FORMAT FOR SUBMISSION OF PROTOCOL INVOLVING RESEARCH IN HUMAN SUBJECTS FOR CLEARANCE BY ETHICS SUB-COMMITTEE AND COMMITTEE OF AIIMS FOR DM / M.Ch / Ph.D/ MD / MS / MHA / M.Sc / M.Biotech. STUDENTS (FOR THESIS OR DISSERTATION)

12 copies of the Research Project along with Covering letter, copy of protocol and 'soft copy' on CD with following information be submitted to the Member Secretary, Ethics Sub-committee at Room No. 102/108, 1st Floor, Old OT Block, AIIMS, Tel No.4579. The submission must be accompanied by informed consent and Patient Information Sheet in both English and Hindi before it can be considered for placing for the Committee. The format is also available at www.aiims.edu / www.aiims.ac.in

The research projects proposal submitted should be as follows:

1. Full Title of Study:	
2. Name of Candidate / Department	_____ Signature_____
Please Specify the degree	M.Sc / M.Biotech / MD / MS / MHA /Ph.D / DM / MCh
3. Name of Faculty (Guide/Co-guide) (with designation & department) 3.1_____ 3.2 _____ 3.3 _____ 3.4 _____ 3.5_____ (Expand if any more co-guides)	Signatures (Should preferably be signed by at least two guides / co-guides) 3.1_____ 3.2 _____ 3.3 _____ 3.4 _____ 3.5_____
4. Objectives of the study	4.1_____ 4.2_____ 4.3_____ 4.4_____ 4.5_____

5. Justification for the conduct of the study	
6. Methodology	6.1. Number of Patients: 6.2. Inclusion criteria a)_____ b)_____ c)_____ d)_____ 6.3. Exclusion criteria a)_____ b)_____ c)_____ d)_____ 6.4. Control(s) 6.5. Study design 6.6. Dosages of drug 6.7. Duration of treatment 6.8. Investigation 6.9. Others
7. Permission from Drug Controller General of India (DCGI)	1. ☐ Required 2. ☐ Not required 3. ☐ Received 4. ☐ Applied when:_____
8. Permission from DGFT if applicable	1. ☐ Required 2. ☐ Not required 3. ☐ Received 4. ☐ Applied when:_____
9. a) Safety measures for proposed interventions b) Results of relevant laboratory tests c) Result of studies in human	a)_____ b)_____ c)_____
10. Plans to withdraw standard therapy During conduct of research	☐ Yes ☐ No Remarks:_____
11. Plan for provision of coverage for medical risk during the study period	

12. How you will maintain confidentiality of subject?	
13. **Costs Involved (Appx. in Rs.)** 13.1 Investigations 13.2 Disposables 13.3 Implants 13.4 Drugs / Contrast Media **Who will bear the costs of the requirements?**	 13.1_____ 13.2_____ 13.3_____ 13.4_____ 1.☐ Patient 2.☐ Project 3. ☐ Exempted 4.☐ Other Agencies (Name)_____

13. Patient Information Sheet (PIS)/ Informed Consent Form (ICF): The project must be accompanied by the Patient Information Sheet addressed to patient. The Informed Consent Form to be used in the study should be signed by two witness. While formulating the patient information sheet, investigator must provide the subjects with the following information in simple language, which can be understood by them both in English and Hindi:

i) Aims and methods of the research
ii) Expected duration of the subject participation
iii) The benefits to be expected from the research to the subject or to others
iv) Any risk to the subject associated with the study
v) Maintenance of confidentiality of records
vi) Provision of free treatment for research related injury
vii) Compensation of subjects for disability or death resulting from such injury
viii) Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.
ix) Amount of blood sample or any other tissues an quantity to be taken should be mentioned in PIS in ml
x) Costs and source of investigations, disposables, implants and drugs / contrast media must be mentioned in the PIS.
xi) Telephone number/contact number of the candidate and one of the investigator must be mentioned in the PIS at the top of the page.
xii) In case of the drug trials:
    a. The chemical name of the drug, date of its manufacturing and batch number must be mentioned.
    b. Initial Bio-equivalent study of the drug/references should be avoided.
xiii) Informed Consent Form should state that the patient has been informed about the study and agrees to a part of the study. It should have space for signatures by patient, doctors and two witnesses (Annexure 1)

(Students are requested to prepare the translation in simple Hindi on their own for both PIS and ICF should be enclosed herewith)

14.Attached documents (If any)	14.1_____ 14.2_____ 14.3_____ 14.4_____

Six monthly progress reports to be sent to the Dean's office as given in the Annexure 2

INFORMED CONSENT FORM **Annexure-I**

Protocol / Study number:_____
Patient identification number for this trial: _____
Title of project:_____
Name of Principal Investigator: _____Tel.No(s)._____

The contents of the information sheet dated …….. (Version)…….. that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

The nature and purpose of the study and its potential risks / benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from …… (Company name) or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

---------- Date:
(Signature / Left Thumb Impression) Place:

Name of the Participant: _____
Son / Daughter / Spouse of:_____
Complete postal address: _____

This is to certify that the above consent has been obtained in my presence.

Signature of the Principal Investigator Date:
Place:

1) Witness – 1

Signature

Name:
Address:

2) Witness – 2

Signature

Name:
Address:

NB Three copies should be made, for (1) patient, (2) researcher, (2) Institution

Six monthly progress of Project **Annexure-II**

1st

Progress:
Side Effect if any:
Amendments if any:
Discontinuation reasons:
Data Safety Monitoring Committee Report:

2nd

Progress:
Side Effect if any:
Amendments if any:
Discontinuation reasons:
Data Safety Monitoring Committee Report:

3rd

Progress:
Side Effect if any:
Amendments if any:
Discontinuation reasons:
Data Safety Monitoring Committee Report:

4th

Progress:
Side Effect if any:
Amendments if any:
Discontinuation reasons:
Data Safety Monitoring Committee Report:

5th

Progress:
Side Effect if any:
Amendments if any:
Discontinuation reasons:
Data Safety Monitoring Committee Report:

6th

Progress:
Side Effect if any:
Amendments if any:
Discontinuation reasons:
Data Safety Monitoring Committee Report: