

SOP -1

Preparation of Standard Operating Procedures for Institutional Ethics Committee (IEC), IGIDS

PURPOSE:

The SOPs should provide clear, unambiguous instructions so that the related activities of the committee are conducted in accordance with Indian regulations and relevant, national and international ethical guidelines for Institutional Ethics Committee (IEC), IGIDS

SCOPE

This SOP covers the procedures of writing, reviewing and amending the SOPs of Institutional Ethics Committee (IEC), IGIDS. This SOP also specifies the glossary or terms of reference of the Institutional Ethics Committee (IEC), IGIDS.

RESPONSIBILITY:

It is the responsibility of the Chairperson/member secretary of the IEC in consultation with the members and Principal, IGIDS to formulate new SOPs or to revise existing SOPs.

DETAILS AND PROCEDURE:

1. The IEC will assess the need for SOP/s revision in consultation with the Member Secretary and Chairperson. The committee can propose new / modified SOP/s as needed and draft the SOP/s in consultation with the IEC members and involved administrative staff. The committee will also review the draft SOP and make it available to the Principal Investigators/Research scholars of IGIDS.

Prepared by:
Prof. Manoharan PS
Member, IEC

Prepared by:
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Member Secretary, IEC, IGIDS

Verified by:
Prof. Dr. Aruna Sharma
Principal-IGIDS, SBV

Approved by:
Prof. Dr. R. Madhavan Nirmal
Chairman, IEC, IGIDS, SBV

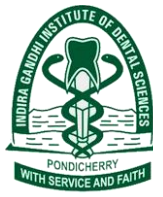




INSTITUTIONAL ETHICAL COMMITTEE

INDIRA GANDHI INSTITUTE OF DENTAL SCIENCES

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



2. When the need for a new SOP has been identified and agreed upon, a draft will be written

by one or more designated members of the Institutional Ethics Committee(IEC),IGIDS. After incorporating the suggestions put forth by members of IEC, the SOP draft will be validated by the chairperson and member secretary with due approval from the Principal, IGIDS.

3. The IEC members and support staff will review SOPs at least once in every 3years/whenever regulatory guidelines are revised.

4. Glossary for Institutional Ethics Committee(IEC), Indira Gandhi Institute of Dental Sciences (IGIDS),Sri Balaji Vidyapeeth (SBV) Deemed to be University, Puducherry

i) SOP (Standard Operating Procedure): Detailed, written instructions, in a certain format, describing activities and actions undertaken by the IEC to achieve uniformity of the performance of a specific function. The aim of the SOPs is to simplify the functioning, while maintaining high standards of Good Clinical Practice

ii) IEC Members: Individuals serving as regular members of the Institutional Ethics Committee. The Board has been constituted in accordance with the IEC membership requirements set forth in New Drug and Clinical Trial approval regulations 2019 dated 19 March 2019 GSR-227-E and ICMR 2017

iii) Purpose: Summarized and explains the objectives of the procedure

iv) Scope: Stated the range of activities that the SOP applies to

v) Responsibility: Refers to person(s) assigned to perform the activities involved in the SOP

vi) Detailed instructions: Describes procedures step by step in short and clear sentences

vii) IEC: Institutional Ethics Committee independent body whose responsibilities are to ensure the protection of the rights, safety and well-being of human participants involved in a clinical trial (at sites which do not have EC/EC not functional as per New Drugs and Clinical Trial Rules, 2019 and to provide public assurance of that protection.

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SRI BALAJI VIDYAPEETH

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