

RESPONSIBILITY, COMPOSITION AND PROCEDURES OF INSTITUTION ETHICS SUB-COMMITTEE

Composition of 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 **of the students registered at All India Institute of Medical Sciences, New Delhi, only.** This Committee is as follows:

1.	Dr. Ravinder Kumar Batra	Professor of Anaesthesiology	Chairman
2.	Dr. Renu Saxena	Professor and Head, Haematology	Member
3.	Dr. Shashi Kant	Professor	
		Centre for Community Medicine	Member
4.	Dr. Arvind Bagga	Professor of Paediatrics	Member
5.	Dr. Kalpana Luthra	Assoc. Professor of Biochemistry	Member
6.	Dr. Ashok Kumar	Professor, Dept of Obs. & Gynae	Member
		MAMC, New Delhi	
7.	Dr. Praveen Agarwal	Professor of Emergency Medicine	Member
8.	Dr. Anurag Srivastava	Professor of Surgery, AIIMS	Member
9.	Dr. Radhika Tandon	Professor of Ophthalmology	Member
10.	Dr. Manju Vatsa	Principal, College of Nursing	Member
11.	Dr. S.B. Gaikwad	Professor of Neuro-Radiology	Member
12.	Dr. Ravinder Kumar Goswami	Sub-Dean (Research)	Member
13.	Dr. Naval Kishore Vikram	Associate Professor of Medicine	Member
14.	Dr. G. Karthikeyan	Additional Professor of Cardiology	Member
15.	Dr. Rakesh Yadav	Sub-Dean (Acad.), Additional	
		Professor of Cardiology,	Member, Secretary

Responsibility:

To ensure that the research projects/ dissertation/ thesis 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 thesis/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 vetted by the Institution Ethics Committee.

The committee expects from the investigators:

- Lucidly written research protocol
- 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 (07 members out of 15 will make a quorum). But approval of a project/dissertation/thesis requires consensus 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 will be responsible for writing the minutes of the Institution Ethics Sub-Committee meeting.

The minutes will be placed by the Member Secretary 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 applicant of a proposal for Thesis or Dissertation is required to submit 15 copies of his/her application letter and copies of the following documents.

- 1) Information as desired in the “Format for submission” as on AIIMS website.
- 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, in a simple layman’s language in a narrative form, directed to Participant /LAR, covering all the points given on the website.
- 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 15th of any month will be processed in the coming Institution Ethics Committee/ Sub-Committee meetings and those received after 15th 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.

Not more than forty thesis protocols will be reviewed/ discussed during each meeting.

The committee will give its opinion on the protocol 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.

This SOP is effective w.e.f. 15th March, 2012

(Dr Rakesh Yadav)
Member Secretary
Ethics Sub-Committee