IEC APPLICATION FORM

To

The Member Secretary,

IEC, M.K.C.G. Medical College,

Berhampur.

(for IEC office use only)
Date of Receipt by IEC: _____ Sl. No.: _____
Date of Amendments suggested by IEC: _____
Depts.: _____
Date of resubmission to IEC: _____
Date of approved by IEC: _____ Approval No.: _____

APPLICATION FORM FOR PERMISSION OF RESEARCH PROJECT / DISSERTATION.

Title of the project (in Capital Letters**)**

_____
_____
_____
_____

	Name	**Designation**	**Dept. & Inst.**
Principal Investigator (in Capital Letter)			
Co-Investigator (in Capital Letter)			
Guide (in Capital Letter)			
Duration of Study			
Place of study			

Non-sponsored study □ **Sponsored study** □

If Non-Sponsored Study
Thesis/dissertation □ ICMR student ship □ Other Academic □
Please mention approx. date of completion (month & year)_____

If Sponsored study whether
1. Indian □ a) Government □ b) Industry □ c) Institutional □
2. International □ a) Government □ b) Private □ c) UN agencies □
3. Industry □

Address of Sponsor:

Total Budget : Rs._____
Research Fund will be deposited in (please specify)_____
Please give details of allocation of budget in attachment.

1.Type of Study :
Prospective □ Retrospective □
Single center □ Multicentric □ If multicentric, how many centres _____

2. Does the study involve use of : Drug / Vaccine □ Device □ Alternative Medicine □
Any other □ Not Applicable □ If other, please specify _____

i) Is the test drug / device marketed in India **Yes** □ **No** □
Is it marketed in other countries: **Yes** □ **No** □ Specify _____
If **marketed** in India, please **attach package insert**
If **not marketed** in India, please **attach Drugs Controller General (India) [DCG(I)]permission**.

ii) Is the test drug an Investigational New Drug (IND)? Yes □ **No** □
If yes, please submit Investigator's Brochure which contains data of pre-clinical studies.
If IND, please also attach DCG(I) permission.

iii) Does the test drug involve a change in use, dosage, route of administration? **Yes** □ **No** □
If yes, please attach copy of DCG(I) permission.

3. Clinical Trial is : Phase I □ Phase II □ Phase III □ Phase IV □

4. Subject selection:
i) Number of subjects at this centre If multicentric, total number of subjects

ii) Vulnerable subjects Yes □ No □ ***(If yes, tick the appropriate boxes)***
pregnant women □ children □ elderly □ fetus □ illiterate □
handicapped □ seriously/terminally ill □ mentally challenged □
economically/socially backward □ any other □
If other, please specify_____

iii) Special group subjects Yes □ No □ ***(If yes, tick the appropriate boxes)***
employees □ students □ nurses/dependent staff □ any other □
If other, please specify _____

5. Does the study involve use of		
i) fetal tissue or abortus	Yes	No
ii) organs or body fluids	Yes	No
iii) recombinant/gene therapy If yes, please submit a copy of Genetic Engineering Advisory Committee (GEAC) permission.	Yes	No
iv) ionising radiation/radioisotopes If yes, please submit a copy of Bhaba Atomic Research Centre (BARC) permission.	Yes	No
v) infectious / biohazardous specimens	Yes	No
vi) Will pre-existing/stored/left over samples be used?	Yes	No
vii) Will samples be collected for banking/future research	Yes	No
viii) Will any sample collected from patient be sent abroad? If yes, please submit a copy of Director General of Foreign Trade (DGFT) permission.	Yes	No
ix) Is there any collaboration with any foreign lab., clinic, hospital or any other Institution? If yes, please submit a copy of Health Ministry Screening Committee (HMSC) approval.	Yes	No
6. Will any advertising be done for recruitment of Subjects? (Posters, flyers, brochures, etc.) If yes, kindly attach a copy for IEC review.	Yes	No
7. Data Monitoring i) Is there a Data & Safety Monitoring Board / Committee (DSMB) ?	Yes	No
ii) Is there a plan for interim analysis of data?	Yes	No
iii)For how long will the trial data be stored? _____years		

8. Is there compensation for participation? If Yes, Monetary □ In kind □ Specify amount / type: _____	Yes	No
9. Are there any arrangements for compensation of trial related injury? **Yes** □ **No** □ Please submit a copy of the insurance policy if it is available.		

We hereby declare the information given above is true and that we do not have any financial or non - financial conflict of interest.

Signature of Principal Investigator / U.G / P.G. Student with date

Signatures of Co- investigators with date

Forwarded by Heads of Department(s)
(Stamp/Seal of the Department(s) with date)

Check List of Documents

Sl. No.	Document	Status		Page No.
		Yes	No	
1	IEC application form			
2	Summary of protocol			
3	Protocol			
4	Amendments to protocol			
5	Informed consent document in English			
6	Informed consent documents in Regional languages (Total No.:)			
7	Back translations of Informed consent documents			
8	Amendments to the informed consent document			
9	Case Record Form / Questionnaire			
10	Principal investigators Current Curriculum Vitae			
11	Subject recruitment procedures: advertisement, letters to doctors, notices			
12	Investigator Brochure			
13	Approval letter from relevant local hospital (medical, administrative) management that the trial site has adequate facilities, including laboratories, equipments and sufficient medical, paramedical, and clerical staff to support the trial and to deal with all reasonable foreseeable emergencies in compliance with existing regulations.(As per World Health Organization WHO Technical Report Series, No. 850, 1995, Annex 3 Guidelines for good clinical practice (GCP) for trials on pharmaceutical products)			
14	Ethics Committee clearance of other centers (Total No.)			
15	Insurance policy			
16	Drugs Controller General (India) [DCG(I)] clearance			
17	Investigator's agreement with sponsor			
18	Investigator's undertaking to DCG(I)			
19	Health Ministry Screening Committee (HMSC)approval			
20	Bhabha Atomic Research Centre (BARC) approval			
21	Genetic Engineering Advisory Committee (GEAC)approval			
22	Director General of Foreign Trade (DGFT) approval			
23	FDA marketing/manufacturing license for herbal drugs.			
24	Other Documents			