

**Standard Operating Procedures of Institutional Ethics Committee**

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

**Title: Review of Resubmitted Protocols**

**SOP Code: 13/V1.4**

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

**Page Nos: 188 to 192**

### 13.1. Purpose

This SOP describes how resubmitted study protocols are managed, re-reviewed and approved by the IEC.

### 13.2. Scope

This SOP applies to study protocols that have been reviewed earlier with recommendations from IEC for some corrections in the initial review process.

### 13.3. Responsibility

It is the responsibility of the IEC Secretariat to ensure the completeness of the resubmitted documents and to notify the Chairperson that a protocol previously approved with conditions for revision has been resubmitted to the IEC for reconsideration.

A re-submitted protocol may be reviewed and approved by primary reviewers and Chairperson, or full IEC. Decision for the review of the protocol should be determined by the IEC at the time of the initial review and mentioned in the minutes of the Ethics Committee meeting in which the proposal was discussed.

### 13.4. Flow chart

Sr. No.	Activity	Responsibility
1	Receive resubmitted protocol package	Secretariat
2	Review the revised protocol	Primary reviewers
3	Sending the protocol to primary reviewers/ full IEC	Secretariat
4	IEC Meeting	IEC Members
5	Communicate the IEC decision	IEC Secretariat
6	Document the decision	IEC Secretariat

### 13.5. Detailed instructions

#### 13.5.1 Receive protocol resubmitted package.

##### ***Check the received packages for:***

Minutes of previous EC meeting

- a. Response to the comments by Investigators
- b. Checklist, form **AF/1.1/06/V2.1** (see ANNEX 1.1 of SOP 6)

- c. Revised version of protocol and related documents such as the informed consent document, data collection or case report forms, diary sheets etc. are included as part of the package.
- d. Changes made to the documents should be bold and the deleted matter should be made strikethrough for easy verification of the corrections done by the investigators.
- e. Put the stamp, write the date and acknowledge the receipt of the protocol.

### **13.5.2 Review the revised protocol at the Secretariat level**

- a. Check the received protocol as per Checklist (Section F), form **AF/1.1/06/V2.1** (see ANNEX 1.1 of SOP 6)
- b. Refer to the meeting minutes as guidance for the review.
- c. Ensure that the response to comments of EC members as mentioned in the minutes is given by the investigator and page numbers where changes are made are mentioned in the proposal
- d. Make further comments if the response is not satisfactory and the changes have not been incorporated in the study proposal.
- e. The Primary reviewers will write their comments on the Project Review Report form and will put signatures with a date.
- f. Notify the IEC Secretariat.
- g. Ask the Principal Investigator to make the necessary revisions.
- h. Send the resubmitted proposal with incorporated changes to reviewers as per the decision in the minutes in the form of soft copies on which comments can be obtained.
- i. Soft copies will be sent to the reviewers, Chairperson and Member Secretary if the proposal goes to the full committee as per the decision in the minutes.
- j. If the proposal has only minor modifications as decided in the previous full board meeting, the proposal with incorporated changes is sent to the member secretary who may either review the revised proposal himself/herself or may instead send it only to the same primary reviewers who initially reviewed the proposal.
- k. Following the receipt of comments on the revised proposals, the Secretariat to inform the Member Secretary. Follow the instructions in 5.4 respectively.

### **13.5.3 IEC meeting**

***If the IEC previously decided that major modifications are to be made in the proposal, then the revision will be processed as:***

- i In the normal course, the primary reviewer presents a brief oral or written summary of the study design and gives her/his comments to the IEC members.
- ii However, if major concerns are indicated during the review of the revised and re-submitted projects (Version 2), the PIs are requested to make a brief presentation of the projects followed by provision of responses/clarifications to the comments of the reviewers
- iii The Chairperson leads discussion on the protocol revision.

- iv Further recommendations for modifications to the protocol, consent form, as requested by the Committee are noted in the meeting minutes as 'with modifications made by IEC and will be communicated to the investigator.
- v The Chairperson takes a consensus of the EC members on the revision as follows:
  - a. Approved without change
  - b. Minor changes suggested/ clarifications on minor issues sought: Answers to be reviewed by Member- Secretary and one/ more primary reviewer(s) if required.
  - c. Major changes suggested/ clarifications on major issues sought: Answers to be reviewed by Member- Secretary and one/ more primary reviewer(s) and PI's response to be reviewed at the next full-committee meeting.
  - d. Disapproved

#### **13.5.4. Written Communication of the Decision**

- i The Secretariat then prepares the Approval letter and gets the member Secretary's and Chairperson's signature.
- ii If the study is approved, the Committee determines the frequency of Continuing Review for each study (usually it should be once a year).
- iii The Secretariat sends an Approval letter to the investigator notifying the IEC decision and schedule of continuing review.
- iv The letter contains, at a minimum, a listing of each document approved, the date set by the Committee for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study.
- v If the Committee requires modifications to any of the documents, the Secretariat sends a written request of the specific changes to the investigator to make the necessary changes and resubmit the documents to the IEC.

#### **13.6. ANNEX**

ANNEX 1      AF/EC/01/13/V1.4      Document History

## 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	<ul style="list-style-type: none"> <li>● Correction in bullet 5.2 Review the revised protocol Included</li> <li>Minor modifications for expedited review</li> <li>Major modification for full board review and deleted the following</li> <li>* Approve the study to start with Committee approved modifications to the consent = <i>Approved with minor modification</i></li> <li>* Require modifications to items noted at the convened meeting and follow -up by the Chairperson, after receipt of the requested modifications = <i>Approved with major modification</i></li> </ul>
Dr. Ragini Kulkarni	Version 1.2	7 <sup>th</sup> November 2017	<ul style="list-style-type: none"> <li>● Pg. 3, point 3 modified as primary reviewers or full IEC</li> <li>● Pg. 3, Flow chart, Affiliated members replaced with Primary reviewers</li> <li>● Pg. 4, 5.2 'Affiliated members' and bullet 5 'Internal members' replaced with 'Primary reviewers'</li> <li>● Pg. 4, 5.2 bullet 10, external reviewers to be deleted</li> <li>● Pg. 5, flow chart diagram, External replaced with Primary</li> </ul>
Dr. Beena Joshi	Version 1.3	1 <sup>st</sup> May 2019	<ul style="list-style-type: none"> <li>● SOP no. changed from 11 to 13</li> <li>● Reference for Checklist changed appropriately in 5.1 &amp; 5.2</li> </ul>
Dr. Vikrant Bhor	Version 1.4	8 <sup>th</sup> November 2024	<ul style="list-style-type: none"> <li>● Changes in the review process of the revised protocol are done.</li> <li>● If major concerns are indicated in the review of a revised resubmitted protocol, PI is allowed to give a brief presentation with clarifications to EC comments is now implemented.</li> </ul>