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

Submit fifteen (15) copies of the Research Project along with Covering letter and 'soft copy' on CD with the following information to the Member Secretary, Institution Ethics Committee at Room No. 102, 1st Floor, Old OT Block, AIIMS, Tel No.**4579.** The Principle Investigator must submit protocol through Head of Department.

No research project shall be / can be started unless ethics clearance/approval is obtained. Please bear in mind that no retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor wetted by the Institution Ethics Committee.

All submissions should be made in the prescribed Format of the **Institution Ethics Committee** with signatures of all the investigators. The submission must be accompanied with *Participant Informed Consent Form* (PICF) and *Participant Information Sheet* (PIS), both in English and Hindi, in an **understandable layman's language** before it can be considered for placing before the Institution Ethics Committee. Also ensure that all the pages are numbered.

Project Submission Time: Submissions will be received on all days. Proposals received till 15th of any month will be processed in the coming Institution Ethics Committee meeting and those received after 15th will be processed in the next Institution Ethics Committee meeting. All meetings of Institution Ethics Committee will be held as far as possible on first Monday of Jan, Feb, March, April, May, June, July, August, September, October, November, and December.

While submitting replies raised by the Institution Ethics Committee, the candidates are advised to mention the Institution Ethics Committee reference number/s and also attach a copy of the comments of the Institution Ethic Committee. Moreover if the approval is required in a particular format, the same may be submitted in a CD.

Amendment Submission: While submitting amendments in protocols a covering letter should be provided clearly stating the changes in a tabulated form and a certificate by the PI that the changes made in the protocol will not hamper the safety of the subject in anyway.

The research projects / proposal submitted should be as follows:

1. Full Title of Study:		
1a. AIIMS Temporary Research Section Number for all clinical trials which are privately funded		
2. Name of Investigators / co-investigators (permanent AIIMS Staff) with designation and departments	Signatures	No. of projects already with investigator
2.1_____	2.1_____	_____
2.2 _____	2.2 _____	_____
2.3 _____	2.3 _____	_____
2.4 _____	2.4 _____	_____

2.5_____ (Expand if more co-investigators)	2.5_____
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 specifically related to projects_____ 5.9 Permission to use copyrighted Questionnaire/proforma 5.10. 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. ☐ roject 3. ☐ xempted 4. ☐ Other Agencies (Name)_____
13. Participant Information Sheet *(mark √ if yes)*	☐ Attached English version ☐ Attached Hindi version ☐ *Certified that Hindi version is a true translation of English version*
14. **Participant Informed Consent Form** *(mark √ if yes)*	☐ Attached English version ☐ Attached Hindi version ☐ *Certified that Hindi version is a true translation of English version*
15. 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
16. Whether any work on this project has started or not?	☐ *(mark √ if yes, X if no)* *(Please enclose a separate certificate to this effect).*
17.Attached documents (If any)	17.1 Covering letter, through proper channel. 17.2 Copy of the detailed protocol is mandatory. 17.3 Brief CV of Investigators (including No. of projects with Principal Investigator) 17.4 Investigator's Brochure 17.5 Undertaking that the study shall be done in accordance with ICMR and GCP guidelines 17.6 In case of multicentric study, IEC clearance of other centres must be provided 17.7 Definite undertaking as to who will bear the expenditure of injury related to the project 17.8 In case an insurance cover is intended, Insurance certificate must be provided (as per ICMR guidelines) 17.9 Permission as mentioned in column 5.9 17.10 Certificate/undertaking as mentioned in column 16 17.11 Investigator should provide undertaking what they will do with the leftover sample tissue. 17.12 Others
18. In case of clinical trials CTRI status	