



RESEARCH PROPOSAL FORMAT FOR INSTITUTIONAL REVIEW COMMITTEE

Part A: General information

1.	Project title		
2.	Student researcher (Name, Designation & Department)		
	Email ID		
	Mobile		
3.	Guide and co-guides (Name, Designation, Department) (Add rows if needed) (Please attach a one-page biosketch for Guide and each co-guide)	Name, designation, email id and contact number	Department
4.	Details in case of inter-institutional projects		
	Name of the co-ordinating institution	If Applicable	
	Is a copy of the protocol submitted to the co-ordinating center enclosed?		
5.	Duration of study		
6.	Funding source (name)	If Applicable	
	Overall project amount		
	Funding approved?	<input type="checkbox"/> Yes (attach sanction letter) <input type="checkbox"/> Submitted <input type="checkbox"/> No	
7.	Detailed budget (Including the expenditure that will be incurred by the institution for the project)	If Applicable	



6.	Subjects	
a.	Study groups (number, names and definitions)	
b.	Study participants (inclusion and exclusion criteria– for each group)	
c.	Source of subjects / setting	
d.	Is sampling involved? If yes, please indicate the population, and sampling method	
e.	Is randomization involved? If yes, details of procedure	
f.	Is allocation concealment involved? If yes, details?	
g.	Is blinding involved? If yes, methods.	
7.	Details of interventions (only for interventional studies)	
a.	Details of drugs, devices, or invasive /non-invasive procedures for interventional studies	
8.	Data safety monitoring plan	
9.	Procedures (please provide details, including data collection procedures, their timing and frequency, standardization of relevant techniques, etc.)	
	Withdrawal criteria (Circumstances that could lead to a decision to withdraw the participant from the study)	
	Rescue criteria (Measures that will be taken in case of expected adverse outcomes)	
10.	Ethical considerations	
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	
11.	Variables (for a, b, list only those that you wish to analyse)	
a.	Independent	
b.	Dependent	
c.	Confounding/interacting	
d.	Any other comments	



12.	Plan for statistical analysis, including tests to be used if any. [A table may be given for variables, data type (score, continuous/interval) distribution, summary statistics (mean/median/proportion), no. of groups and Statistical test(s) to be used]	
13.	Sample size	
	a. Assumptions	
	b. Method used	
	c. Initial estimate	
	d. Corrected estimate (after considering losses)	
14.	Relevant references (max 20, Vancouver style, cited sequentially in text above)	

15. Enclosures

a.	Data collection proforma	
b.	Questionnaire(s)	
f.	Others (please specify)	

16. Declaration

Title of the Study:

I take full responsibility and accountability for planning, execution and adverse events occurring during the study. The data collected and records will be retained by me for a period of three years.

Signature of Guide

17. Signatures with dates

(Student Researcher's signature)	
(Guide's signatures)	
(Co-guide's signature)	
Research Coordinator Signature	
Signature of the Principal	



Format for Curriculum Vitae for Investigators (Guides and Co-guides)

1.	Name	
2.	Designation	
	Department	
	Institution/organization	
3.	Mobile number	
4.	Email ID	
5.	Qualifications	
6.	Projects undertaken in the last 5 years (brief title, funding source, amount, status)	
7.	Relevant research training/experience in the area	
8.	Relevant publications (All publications in the last five years and other publications relevant to the current study; Vancouver format)	
9.	Signature and date	



RESEARCH PROPOSAL FORMAT FOR

INSTITUTIONAL HUMAN ETHICAL COMMITTEE

1. Title of the project:
2. Name and department/address of the Student Researcher:
3. Name of Faculty (Guide/Co-guide) with designation & department:
4. Date of approval by Institutional Review committee:
5. Ethical issues involved in the study [Along with level of risk, the risks should be written in detail. If you feel there will be no risk, give justification]:

less than minimal risk / minimal risk / minor increase over minimal risk/more than minimal risk to the study subjects (for guidance please consult “National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017” –)

6. Benefit of the study:
7. Details of Informed Consent Process:
 - a) Who will take the informed consent?
 - b) When will the informed consent be taken?
 - c) How will the informed consent be taken?
 - d) Where will the informed consent be taken?
8. Do you need exemption from obtaining Informed Consent from study subjects - if so give justifications?
9. Whether Consent forms in English and in local language are enclosed? *(if the consent form in local language is not applicable, appropriate explanations must be provided)*
10. Documents attached
 - a. Waiver Application Form (Annexure-1)-if applicable
 - b. Review Exemption Application Form (Annexure-2)-if applicable
 - c. Brief CV of Guides and Co-Guides (including no. of projects with him/her) - Needed for all Investigators for each project separately
 - d. For student projects, the guide should give a signed statement on a separate sheet with details of the project proposal that “I take full responsibility and accountability for planning, execution and adverse events occurring during the study. The data collected and records will be retained by me for a period of three years”.
 - e. Investigator’s brochure
 - f. Others



11. Conflict of interest for any other investigator(s) (if yes, please explain in brief)
12. We, the undersigned, have read and understood this protocol and hereby agree to conduct the study in accordance with this protocol and to comply with all requirements of the ICMR guidelines (2017)

Signature of the Student Researcher:
(Name & Designation)

Signature of the Guide:
(Name & Designation, Department
Seal and Date)

Signature (s) of the co-guide:
(Name & Designation, Department,
Seal and Date)

Note: The proforma must be accompanied by Informed Consent Document (ICD) in English and Tamil. Informed Consent Document should comprise Patient Information Sheet and the consent form. The investigator must provide information to the subjects in a simple language, and it should address the subjects, in a dialogue format. Studies involving children below 7 years should include parent / LAR consent form, while studies involving children above 7 years and below 18 years of age should also include written assent form for children 12-18 years of age and verbal assent for children 7-12 years to be mentioned in parent/LAR consent form, in addition to parent / LAR consent form.

Declaration

Title of the Study:

I take full responsibility and accountability for planning, execution and adverse events occurring during the study. The data collected and records will be retained by me for a period of three years.

Signature of Guide
(Name and Designation of Guide)



INFORMED CONSENT DOCUMENT (ICD)PART-1
PATIENT / PARTICIPANT INFORMATION SHEET

INFORMATION FOR PARTICIPANTS OF THE STUDY

Instructions - This is the patient information sheet. It should address the participant of this study. Depending upon the nature of the individual project, the details provided to the participant may vary. A separate consent form for the patient/test group and control (drug/procedure or placebo) should be provided as applicable. **While formulating this sheet, the investigator must provide the following information as applicable in a simple language in English and Tamil which can be understood by the participant. (Do not copy & paste from the study protocol). Do not use technical terms in the PIS. **If participants are children, the participant information sheet should address the parents /LAR of the children and should be worded accordingly.****

- Title of the project
- Name of the Student Researcher/Guide/Co-Guides
- Purpose of this project/study
- Procedure/methods of the study
- Expected duration of the subject participation
- The 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
- Reimbursement 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 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



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DEVOTION DEDICATION DISCIPLINE

Ariyur, Puducherry - 605 102



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- Possible current and future uses of the data to be generated from the research and if the data is likely to be used for secondary purposes or would be shared with others, this should be mentioned
- You are encouraged to seek further clarification if unable to understand any component of the PIS.

Contact details of the Principal investigator (PI):

Signature of the participant:

Signature of the investigator:

Place:

Date :



INFORMED CONSENT DOCUMENT (ICD) PART-2

INFORMED CONSENT FORM

Title of the project:

Participant's name:

Address:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I confirm that I have understood about the compensation and the risks and benefits involved in this research. I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving any reason, and without my routine medical care in this hospital being affected. I understand that confidentiality of my identity will be maintained during the research period, after its completion as well as during publication of the results. Only investigator, ethics committee, institutional or regulatory authorities may have access to my information when required.

I have been given a copy of information sheet giving details of the study. I volunteer to participate in the above mentioned study.

Name and Signature/thumb impression of the participant: _____ Date: _____

Signature of the witness with date: _____ Date: _____

Name and address of the witness for illiterate participants:

Signature of the investigator with date: _____ Date: _____



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CONSENT FORM (for participants less than 18 years of age and for patients who cannot consent)

Parent/Legally authorized/acceptable representative (LAR)

Title of the project:

Participant's name:

Address:

Parent/LAR's name:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I confirm that I have understood about the compensation and the risks and benefits involved in this research. I understand that my child's/ward's participation in the study is voluntary and that I am free to withdraw at any time without giving any reason, and without my child's/ward's routine medical care in this hospital being affected. I understand that confidentiality of my child's/ward's identity will be maintained during the research period, after its completion as well as during publication of the results. Only investigator, ethics committee, institutional or regulatory authorities may have access to my child's/ward's information when required.

I have been given a copy of information sheet giving details of the study. I volunteer my child/ward to participate in the above mentioned study.

Verbal assent taken for children 7-12 year of age: Yes/No

Name and Signature/thumb impression of the parent/LAR: _____ Date: _____

Signature of the witness with date: _____ Date: _____

Name and address of the witness for illiterate participants:

Signature of the investigator with date: _____ Date: _____



ASSENT FORM

(for children above 12 years and below 18 years of age)

Assent form to participate in a clinical research

Child Participant's name:

Date of birth/Age:

Parent/LAR's name:

Address:

Title of the project:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I confirm that I have understood about the compensation and the risks and benefits involved in this research. 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 the medical care that will normally be provided by the hospital being affected. 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). I understand that following completion of study as well as during publication of the results, confidentiality of my identity will be maintained. I have been given an information sheet giving details of the study. I fully assent to participate in the above study.

Signature of the child participant:
(If child knows to sign/Thumb impression)

Date:

Signature of the parent or guardian:

Date:

Name and address of the witness :

Signature of the witness:

Date:

Signature of the Investigator :

Date:

(Assent form should be accompanied by patient / participant information sheet for children in a simple language comprehensible to a child from 12-18 years; Verbal assent to be recorded in LAR consent form for children 7-12 years of age and written assent form for children from 12-18 years of age. Language used should be simpler for children in the age group 7-12 years compared to children in the age group >12-18 years)



Annexure-1

Application form for requesting waiver of consent

1. *Student researcher's and Guide's name:*
2. *Department:*
3. *Title of project:*
4. *Names of co-guides and Department/s:*
5. *Request for waiver of informed consent:*
 - Please tick the reason(s) for requesting waiver (Please refer the back of this annexure for criteria that will be used by IEC to consider waiver of consent).*
 - [1] Research involves 'not more than minimal risk'*
 - [2] There is no direct contact between the researcher and participant*
 - [3] Emergency situations as described in ICMR Guidelines*
 - [4] Any other (please specify)*
 - Statement assuring that the rights of the participants is not violated:*
 - State the measures described in the Protocol for protecting confidentiality of data and privacy of research participant:*

Student Researcher and Guide signature with date:

Final decision at full board meeting held on:

Waiver granted: YesNo.....

If not granted, reasons,

Signature of the Chairperson with Date:



ANNEXURE-2

REVIEW EXEMPTION APPLICATION FORM

1 Student Researcher and Guide Name: _____

2 Department: _____

3 Title of Project: _____

4 Names of other participating staff and students: _____

5 Brief description of the project:

Please give a brief summary (approx. 300 words) of the nature of the proposal, including the aims/objectives/hypotheses of the project, rationale, participants' description, and procedures/methods to be used in the project:-

6 State reasons why exemption from ethics review is requested?

- Audits of educational practices
- Research on microbes cultured in the laboratory
- Research on immortalized cell lines
- Research on cadavers or death certificates provided such research reveals no identifying personal data
- Analysis of data freely available in public domain
- Any other

(This should include justification for exemption e.g. study does not involve human participants. If exemption is being requested on the basis of low risk involved in the study please refer to the backside of this annexure.)

Student Researcher and Guide signature with date::

Forwarded by the Head of the department:

Name: _____ **Signature:** _____

Date _____



Recommendations by the IEC Member Secretary:

Exemption

Cannot be exempted

Reasons _____ Discussion at fullboard

Signature of the Member Secretary: _____

Date _____ **Final Decision:**

Exemption

Cannot be exempted

Reasons _____

Discussion at full board

Signature of the Chairperson: _____

Date _____

Final Decision at Full Board meeting held on _____

Signature of the Chairperson: _____

Date _____

No research can be counted as low risk if it involves:

- (i) Invasive physical procedures or potential for physicalharm
- (ii) Procedures which might cause mental/emotional stress or distress, moral or culturaloffence
- (iii) Personal or sensitiveissues
- (iv) Vulnerable groups
- (v) Cross cultural research
- (vi) Investigation of illegalbehaviour(s)
- (vii) Invasion ofprivacy
- (viii) Collection of information that might be disadvantageous to theparticipant
- (ix) Use of information already collected that is not in the public arena which might be disadvantageous to theparticipant



- (x) Use of information already collected which was collected under agreement of confidentiality
- (xi) Participants who are unable to give informed consent
- (xii) Conflict of interest e.g. the researcher is also the lecturer, teacher, treatment-provider, colleague or employer of the research participants, or there is any other power relationship between the researcher and the research participants.
- (xiii) Deception
- (xiv) Audio or visual recording without consent
- (xv) Withholding benefits from “control” groups
- (xvi) Inducements
- (xvii) Risks to the researcher

This list is not definitive but is intended to sensitize the researcher to the types of issues to be considered. Low risk research would involve the same risk as might be encountered in normal daily life.

Please check that your application / summary has discussed:

- Procedures for voluntary, informed consent
- Privacy & confidentiality
- Risk to participants
- Needs of dependent persons
- Conflict of interest
- Permission for access to participants from other institutions or bodies
- Inducements

In some circumstances research which appears to meet low risk criteria may need to be reviewed by the IEC. This might be because of requirements of:

- The publisher of the research
- An organisation which is providing funding resources, existing data, access to participants etc.

**CHECK LIST***(To be filled and duly signed by the Student Researcher and Guide)*

Title of the study:

Name of the Student Researcher/Guide:

Designation & Department:

S.No	Items	Yes/No
1	Exact title as approved by IRC	
2	Date of IRC approval mentioned in proper format (dd/mm/yyyy)	
3	Adequate literature review with justification for the study mentioned	
4	Detailed description about methodology (Study design, number of groups, sample size etc)	
5	No mirror statement in Inclusion/Exclusion criteria (Ex: Age <18 in inclusion & Age >18 in exclusion)	
7	Adequate justification for exemption from obtaining informed consent given (if applicable) .	
9	Informed Consent Document in both English and Tamil attached	
10	Information to the participant/ parent/guardian in layman (simple) language.	
11	Validated questionnaire both in Tamil and English attached (if study involves interview/ questioning)	
12	Signature of all investigators (Principal & Co-investigator) and Head of corresponding department obtained with date	
13	Compensation mentioned as per guidelines in consent form part 1	
14a	Confidentiality mentioned as per guidelines in consent form part 1	
14b	Separate consent form for subjects < 7 yrs attached (if applicable)	
15	Separate assent form for subjects > 7 yrs< 18 yrs attached (if applicable)	
16	Separate consent form for cases and controls attached (if applicable)	
17	Ethical issues explained in detail with level of risk	
18a	No discrepancy between tamil and English consent form	
18b	Declaration form from Guide regarding overall responsibility for the research	
19	Declaration form from principal investigators / Guide stating that all procedures used in the study are standard and professionally acceptable	

Date:

Signature of Student Researcher:

Signature of Guide:

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