Title: Continuing Review of Study Protocol

SOP Code: SOP/13/V1.2

Effective date: 07/11/2017

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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, however the frequency of continuing review will be determined based on the risk assessed in the protocol. 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 Member Secretary ↓	IEC Secretariat
4	Incorporate the reports in the Agenda of the forthcoming meeting ↓	IEC Secretariat
5	Send package to all IEC members and Chairperson ↓	IEC Secretariat
6	Protocol Continuing review process in IEC Meeting ↓	IEC Secretariat, IEC Members and Chairperson
7	Approval of minutes ↓	Chairperson
8	Providing Minutes and Approval Letter to PI	IEC Secretariat

5.1 Remind Principal Investigator for continuing review submission

The Secretariat will send an e-mail to Principal Investigator regarding submission of the Annual Report on due date. 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 second reminder will be sent and Principal Investigator will need to give justification for delay in submission of reports.

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/V1.5 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/V1.5 (Management of Protocol Submission)

5.2.3 Store the continuing review document

- Store the original documents in the protocol specific file.

5.2.4 Notify and provide the document to the Member Secretary and all IEC members.

5.2.5 Place it in the IEC meeting Agenda

5.3 Protocol Continuing Review Process during IEC Meeting

The protocol submitted for continuing review will be reviewed by the IEC member during the meeting.

5.4 Approval of Minutes by the Chairperson

The minutes will be approved by the Chairperson within 15 days.

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

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/V1.2**
ANNEX2 **AF/EC/02/13/V1.2**

ANNEX 1 **AF/EC/01/13/V1.2**

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
Dr. Ragini Kulkarni	Version 1.2	7th November 2017	Pg. 3 point 2 added the sentence 'however the frequency of continuing review will be determined based on the risk assessed in the protocol' Pg. 3, Flow chart modified Pg. 4, Modified point no. 5.1 Pg. 4, Modified point no. 5.2.4 Pg. 4, Point no. 5.2.5 & Point no. 5.2.6 deleted. Pg. 4, Description to point 5.3 & 5.4 added

ANNEX2 **AF/EC/02/13/V1.2**

Template for Continuing Review Report

Project No: Principal Investigator:

Name of the project:

Name of the Co-Investigator:

Collaborators:

Duration of the study:

Presented to EC – date: Approval date:

Study initiation- date

Amendments if any:

Approval given for the Amendment:

Financial Status

Objectives:

Sample size:

Number of study participants enrolled: Number of drop outs/ withdrawn:

Summary of the work done (preferably in 1-2 paragraphs):

Number on study/follow-up:

Impact of any additional information appeared in the literature: Risk benefit ratio:

Number of AE/SAE: Change in risk benefit ratio:

Completion/Termination of the study – date

Any protocol deviation and violations:

Impact of any information evolved from the protocol/ similar research:

Publication:

Signature of the Principal Investigator with date: