STANDARD OPERATING PROCEDURES
ALL INDIA INSTITUTE OF MEDICAL SCIENCES, NEW DELHI
INSTITUTE ETHICS SUB-COMMITTEE

Responsibility:

To ensure that the research projects that are carried out at All India Institute of Medical Sciences

- Are sound in design, have statistical validity and are conducted according to the Indian Council of Medical Research and International Conference on Harmonisation/Good Clinical Practice guidelines
- Do not compromise right, safety and benefits of the patients or volunteers/ study participants.
- 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.
- **All serious adverse events observed during conduct of the study should be reported with all the details to the Institute Ethics Committee within twenty four hours and should be reported within ten days to The Drugs Controller General (India), Directorate General of Health Services, Central Drugs Standard Control Organization, New Delhi.***
- To keep informed of amendments to any study related documents
- To keep informed of study discontinuation with reasons.

**THE GAZETTE OF INDIA : EXTRA ORDINARY PART II – Sec. 30(i) page no. 10*

Composition of Ethics Sub-Committee

In order to streamline the work of Institute Ethics Committee, an Institute 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.** The report of this committee will be submitted in the meeting of Institute Ethics Committee for approval. 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	Professor of Biochemistry	Member
6.	Dr Ashok Kumar	Professor, Dept of Obs. & Gynae MAMC, New Delhi	Member
7.	Dr. Praveen Agarwal	Professor of Emergency Medicine	Member
8.	Dr. Anurag Srivastava	Professor & Head of Surgery, AIIMS	Member
9.	Dr. Radhika Tandon	Professor of Opthalmology	Member
10.	Dr. Manju Vatsa	Principal, College of Nursing	Member
11.	Dr. S.B.Gaikwad	Professor of Neuro-Radiology	Member
12.	Dr. Pramod Kumar Garg	Sub-Dean (Research), Prof. of Gastroenterology	Member
13.	Dr. Naval Kishore Vikram	Additional Professor of Medicine	Member
14.	Dr. G. Karthikeyan	Additional Professor of Cardiology	Member
15.	Dr. Virinder Kumar Bansal	Sub-Dean (Acad.), Addl. Professor of Surgery,	Member-Secretary

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 Sub-Committee to chair.

Procedures:

A quorum is required for all meetings (8 members out of 15 make a quorum). Approval of a protocol is made by consensus of members present at the meeting. The members can voluntary withdraw from membership of Institute Ethics Committee after giving due justification and permission of appointing authority. In case a member is absent from Institute Ethics Sub-Committee meeting, the following is considered: Since the projects are circulated prior to two weeks of Institute Ethics Sub-Committee meeting, if no objection / comments are obtained from that member, they are considered to be approved by that member. Serious Adverse Effects should be reported to Institute Ethics Sub-Committee/Institute Ethics Committee within 24 hours and to DCGI within 10 working days.

Efforts are made to ensure that individuals or communities invited for research are selected in such a way that the burdens and benefits of the research are equally distributed. These vulnerable populations include:

a. Racial inequalities
b. Economically or socially disadvantaged
c. Mentally challenged and mentally differently able persons with reduced autonomy (prisoners, students, subordinates, employees, service personnel)

After three years, some new members who have been earlier trained in research methodology workshop are appointed while retaining some older members for guiding them by their hands-on-training in Ethics Committee.

All applicants have to give an undertaking declaring their conflict of interest. Regarding projects from members of Institute Ethics Sub-Committee, these members should voluntarily withdraw from the Institute Ethics Sub-Committee meeting while making a decision on that project which evokes a Conflict of Interest. This may be indicated to the Chairman prior to the review and be recorded so in the minutes. (All members shall sign a declaration on conflict of interest).

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 Members and Chairman of both Institute Ethics Sub-Committee and Institute Ethics Committee and after their approval, the comment letters to applicants may be dispatched after the signature of Member-Secretary of the Institute Ethics Committee and Institute Ethics Sub-Committee. After the meeting, the approval of the members of the Institute Ethics Committee and Institute Ethics Sub-Committee is obtained on the same day of the meeting.

The applicant of a proposal is required to submit 15 copies of his / her application letter and copies of the following documents:

1) Research Protocol
2) Information as desired in the "Format for Submission"
3) Investigator's Brochure
4) Participant Informed consent form and Participant information sheet in English and translated language in a simple layman's language, in a narrative form directed to Participant/LAR, covering all the points given on the website
5) Any other project – specific document.
6) Certificate that no work has started.
7) Certificate that work will be done as per Indian Council of Medical Research/Good Clinical Practice guidelines
8) Permission to use copyrighted questionnaire and proforma

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 Institute Ethics Sub-Committee meeting and those received after 15th will be processed in the next Institute Ethics Sub-Committee meeting. All meetings of Institute Ethics Committee will be held as far as possible on first Monday of January, February, March, April, May, June, July, 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 / expedited review is required. 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. Members voluntarily withdraw from the Institute Ethics Sub-Committee meeting while making a decision on an application which evokes a conflict of Interest which may be indicated in writing to the Chairman prior to the review and be recorded so the minutes. All members shall sign a declaration on conflict of interest.

Serious Adverse Response should be submitted to Contract Research Organisation / Institute Ethics Committee within twenty four hours. In order to assist the Institute Ethics Committee for monitoring of adverse events in clinical trials, a Sub-committee has been constituted vide Memorandum no. F.20-29/2013-Estt.-I dated 13.08.2013. Its function includes giving opinion on causality of Serious Adverse Events and submit it to DCGI within 21 days of occurrence, with intimation to Institute Ethics Sub-Committee/Institute Ethics Committee and also decide the amount of compensation to be given to the patients with trial related injury along with monitoring of clinical trials.

This Standard Operating Procedure is effective w.e.f. 30th December, 2013.

(Dr Virinder Kumar Bansal)
Member-Secretary
Institute Ethics Sub-Committee