KARNATAKA STATE OPEN UNIVERSITY

APPLICATION FOR PERMISSION FOR STUDIES ON HUMAN SUBJECTS

1. Name & Address of the department:

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

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

Date:

Place: Chief Investigator

For Office use only

Proposal number

Date of receipt Date received after revision

Approval date Expiry date

Secretary Chairman

KARNATAKA STATE OPEN UNIVERSITY

FORM-A

APPLICATION FOR PERMISSION FOR STUDIES ON HUMAN SUBJECT

	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

KARNATAKA STATE OPEN UNIVERSITY

FORM-B

Proforma for routine PG class work (Practicals) involving Human Subjects.

1. Name of the Department:
2. List of Practicals and Nature of each practical in brief:
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

KARNATAKA STATE OPEN UNIVERSITY

INSTITUTIONAL HUMAN ETHICAL COMMITTEE (IHEC)

FORM – C

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 centre Multicentric Behavioural

(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]

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)

Checklist for attached documents:

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