

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

14 copies of the Research Project along with Covering letter and soft copy on CD with full following information be submitted to the Member Secretary, Ethics Committee / Sub committee at Room No. 102, 1<sup>st</sup> Floor, Old OT Block, AIIMS, Tel No.4579.

The research projects proposal submitted should be as follows:

1. Full Title of Study:	
2. Name of Candidate / Department	_____ Signature _____
M.SC/MD/MS/MHA/M.Biotech?Ph.D	
3. Name of Faculty (Guide/Co-guide) 3.1 _____ 3.2 _____ 3.3 _____ 3.4 _____ 3.5 _____ (Expand if any more co-guides)	Signatures (Should preferably be signed by at least two guides / 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 6.9. Others
7. Permission from Drug Controller General of India (DCGI)	1. <input type="checkbox"/> Required      2. <input type="checkbox"/> Not required 3. <input type="checkbox"/> Received      4. <input type="checkbox"/> 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 in research	<input type="checkbox"/> Yes <input type="checkbox"/> No Remarks: _____
10. Plan for provision of coverage for medical risk	
11. How you will maintain confidentiality of subject?	
12. <b>Costs Involved (Appx. in Rs.)</b> 12.1 Investigations 12.2 Disposables 12.3 Implants 12.4 Drugs / Contrast Media  <b>Who will bear the costs of the requirements?</b>	12.1 _____ 12.2 _____ 12.3 _____ 12.4 _____  1. <input type="checkbox"/> Patient 2. <input type="checkbox"/> Project 3. <input type="checkbox"/> Exempted 4. <input type="checkbox"/> Other Agencies (Name) _____
13. Patient Information Sheet <i>(mark √ if yes)</i>	<input type="checkbox"/> <b>English</b> <input type="checkbox"/> <b>Hindi</b> <input type="checkbox"/> <i>Certified that Hindi version is a true translation of English version</i>
14. Whether any work on this project has started or not?	<input type="checkbox"/> <i>(mark √ if yes, X if no)</i> <i>(Please enclose a separate certificate to this effect).</i>
15. Attached documents (If any)	15.1 _____ 15.2 _____ 15.3 _____ 15.4 _____ 15.5 _____