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 ósoft copyô on CD with the following information to be submitted to the Member Secretary, Ethics Committee at Room No. 102, 1st Floor, Old OT Block, AIIMS, Tel No**.4579.** The Principle Investigator must submit protocol written by him through Head of Department. The submission must be accompanied with Informal Consent and Patient Information Sheet in both English and Hindi before it can be considered for placing before the Ethics Committee.

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)_____ 6.4. 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** *(mark √ if yes)*	☐ **English** ☐ **Hindi** ☐ *Certified that Hindi version is a true translation of English version*
14. 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
15. Whether any work on this project has started or not?	☐ *(mark √ if yes, X if no)* *(Please enclose a separate certificate to this effect).*
16.Attached documents (If any)	16.1 Brief CV of Investigators (including No. of projects with him) 16.2 Investigatorôs Brochure 16.3_____ 16.4_____