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

You are required to submit your research project through email and hard copy of the Research Project in original along with Covering letter to the Member-Secretary, Institute Ethics Committee at Room No. 328, Block I, Department of Biochemical Engineering, IIT Delhi. Internal telephone: 1057.
Email: elangovan@dbeb.iitd.ac.in.

- Hard copy will be used for record and soft copy will be used for all review process.
- All soft copy should be summited in PDF format only
- Check list of documents to be submitted for each application
    a) Institute ethics application form (dually signed by all investigators)
    b) Covering letter forwarded through department/center head
    c) Complete research proposal (Justification, methodology, safety, confidentiality and budget)
    d) 2-3 ppt slides (Overview of study, methods flow chart and other details)
    e) Patient information sheet (English & Hindi)
    f) Patient informed consent sheet (English & Hindi)
    g) CV of all the investigators
    h) Investigators brochure (infrastructure available)
    i) Undertaking that the study will done in accordance with ICMR and GCP guidelines
    j) Undertaking of who will bear the expenditure in case of injury related to study
    k) In case of multicentric study, IEC clearance of other centers must be provided
    l) Investigator should provide dated undertaking what they will do with the leftover sample tissue
    m) Other documents as applicable

The Principal Investigator must submit the protocol forwarded by Head of The Department. All submissions should be made in the prescribed Format of the **Institute Ethics Committee** with signatures of all the investigators on the hard copy. All the pages must be numbered. 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. 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.

Institute Ethics Committee Format for Projects:

<table>
<tr><td>1. Full Title of Study:</td><td colspan="2"></td></tr>
<tr><td>1a. Temporary Research Section Number for all Clinical Trials which are privately funded</td><td colspan="2"></td></tr>
<tr><td>2. Name of Investigators / co- investigators (permanent IITD 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</td><td>Signatures

2.1_____
2.2 _____
2.3 _____
2.4 _____
2.5_____</td><td>No. of projects already with investigator</td></tr>
<tr><td>3. Objectives of the study</td><td colspan="2">3.1_____
3.2_____
3.3_____
3.4_____
3.5_____</td></tr>
<tr><td>4. Justification for conduct of this study</td><td colspan="2"></td></tr>
<tr><td>5. Methodology</td><td colspan="2">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 _____</td></tr>
</table>

	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
14. Participant Informed Consent Form **(mark √ if yes)**	☐ English ☐ Hindi
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 (facility available)

	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 Investigator should provide dated undertaking what they will do with the leftover sample tissue 17.11 Others
18. In case of clinical trials CTRI status	

(Form to be submitted to : Dr. Ravi Elangovan, DBEB, IIT Delhi)