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  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. & Gynaecology  Member
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 wetted 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