

**ALL INDIA INSTITUTE OF MEDICAL SCIENCES,
NEW DELHI
INSTITUTION ETHICS COMMITTEE
(Responsibility, Composition and Procedures)**

Responsibility:

To ensure that the research projects that are carried out in AIIMS Hospital

- Are sound in design, have statistical validity and are conducted according to the ICMR and ICH/GCP guidelines
- Do not compromise safety of the patients or volunteers
- 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 / Approval is obtained and that no retrospective / post facto Ethics Clearance/ Approval can be provided to research projects which were neither submitted nor wetted by the Institution Ethics Committee.

The committee expects from the investigators:

- A progress report on six monthly basis or more frequently as the committee feels it.
- A report of each serious event when observed during the conduct of the study
- To keep informed of amendments to any study related documents
- To keep informed of study discontinuation with reasons.

Composition:

The Institution Ethics Committee consists of 14 members

- 8 members are from inside AIIMS
- 6 members are from outside AIIMS
- Out of 14 members 2 members are ladies

These members are as follows:

a) Outside AIIMS

- i) Prof. J.P. Wali, Former Professor of Medicine, AIIMS (Chairperson)
- ii) Sh. Mukul Gupta, Sr. Advocate, Ex-SLC, AIIMS (Legal Representative)
- iii) Dr. Vijay Kumar, Scientist-F/Deputy Director General (Sr. Grade), ICMR, Ansari Nagar, New Delhi, (Ethicist)
- iv) Dr. A. M. Khan, Head, Department of Social Sciences, National Institute of Health and Family Welfare Munirka, New Delhi (Social Scientist)
- v) Prof. S.S. Siddhu Ex.-Prof & Head, Dept. Of Dental Surgery, AIIMS (Clinician)
- vi) Dr. D.R. Saini Principal DPS School R.K.Puram Sector-12 New Delhi (Lay Person)

b) Inside AIIMS

- i) Prof. Shashi Wadhwa, Dean & Head, Dept. of Anatomy (Basic Scientist)
- ii) Prof. Y.K. Gupta, Head, Dept. of Pharmacology (Basic Scientist)
- iii) Prof. A.B. Dey, Professor, Dept. of Medicine, Dean (Research) AIIMS, New Delhi (Clinician)
- iv) Prof. Peush Sahni, Professor & Head, Dept. of G.I. Surgery and Editor, National Medical Journal of India (Clinical)
- v) Prof. Praveen Aggarwal, Professor-in-charge, Emergency Medicine, (Clinical)
- vi) Dr Ravinder Kumar Batra, Professor Department of Anaesthesiology & Chairman of Ethics Sub- Committee (Clinician)
- vii) Dr Rakesh Yadav, Associate Professor, Dept. of Cardiology, Sub-Dean, & Member –Secretary, Ethics Sub-Committee (Clinician)
- viii) Prof. Renu Saxena, Head, Dept. of Hematology (Member Secretary).

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 Institution Ethics Committee to chair. .

Procedures:

A quorum is required for all meetings (7 members out of 14 make a quorum). Approval of a project is made by consequences of members present at the meeting.

The notice of each meeting with the agenda is sent out to the members at least one week before the meeting.

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 chairman and after his approval the comment letters to applicants may be dispatched after the signature of Member Secretary of the Institution Ethics Committee. The minutes will be placed for information and signed by the other members of Institution Ethics Committee in the next Institution Ethics Committee meeting.

In order to streamline the work of Institution Ethics Committee, an Institution Ethics Sub-Committee has been formed to assist in evaluation of ethical angles of the MBBS / M.Sc./ M.Biotech/MD/MS/MHA/DM/M.Ch./Ph.D thesis/dissertation. The report of this committee will be submitted in the meeting of Institution Ethics Committee for approval.

The applicant of a proposal is required to submit 14 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 ICMR/GCP guidelines
- 8) Permission to use copyrighted questionnaire and proforma
- 9) Updated brief CV of Principle Investigators

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 Institution Ethics Committee meeting and those received after 15th will be processed in the next Institution Ethics Committee meeting. All meetings of ethics committee will be held as far as possible on first Monday of Jan, Feb, March, April, May, June, July, August, September, October, November and December and those of Institution Ethics Sub-Committee on the immediately preceding Friday of the above dates.

Not more than thirty five projects will be reviewed / discussed during each meeting.

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 Institution Ethics Committee will be held in the office of the Member Secretary of Institution Ethics Committee.

This SOP is effective w.e.f. 2nd July, 2012

(Dr. Renu Saxena)
Member Secretary
Ethics Committee