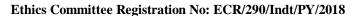


INSTITUTIONAL ETHICAL COMMITTEE

INDIRA GANDHI INSTITUTE OF DENTAL SCIENCES





SOP: 4

RESPONSIBILITIES AND TRAINING REQUIREMENT OF MEMBERS OF IEC, IGIDS

PURPOSE

To define the general responsibilities of the members of IEC including training requirement.

SCOPE

Applicable to IEC members, IGIDS.

RESPONSIBILITY

Dean (Head of the Institute), Chairman and members of the IEC are responsible for implementing this SOP.

PROCEDURE

- 1. All IEC members must familiarize themselves with the ICMR guidelines for research involving human participants, Schedule Y of the Drugs and Cosmetics Act, the Declaration of Helsinki, ICH-GCP guidelines, CONSORT and other relevant guidelines. They are also advised to attend any workshop conducted in this regard.
- 2. IEC members are expected to display their full commitment and responsibility in maintaining the ethics of research; they should respect divergent opinions and should maintain confidentiality.

Prepared by: Prof. Manoharan PS Member,IEC Prepared by: Prof. Dr. Pratebha B Member Secretary, IEC, IGIDS

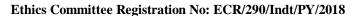
Verified by: Prof. Dr. Aruna Sharma Principal-IGIDS, SBV Approved by: Prof. Dr.R. Madhavan Nirmal Chairman, IEC, IGIDS, SBV





INSTITUTIONAL ETHICAL COMMITTEE

INDIRA GANDHI INSTITUTE OF DENTAL SCIENCES





3. The Member Secretary shall fix the date of the meeting following discussions with the Chairman and other committee members; he/ she will send the soft copies containing the details

of the research proposals to all the members at least ten days before the planned IEC meeting; all the members are expected to come prepared and should point out the lacunae and suggest ways to improve the study.

- 4. After the meeting is over, all the Members should return the CDs / document papers containing the research proposals to the Member Secretary and should not retain any copy with them
- 5. A member of IEC is expected to attend all the IEC meetings; in case, if he/she is unable to attend, the same should be intimated to the Member Secretary at least one day prior to the meeting
- 6. All IEC members are expected to declare competing conflicts of interest with respect to research proposals or investigators, if any, prior to the commencement of each meeting
- 7. IEC members are expected not to be present during presentation of proposals in which they are co-investigators/guides/co-guides unless requested to answer clarifications; they may present proposals if they are principal investigators, but in both situations should leave the room before IEC discussions and decisions
- 8. Training of new IEC Members
- i) Every time a new committee is constituted, the members must undergo initial training on ethics in clinical research and good clinical research and SOPs
- ii) An individual selected as a new member of the IEC may be required to attend at least one meeting as an 'Observer' before being inducted as a member of the IEC. Member Secretary or an IEC member will provide an introductory training/orientation to the new member

Prepared by: Prof. Manoharan PS Member,IEC Prepared by: Prof. Dr. Pratebha B Member Secretary, IEC, IGIDS

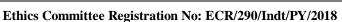
Verified by: Prof. Dr. Aruna Sharma Principal-IGIDS, SBV Approved by: Prof. Dr.R. Madhavan Nirmal Chairman, IEC, IGIDS, SBV





INSTITUTIONAL ETHICAL COMMITTEE

INDIRA GANDHI INSTITUTE OF DENTAL SCIENCES





iii) The IEC Member Secretary, members, Chairperson shall be encouraged to receive continued training by participating in a workshop, conference and / or retraining program related to research ethics, as a delegate, faculty, facilitator, etc. at least once every year.

iv) The IEC can conduct workshops on ethics in clinical research and good clinical research practices from time to time to impart training to the IEC Members to the Institutional faculty members

Prepared by: Prof. Manoharan PS Member,IEC Prepared by: Prof. Dr. Pratebha B Member Secretary, IEC, IGIDS

Verified by: Prof. Dr. Aruna Sharma Principal-IGIDS, SBV Approved by: Prof. Dr.R. Madhavan Nirmal Chairman, IEC, IGIDS, SBV

