From,

Dr.XYZ,
UG/PG- year,
Departmentofxxx,
TagoreMedicalCollegeandHospital,
Chennai

To,
TheCoordinator
Scientific Review Committee (SRC)
TagoreMedicalCollegeandHospital,
Chennai

ThroughproperChannel

RespectedMa'am/Sir,

Sub:-Requestforthesisproposalapproval fromScientific Review Committee (SRC).

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 "xxxxxxxxxxxx".

Ihaveenclosed thethesisprotocol herewith.Kindly do the needful.

Thankyou,

Yours faithfully,
Dr.XYZ.

Forwardingsignatureand sealbytheGuide.

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)

Application for Submission of Research Proposals to SRC Review

SRC No.	Project type Faculty/PG/UG/Ph.D/ STS,others,specify _____	Date of Submission

SECTIONA-BASIC INFORMATION

Title of Research Proposal:

_____

_____

_____

DetailsofInvestigators:

NAME	QUALIFICATION/ DESIGNATION/DEPARTMENT	ADDRESSFORCOMMUNICATION (WITH CONTACT NUMBERS & E-MAILID)
Principal Investigator		
Co-investigators/FacultyGuide		
1		
2		
HOD of the department		

[Kindlyattach CVofallInvestigators intherecommendedformat.]

Novelty of the study :

[Describehowtheproposalchallengesand seeksto shiftthecurrentresearch/knowledge/clinicalpractice paradigms etc. by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventionsetc.Mentioniftherеisarefinement,improvement,ornewapplicationoftheoreticalconcepts, approaches or methodologies, instrumentation, or interventions in the proposed study].

Funding details & Budget:

TotalestimatedBudgetforstudy:

□Self-funding □Institutionalfunding

□ Funding agency, specify _____*(enclosesanctionletter)*

RESEARCH RELATED INFORMATION

1.Typeofstudy		
□ Basicsciences □ Retrospective □ Prospective □ Qualitative □ Quantitative □ Mixed method	□ Clinical □ Epidemiologicalor Public health □ Socio-behavioural □ Biological samples □ Single-centre □ Multi-centre	□ Cross-sectional □ Case-control □ Cohort □ Clinical trial □ Systematic review □ Any other, specify _____
2.Statusof Review □New □ Revised		
3.Clinicaltrial(fillthefollowing 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.Isitapproved& marketed?	□InIndia□UK&Europe□USA□Othercountries, _____	
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? Ifyes,dateofpermissionobtained *(Encloseapprovalletter)*	□Yes□No □Yes□No ___/___/_____	
d.IsitanInvestigationalNewDrug(IND)? If yes, IND number: Investigator'sbrochureenclosed? In vitro studies data enclosed? Preclinicalstudiesdone? Clinical study is in Phase _____ Are youaware ofthisstudy or similar study being done elsewhere? Ifyes,enclosedetails.	□Yes□No _____ □Yes□No □Yes□No □Yes□No □I □II □ III □ IV □Yes□No	
4.Purposeofthe study:	□ Dissertation □ Short study □ Conference/Publication purpose	
5.Animalstudy: □ Animal study (ifapplicable)	ApprovalfromInstitutionalAnimalethics committee	

DETAILED RESEARCH PROPOSAL

I. Titleoftheproject

(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

(Trytoanswerthefollowingquestions(basedondetailedliteraturerevieworothersourcesofevidence) & cite relevant references in the text (with a maximum word limit of 300)

1. *Whatis therelevanceofyour study,highlighting thecurrentstateof knowledge?*
2. *Whatledyoutocomeupwithyourresearch question?*
3. *Whatarethegaps in knowledge?*
4. *Whatisyourresearchquestion? Kindlyaddjustificationforyourresearchstudy)*

III. Objectives:

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

IV. Hypothesisofthestudy:

NULL HYPOTHESIS	
ALTERNATE HYPOTHESIS	

V. Briefreviewof literature

-Minimumof5relevantreferences;Expectedinchronologicalorhistoricalorder
-Recentreferenceslessthan5yearspreferred
-Criticallyreadthearticleswithemphasisonsummaryofthearticle;keyfindings;methodologyused;how the article relates to the study; accurate reference
[Reviewtobewrittencohesivelytobuildjustificationfortheresearchquestiontobe addressed with reference of key publications]

VI. Materials&Methods

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

b) Studysetting:*(thesettingwherestudyistobeconducted;thedepartmentorhospitalorcommunity/Incampus /Outcampus)*

c) Study duration:*(Durationin months)*

d) Study Period:*(Starting-monthandyeartofinishing-monthandyear;e.g.,September2023toMarch 2024)*

e) Study population: *(thepopulationwhowouldbeconsideredforthestudy,givetherationaleforthe choice of cases (and controls, if applicable). For matched studies, give matching criteria and the number of controls per case))*

f) Inclusion criteria *(specifyexactlywhoamongthestudypopulationwillbeeligibletoenterthestudy)*

g) Exclusion criteria:

h) Sampling:

1. Samplingframe:
2. Samplingmethod:
3. Samplesizewithcalculationmethods: *(basedonpreviousliteratureusingappropriate 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 ofquestionnaire;*
- *If well-known standard questionnaires or scales are used, confirm copyright details and add proof for confirmation of permission to use, wherever applicable;*
- *Ifinstrumentsareused,mentionthemanufacturerandstandardizationprocedure*

k) Methodology[Sample and Data collection procedures]:

*(Detailed procedure to include the setting; Procurement of reagents, drugs, cell lines, microrganisms (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;PostTrialbenefitsandcare;Protocolsfordealingwithcomplications,researchrelated 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)

-Softwarethat willbe usedfor data entry& dataanalysis with version

k) Expected outcomes:

(Explainshowtheproposalwilladdresstheneedsshowninthestatementofproblemandachievethe objectives-Primary and secondary end points of the study)

l) Inter-departmentalcollaboration:

(Kindly describe arrangements with institutional diagnostic service units/departments that are being used forthisresearchproject,ifapplicable;kindlyaddletterofpermissionfromconcernedHeadofDepartments 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)

Signatureofthe Principalinvestigator **SignatureoftheGuide** **SignatureoftheHOD**

Annexures:

1. Questionnaireifapplicablewithdetailsofvalidation/emailfromauthorif questionnaire published in a journal is being used as applicable
2. Patientinformationsheet
3. Informedconsentform inEnglishand tamil
4. Permissionlettersfromcollaboratingdepartments/institutionsifanytobeenclosed

[FormatforCV,PATIENTINFORMATIONSHEET,INFORMEDCONSENTisattached]

Format for Curriculum-vitae of Investigator(s)

Name:	
Presentaffiliation:*(Jobtitle,department&organization)*	
Address:	
Telephonenumber:	
Emailaddress:	
Qualifications:	
Numberofyearsof workexperience(after post-graduation)	
Previousaffiliations:(inthelastfiveyears)	
Projectsundertakeninthelast5 years:	
Relevant research training/experience in the area (*Details of any relevant training in thedesignorconductofresearch,forexampleinEthicsTraining,Humanparticipants' 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*)	
Relevant publications *(Give references to all publications in the last five years plusother publications relevant to the current application):*	
Signature	Date

Participant Information Sheet

Titleofthe project:

Nameofthe Investigators:

Institution:

-Purposeofthisproject/study

-Procedure/methodsofthestudy

-Expecteddurationofthesubjectparticipation

-Benefitstobeexpectedfromtheresearchtotheparticipantortoothersand the post-trial responsibilities of the investigator

-Anyrisksexpectedfromthestudytotheparticipant

-Maintenanceofconfidentialityofrecords

-Provisionoffreetreatmentforresearchrelatedinjury

-Compensationforparticipatinginthestudy

-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

-Possiblecurrentandfutureusesofthebiologicalmaterialandofthedatato be generated from the research and if the material is likely to be used for secondarypurposesorwouldbesharedwithothers,thisshouldbementioned

-AddressandmobilenumberofPrincipalinvestigators:

Signature of the Investigator: _____ Date: _____

Signature of the Participant: _____ Date: _____

Format for Informed Consent Form for Participants

Study title:

_____

_____

_____

Principal Investigator:

Institution:

Participant'sname:

Dateof birth/Age:

i. I confirm that I ***have read/ have been explained (delete as appropriate)***, and I have understood the information sheet dated _____forthe 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(deleteasappropriate)***,Scientific Review Committee, andtheregulatoryauthorities will notneedmypermissiontolookatmyhealthrecordsbothinrespectofthecurrentstudy andanyfurtherresearchthatmaybeconductedinrelationtoit,evenifIwithdrawfrom 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 purposes.

v. Iagreeto takepartin theabovestudy.

Signature of the participant: _____ Date:

_____

Signature of the witness: _____ Date:

_____

Name&address ofthe witness:

Signature of the Investigator: _____ Date:

_____