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

**YENEPOYA deemed to be UNIVERSITY**

**MANGALORE, KARNATAKA**



**PROFORMA FOR REGISTRATION OF**

**ACADEMIC CLINICAL TRIAL/DISSERTATION/SHORT STUDY**

**PART A: PERSONAL DETAILS**

|  |  |  |  |
| --- | --- | --- | --- |
|  | 1 | Name of the Principal Investigator: (Faculty/ PhD Scholar/ PG/UG/) |  |
|  | 2 | Name of the Department and College |  |
|  | 3 | Name of the Course (in case the PI is a student) |  |
|  | 4 | Date of admission to course (in case PI is a student) |  |
|  |  |  |  |
|  | 5 | Contact details of the PG/PI |  |
|  |  |  |  |
|  | 6 | Name of the PG Guide/Co-guides/Co-investigator/Research team members (with designation and affiliation) |  |

**PART-B: PROJECT DETAILS**

1. TITLE OF THE RESEARCH TOPIC:

2. RESEARCH OBJECTIVE:

HYPOTHESIS:

3. INTRODUCTION & BACKGROUND:

NEED FOR THE STUDY:

4. REVIEW OF LITERATURE (Vancouver style of referencing and in-text citation):

5. STUDY DESIGN AND METHODOLOGY:

A. TYPE OF STUDY:

B. SOURCE OF DATA:

C. STUDY SITE:

D. STUDY DURATION:

E. SAMPLE SIZE:

F. SAMPLING TECHNIQUE:

G. STUDY TOOL:

H. VALIDATION & RELIABILITY TESTING (IF ANY):

I. INCLUSION CRITERIA:

J. EXCLUSION CRITERIA:

K. RANDOMIZATION (IF ANY):

L. DETAILS OF CLINICAL EXAMINATION: (IF ANY)

M. DETAILS OF STUDY QUESTIONNAIRE: (IF ANY)

N. DETAILS OF STATISTICAL ANALYSIS: (IF ANY)

O. DETAILS OF THE METHODOLOGY:

6. WORK PLAN:

7. ETHICAL ISSUES:

8. BIOSAFETY ISSUES:

9. UTILIZATION OF RESULTS OF RESEARCH AND SPECIFIC DELIVERABLES:

10. REFERENCES (in Vancouver Style)

11. PROFORMA (attach pro forma or questionnaire, if any)

12. PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM

(Please attach English and local language versions)

13. CURRICULUM VITAE OF PG/PI, CO-GUIDE (IF ANY) AND GUIDE

**PART C: RECOMMENDATIONS AND SIGNATURES**

|  |  |
| --- | --- |
| Name of the student |  |
| Signature of the 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 |  |

**STATEMENT BY PG/PI ON RESEARCH INTEGRITY**

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_ do hereby declare that this study will be carried out by me under supervision of my guide \_\_\_\_\_\_\_\_\_\_\_\_\_ 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).

Date: Signature & Name of the PI

Place:

**STATEMENT BY PG GUIDE ON RESEARCH INTEGRITY**

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_ postgraduate guide, department of \_\_\_\_\_\_\_\_\_\_, do hereby declare that this study will be carried out by my student, under my direct supervision 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).

Date: Signature & Name of the PI

Place:

**FORMAT FOR COVERING LETTER:**

FROM,

TO,

**THE MEMBER-SECRETARY**

YENEPOYA ETHICS COMMITTEE - 1

YENEPOYA DEEMED TO BE UNIVERSITY

MANGALORE KARNATAKA INDIA

**Through proper channel**

SUB: ETHICAL CLEARANCE FOR SYNOPSIS/DISSERTATION/RESEARCH PROTOCOL

Respected Sir/Madam,

I \_\_\_\_\_\_\_\_\_\_\_\_ am conducting a study as a part of my postgraduate course requirement/eligibility on **“\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_”** under the guidance of \_\_\_\_\_\_\_\_\_\_\_\_ 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 the ethical clearance for this study.

Thanking You,

Yours Sincerely

PI Sign

Date:

Place: MANGALORE