH Medical Superintendent (if any part of the study is conducted at TMCH Hospital)	
6.	Permission from **Dean (for all studies)**	
7.	Detailed Research Protocol	
8.	Has the sampling size details and sample calculation details been mentioned (With proper references and formulas used in calculation)	
9.	Has the societal outcome of the study been mentioned?	
10.	Have ethical issues in patient handling been addressed in detail?	

11.	Is confidentiality of participant details guarded?	
12.	Are details about compensation to participants enclosed in protocol?	
13.	Are the participants free to withdraw from the study at any point?	
14.	Are the budget details of the study enclosed?	
15.	Informed consent form Part 1 and Part 2 in **English and Tamil**	
16.	Is the study a clinical trial using drug/ device/ vaccine?	
17.	If so, has the drug/ device or vaccine been approved for use in India (document required)	
18.	Is DCGI permission required for the clinical trial under any special circumstance?	

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DECLARATION

We, the undersigned, have read and understood this protocol and hereby agree to conduct the study in accordance with this protocol and all requirements of the latest ICMR Guidelines for Biomedical and Health Research involving Human Participants.

Signature of the Investigators:

Signature of the Head of Department:

Signature of the Co-investigators:

Signature of the Heads of the Department of co-investigators:

Signature of the Head(s) of the Department of collaborating Department(s):