

Institutional Ethics Committee (Human Studies)

Indira Gandhi Medical College, Shimla

GENERAL GUIDELINES

1. **Meeting dates:** The meeting of Institute Ethics Committee will be held in the first week of the months of April, August and December.
2. **Project Submission Deadline:** 5th day of March/ 5th day of July/ 5th day of November. Applications received after the deadline will be taken up in the next meeting.
3. All proposals should be submitted in the prescribed application form (Form IA/IB/II/IV/V whichever applicable) as mentioned in the Standard Operating Procedures (SOPs) available on the website.
4. All relevant documents and the required number of copies should be enclosed with application form.
5. A total of 10 hard copies (3 hard copies in case of thesis protocols) should be submitted to the IEC Secretariat and one soft copy in pdf format to be mailed to **email id- iec.igmc.sml@gmail.com** from the **email of the Principal Investigator of the project or email of the postgraduate student/ Guide (for MD/MS/DM/M.Ch/Ph.D thesis protocols) or guide in case of (MBBS student projects)**. The proposal should be complete in all aspects.
6. For research projects involving clinical drug trials, the project also needs to be registered with the Clinical Trial Registry in ICMR (CTRI). For details visit Website: **www.ctri.nic.in**
7. In case a clinical trial is to be conducted in collaboration with an international agency, it is mandatory to register the trial with the Health Ministry's Screening Committee. (**<https://www.icmr.nic.in/content/guidelines>**)
8. The date of meeting will be intimated to the researcher, to be present, if necessary to offer clarifications or will be called during the meeting, if needed.
9. The IEC will review every research proposal on human participants before the research is initiated.
10. After the research is initiated it is compulsory for the Principal Investigator to submit the annual progress report (**Annexure 13**) of the research (or earlier if desired by the IEC).
11. Final report (**Annexure 12**) should be submitted at the end of the study.
12. For resubmitted proposals (**Annexure 14**), 3 hard copies along with soft copy on email of the Institutional Ethics Committee (**from the email of the Principal Investigator of the project**) should be submitted. Point wise reply to IEC letter of comments to be given in the covering letter.

13. Premature termination/ suspension/ discontinuation of the study is to be informed to the Institutional Ethics Committee(human Studies) IGMC, Shimla.
14. Any Severe Adverse Effect (SAE) or any unexpected adverse event should be reported to the Institutional Ethics Committee within 24 hours. The report of any SAE or unexpected adverse event after analysis must be submitted to Chairman IEC and Head of Institution where trial is being conducted with 14 calendar days of SAE.(**Annexure 11**)
15. The requisite application fee wherever applicable to be submitted at the time of application or before the letter of permission by IEC.
16. For further details refer to the Standard Operating Procedures (SOP) provided on the IGMC website.
17. You are also requested to consult following documentsbefore submission of the proposal.
 - the ICMR National Ethical Guidelines on Biomedical Research involving Human participants 2017(https://icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf),
 - New Drugs and Clinical Trials Rules 2019 https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf
 - Guidelines for Good Clinical Practice- ICH (https://www.ich.org/fileadmin/Public_Web_Site/ICH.../E6/E6_R1_Guideline.pdf)

Important information

The documents should be submitted to: Sh. Nitya Nand Sharma Suptd. Sr Grade II, Academic Section,Principal Office, Indira Gandhi Medical College Shimla

A complete set of documents should also be emailed to iec.igmc.sml@gmail.com

Incomplete applications will be returned.