Title: Audit and Inspection of the IEC

SOP Code: SOP/24/V1.0

Effective date: 03/05/2013

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1. Purpose

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

2. Scope

This SOP applies to *NIRRH Ethics Committee for Clinical Studies* IEC Office.

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.

4. Flow chart

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

5. Detailed instructions

5.1 Receive a Call for an Audit / Inspection

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

5.2 Prepare for the audit / Inspection

- Get a checklist AF/EC/01/24/V1.0 (see ANNEX 1).
- Go through all steps on the list.
- Check if all documents are labeled and kept in the right order for easy and quick search.
- Check for any missing or disorganized records.
    - ✓ Background and training records of IEC members

- ✓ Application Submission Records
- ✓ Protocol Assessment Records
- ✓ Communication Records
- ✓ Amendment Approval
- ✓ Meeting Agenda, Minutes, Approval letters
- ✓ Active files
- ✓ Continuing and Final reports

- Reserve a meeting room and all necessary facilities.
- Review the IEC SOPs.
- Make sure that no omission or deviation exists.
- Make sure to have good reasons for any omission or deviation.
- Inform IEC members about the inspection date so that they are able to attend the audit/inspection meeting.

5.3 During the Audit / Inspection

- The Chairperson or the Secretariat welcomes and accompanies the auditors/inspectors to the reserved meeting room.
- Members and some key staff must also be present in the meeting room.
- The conversation starts with the auditor/inspector stating the purpose of the visit and what kind of information and data are needed.
- Answer questions of the auditors/inspectors clearly, politely and truthfully with confidence and straight to the point.
- Find and get all information and files requested by the auditors/inspectors.
- Take note of the comments, recommendation of the auditors/inspectors.

5.4 Discuss the Issues

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

5.5 Record the Audit/Inspection Event

- Keep record of the report on the audit/inspection meeting in the audit/inspection file.
- Record also the findings from the internal follow-up audit in the internal audit file.

6. Glossary

Audit A systematic and independent examination of research trial approval activities and documents to determine whether there view and approval activities were conducted and data were recorded and accurately reported according to the SOPs, GCP,

Declaration of Helsinki and applicable regulatory requirements

Inspection — The act by a regulatory authorities of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authorities to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organizations (CRO) facilities, Office of Ethics Committees, or at other establishments deemed appropriate by the regulatory authorities

7. References

7.1 World Health Organization, Operational Guidelines for Ethics Committees that review Biomedical Research, 2000.
7.2 International Conference on Harmonization, Guidance on Good Clinical Practice (ICHGCP) 1996.
7.3 World Health Organization, Surveying and Evaluating Ethical Review Practices, Feb. 2002
7.4 Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006

8 ANNEX

ANNEX 1 AF/EC/01/24/V1.0 Audit and Inspection Checklist

ANNEX 1 AF/EC/01/24/V1.0

Audit and Inspection Checklist

□Internal Audit □External □Audit Inspection	Date:
The date(s) which the audit/inspection has been agreed for:	
Review the SOPs and note details of any omissions or deviations, with reasons	
Check the files for the presence of all signed documents. Note any that are missing and actions taken. ✓ Background and training records of IEC members ✓ Application Submission Records ✓ Protocol Assessment Records ✓ Communication Records ✓ Amendment Approval ✓ Meeting Agenda, Minutes, Approval letters ✓ Active files ✓ Continuing and Final reports	
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: …… Name and Signature	Date:……..