Title: Review of Final Report

SOP Code : SOP/14/V1.1

Effective date : 24/09/2014

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1. Purpose

The purpose of this SOP is to provide instructions on the review and follow up, if appropriate, of Final Reports for any study previously approved by the NIRRH Institutional Ethics Committee for Clinical Studies.

2. Scope

This SOP applies to the review and follow-up of the Final Report which is an obligatory review of each investigator's activities presented as a written report of studies completed to the IEC. The Institutional Ethics Committee for Clinical Studies provides a Study Report Form for Protocol Termination/ Completion refer ANNEX 4 (AF/EC/04/06/V1.3) of SOP/06/V1.3 which is to be followed by the investigators for submission of Final report.

3. Responsibility

It is the responsibility of the IEC secretariat to review the report for completeness before making copies for the EC meeting.

4. Flow chart

No.	**Activity**	**Responsibility**
1	Activities before the EC meeting ↓	IEC
2	Activities during the EC meeting ↓	IEC Secretariat / Members / Chairperson
3	Activities after the EC meeting	IEC Secretariat

5. Detailed instructions

5.1 Before each EC Meeting

- See SOP/06/V1.3 (Management of Protocol Submission) for receiving and checking the report packages.
- The Member Secretary and affiliated members will review the submitted report and the Principal Investigator will make the changes if needed.
- The Principal Investigator to make sufficient number of hard copies with the incorporated changes.
- The Secretariat to send the copies to the external members and Chairperson.

5.2 During the EC Meeting

- Each EC member reviews and gives their comments on a copy of the Final Report.
- The Chairman entertains any discussion of the study.

- If appropriate to the discussions, an IEC member may call for consensus on whether to request further information or to take other action with the investigator.
- Summarize what action should be taken.

5.3 After the EC Meeting

- Notify the investigator of the decision.
- Accept and file the Final Report, if no action is taken.
- Note the decision in the meeting minutes.
- Consider the study as closed.
- Send the approved minutes to the investigator.
- Archive the entire study protocol and the report.

6. References

6.1 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.

6.2 International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

6.3 Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006