

Format for submission of Research proposal in IRC

SECTION- 1

PART A – GENERAL INFORMATION

1. Title of the Proposal:
2. Name of principal investigator, with mobile numbers, email ID:
3. Department affiliated, Designation :
4. Name (s), Designation (s) & Addresses of co-investigators (s) with mobile numbers & email ID:
5. State whether it is intradepartmental or interdepartmental:
6. If the study is interdepartmental
 - (i) State the names of collaborating departments:
 - (ii) State whether consent has been obtained from the

PART B – TECHNICAL DETAILS

1. Title of the research proposal
2. Introduction
 - A. Problem statement
 - B. Rationale
 - C. Novelty
 - D. Expected outcome and application
3. Research question(s)
4. Research hypothesis (es), if any
5. Aim and objectives: Primary objective(s) & secondary objective(s)
6. Review of literature
7. Methodology
 - A. Study design, study setting, study period
 - B. Study population/ participants (human, animals or both)
 - a. Inclusion criteria
 - b. Exclusion criteria
 - c. Withdrawal criteria, if any
 - d. Rescue criteria, if applicable (starting symptomatic therapy either to control symptoms of disease or to overcome lack of adequate efficacy of the study drug or placebo)
 - e. Number of groups to be studied, identify groups with definition
 - C. Sampling
 - a. Sampling population
 - b. Sample size calculation
 - c. Sampling technique
 - D. Randomization details (for interventional studies)
 - E. Study procedure,
 - F. Data collection methods including settings and periodicity, outcome measurement
 - G. If clinical trial, whether registration with CTRI will be done
 - H. Are the drugs/devices to be used approved for these indications by Drug Controller General of India (DCG-I)? (Enclose the approval letter for the drug/device from DCG-I for trial on humans or give undertaking to get the approval from DCGI; For all drugs and devices submit documents showing DCGI approval for the proposed indication of the study)
 - I. List of variables and their measurement methods with standardization techniques
 - a. Independent variables
 - b. Outcome variables
 - c. Confounding and interacting variables

- J. List variable wise statistical tests to be used for data analysis
- 8. List risks and benefits of the study
- 9. Relevant references for the project
(Minimum 10, Maximum 20) (in Vancouver style)
- 10. Enclosures
 - A. Brief CV of investigator, co investigators
 - B. Data collection proforma
 - C. Questionnaires
 - D. Consent form
 - E. Other relevant papers

A. Signature of the Principal Investigator
(Name & Designation)

Signature of the co investigators
(Name & Designation, Department,
Seal and Date)

Signature (s) of the co investigators
(Name & Designation, Department,
Seal and Date)

Signature of Head of the Department
of the candidate
(Name & Designation, Department,
Seal and Date)

B. Signature(s) of the Co-investigator from
collaborating department (s)
(Name & Designation, Department,
Seal and Date)

Signature(s) of Head(s) of the Collaborating
department (s)
(Name & Designation, Department,
Seal and Date)

