

From,

Dr. XYZ,
UG/PG- year,
Department of xxx,
Tagore Medical College and Hospital,
Chennai

To,
The Coordinator
Institutional Research Committee
Tagore Medical College and Hospital,
Chennai

Through proper Channel

Respected Ma'am / Sir,

Sub: - Request for thesis proposal approval from Institutional Research Committee.

I, Dr. XYZ First Year PG in the Department of ABCD, would like to submit my thesis protocol for Institutional Research Committee approval. The title of the proposed thesis is "xxxxxxxxxxxxxxxx".

I have enclosed the thesis protocol here with. Kindly do the needful.

Thank you,

Yours faithfully,
Dr.XYZ .

Forwarding signature and seal by the Guide.



TAGORE MEDICAL COLLEGE & HOSPITAL

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(Affiliated to the Tamil Nadu Dr.MGR Medical University & Recognized by the Ministry of Health & Family welfare, Govt. of India New Delhi)

Application for Submission of Research Proposals to IRC Review

IRC No.	Project type Faculty/ PG/ UG/ Ph. D/ STS, others, specify _____	Date of Submission
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SECTION A- BASIC INFORMATION

Title of Research Proposal:

Details of Investigators:

NAME	QUALIFICATION/ DESIGNATION/ DEPARTMENT	ADDRESS FOR COMMUNICATION (WITH CONTACT NUMBERS & E-MAIL ID)
Principal Investigator		
Co-investigators/ Faculty Guide		
1		
2		
HOD of the department		

[Kindly attach CV of all Investigators in the recommended format.]

Novelty of the study :

[Describe how the proposal challenges and seeks to shift the current research/knowledge/clinical practice paradigms etc. by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions etc. Mention if there is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions in the proposed study].

Funding details & Budget:

Total estimated Budget for study:

- ☐ Self-funding ☐ Institutional funding
- ☐ Funding agency, specify _____(*enclose sanction letter*)

RESEARCH RELATED INFORMATION

1.Type of study	
☐ Basic sciences ☐ Retrospective ☐ Prospective ☐ Qualitative ☐ Quantitative ☐ Mixed method	☐ Clinical ☐ Epidemiological or Public health ☐ Socio-behavioural ☐ Biological samples ☐ Single-centre ☐ Multi-centre
☐ Cross-sectional ☐ Case-control ☐ Cohort ☐ Clinical trial ☐ Systematic review ☐ Any other, specify _____	
2. Status of Review ☐ New ☐ Revised	
3. Clinical trial (fill the following information, if applicable)	
a. Does the study involve use of any of the following?	☐ Drug ☐ Device ☐ Vaccines ☐ Indian/ Alternative systems of medicine ☐ Any other, _____ ☐ Not applicable
b. Is it approved & marketed?	☐ In India ☐ UK & Europe ☐ USA ☐ Other countries, _____
c. Does it involve a change in use, dosage, route of administration? If yes, Drug Controller General of India (DCGI) or any other regulatory authority's permission obtained? If yes, date of permission obtained (<i>Enclose approval letter</i>)	☐ Yes ☐ No ☐ Yes ☐ No ____/____/____
d. Is it an Investigational New Drug (IND)? If yes, IND number: Investigator's brochure enclosed? In vitro studies data enclosed? Preclinical studies done? Clinical study is in Phase _____ Are you aware of this study or similar study being done elsewhere? If yes, enclose details.	☐ Yes ☐ No _____ ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ I ☐ II ☐ III ☐ IV ☐ Yes ☐ No
4.Purpose of the study:	☐ Dissertation ☐ Short study ☐ Conference /Publication purpose
5.Animal study: ☐ Animal study (if applicable)	Approval from Institutional Animal ethics committee

DETAILED RESEARCH PROPOSAL

I. Title of the project

(not too long/ short; avoid abbreviations and jargons; kindly make sure it includes the following components, as applicable- objectives; major outcome variable(s); major predictor variable(s); setting; subjects; study design)

II. Background/ Introduction

(Try to answer the following questions (based on detailed literature review or other sources of evidence) & cite relevant references in the text (with a maximum word limit of 300)

- 1. What is the relevance of your study, highlighting the current state of knowledge?*
- 2. What led you to come up with your research question?*
- 3. What are the gaps in knowledge?*
- 4. What is your research question? Kindly add justification for your research study)*

III. Objectives:

(Objectives are clear statements, which specify what and how we are planning to do; Specify primary and secondary, where applicable)

IV. Hypothesis of the study:

NULL HYPOTHESIS	
ALTERNATE HYPOTHESIS	

V. Brief review of literature

-Minimum of 5 relevant references; Expected in chronological or historical order

-Recent references less than 5 years preferred

-Critically read the articles with emphasis on summary of the article; key findings; methodology used; how the article relates to the study; accurate reference

[Review to be written cohesively to build justification for the research question to be addressed with reference of key publications]

VI. Materials & Methods

a) Study design: *(cross-sectional/case-control/cohort/(randomized) clinical trial/prospective/retrospective)*

b) Study setting: *(the setting where study is to be conducted; the department or hospital or community/Incampus /Outcampus)*

c) Study duration: *(Duration in months)*

d) Study Period: *(Starting- month and year to finishing-month and year; e.g., September 2023 to March 2024)*

e) Study population: *(the population who would be considered for the study, give the rationale for the choice of cases (and controls, if applicable). For matched studies, give matching criteria and the number of controls per case))*

f) Inclusion criteria *(specify exactly who among the study population will be eligible to enter the study)*

g) Exclusion criteria:

h) Sampling:

1. Sampling frame:
2. Sampling method:
3. Sample size with calculation methods: *(based on previous literature using appropriate formulae or software/ pilot study/ ____)*

i) Study tools:

- *Describe the specifics of study tool- questionnaire/ Proforma/ instrument/ procedures etc.; add a copy of questionnaire or Proforma in English & local language;*
- *List the different sections of questionnaire or Proforma; include details of pretesting or validation of questionnaire;*
- *If well-known standard questionnaires or scales are used, confirm copyright details and add proof for confirmation of permission to use, wherever applicable;*
- *If instruments are used, mention the manufacturer and standardization procedure*

k) Methodology [Sample and Data collection procedures]:

*(Detailed procedure to include the setting; Procurement of reagents, drugs, cell lines, microorganisms (as applicable), Invitro and in-vivo procedures; person who will collect the data etc.; Detailed descriptions of the **process of data collection** includes both physical procedures by which data are gathered (e.g., venipuncture for blood, biopsy, endoscopy etc) or **interventions** (administering medications, use of a medical device, activity, surgical procedures, counselling etc.).*

l) Interventional Studies should include the following:

(Intervention and Comparator agent; Randomization; Allocation concealment, Blinding and masking; Detailed diagrammatic Algorithm of the study; Protocol variations: (Any rules for interim analyses, withdrawal of participants, premature stopping of trial); Data monitoring committee; Post Trial benefits and care; Protocols for dealing with complications, research related injuries etc.)

j) Statistical Methods and Data analysis:

(Describe all statistical methods, including those used to control for confounding and examine subgroups and interactions. How will missing data be handled? If applicable, how will matching of cases and controls be handled? Describe any proposed sensitivity analyses)

-Software that will be used for data entry & data analysis with version

k) Expected outcomes:

(Explains how the proposal will address the needs shown in the statement of problem and achieve the objectives- Primary and secondary end points of the study)

l) Inter-departmental collaboration:

(Kindly describe arrangements with institutional diagnostic service units/departments that are being used for this research project, if applicable; kindly add letter of permission from concerned Head of Departments where applicable)

m) Social impact and benefits of the study :

n) Ethical considerations

(Details of vulnerable or special population if applicable; details on how privacy and confidentiality will be protected; describe type of consent; conflicts of interest if any)

o) Implications of the study:

(Explain how this research will expand current state of knowledge; provide new insights or lead to other research; provide evidence for or against a hypothesis; impact policy decisions at individual/ community or institutional level etc.)

p) Budget : If applicable

q) References

(Maximum 20; at least 50% of references should be dated < 10 years; in Vancouver style, to be cited sequentially in the text of the project)

**Signature of the
Principal investigator**

Signature of the Guide

Signature of the HOD

Annexures :

1. Questionnaire if applicable with details of validation/ e mail from author if questionnaire published in a journal is being used as applicable
2. Patient information sheet
3. Informed consent form in English and tamil
4. Permission letters from collaborating departments/ institutions if any to be enclosed

[Format for CV, PATIENT INFORMATION SHEET, INFORMED CONSENT is attached]

Format for Curriculum-vitae of Investigator(s)

Name:	
Present affiliation: <i>(Job title, department & organization)</i>	
Address:	
Telephone number:	
Email address:	
Qualifications:	
Number of years of work experience (after post-graduation)	
Previous affiliations: (in the last five years)	
Projects undertaken in the last 5 years:	
Relevant research training/experience in the area <i>(Details of any relevant training in the design or conduct of research, for example in Ethics Training, Human participants' protection courses, Clinical Trials Regulations, Good Clinical Practice, Consent, Research ethics training or other training appropriate to non-clinical research. Give the date of the training)</i>	
Relevant publications <i>(Give references to all publications in the last five years plus other publications relevant to the current application):</i>	
Signature	Date

Participant Information Sheet

Title of the project:

Name of the Investigators:

Institution:

- Purpose of this project/study
- Procedure/methods of the study
- Expected duration of the subject participation
- Benefits to be expected from the research to the participant or to others and the post-trial responsibilities of the investigator
- Any risks expected from the study to the participant
- Maintenance of confidentiality of records
- Provision of free treatment for research related injury
- Compensation for participating in the study
- Compensation to the participants for foreseeable risks and unforeseeable risks related to research study leading to disability or death.
- Freedom to withdraw from the study at any time during the study period without the loss of benefits that the participant would otherwise be entitled
- Possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, this should be mentioned
- Address and mobile number of Principal investigators:

Signature of the Investigator: _____

Date:

Signature of the Participant: _____

Date:

Format for Informed Consent Form for Participants

Study

title:

Principal Investigator:

Institution:

Participant's name:

Date of birth/Age:

- i. I confirm that I ***have read/ have been explained (delete as appropriate)***, and I have understood the information sheet dated _____ for the above study and have had the opportunity to ask questions.
- ii. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
- iii. I understand that ***the Sponsor of the clinical trial, others working on the Sponsor's behalf (delete as appropriate)***, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.
- iv. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).
- v. I agree to take part in the above study.

Signature of the participant: _____

Date:

Signature of the witness: _____

Date:

Name & address of the witness:

Signature of the Investigator: _____

Date:
