

**Standard Operating Procedures of Institutional Ethics Committee**

**ICMR – NIRRH Ethics Committee for Human Studies**

**Title: Audit / Inspection**

**SOP Code: 26/V1.2**

**Dated: 8<sup>th</sup> November 2024**

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### 26.1. Purpose

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

### 26.2. Scope

This SOP applies to the *ICMR-NIRRH Ethics Committee for Human Studies* IEC Office.

### 26.3. 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.

### 26.4. Flow chart

Sr. No.	Activity	Responsibility
1	Have an Audit / Inspection	IEC Chairperson / Director of the Institution
2	Prepare for the audit / Inspection	IEC Secretariat / Members and Chairperson
3	Meet the Auditor / Inspection	IEC Secretariat / Members and Chairperson
4	Discuss the Issues	IEC Secretariat / Members and Chairperson
5	Record the Event	IEC Secretariat

### 26.5. Detailed instructions

#### 26.5.1 Receive a Call for an Audit / Inspection

- i Receive a notice Audit / Inspection of inspection visit
- ii The Member Secretary / Chairperson inform the Director or Head of Institution.
- iii The Chairperson informs IEC members to get ready.

#### 26.5.2 Prepare for the Audit / Inspection

- i Get a checklist **AF/01/26/V1.2** (see ANNEX 1).
- ii Go through all steps on the list.
- iii Check if all documents are labeled and kept in the right order for easy and quick search.
- iv Check for any missing or disorganized records.
  - a. Membership files of IEC members
  - b. Application Submission Records
  - c. Protocol Assessment Records
  - d. Communication Records

- e. Amendment Approval
  - f. Meeting Agenda, Minutes, Approval letters
  - g. Active files
  - h. Continuing and Final reports
- v Reserve a meeting room and all necessary facilities.
- vi Review the IEC SOPs.
- vii Make sure that no omission or deviation exists.
- viii Make sure to have good reasons for any omission or deviation.
- ix Inform IEC members about the inspection date so t they can attend the audit/inspection meeting.

#### **26.5.3 During the Audit / Inspection**

- i The Chairperson or the Secretariat welcomes and accompanies the auditors/inspectors to the reserved meeting room.
- ii Members and some key staff must also be present in the meeting room.
- iii The conversation starts with the auditor/inspector stating the purpose of the visit and what kind of information and data are needed.
- iv Auditor/inspector should sign the Confidentiality agreement and COI agreement prior to handling any records in the EC office
- v Answer questions of the auditors/inspectors clearly, politely, and truthfully with confidence and straight to the point.
- vi Find and get all information and files requested by the auditors/inspectors.
- vii Take note of the comments and recommendations of the auditors/inspectors.

#### **26.5.4 Discuss the Issues**

- i Review the comments and recommendations of the auditors/inspectors.
- ii Write a report and have it approved by the Chairperson.
- iii The Chairperson calls for the correction.
- iv Allow appropriate time for correction and improvement process.
- v Carry an internal follow-up audit.
- vi Evaluate the outcome.
- vii Report the outcome to the Chairperson.

#### **26.5.5 Record the Audit/Inspection Event**

- i Keep a record of the report on the audit/inspection meeting in the audit/inspection file.
- ii Record the internal follow-up audit findings in the internal audit file.

### **26.6 ANNEX**

ANNEX 1	AF/01/26/V1.2	Audit and Inspection Checklist
ANNEX 2	AF/01/26/V1.2	Document History

**Audit and Inspection Checklist**

Internal Audit/ External Audit /Audit Inspection	Date:
The date(s) on which the audit/inspection has been agreed to:	
Review the SOPs and note details of any omissions or deviations, with reasons	
<p>Check the files for the presence of all signed documents. Note any that are missing and actions taken.</p> <ol style="list-style-type: none"> <li>1. Background and training records of IEC members</li> <li>2. Application Submission Records</li> <li>3. Protocol Assessment Records</li> <li>4. Communication Records</li> <li>5. Amendment Approval</li> <li>6. Meeting Agenda, Minutes, Approval letters</li> <li>7. Active files</li> <li>8. Continuing and Final reports</li> </ol>	
Are any documents known to be missing from the study master file?	
Which personnel and members will be available? Give details of times and dates.	
What arrangements are there in the event the auditor/inspector needs to make copies of documents?	
Completed by: .....	Date:.....
Name and Signature	

## Document History

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1.0	3 <sup>rd</sup> May 2013	Final approved copy
Dr. Beena Joshi	Version 1.1	1 <sup>st</sup> May 2019	Sop no. Changed from 24 to 26 Document History added
Dr. Vikrant Bhor	Version 1.2	8 <sup>th</sup> November 2024	All bullets are numbered. ● 26.5.2 (iv) missing or disorganized records modified