**YENEPOYA \_\_\_\_\_\_\_\_\_\_\_\_ COLLEGE**

**YENEPOYA (deemed to be UNIVERSITY)**

**MANGALORE, KARNATAKA**



**ACCREDITED BY NAAC WITH GRADE A+**

**PROFORMA FOR REGISTRATION OF**

**ACADEMIC CLINICAL TRIAL/FACULTY RESEARCH/PhD THESIS/**

**PG DISSERTATION/SHORT STUDY**

**PART A: PERSONAL DETAILS**

|  |  |  |
| --- | --- | --- |
|  | Name of the Principal Investigator: |  |
|  | PI’s Designation and Name of the Department and College/Centre | Designation:  Department:  College/Centre:  Employee code/Campus id: |
| 1. 3 | Name of the Course (in case the PI is a student/scholar) |  |
| 1. 4 | Date of admission to course (in case PI is a student/scholar) |  |
| 1. 5 | Contact details of the PI | Valid mobile number:  Active email id: |
| 1. 6 | Name(s) of the PG Guide/Co-guides/Co-investigators/Research team members (with designation, affiliation, phone numbers and email ids) |  |

**PART B: PROJECT DETAILS**

1. **TITLE OF THE RESEARCH TOPIC:**
2. **EXECUTIVE SUMMARY:**
3. **INTRODUCTION & BACKGROUND:**
4. **NEED FOR THE STUDY:**
5. **RESEARCH QUESTION:** 
   1. **RESEARCH QUESTION OR HYPOTHESIS (ALTERNATE/NULL)**
   2. **AIM**
   3. **OBJECTIVES**
6. **REVIEW OF LITERATURE (Please follow Vancouver style of referencing and in-text citation):**
7. **METHODOLOGY:** 
   1. **STUDY DETAILS:** 
      1. **STUDY DESIGN:**
      2. **STUDY SITE:**
      3. **FUNDING DETAILS:**
      4. **STUDY DURATION:**
   2. **PARTICIPANT DETAILS:** 
      1. **SOURCE OF DATA:**
      2. **SAMPLE SIZE:**
      3. **METHOD OF SAMPLING (SAMPLING TECHNIQUE):**
      4. **RANDOMIZATION AND BLINDING (IF ANY):**
      5. **INCLUSION CRITERIA:**
      6. **EXCLUSION CRITERIA**
      7. **WITHDRAWAL CRITERIA**
      8. **DISCONTINUATION CRITERIA**
   3. **STUDY TOOL:** 
      1. **DESCRIPTION (QUESTIONNAIRE; INTERVIEW SCHEDULE; SCALES; SCORES; DATA COLLECTION FORM; PROFORMA; ETC)**
      2. **VALIDATION**
      3. **PRETESTING**
   4. **METHOD:** 
      1. **DETAILS OF THE METHODOLOGY INCLUDING DETAILS OF SAMPLE COLLECTION:**
      2. **DETAILS OF ANALYSIS: (Including statistical tests)**
8. **WORK PLAN (Timeline or Gantt Chart):**
9. **BUDGET:**
10. **ETHICAL ISSUES:**
11. **Ethical guidelines followed:**
12. **Ethical approval:**
13. **Informed consent:**
14. **Vulnerable population:**
15. **Standard of care:**
16. **Harms:**
17. **Benefits:**
18. **Risk-benefit ratio:**
19. **Privacy:**
20. **Confidentiality:**
21. **Requisite permissions/approvals/agreements/MoU/MTA:**
22. **BIOSAFETY ISSUES:**
23. **UTILIZATION OF RESULTS OF RESEARCH & SPECIFIC DELIVERABLES:**
24. **REFERENCES (in Vancouver Style)**
25. **LIST OF ANNEXURES:**
26. **DATA COLLECTION FORM (**Case Record Form, Performa or questionnaire, if any)
27. **PARTICIPANT INFORMATION SHEET/INFORMED CONSENT FORM**

1. **CURRICULUM VITAE OF PG/PI, CO-GUIDE (IF ANY) AND GUIDE**
2. **STATEMENT BY RESEARCHERS ON RESEARCH INTEGRITY**

We do hereby declare that this study titled “\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_”will be carried out by me/us upholding the principles enshrined in the Declaration of Helsinki, and simultaneously abiding by the ICMR’s National Ethical Guidelines for Biomedical and Health Research involving Human Participants (2017)/New Drugs and Clinical Trials Rules, 2019 and Indian GCP (in case of academic clinical trials)

Date: Signature & Name of the PI

Place:

Date: Signatures & Names of all the Co-investigators (guide/co-guide)

Place:

**PART C: RECOMMENDATIONS AND SIGNATURES**

*Part C to be filled in only if the PI is a student or PhD scholar*

|  |  |
| --- | --- |
| Name of the PI (or student) |  |
| Signature of the PI (or student) |  |
| Remarks/recommendations of the co-guide (if any) |  |
| Name & Designation of the Co-Guide (if any) |  |
| Signature of the Co-Guide (if any) |  |
| Remarks/recommendations of the Guide (if any) |  |
| Name & Designation of the Guide |  |
| Signature of the Guide |  |
| Signature (with seal) of the Head of the Department |  |
| Signature (with seal) of the Head of the Institution |  |

**FORMAT FOR COVERING LETTER:**

From,

To,

**The Member-Secretary**

Yenepoya Ethics Committee - 1/2 (strike off whichever is not applicable)

Yenepoya (deemed to be University)

Deralakatte Mangalore 575018 Karnataka India

**Through proper channel**

Subject: Request for ethics committee approval for faculty study/student synopsis/PhD thesis proposal

—-----------------------------------------------------------------------------------------------------------------

Respected Sir/Madam,

I \_\_\_\_\_\_\_\_\_\_\_\_ am conducting a study on **“\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_”** from the Department of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ College.

I am attaching a copy of my synopsis/protocol along with this letter. I request you to kindly grant me approval for this study.

Thanking You,

Yours Sincerely

PI Signature

Date:

Place: Mangalore