

STANDARD OPERATING PROCEDURES
ALL INDIA INSTITUTE OF MEDICAL SCIENCES, NEW DELHI
INSTITUTE ETHICS COMMITTEE FOR POST GRADUATE RESEARCH FOR
CLINICAL SCIENCE

Responsibility:

To ensure that the research projects that are carried out at All India Institute of Medical Sciences

- Are sound in design, have statistical validity and are conducted according to the Indian Council of Medical Research and International Conference on Harmonisation/Good Clinical Practice guidelines
- Do not compromise right, safety and benefits of the patients or volunteers/ study participants.
- Are conducted under the supervision of trained medical / bio-medical persons with the required expertise
- Include solely, patients or participant who have given voluntary and informed consent

It may be ensured that no research project shall be / can be started unless Ethics Clearance / Approvals obtained and that no retrospective / post facto Ethics Clearance/ Approval can be provided to research projects which were neither submitted nor wetted by the Institute Ethics Committee for Post Graduates Research.

The committee expects from the investigators:

- A progress report on six monthly basis or more frequently as the committee feels it.
- All serious adverse events observed during conduct of the study should be reported with all the details to the Institute Ethics Committee within twenty four hours and should be reported within ten days to The Drugs Controller General (India), Directorate General of Health Services, Central Drugs Standard Control Organization, New Delhi.*
- To keep informed of amendments to any study related documents
- To keep informed of study discontinuation with reasons.

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Composition of Institute Ethics Committee for Post Graduates Research:

In order to streamline the Post Graduates thesis Research work, an independent Institute Ethics Committee for Post Graduates Research has been formed to assist in evaluation of ethical issues of the MBBS/M.Sc./M.Biotech/MDS/MHA/MD/MS/Ph.D/DM/MCh dissertation/thesis of the students registered at All India Institute of Medical Sciences, New Delhi, only. In order to assist the Institute Ethics Committee for Post Graduates Research for reviewing of Basic Science research there will be one sub-committee for Post Graduates Basic Science Research under the Institute Ethics Committee for Post Graduates Research. The report of this sub-committee will be submitted in the meeting of Institute Ethics Committee for Post Graduates Research for

approval. The members of Institute Ethics Committee for Post Graduate Research are as follows:

1. **Prof. S.C. Tiwari, Chairman**
Member-Institute Ethics committee, Clinician
Former HOD Department of Nephrology, AIIMS, New Delhi.
2. **Prof. S.K. Kabra, - Professor-Clinician**
Member-Institute Ethics Committee for Post Graduates Research
Dept. of Paediatrics, AIIMS, New Delhi
3. **Prof. Rita Sood,- Professor,- Clinician**
Member-Institute Ethics Committee for Post Graduates Research
Professor, Deptt. of Medicine , AIIMS, New Delhi
4. **Prof. Suman Kumar,- Lay person**
Member-Institute Ethics Committee for Post Graduates Research
Principial Blue Bell School, Kailash colony, New Delhi
5. **Dr. Banusri Velpandian, L.L.B.-Legal Person**
Member-Institute Ethics Committee for Post Graduates Research
ADVOCATE,Enrolment No. D/1435/2001
DELHI BAR COUNCIL
R/o E-17, Ayurvigyan Nagar,
New Delhi-110049
6. **Prof.. Rama V. Baru,- Social Scientist**
Member-Institute Ethics Committee for Post Graduates Research
Professor, Centre of Social Medicine and Community Health
Social Sciences, JNU, New Delhi
7. **Dr. Jagriti Bhatia, Addl. Prof.- Basic Medical Scientist**
Member-Institute Ethics Committee for Post Graduates Research
Deptt. of Pharmacology,AIIMS, New Delhi-29
8. **Prof. Neerja Bhatla, Professor - Clinician**
Member-Institute Ethics Committee for Post Graduates Research
Professor, Deptt. ofObst. &Gynae, AIIMS, New Delhi
9. **Dr. JAGDISH CHANDER SURI, Professor- Clinician**
Department of Pulmonary,
Critical Care and Sleep Medicine
Safdarjung Hospital,
New Delhi-110023

10. Dr. Vimi Rewari- Professor-Clinician

Member- Institute Ethics Committee for Post Graduates Research
Deptt. of Anaesthesiology, AIIMS, New Delhi

11. Prof. Rohit Bhatia – Professor- Clinician

Member-Institute Ethics Committee for Post Graduates Research
Professor, Deptt. of Neurology, AIIMS, New Delhi

12. Prof. Ambuj Kumar- Professor-Clinician

Member-Institute Ethics Committee for Post Graduates Research
Professor, Deptt. of Cardiology, AIIMS, New Delhi

13. Prof. Maneesh Singhal- Professor- Clinician

Member-Institute Ethics Committee for Post Graduates Research
Additional Professor, Deptt. of Surgery, AIIMS, New Delhi

14. Dr. V.K. Bansal- Professor-Clinician

Member-Institute Ethics Committee for Post Graduates Research
Sub-Dean(Academic)
Additional Professor, Deptt. of Surgery, AIIMS, New Delhi

15. Dr. Pramod Kumar Garg- Professor-Clinician

Member-Institute Ethics Committee for Post Graduates Research
Sub-Dean(Research)& Member Secretary - Institute Ethics committee
Professor, Deptt. of Gastroenterology, AIIMS, New Delhi

16. Dr. Sanjeev Sinha, Addl. Prof.-Clinician

Member Secretary - Institute Ethics Committee for Post Graduates Research
Addl. Prof. of Medicine, AIIMS, New Delhi

If a member is unable to attend a meeting his/her opinion on the project on the agenda may be submitted in writing to the Chairperson of the Committee before the date of the meeting or decision. The decision of the committee is taken by majority vote. If Chairman is absent he can nominate a person from the Institute Ethics Committee for Post Graduates Research to chair.

Procedures:

A quorum is required for all meetings (8 members out of 15 make a quorum). Approval of a protocols made by consensus of members present at the meeting. The members can voluntary withdraw from membership of Institute Ethics Committee after giving due justification and permission of appointing authority. In case a member is absent from Institute Ethics Committee for Post Graduates Research the following is considered: Since the projects are circulated prior to two weeks of Institute Ethics Committee for Post graduates Research meeting, if no objection / comments are obtained from that member, they are considered to be approved by that member.

Serious Adverse Effects should be reported to Institute Ethics Committee for Post graduates Research/Institute Ethics Committee within 24 hours and to DCGI within 10 working days. Efforts are made to ensure that individuals or communities invited for research are selected in such way that the burdens and benefits of the research are equally distributed. These vulnerable populations include:

- a. Racial inequalities
- b. Economically or socially disadvantaged
- c. Mentally challenged and mentally differently able persons with reduced autonomy

(prisoners, students, subordinates, employees, service personnel)

After three years, some new members who have been earlier trained in research methodology workshop are appointed while retaining some older members for guiding them by their hands-on training in Ethics Committee. All applicants have to give an undertaking declaring their conflict of interest. Regarding projects from members of Institute Ethics Committee for Post Graduates Research, these members should voluntarily withdraw from the Institute Ethics Committee for Post graduates meeting while making a decision on that project which evoke a Conflict of Interest. This may be indicated to the Chairman prior to the review and be recorded so in the minutes. (All members shall sign a declaration on conflict of interest).

The chairman appoints a member to write the minutes of the meetings: It is the Member-Secretary who writes the minutes. Minutes are circulated to the Members and Chairman of Institute Ethics Committee for Post Graduates and after their approval, the comment letters to applicants may be dispatched after the signature of Member-Secretary of the Institute Ethics Committee for Post Graduates Research. After the meeting, the approval of the members of the Institute Ethics Committee for Post Graduates Research is obtained on the same day of the meeting.

The applicant of a proposal is required to submit 10 copies of his / her application letter and copies of the following documents:

- 1) Research Protocol
- 2) Information as desired in the "Format for Submission"
- 3) Investigator's Brochure
- 4) Participant Informed consent form and Participant information sheet in English and translated language in a simple layman's language, in a narrative form directed to Participant/LAR, covering all the points given on the website
- 5) Any other project – specific document.
- 6) Certificate that no work has started.
- 7) Certificate that work will be done as per Indian Council of Medical Research/Good Clinical Practice guidelines
- 8) Permission to use copyrighted questionnaire and proforma

The schedules of submitting the proposal is as follows:

Submissions will be received on all days. Proposals received till 15th of any month will be processed in the coming Institute Ethics Committee for Post Graduates Research meeting and those received after 15th will be processed in the next Institute Ethics Committee for Post Graduates Research meeting. All meetings of Institute Ethics Committee for Post Graduates Research will be held as far as possible on 3rd Wednesday of the month of January, February, March, April, May, June, July, August, September, October, November and December.

The committee will give its opinion on the project in writing in one of the following ways:

Approval / Disapproval

Modification before approval

Discontinuation of previously approved project

The Chairman / Member-Secretary of the committee may provisionally approve without calling a full meeting in case where only administrative amendment has been made / expedited review is required. This decision will be ratified at the next full committee meeting and minuted. All documents pertaining to the Institute Ethics Committee Post Graduates Research will be held in the office of the Member-Secretary of Institute Ethics Committee Post Graduates Research. Members voluntarily withdraw from the Institute Ethics Post Graduates Research & Sub-Committee meeting while making a decision on an application which evokes a conflict of Interest which may beificated in writing to the Chairman prior to the review and be recorded so the minutes. All members shall sign a declaration on conflict of interest.

Serious Adverse Response should be submitted to Contract Research Organisation / Institute Ethics Committee Post Graduates within twenty four hours. In order to assist the Institute Ethics Committee Post Graduates Research for monitoring of adverse events in clinical trials, a Sub-committee for Serious Adverse Events has been constituted vide Memorandum no.F.20-29/2013-Estt.-I dated 09.01.2014. Its function includes giving opinion on causality of Serious Adverse Events and submit it to DCGI within 21 days of occurrence, with intimation to Institute Ethics Committee for Post Graduates Research/Institute Ethics Committee and also decide the amount of compensation to be given to the patients with trial related injury along with monitoring of clinical trials.

This Standard Operating Procedure is effective w.e.f. 25.11.2014

(Dr Sanjeev Sinha)

Member-Secretary-Institute Ethics Committee for Post Graduates Research
Addl. Prof. of Medicine, AIIMS, New Delhi