

## **Standard Operating Procedures of Institutional Ethics Committee**

**ICMR – NIRRH Ethics Committee for Human Studies**

**Title: Review of Completion/ Final Report**

**SOP Code: 16/V1.5**

**Dated: 8<sup>th</sup> November 2024**

**Pages: 204 to 206**

### 16.1. 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 ICMR-NIRRH Institutional Ethics Committee for Human Studies.

### 16.2. Scope

This SOP applies to the review of completion/final report and how frequently reminders to are to be sent for submitting the Final Report which is an obligatory submission to the IEC by the investigator as a written report of completed study. The Institutional Ethics Committee for Human Studies provides a Study Completion/Final Report format, refer ANNEX1, AF/01/16/V1.4 of SOP/16/V1.4 which is to be followed by the investigators for submission of Final report.

### 16.3. Responsibility

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

### 16.4. Flow chart

Sr. 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

### 16.5. Detailed instructions

#### 16.5.1 Before each EC Meeting

- See **ANNEX 10, AF/10/06/V2.2 of SOP/06/V2.2** for receiving and checking the report packages.
- The IEC Secretariat will check the submitted report for completion.
- The Principal Investigator has to make a sufficient number of hard copies.
- The Secretariat will send copies to all the members.

#### 16.5.2 During the EC Meeting

- Each EC member reviews and gives their comments on a copy of the Final Report.
- The Chairman leads the discussion on the study.
- If appropriate to the discussions, an IEC member may call for consensus on whether to request further information or to take any other action with the investigator.
- Summarize what action should be taken.

### 16.5.3 After the EC Meeting

- Notify the investigator of the decision.
- Accept and file the Final Report, if no further action is required.
- 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.

### 16.6. ANNEX

ANNEX 1 Document history AF/01/16/V1.4

#### ANNEX 1

AF/01/16/V1.4

#### Document history

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1.0	3 <sup>rd</sup> May 2013	Final approved copy
Dr. Ragini Kulkarni	Version 1.1	24 <sup>th</sup> September 2014	5.2.4 Deletion of the sentence "Provide....in which" the sentence has been modified
Dr. Ragini Kulkarni	Version 1.2	7 <sup>th</sup> November 2017	Point 5.1 replaced 'External Members to 'EC members' and the 2 <sup>nd</sup> and 3 <sup>rd</sup> sentence has been reframed.
Dr. Beena Joshi	Version 1.3	1 <sup>st</sup> May 2019	SOP no. changed from 14 to 16
Dr. Vikrant Bhor	Version 1.4	8 <sup>th</sup> November 2024	All bullets are numbered. 16.1 Last point modified as '..... all the members'