

**ALL INDIA INSTITUTE OF MEDICAL SCIENCES  
NEW DELHI  
INSTITUTE 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 Institute 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 Institute Ethics Committee consists of 10 members**

- 5 members are from inside AIIMS
- 5 members are from outside AIIMS
- Atleast 2 members are ladies,

**These members are as follows:**

**a) Outside AIIMS**

- i) Prof. J.P. Wali, Former Professor of Medicine, AIIMS (Chairman)
- ii) Justice S.R. Singh (Retd. Justice, High Court) (Legal person)
- iii) Dr. Ganga Prasad Vimal, Former Chairperson and Prof. Centre of Indian Languages, JLN University and Ex-Director, Central Hindi Dte., Govt. of India (lay person).
- iv) Dr. Vijay Kumar, Scientist-F/Deputy Director General (Sr. Grade), ICMR, Ansari Nagar, New Delhi (Ethicist)

- v) Dr Sushma Yadav, Member, Ethics Committee, Dr Ambedkar Chair in Social Justice, Indian Institute of Public Administration, IP State, New Delhi (Social Scientist)

**b) Inside AIIMS**

- i) Prof. Rani Kumar, Dean
- ii) Prof. Suneeta Mittal, HOD, Dept. of Obst. & Gynae, Clinical Scientist
- iii) Prof. Y.K. Gupta, HOD, Dept. of Pharmacology, Laboratory Scientist
- iv) Dr. Peush Sahni, Editor, National Medical Journal of India , Clinical Scientist
- v) Dr. Renu Saxena, Professor & Head, Dept. of Hematology, Member Secretary

**c) Special Invitee**

- i. Dr Ravinder Kumar Batra, Chairman, Institute Ethics Sub-Committee
- ii. Dr A.B. Dey, Chairman, Research Committee, AIIMS
- iii. Dr Sunil Chumber, Member Secretary, Institute Ethics Sub-Committee

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 to chair. Professor in charge, Research, Chairman and Member-Secretary of Institute Ethics Sub-Committee may be special invitee for the Institute Ethics Committee to maintain continuity.

**Procedures:**

A quorum is required for all meetings (5 members out of 10 make a quorum). .

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 Institute Ethics Committee. The minutes will be placed for information to the members of Institute Ethics Committee in the next Institute Ethics Committee meeting.

In order to streamline the work of Institute Ethics Committee, an Institute Ethics Sub-Committee has been formed to assist in evaluation of ethical angles of the B.Sc/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 Institute Ethics Committee for approval.

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) Investigator's Brochure
- 3) Participant Informed consent form and Participant information sheet in English and translated language
- 4) Any other project – specific document.
- 5) Certificate that no work has started.
- 6) Permission to use copyrighted questionnaire and proforma
- 7) Updated brief CV of Principle Investigator

**The schedules of submitting the proposal is as follows:**

Submissions will be received on all days. Proposals received till 15<sup>th</sup> of any month will be processed in the coming Institute Ethics Committee meeting and those received after 15<sup>th</sup> will be processed in the next Institute Ethics Committee meeting. All meetings of ethics committee will be held as far as possible on first Monday of Jan, Feb, March, April, May, August, September, October, November and December and those of Institute Ethics Sub-Committee on the immediately preceding Friday of the above dates.

**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. This decision will be ratified at the next full committee meeting and minuted. All documents pertaining to the Institute Ethics Committee will be held in the office of the Member Secretary of Institute Ethics Committee.

(Dr. Renu Saxena)  
Member Secretary  
Ethics Committee