

#### INSTITUTIONAL ETHICAL COMMITTEE

#### **INDIRA GANDHI INSTITUTE OF DENTAL SCIENCES**



Ethics Committee Registration No: ECR/290/Indt/PY/2018

**SOP: 15** 

# APPROVAL OF RESEARCH PROPOSALS

Functioning of Institutional Ethics Committee

The Institutional Ethics Committee meetings are scheduled 4 times in a year, thrice in a year for undergraduate and postgraduate student and faculty projects, ICMR-STS projects and once for Postgraduate Dissertation review.

Following are the tentative calendar dates of IEC meeting;

☐ February - Faculty projects; PG non dissertation protocols, UG projects

☐ June – Faculty projects; PG non dissertation protocols, UG projects

☐ December – post graduate dissertations

All the protocols vetted by the Internal review board (IRB)which after approval by IRB are verified and received by the Member Secretary of IEC are taken up for IEC review on the above scheduled dates.

ECs should register and follow the quorum requirements specified by CDSCO before reviewing clinical trials on 'new drugs' as per Schedule Y and its amendments. The ethics committee meeting will be scheduled within a month of circulating the protocols among the IEC members with due consideration to the IEC quorum as per CDSCO recommendations. The meeting will be held in the 7th floor, conference hall, New block, IGIDS, SBV. During the meeting, all those protocols which the committee members agreed to approve in absentia will be discussed during the board meeting. The rest of the protocols which require clarification from the principal investigators are

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





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made to present their protocols in front of the committee for approval. A short 3 min presentation format of their protocol is scrutinized by the members for appropriateness, feasibility, scientific and ethical content of the research project

The minutes of the meeting are prepared and circulated among the principal investigators and the ethics committee members within a week interval. The Member Secretary of Ethics committee finally verifies the protocol for incorporation of recommendations made by the Ethics Committee. The approval certificates are issued on submission of corrected protocols within a month of Ethics Committee meeting provided all the necessary modifications mentioned by the IEC are done.

All the IEC approved and deferred protocols are maintained in the office of the Ethics Committee for a minimum period of 5 years, both in the form of hard and soft copy.

The IEC approval is valid for three years or the duration of the project whichever less is. Any serious adverse events occurring during the course of the study should be reported to the IEC within a period of 24 hours. Any change in the study procedure/site/investigator should be informed to the IEC.

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