INDIRA GANDHI INSTITUTE OF MEDICAL SCIENCES
SHEIKHPURA, PATNA - 800014

FORMAT FOR SUBMISSION OF PROTOCOL INVOLVING RESEARCH IN HUMAN SUBJECTS FOR CLEARANCE BY INSTITUTE ETHICS SUB-COMMITTEE OF IGIMS FOR DM /M.Ch/ MD / MS / MHA / MDS /M.Sc / M. Biotech./MBBS AND Ph.D STUDENTS (FOR THESIS OR DISSERTATION)

- Submit fourteen (14) copies of the Research Project along with Covering letter and 'soft copy' on CD with following information to the Member Secretary, Institute Ethics Sub-Committee IGIMS**.** The Investigator must submit protocol through Chief Guide and Head of Department who ensures that the project has been wetted both from the scientific and ethical point of view.

- 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 ethics committee.

- All submissions should be made in the prescribed Format of the **Institute Ethics Sub-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**. Also ensure that all the pages are numbered.

- **Project Submission Time**: Submissions will be received on all working days. Proposals received till 15th of any month will be processed in the coming Institute Ethics Sub-Committee meetings and those received after 15th will be processed in the next Institute Sub-Committee meetings.

- Next meetings of Institute Ethics Sub-Committee on the first Monday in the month of February.

- While submitting replies raised by the Sub-Committee, the candidates are advised to mention the Institute Ethics Committee/Sub-Committee reference number/s and also attach a copy of the comments of the Institute Ethic Committee/Sub-Committee.

- It is desirable that topics pertaining to clinical/drug trials should be avoided as thesis topics to Ph.D / DM / M.Ch / MD / MS / MHA / MDS / M.Sc. / M.Biotech and MBBS students. In case these are given, appropriate DCGI permission should be available.

- **Reply Submission**: While submitting reply raised by the Sub-Committee, the Investigators are advised to submit these through Chief-Guide. They should also mention the Sub-Committee Reference number/s and also attach a copy of the comments of the Sub-Committee. These changes should be incorporated as a soft copy in the CD.

- **Amendment Submission:** While submitting amendments in protocols a covering letter should be provided clearly stating the changes and soft copy of the same should be submitted in a CD.

The research projects proposal submitted should be as follows:

1. Full Title of Study:	
2.1 Name & signatures of the candidate 2.2 Department 2.3 Degree/course 2.4 Batch of admission to course 2.5 Month & year of submission of thesis	2.1_____Signatures_____ 2.2_____ 2.3 B.Sc/MBBS/M.Sc/MD/MS/MHA/MDS/M.Biotech/MCh/ DM/ Ph.D (encircle) 2.4 January/July _____ (year) 2.5 June/November _____(year)
3. Name of Faculty & Department (Guide/Co-guide) 3.1_____ 3.2 _____ 3.3 _____ 3.4 _____ 3.5_____ (Expand if any more co-guides)	Signatures (Guide/Co-Guides) 3.1_____ 3.2 _____ 3.3_____ 3.4 _____ 3.5_____
4. Objectives of the study	4.1_____ 4.2_____ 4.3_____ 4.4_____ 4.5_____
5. Why this study is required? Please provide brief justification.	
6. Methodology	6.1. Number of Patients: 6.2. Inclusion criteria a)_____ b)_____ c)_____ d)_____ 6.3. Exclusion criteria a)_____ b)_____

	c)_____ d) _____ 6.4. Control(s) 6.5. Study design 6.6. Dosages of drug 6.7. Duration of treatment 6.8. Investigation specifically related to projects 6.9 Permission to use copyrighted Questionnaire/profroma 6.9. Others 6.10 Brief Methodology
7. Permission from Drug Controller General of India (DCGI)	1. ☐ Required 2. ☐ Not required 3. ☐ Received 4. ☐ Applied when:
8. Permission from DGFT , if required	1. ☐ Required 2. ☐ Not required 3. ☐ Received 4. ☐ Applied when:
9. a) Safety measures for proposed interventions b) Results of relevant laboratory tests c) Result of studies in human	a)_____ b)_____ c)_____
10. Plans to withdraw standard therapy in research	☐ Yes ☐ No Remarks:_____
11. Plan for provision of coverage for medical risk	
12. How you will maintain Confidentiality of subject?	
13. **Costs Involved (Appx. in Rs.)** 13.1 Investigations 13.2 Disposables 13.3 Implants 13.4 Drugs / Contrast Media **Who will bear the costs of the requirements?** *(mark √)*	13.1_____ 13.2_____ 13.3_____ 13.4_____ 1. ☐ Patient 2. ☐ Project 3. ☐ Exempted 4. ☐ Other Agencies (Name)_____
14. Participant Information Sheet *(mark √ if yes)*	☐ Attached English version ☐ Attached Hindi versiom ☐ *Certified that Hindi version is a true translation of English version*

15. Participant Informed Consent Form *(mark √ if yes)*	☐ Attached English version ☐ Attached Hindi versiom ☐ *Certified that Hindi version is a true translation of English version*
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 Undertaking that the study shall be done in accordance with ICMR and GCP guidelines 17.4 In case of multicentric study, IEC clearance of other centers must be provided 17.5 Definite undertaking as to who will bear the expenditure of injury related to the project 17.6 In case an insurance cover is intended, Insurance certificate must be provided (as per ICMR guidelines) 17.7 : Permission as mentioned in 6.9 17.8: Certificate/undertaking as mentioned in 16 17.9 In case of Clinical trials, proof of registration of Clinical trial with ICMR needs to be submitted. 17.10 Investigator should provide undertaking what they will do with the leftover sample tissue 17.11 Soft Copy on CD: 17.12 Others: