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

Submit six (6) copies of the Research Project 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 also be submitted in a soft copy in two PDF files separately on a single CD containing the following in SEQUENCE:**

PDF 1 (Signed copies):

1. Covering letter (through the Head of Department)
2. First or signed page/s of the Format
3. Undertaking that the work has not started and that the work will be done as per ICMR/GCP guidelines
4. Undertaking that the scales/questionnaires/scores to be used are not copyrighted or permission to use them has been obtained
5. Any other signed document/s
6. Dully filled application in the Institute Ethics Committee Format
7. Project proposal
8. PIS & PICF in English & Hindi
9. Short CV of PI & Co-PI. The CV should not exceed 2 pages
10. All the Undertakings.
11. Undertaking for Biosafety Clearance and left over samples if applicable.

PDF 2:

1. Duly filled format of Ethics Committee except signed first page/s
2. All relevant Participant Information Sheets in English and Hindi
3. All relevant Participant Informed Consent Forms in English and Hindi
4. Copy of the Research Project
5. Detailed budget
6. Any other relevant annexures

Please also submit your all the documents by e-mail at Institute Ethics Committee mail i.e. ethicscommitteeaiims@gmail.com.

The Principal 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 Institute Ethics Committee.

All submissions should be made in the prescribed Format of the **Institute 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 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. 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 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 Monday of Jan, Feb, March, April, May, June, July, August, September, October, November, and December.

While submitting replies raised by the Institute Ethics Committee, the candidates are advised to mention the Institute Ethics Committee reference number/s and also attach a copy of the comments of the Institute 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 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 2.1_____ 2.2 _____ 2.3 _____ 2.4 _____ 2.5_____ (Expand if more co-investigators) 2.6 Email ID of the Principal Investigator	Signatures No. of projects already with investigator 2.1_____ 2.2 _____ 2.3 _____ 2.4 _____ 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. ☐ Project 3. ☐ Exempted 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 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 16 17.11 Investigator should provide undertaking what they will do with the leftover sample tissue 17.12 **Soft copy of all the documents in PDF in a two separate files (signed & unsigned) on a single CD** 17.13 Others
18. In case of clinical trials CTRI status	