Standard Operating Procedures of Institutional Ethics Committee

ICMR – NIRRCH Ethics Committee for Human Studies

Title: Continuing Review and Extension of Study Protocol

SOP Code: 15/V1.4 Dated: 8th November 2024 Pages: 199 to 203

15.1 Purpose

This SOP describes how continuing review reports of previously approved protocols of ICMR-NIRRCH Ethics Committee for Human 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.

This SOP also provides guidance on seeking extensions for the approved studies

15.2 Scope

This SOP applies to conducting any continuing review reports 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 the duration of the study, the IEC may choose to review or monitor the protocols more frequently (more than once a year).

15.3 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 modifications, and disapproved. The approval will be given based on the frequency of the risk.

15.4 Flow chart

Sr. No.	Activity	Responsibility
1	a. Accept continuing review report between 10th month to 11th month from date of approval b. Accept request for extension 2 months before expected approved completion date	IEC Secretariat
2	a. Manage continuing review report b. Manage request for extension 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 the package to all IEC members and the Chairperson	IEC Secretariat
6	Discussion of Continuing Review Report in IEC Meeting	IEC Secretariat, IEC Members, and Chairperson
7	Approval of minutes	Chairperson
8	Providing Minutes and Approval Letter to PI	IEC Secretariat

15.5 Detailed instructions

15.5.1 Timeline for Submission

a. Continuing Review Report (CRR)

The Secretariat may send an e-mail reminder to the Principal Investigator regarding the submission of the Continuing Review Report on the due date.

It is the responsibility of the Principal Investigator to submit the continuing review report in the 10^{th} month to the 11^{th} month from the date of approval as indicated on the approval letter (irrespective of initiation of the study) so that the study continuation will not be affected. PI may kindly note that this will be considered non-compliance to the EC guidelines set as per the SOP.

If the report is not received, at the end of 12^{th} month, a second reminder may be sent.

If the report is not yet submitted the EC secretariat will intimate this non-compliance to the committee.

The committee can then decide to take necessary action with regard to the continuation of the project. Principal Investigator will need to give justification for the delay in submission of the report.

b. Request for Extension

Request for extension of the previously approved protocols of ICMR-NIRRCH Ethics Committee for Human Studies must be made 2 months prior to the expected approved completion date in the template provided giving full justification.

If the **study duration stated in the initial request is over, the PI needs to submit the request for an extension stating the duration required. Until the committee approves, Principal Investigator cannot continue the study.**

If the request comes close to the expected completion date, then the study will be suspended until EC Committee approves the extension of the study.

If the study is not initiated due to unavoidable reasons by the stipulated time frame/ duration asked by the Principal Investigator in the initial proposal which has come to an end, the EC should be intimated about the status.

If the duration of approval expires, EC may consider this as a new proposal when Principal Investigator wishes to initiate the study.

15.5.2 Manage documents upon receipt.

1. Receive a continuing review report submitted and send it to the assigned reviewer.
2. Receive a request for an extension submitted and send it to the assigned reviewer.
3. Upon receipt of the document, the Secretariat of the IEC should perform the following:

15.5.2.1 Initial and date on the submitted documents

See SOP/09/V1.7 (5.2.1.4 and 5.2.1.6) for procedures on receipt of the submitted report.

15.5.2.2 Verify the contents of the document

a. Make sure that the document of continuing review report form include **ANNEX 8, AF/8/06/V2.2** and document for request of extension form include **ANNEX 9, AF/9/06/V2.2 (SOP 6)**
b. Verify the dates & other information as per the EC file records

15.5.2.3 Store the continuing review document

Store the original documents in the protocol-specific file.

15.5.2.4 Notify and provide the document to the Member Secretary and assigned reviewer.

15.5.2.5 Place it in the IEC meeting Agenda

15.5.3 Protocol Continuing Review Process during IEC Meeting

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

15.5.4 Approval of Minutes by the Chairperson

The Chairperson will approve the minutes within 15 days of the meeting.

15.5.5 Provide decision - Approval letter for continuing review report and request for an extension to be given to the Principal Investigator.

15.6 ANNEX

ANNEX 1 AF/01/15/V1.3 Document History

ANNEX 1 **AF/EC/01/15/V1.3**

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
Dr. Beena Joshi	Version 1.3	1st May 2019	SOP no. changed from 13 to 15 Modified ICMR common ethics review form for Continuing Review Report format and Request for extension added
Dr. Beena Joshi	Version 1.4	4th January 2021	5.1 Request for extension 3rd & 4th para about non-initiated study is added.
Dr. Vikrant Bhor	Version 1.5	8th November 2024	All bullets are numbered.