

**Format for submission of research proposal in IRC (students)**

**SECTION- 1**

**PART A – GENERAL INFORMATION**

1. Title of the Proposal:
2. Name of the student with mobile numbers, email ID:
3. Name of the course studying:
4. Month and Year for appearing in Final Exams for completing the course:
5. Name (s), Designation (s) & Addresses of the guide and co-guide (s) with mobile numbers & email ID:
6. Has the student received any award for research projects — Yes/No:  
(If yes – year and title of the project)
7. State whether it is intradepartmental or interdepartmental:
8. 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 project
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
  - G. If the 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 guide and co-guides
- B. Data collection proforma
- C. Questionnaires
- D. Consent form (English version)
- E. Other relevant papers

11. Undertaking for DCGI approval

12. Declarations by guide

A. 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)

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

B. Signature(s) of the Co-guide 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)

## **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 & designation of guide)

