

RESPONSIBILITY, COMPOSITION AND PROCEDURES OF INSTITUTIONAL ETHICS SUB-COMMITTEE

Composition of Ethics Sub-Committee

In order to streamline the work of Ethics Committee, an Ethics Sub Committee has been formed to assist in evaluation of ethical issues of the M.Sc./ M.Biotech / MHA / MD/ MS / Ph.D/ MCh dissertation/thesis. This Committee is as follows:

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| 1. Dr. Ravinder Kumar Batra | Professor of Anaesthesiology | Chairman |
| 2. Dr. Renu Saxena | Professor and Head, Haematology | Convenor, Secretary of Ethics Committee |
| 3. Dr. Shashi Kant | Professor Centre for Community Medicine | Member |
| 4. Dr. Arvind Bagga | Professor of Paediatrics | Member |
| 5. Dr. Kamal Kishore | Professor of Pharmacology | Member |
| 6. Dr. Rajinder Parshad | Addl. Professor of Surgery | Member |
| 7. Dr. Kalpana Luthra | Assoc. Professor of Biochemistry | Member |
| 8. Dr. Rakesh Yadav | Assoc. Professor of Cardiology, | Member |
| 9. Dr. Pradeep Vankatesh | Assoc. Professor of Ophthalmology | Member |
| 10. Dr. Sanjay Thulkar | Assoc. Professor of Radio-diagnosis | Member |
| 11. Dr. Vineet Ahuja | Associate Professor of Gastroenterology | Member |
| 12. Dr. Ashok Kumar | Professor, Dept of Obs. & Gynae MAMC, New Delhi | Member |
| 13. Dr. Rakesh Mahajan | Sr Consultant, Apollo Hospital, New Delhi | Member |
| 14. Dr. Sunil Chumber | Sub-Dean (Acad.), Addl. Professor of Surgery | Member- Secretary |

Responsibility:

To ensure that the research projects/ dissertation/ thesis are carried out at AIIMS and associated divisions or centers or hospitals -

- 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/biomedical persons with the required expertise
- Include, solely, patients who have given voluntary and informed consent

The committee expects from the investigators:

- Lucidly written research projects
- A progress report on six monthly basis or more frequently as the committee feels it.
- A report of any adverse event when observed during the conduct of the study
- To be keep it informed of any amendment to the study or in the study documents
- To be keep it informed of study discontinuation with reasons.

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. If the Chairman is unable to chair any meeting due to any reason he shall nominate one of the members of the Ethics Sub-Committee to chair the meeting.

Procedures:

A quorum is required for all the meetings (7 members out of 14 will make a quorum). But approval of a project/dissertation/thesis requires voting by a show hand by 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.

Member secretary/Convener will be responsible for writing the minutes of the Ethics Sub-Committee meeting.

The minutes will be placed by the Member Secretary/Convener of Ethics Sub-Committee, before the members of Ethics Committee in the following Ethics Committee meeting for ratification. After approval from Ethics Committee, the letters to the applicants will be issued with the signatures of the Member Secretary of the Ethics Sub-Committee and Member Secretary of Ethics Committee. The Minutes will be circulated to the members of Ethics Sub-Committee within two weeks of the meeting.

The applicant of a proposal for Thesis or Dissertation is required to submit 14 copies of his / her application letter and copies of the following documents.

- 1) Information as desired in the "Format for submission".
- 2) Informed consent form in English and Hindi, with space for signatures, name, and address of the witness.
- 3) Patient Information Sheet (PIS) in English and Hindi
- 4) Any other project / thesis / dissertation specific document
- 5) Protocol
- 6) CD containing all of the above information.

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 ethics committee meeting and those received after 15th will be processed in the next ethics committee meeting. All meetings of ethics committee will be held on first Monday of January, February, March, April, August, September, October, November and those of ethics Sub Committee on the immediately preceding Friday of the above dates:

| Date of meeting of ethics Sub-Committee | Date of meeting of ethics committee |
|--|--|
| 2 nd August 2008 | 4 th August 2008 |
| 29 th August 2008 | 1 st September 2008 |
| 3 rd October 2008 | 6 th October 2008 |
| 31 st October, 2008 | 3 rd November 2008 |
| 28 th November, 2008 | 1 st December, 2008 |
| Break | Break |
| 2 nd January 2009 | 5 th January 2009 |
| 30 th January 2009 | 2 nd February 2009 |
| 27 th February 2009 | 2 nd March 2009 |
| 3 rd April 2009 | 6 th April 2009 |
| 1 st May, 2009 | 4 th May, 2009 |
| Break | Break |

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 cases where only administrative amendment has been made. The chairman will inform other members of the committee of the amendments and his decision. The decision will be ratified at the next full committee meeting and this will be recorded in the minutes. All documents pertaining to the Ethics Sub-Committee will be held in the office of the Ethics Committee under charge of the Secretary Ethics Committee.