

Covering letter – Dissertation proposals by MD/MS/M. Ch/DM/MSc/MDS/PhD

From,

Date:

To,
The Member-Secretary,
Clinical Research Ethics Committee,
NSMCH, Bihta, Patna.

Sub: Submission of Research Proposal to Clinical Research Ethics Committee – reg.

Madam,

I am hereby submitting my Research Proposal for approval by the Clinical Research Ethics Committee.

The details of the proposal are as follows:

Title of the proposal :

Name of the PG Student :

PG Year [JR/SR] :

Department :

Session/Year of admission :

Name of the Guide :

Designation of the Guide :

Department :

Submission checklist:

Sr. No.	Formats	Yes/No
1.	Clinical Research Ethics Committee format	
2.	Funding statement/ declaration	
3.	Declaration to conduct the research on ethical principles and guidelines	

Thanking you,
Yours sincerely,

Format

**FOR SUBMITTING PG DISSERTATION PROPOSAL FOR CONSIDERATION BY
CLINICAL RESEARCH ETHICS COMMITTEE**

SECTION- 1

PART A – GENERAL INFORMATION

1. Title of the dissertation :
2. Name of the candidate :
3. Contact & Email ID :
4. Name of the course studying :
5. Session/Year of admission :
6. Month and year of appearing for final examination:
7. Month and year of submitting dissertation:
8. Name (s), Designation (s) & Addresses of the guide and co-guide (s) with mobile numbers and email ID:

Details of Guide				
Name	Designation	Office Address	Mobile Number	Email Address
Details of Co-guide/s (Co-guide is mandatory, you may..)				

9. A. State whether it is intradepartmental or interdepartmental: (Encircle one option)

Intradepartmental / Interdepartmental

- B. If the study is interdepartmental:

- I. State the names of collaborating departments:

- II. State whether consent has been obtained from them:

10. Total funds required for the study (in rupees):

11. Source of funding:

PART B - TECHNICAL DETAILS

1. Title of the dissertation:

2. Introduction:

A. Problem statement

B. Rationale

C. Novelty

D. Expected outcome and application

Research question(s):

3. Research hypothesis (es), if any:

4. Aim and objectives:

Aim:

Objectives:

I. Primary objective(s)

II. Secondary objective(s)

Review of literature: (up to 1000 words):

5. **Methodology:**

A. Study design

B. Study participants

a. Inclusion criteria

b. Exclusion criteria

c. 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

E. Study procedure:

F. Data collection methods including settings and periodicity:

G. PG Thesis registration with **CTRI** number:

H. Are the drugs/ devices to be used approved for these indications by Drug Controller General of India (DCG-I)- **CDSCO ONLINE PORTAL SYSTEM**? (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. Statistical analysis plan:

K. Limitations of Study:

6. List risks and benefits of the study:

7. Plagiarism Check:

8. Budget [Justification of budget to be provided]

9. Relevant references for the project:
(Minimum 10, Maximum 20) (in Vancouver style)

10. Enclosures:

- A. **Data collection proforma**
- B. **Questionnaires**
- C. **Consent form (English and Hindi version)**
- D. **Other relevant papers**

11. Undertaking for DCGI approval: (When?)

12. Declarations by guide: **(Type content of declaration)**

Signature of the candidate (Name & Designation)	
Signature of the Guide (Name & Designation)	
Signature (s) of the Co-guide from the Department (Name & Designation)	
Signature of Head of the Department (Name & Designation)	
Signature (s) of the Co-guide from the Collaborative Department(s) (Name & Designation)	
Signature (s) of the Head from the Collaborative Department(s) (Name & Designation)	

DECLARATION OF ETHICAL CONDUCT IN RESEARCH

Title of the Study:

Name of the Student:

Name of the Department:

Name of the Guide:

Name of the Co-Guide/s:

Departments of the Co-Guide/s:

I (We) hereby declare that, the proposed research study shall be conducted as per the ethical principles and guidelines laid down by ICMR, WHO and ICH-GCP. The identity and the medical and non-medical information of the deceased obtained during the study will be kept confidential and will not be shared in any manner to others except the regulatory authorities like members of CREC (Clinical Research Ethics Committee) etc. The research shall be conducted for academic purpose only. The result (s) of the research may be presented or published in a scientific conference or journal without disclosing the identity of the subject participants.

Signature of the PG student	
Signature of the PG Guide	
Signature of the PG Co - Guide	

Date:

Place: