Submit Sixteen (16) copies of the all documents along with Covering letter to the Member Secretary, Institute Ethics Committee, Dhanvantari O.P.D. Block, S.M.S. Hospital, Jaipur. **The documents should also be submitted in a soft copy in PDF files a single CD containing the following in SEQUENCE:**

PDF (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. Duly filled format of Ethics Committee except signed first page/s
5. All relevant Participant Information Sheets in English and Hindi
6. All relevant Participant Informed Consent Forms in English and Hindi
7. Copy of Thesis Protocol
8. Budget(if applicable)
9. Any other relevant annexures / Any other signed document/s

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 thesis work 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 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 /Legal Authorized Representative, covering all the points given on the website.** 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 and Institute Ethics Sub-Committee meetings and those received after 15th will be processed in the next Institute Ethics Committee and Institute Sub-committee meetings.

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

Reply Submission: While submitting reply raised by the Ethics Committee/Sub-Committee, the Investigators are advised to submit these through Chief-Guide. They should also mention the Ethics Committee /Sub-Committee. Reference number/s and also attach a copy of the comments of the Ethic Committee /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 & signature of the candidate	2.1 _____ Signatures _____
2.2 Department	2.2 _____
2.3 Degree/course	2.3 MBBS/M.Sc./MD/MS/M.Ch/ DM/Ph .D(encircle)
2.4 Batch of admission to course	2.4 _____(Year)
2.5 Month & year of submission of thesis	2.5 _____(Year)
2.6 Email ID of the Candidate and Chief Guide.	_____ _____

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. Objective 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 Brief Methodology 6.10 Others (Attach details, if required)
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. Safety measures for proposed interventions	_____
10. Plans to withdraw standard therapy In research, (if any)	☐ Yes ☐ No Remarks:_____
11. Plan for provision of coverage for medical risk, (if any)	
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 Informed Consent Form *(mark √ if yes)*	☐ Attached English version ☐ Attached Hindi version ☐ *Certified that Hindi version is a true translation of English version*
15. Participant Informed Consent Form *(mark √ if yes)*	☐ Attached English version ☐ Attached Hindi version ☐ *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	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	Certificate /undertaking as mentioned in 16
	17.8	In case of Clinical trials, proof of registration of Clinical trial with ICMR needs to be submitted.
	17.9	Investigator should provide undertaking what they will do with the leftover sample tissue
	17.10	**Soft copy of all the documents in PDF in separate files on a single CD**
	17.11	Others :