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

You are required to submit your research project online through Ethics Committee Web Portal, the link of which can be found at AIIMS website at 'Main Menu Bar'.
In addition you should submit one (1) hard copy of the Research Project in original along with Covering letter to the Member-Secretary, Institute Ethics Committee at Room No. 102, 1st Floor, Old OT Block, AIIMS, Tel No. 4579.

The documents should be submitted in PDF format only. The complete list of documents you need to submit is available at the Web Portal.

Through the online submission system, you can:

1. **Submit a fresh project**
2. **Revise the project.**
3. **Amend already approved project.**
4. **Track status of your submitted project.**

The Principal Investigator must submit the protocol forwarded by Head of The Department.

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

All submissions should be made in the prescribed Format of the **Institute Ethics Committee** with signatures of all the investigators on the hard copy. The submission must be accompanied with *Participant Informed Consent Form* (PICF) and *Participant Information Sheet* (PIS), both in English and Hindi, **in a simple layman's language, in a narrative form, directed to Participant /LAR, covering all the points given on the website,** before it can be considered for placing before the Institute Ethics Committee. 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 Institute Ethics Committee meeting and those received after 15th will be processed in the next Institute Ethics Committee meeting. All meetings of Institute Ethics Committee will be held as far as possible on first Friday of Jan, Feb, March, April, May, June, July, August, September, October, November, and December.

Reply Submission: The replies to the comments raised by the Institute Ethics Committee, should be submitted online. In addition a hard copy may be sent for records. And if suggested by the Institute Ethics Committee, a complete modified protocol should be submitted.

Amendment Submission: While submitting amendments in protocols a covering letter, through Chief guide, should be provided clearly stating the changes. And if suggested by the Institute Ethics Committee a complete modified protocol should be submitted.

Institute Ethics Committee Format for Projects:

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 2.1_____ 2.2 _____ 2.3 _____ 2.4 _____ 2.5_____ (Expand if more co-investigators) 2.6 Email ID of the Principal Investigator	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 specifically related to projects_____ 5.9 Permission to use copyrighted Questionnaire/Performa 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?	12.1_____ 1. ☐ Patient 2. ☐ Project 3. ☐ Exempted 4. ☐ Other Agencies (Name)
13. Participant Information Sheet **(mark √ if yes)**	☐ English ☐ Hindi ☐ Certified that Hindi versions is a true translation of English version
14. Participant Informed Consent Form **(mark √ if yes)**	☐ English ☐ Hindi ☐ Certified that Hindi versions 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 not more than two pages (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 centers 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 17.11 Investigator should provide dated undertaking what they will do with the leftover sample tissue 17.12 Others
18. In case of clinical trials CTRI status	