

## SOP -18

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

#### 1.1 Purpose

The purpose of this SOP is to guide how to prepare for an audit of the IEC processes.


**1.2 Scope** This SOP applies to Institutional Ethics Committee of Indira Gandhi Institute of Dental Sciences, Sri Balaji Vidyapeeth.

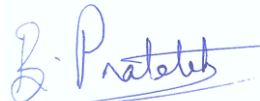
**1.3 Responsibility** It is the responsibility of the Secretariat, the Members, and the Chairperson of the IEC to perform all tasks according to the SOPs and to be well-prepared and available to answer questions during evaluation, audit or inspection visits of authorities.


#### 1.4 Flow chart:


Activity	Responsible person
Prepare an annual report with supporting documents	IEC Chairperson /
Report sent to IQAC, IGIDS, SBV	IEC Secretariat
Call for discussion if any	IEC Secretariat, Principal & IQAC Institutional Coordinator
Discuss the Issues	IEC Secretariat / Members and Chairperson
Audit report generated	IQAC
Remedial or Preparation	IEC Secretariat

#### 1.5 Detailed instructions:

  
**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

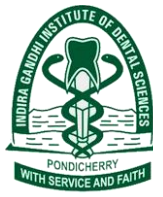




## INSTITUTIONAL ETHICAL COMMITTEE

### INDIRA GANDHI INSTITUTE OF DENTAL SCIENCES

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



#### 1.5.1 Audit Initiation and Planning

##### 1.5.2 Plan for Audit and inform all members

1. Keep all documents ready confirming to the checklist below
2. Fix a date for audit with the IQAC, IGIDS. [Preferably after the end of October or beginning of November]

#### 1.5.2 Confirmity with Checklist

The auditor should check for confirmation to the checklist below and issue a report based on the evaluation

- ✓ Background and training records of IEC members
- ✓ Protocol Application Submission Records
- ✓ Protocol Assessment Minutes
- ✓ Communication Records [Emails/Hardcopy]
- ✓ Amendment/ Modification Approval
- ✓ Meeting Agenda, Minutes
- ✓ Approval letters and final certification
- ✓ Reports of the IEC meets conducted.

#### 1.5.3 Record the Audit/Inspection Event

1. Keep record of the report on the audit/inspection meeting in the audit/inspection file soft copy/hardcopy

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



## SRI BALAJI VIDYAPEETH

Established Under Section 3 of the UGC Act 1956  
PILLAYARKUPPAM,, PUDUCHERRY – 607 402PH: 0413-2516808FAX: 0413- 2516808