Title: Continuing Review of Study Protocol

SOP Code: SOP/13/V1.1

Effective date: 24/09/2014

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1. Purpose

This SOP describes how continuing reviews of previously approved protocols of NIRRH Ethics Committee for Clinical Studies are managed by the Ethics Committee. The purpose of the continuing review is to monitor the progress of the entire study, to ensure continuous protection of the rights and welfare of research participants. Continuing review of the study may not be conducted through an expedited review procedure, unless

1. The study was eligible for, and initially reviewed by, an expedited review procedure; or
2. The study has changed such that the only activities remaining are eligible for expedited review.

2. Scope

This SOP applies to conducting any continuing review of study protocols involving human participants at intervals appropriate to the degree of risk but at least once a year. Depending upon the degree of risk to the participants, the nature of the studies, and the vulnerability of the study participants and duration of the study, the IEC may choose to review or monitor the protocols more frequently (more than once a year).

3. Responsibility

It is the responsibility of the Principal Investigators to submit the study protocols for continuing review as mentioned in the approval letter. The Ethics Committee is responsible for determining the date of continuing review. The period is usually one year as provided in the Approval letter. The IEC is responsible for reviewing the progress made in the protocol, the occurrence of unexpected events or problems, and the rate of enrolment of participants. The protocol, informed consent documents and assent documents are examined to ensure that the information remains accurate. The IEC has the same options for decision making on a continuing review package as for an initial review package. The decision is made as approved, minor modifications, major modification and disapproved. The approval will be given based on the frequency of the risk.

4. Flow chart

No.	Activity	Responsibility
1	Remind PI for continuing review submission ↓	IEC Secretariat
2	Manage continuing review package upon receipt ↓	IEC Secretariat
3	Notify the affiliated members of the IEC& Member Secretary ↓	IEC Secretariat
4	Incorporate the reports in the Agenda of the forthcoming meeting ↓	IEC Secretariat
5	Send package after incorporation of suggestions given by Affiliated members to external experts ↓	IEC Secretariat
6	Protocol Continuing review process in IEC Meeting ↓	IEC Secretariat, IEC Members and Chairperson
7	Approval of minutes ↓	Chairperson
8	Providing Minutes to PI regarding approval	IEC Secretariat

5.1 Remind Principal Investigator for continuing review submission

If the report is not received within one month, the secretariat will remind the Principal Investigator. At the end of three months, if no report is received the study will be suspended.

5.2 Manage continuing review document upon receipt.

- Receive a package of continuing review for each protocol prepared and submitted by the Study Team.
- Upon receipt of the package, the Secretariat of the IEC should perform the following:

5.2.1 Initial and date the submission package

- See SOP/06/V1.3 for procedures on receipt of submitted packages.

5.2.2 Verify the contents of the document

- Make sure that the contents of the package include the continuing review /annual report form ANNEX 3 AF/EC/03/06/V1.3 (Management of Protocol Submission)

5.2.3 Store the continuing review document

- Store the original package in the protocol specific file.

5.2.4 Notify and provide the document to the affiliated members and Member Secretary
Receive comments and suggestions from affiliated members and Member Secretary.

5.2.5 Provide this form to the Principal Investigator for incorporation of comments and suggestions

5.2.6 Receive the document with the changes made in the continuing report document

5.2.7 Place it in the IEC meeting Agenda

5.3 Protocol Continuing Review Process during IEC Meeting

5.4 Approval of Minutes by the Chairperson

5.5 Provide decision - Providing Minutes to Principal Investigator regarding approval.

5.6 Approval letter for continuing review to the Principal Investigator to be given.

6 Glossary

Approved Protocols Protocol that have been *approved without stipulations* or *approved with recommendations* by the IEC may proceed. Protocols that have been *approved with stipulations* by the IEC may not proceed until the conditions set by the IEC in the decision have been met. Protocols should be amended and submitted to the IEC within *one* month for re-review.

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 (ICH-GCP) 1996.

7.3 ICMR guidelines for clinical research. (http://icmr.nic.in/ethical_guidelines.pdf)

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

8. ANNEX

ANNEX 1 **AF/EC/01/13/V1.1**

Document History

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1	20th March 2013	First approved copy
Dr. Ragini Kulkarni	Version 1.1	24th September 2014	5.2.4 Deletion of the sentence "Provide the project review report form in which". The sentence has been modified