

## RESPONSIBILITY, COMPOSITION AND PROCEDURES OF INSTITUTION ETHICS SUB-COMMITTEE

### Composition of Institution Ethics Sub-Committee

In order to streamline the work of Institution Ethics Committee, an Institution Ethics Sub Committee 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. This Committee is as follows:

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. Praveen Agarwal	Professor of Emergency Medicine	Member
7. Dr. Sunil Chumber	Addl. Professor of Surgery	Member
8. Dr. Raju Sharma	Addl. Prof. of Radio-Diagnosis	Member
9. Dr. Rajinder Parshad	Addl. Professor of Surgery	Member
10. Dr. Kalpana Luthra	Assoc. Professor of Biochemistry	Member
11. Dr. Pradeep Vankatesh	Assoc. Professor of Ophthalmology	Member
12. Dr. Sanjay Thulkar	Assoc. Professor of Radio-diagnosis	Member
13. Dr. Vineet Ahuja	Associate Professor of Gastroenterology	Member
14. Dr. Ashok Kumar	Professor, Dept of Obs. & Gynae MAMC, New Delhi	Member
15. Dr. Rakesh Mahajan	Sr Consultant, Apollo Hospital, New Delhi	Member
16. Dr. Dr. Rakesh Yadav	Sub-Dean (Acad.), Associate Professor of Cardiology	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 or participants who have given voluntary and informed consent

It may be ensured that no research project shall be/can be started unless ethics clearance or approval is obtained and that no retrospective/post facto ethical clearance or approval can be provided to research projects which were neither submitted nor wetted by the Institution Ethics Committee.

**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 keep informed of any amendment to the study or in the study documents
- To keep 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 (8 members out of 16 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 Institution Ethics Sub-Committee meeting.

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

The applicant of a proposal for Thesis or Dissertation is required to submit 16 copies of his / her application letter and copies of the following documents.

- 1) Information as desired in the "Format for submission".
- 2) Participant Informed Consent Form (PICF) in English and Hindi, with space for signatures, name, and address of the two witnesses.
- 3) Participant Information Sheet (PIS) in English and Hindi
- 4) Certificate that no work has started.
- 5) Certificate that work will be done as per ICMR/GCP guidelines
- 6) Permission to use copyrighted questionnaire or proforma
- 7) Any other project / thesis / dissertation specific document
- 8) Copy of the Protocol
- 9) 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 15<sup>th</sup> of any month will be processed in the coming Institution Ethics Committee/ Sub-Committee meetings and those received after 15<sup>th</sup> will be processed in the next Institution Ethics committee/Sub-Committee meetings. All meetings of Institution Ethics Committee will be held as far as possible on first Monday of January, February, March, April, May, June, July, August, September, October, November & December and those of Institution Ethics Sub-Committee on the immediately preceding Friday of the above dates:

<b>Date of meeting of Ethics Sub-Committee</b>	<b>Date of meeting of Ethics committee</b>
29 <sup>th</sup> October, 2010	1 <sup>st</sup> November, 2010
3 <sup>rd</sup> December, 2010	6 <sup>th</sup> December, 2010
7 <sup>th</sup> January, 2011	10 <sup>th</sup> January, 2011
4 <sup>th</sup> February 2011	7 <sup>th</sup> February 2011
4 <sup>th</sup> March, 2011	7 <sup>th</sup> March, 2011
1 <sup>st</sup> April, 2011	4 <sup>th</sup> April, 2011
6 <sup>th</sup> May, 2011	9 <sup>th</sup> May, 2011
3 <sup>rd</sup> June, 2011	6 <sup>th</sup> June, 2011
1 <sup>st</sup> July, 2011	4 <sup>th</sup> July, 2011

**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 Institution Ethics Sub-Committee will be held in the office of the Institution Ethics Committee under charge of the Secretary Institution Ethics Committee.