**Research proposal submission format**

**Title of the study**

**Name of Principal Investigator:**

**Date of submission to IRC / IEC**: **IRC / IEC ref no with date of approval:**

**Hard copy (no of copies): Softcopy sent: Yes / No**

**Checklist for submission to IRC (Please tick as appropriate)**

Signature of Principal investigator

Signature of all Co-investigators

Research protocol/proposal in the format

Data collection tool (English)

Data collection tool (Tamil)

Undertaking by the PI that questionnaire is Validated and pretested

Patient information sheet (PIS) (English)

Patient information sheet (Tamil)

Informed consent form (English)

Informed consent form (Tamil)

Intra- departmental Inter-departmental (details)……………………

Inter-institutional (details)……………………………………………………………

Permission letters from relevant authorities (details)…………………………………

Does the study involve vulnerable group? If yes, attach checklist.

Does the study require IBSC permission (involve microorganisms)? If yes, attach IBSC format.

Does the project require expediated review/ full review/ exempt from review?

No. of projects with the PI and Co-PI

If Funded project (details)……………………………………………………………..

**Title of the study**

**Details of investigator(s)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **No.** | **Role of Investigator**  **(PI/ Co-PI/ Co-I/ guide)** | **Name, designation and contact details of the researcher** | **Contribution to the research project** | **Signature with seal** | **Signature of the HOD of the investigator with seal** |
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Conflict of interest if any – Explain briefly

**Research Proposal Format**

1. Title of the study (preferably descriptive title with Setting, Population, Intervention, Condition, outcome & Design)
2. Introduction (justification for the study with what is known, what is not known, what the study proposes to do and how)
3. Research question (PICOT format) or Research hypothesis (if applicable)
4. Research aims and objectives
5. Review of Literature
6. Materials & Methods
   1. Study design, including CTRI number if clinical trial.
   2. Study setting
   3. Study duration
   4. Study population
   5. Inclusion & exclusion criteria
   6. Sample size calculation
   7. Sampling technique
   8. Randomization process and allocation concealment (only for clinical trials)
   9. Data collection tools/ procedures/ interventions
   10. Process of data collection
   11. Operational definitions
7. Variables (dependent and independent), data entry and plan of analysis
8. Ethical considerations including risk involved
9. Implications of the study
10. References
11. Funding sources and Budget
12. Annexures- Patient Information sheet, Consent form, Data collection proforma / questionnaire, Checklist for studies in vulnerable population, MOUs/ Permissions (if applicable)