CENTRE FOR RESEARCH AND DEVELOPMENT
INSTITUTIONAL HUMAN ETHICS COMMITTEE

Proposal formats

FORM - A

APPLICATION FOR PERMISSION FOR STUDIES ON HUMAN SUBJECTS

1. Name & Address of the dept :

2. Name & designation of Investigator :

3. Place where study will be conducted :

4. Date of commencement & duration of study :

5. Funding agency / sponsor :

Investigator's Declaration

Certified that

1. The research proposal is not duplicative of previously reported research
2. All investigators working on this proposal are aware of the ICMR ethical guidelines
3. I / we have reviewed the pertinent scientific literature
4. I / we will obtain approval from IEC before initiating any deviation / changes in the study
5. The study shall be initiated only upon review & approval of IEC
6. I /we shall maintain all the records as per format [form B or C]
7. Informed consent will be obtained & confidentiality of the subjects will be maintained

Place:
Date

Chief Investigator:

For Office use only

Proposal number
Date of receipt
Approval date

Date received after revision
Expiry date

Secretary

Chairman

FORM -B

Proforma for routine PG class work (Practical's) involving Human Subjects.

1. Name of the Department :

2. List of practicals and Nature of each practical in brief. (Including Objectives and Methods to be employed) :

3. Specify the method of Subject selection for Practical class work :

   (a) PG Students
   (b) Patients
   (c) Students (from other Institutions.)
   (d) Any other, specify

4. Specify the source of obtaining blood samples :

UNDERTAKING

It is certified that,

Work is conducted purely as part of routine curriculum by PG students.

Signature of the Teacher-in-charge. Chairperson

Mount Carmel (Deemed to be University), Bengaluru

FORM - A

APPLICATION FOR PERMISSION FOR STUDIES ON HUMAN SUBJECTS

	Name & Designation / Qualification	**Address Tel & Fax no Email**	**Signature**
Name of PI/ PhD candidate			
Research Guide			
Co-PI, if any			
Research fellow			
Place where study will be conducted			
Date of commencement & duration of study			
Funding agency / sponsor			

Investigator's Declaration

Certified that

1. The research proposal is not duplicative of previously reported research
2. All investigators working on this proposal are aware of the ICMR ethical guidelines
3. I / we have reviewed the pertinent scientific literature
4. I/we will obtain approval from IEC before initiating any deviation/changes in the study
5. The study shall be initiated only upon review & approval of IEC
6. I /we shall maintain all the records as per format [form B or C]
7. Informed consent will be obtained & confidentiality of the subjects will be maintained

Place:
Date

Chief Investigator

For Office use only

Proposal number
Date of receipt — Date received after revision
Approval date — Expiry date

Secretary — Chairman

MOUNT CARMEL (Deemed to be UNIVERSITY),
Bengaluru
INSTITUTIONAL HUMAN ETHICS COMMITTEE
(IHEC)

FORM – C

Proforma for submission to Institutional Ethical Committee, for undertaking studies involving human subjects

1. **Title:**

Tick one : PhD ☐ Sponsored project ☐ PG dissertation ☐

2. Details of Investigating Team :

	Name & Designation / Qualification	**Dept. Address Tel & Fax no Email**	**Signature**
Investigator			
Research Guide			
Any Others			
Name of sponsor			
Expertise of the investigating team			

3. Type of Study : Epidemiological ☐ Basic Sciences ☐ Survey ☐

Clinical: Single center ☐ Multicentric ☐ Behavioral ☐

(b) Data Collection: From Records ☐

Using Questionnaire ☐

(c) Any other, specify:

4. Duration of the study :
Probable date of initiation :
Completion :

5. Pre-clinical studies done, if any :
(in brief)
Publications, if any :

Note: It is compulsory to provide all the required information, incomplete applications will be rejected.

6. **Study design**
[Brief description of the proposal – Introduction, aim (s) & objectives, justification for study, methodology describing number of subjects, Inclusion / exclusion criteria, dosages of drug, duration of treatment, potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale. Attach sheet with maximum 500 words. **See page 4 for more details**]

7. Will any advertising be done for recruitment of Subjects?
(posters, flyers, brochure, websites – if so kindly attach a copy)

8. Does the study involve
(a) Anthropometric Measurements : Yes / No
(b) Blood samples : Yes / No
(c) Urine analysis : Yes / No
(d) Lifestyle modification : Yes / No
(e) Other (specify).

If answer is Yes to (b) & (c) mention the tests

9. **Intervention Studies**- Oral
(a) Product evaluation : Yes / No
(b) Dietary : Yes / No
(c) Synthetic : Yes / No
If Yes, is toxicological evaluation carried out.
(d) Known medication : Yes / No
If yes, give a brief summary of dosage, administration, Contra indications (if any)

10. Use of biological/hazardous material : Yes ☐ No ☐
(If the answer is Yes, give details)

11. **Consent :** Written ☐ Oral ☐
i. Subject consent form - enclose
ii. Who will obtain consent? PI/Co-PI ☐ Nurse/Counsellor ☐
Research staff ☐ Any other ☐

12. Risks & Benefits:
i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country? Yes ☐ No ☐
ii. Is there physical / social / psychological risk / discomfort? Yes ☐ No ☐
iii. Is there a benefit
a) to the subject? Direct ☐ Indirect ☐
b) Benefit to society Direct ☐ Indirect ☐
if yes, explain

13. i. Are the subjects remunerated for their involvement in the research? Yes ☐ No ☐
ii. If yes, is this remuneration provided irrespective of their social and economic conditions?
iii. Compensation for travel, Specify amount and type:

14. Data Monitoring i. Is there a data & safety monitoring committee ii. Is there a plan for reporting of adverse events? **If Yes,** reporting is done to: Sponsor ☐ Ethics Committee ☐
15. Is there any conflict of interest? (financial/non-financial) If Yes, specify:

(Signature, Name & Designation of the Applicant)

Place:

Date:

Checklist for attached documents:

1. Form A- 1 copy
2. Project proposal – 2 Copies (Form B or C as applicable)
3. Informed Consent form -1 copy
4. Investigator's brochure for recruiting subjects if any
5. Advertisements /Information brochures
6. Copy of clinical trial protocol and/or Questionnaire
7. Ph. D Registration confirmation letter
8. Project sanction copy

Note: one copy of each of Items 4, 5 & 6 to be attached only if applicable to the study.