

<u>APPLICATION FOR PERMISSION FOR STUDIES ON HUMAN SUBJECTS</u>

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 I Certified that 1. The research proposal is not duplicative of pr 2. All investigators working on this proposal are 3. I / we have reviewed the pertinent scientific I: 4. I / we will obtain approval from IEC before in study 5. The study shall be initiated only upon review 6. I /we shall maintain all the records as per form 7. Informed consent will be obtained & confident maintained Place: Date Investigator For Office use only	reviously reported research e aware of the ICMR ethical guidelines iterature nitiating any deviation / changes in the & approval of IEC mat [form B or C]
Proposal number	
Date of receipt	Date received after revision
Approval date	Expiry date
Secretary	Chairman



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. (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	:
<u>UN</u>	DERTAKING
It is certified that,	
Work is conducted purely as part of a	coutine curriculum by PG students.
Signature of the Teacher-in-charge.	Chairperson

UNIVERSITY OF MYSORE 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

Secretary

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Ι.	. The research	- DEODOSAL IS HOL	. uui	nicative v	o	vious	iv ichonicu	Hoscaron

- 2. All investigators working on this proposal are aware of the ICMR ethical guidelines

3. I / we have reviewed the pertinent scientific	c literature			
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 & confid	dentiality of the subjects will be maintained			
Place:				
Date				
	Chief Investigator			
For Office use only				
Dronogal number				
Proposal number	Data massived often marrial an			
Date of receipt	Date received after revision			
Approval date	Expiry date			

Chairman

UNIVERSITY OF MYSORE

INSTITUTIONAL HUMAN ETHICAL 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 Investiga	ting Team :				
	Name &	Dept. Address			
	Designation /	Tel & Fax no	Signature		
	Qualification	Email			
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)
(posters, rijers, croentare, wecomes in so initiary action in copy)
8. Does the study involve
(a) Anthropometric Measurements : Yes / No
(b) Blood samples : Yes / No
(d) Lifestyle modification : Yes / No
(e) Other (specify).
If answer is Yes to (b) & (c) mention the tests
9. Intervention Studies- Oral
(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 Yes No
to subjects / community / country?
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 L Ethics Committee L
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 each of Items 4, 5 & 6 to be attached only if applicable to the study.