FORMAT FOR SUBMISSION OF PROJECTS INVOLVING RESEARCH IN HUMAN SUBJECTS FOR CLEARANCE BY ETHICS COMMITTEE OF AIIMS

10 copies of the Research Project along with Covering letter and 'soft copy' on CD with the following information to be submitted to the Member Secretary, Ethics Committee at Room No. 102/108, 1st Floor, Old OT Block, AIIMS, Tel No**.4579.** The Principle Investigator must submit protocol written by him through Head of Department who ensures that the project has been wetted both from the scientific and ethical point of view. .
The submission must be accompanied with Informed Consent and Patient Information Sheet in both English and Hindi,(See AIIMS website at www.aiims.ac.in for details / proforma).

Project Submission Time: Submissions will be received on all days. Proposals received till 15th of any month will be processed in the coming Ethics Committee meeting and those received after 15th will be processed in the next Ethics Committee meeting. All meetings of Ethics Committee will be held on first Monday of Jan, Feb, March, April, August, September, October, November and those of ethics Sub Committee on the immediately preceding Friday of the above dates.

The research projects proposal submitted should be as follows:

1. Full Title of Study:		
2. Name of Investigators / co-investigators (permanent AIIMS Staff) with designation and departments 2.1_____ 2.2 _____ 2.3 _____ 2.4 _____ 2.5_____ (Expand if more co-investigators)	Signatures 2.1_____ 2.2 _____ 2.3 _____ 2.4 _____ 2.5_____	No. of projects already with investigator
3. Objectives of the study	3.1_____ 3.2_____ 3.3_____ 3.4_____ 3.5_____	
4. Justification for conduct of this study		

5. Methodology	5.1. Number of Patients: 5.2. Inclusion criteria a)_____ b)_____ c)_____ d)_____ 5.3. Exclusion criteria a)_____ b)_____ c)_____ d)_____ 5.4. Control(s) _____ 5.5. Study design _____ 5.6. Dosages of drug _____ 5.7. Duration of treatment _____ 5.8. Investigation _____ 5.9. Others _____
6. Permission from Drug Controller General of India (DCGI)	1. ☐ Required 2. ☐ Not required 3. ☐ Received 4. ☐ Applied when:_____
7. Permission from DGFT if applicable	1. ☐ Required 2. ☐ Not required 3. ☐ Received 4. ☐ Applied when:_____
8. a) Safety measures for proposed interventions b) Results of relevant laboratory tests c) Result of studies in human	a)_____ b)_____ c)_____
9. Plans to withdraw standard therapy during conduct of research	☐ Yes ☐ No Remarks:_____
10. Plan for provision of coverage for medical risk (s) during the study period	
11. How you will maintain confidentiality of subject?	
12. **Total Budget (Approx. in Rs.)** Who will bear the cost of investigation / implants drugs / contrasts?	1.☐ Patient 2.☐ Project 3. ☐ Exempted 4.☐ Other Agencies (Name)_____

13. Patient Information Sheet (PIS)): The project must be accompanied by the Patient Information Sheet addressed to the patient. While formulating the patient information sheet, investigator must provide the subjects with the following information in a simple language, which can be understood by them 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 in quantity in ml to be taken should be mentioned
x) Costs and source of investigations, disposables, implants and drugs / contrast media must be mentioned.
xi) Telephone number/contact number of Principle Investigator and Co investigator at the top of each page.
xii) In case of drug trials:
    a) The chemical name of the drug, name of the manufacturer, date of its manufacturing and expiry and batch number must be mentioned
    b) Initial Bio equivalent study of the drug / references should be provided

Consent Form

The Informed Consent Form to be used in the study should be signed by two witnesses. The consent form should state that the patient has been informed about the study and agrees to be a part of the study. There should be a certification by PI stating that the Hindi version is reasonably accurate of the English version It should have space for signature by patients, doctor and two witnesses (Appendix 1).

13.Attached documents (If any)	13.1 Brief CV of Investigators (including No. of projects with him) 13.2 Investigator's Brochure 13.3_____ 13.4_____
Conflict of interest for any other investigator(s) (if yes, please explain in brief	1. _____ ☐ Yes ☐ No 2. _____ ☐ Yes ☐ No 3. _____ ☐ Yes ☐ No 4. _____ ☐ Yes ☐ No

INFORMED CONSENT FORM

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

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: