

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

### **ICMR – NIRRCH Ethics Committee for Human Studies**

#### **Title: Review of Protocol Amendments**

**SOP Code: 14/V1.4**

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

**Page Nos: 193 to 198**

#### 14.1. Purpose

The purpose of this procedure is to describe how protocol amendments are managed and reviewed by the IEC

#### 14.2. Scope

This SOP applies to previously approved study protocols but later being amended and submitted for approval by the IEC. Amendments made to protocols may not be implemented until reviewed and approved by the IEC.

#### 14.3. Responsibility

It is the responsibility of the IEC Secretariat to manage protocol amendments. Investigators may amend the contents of protocols from time to time. Amendments may be submitted for either “expedited” review by the same Primary reviewers or full IEC review.

#### 14.4. Flow chart

Sr. No.	Activity	Responsibility
1	Receive the Amendment Package	IEC Secretariat
2	Check for completeness	IEC Secretariat
3	Determine whether Expedited or Full Review	IEC Secretariat / Member Secretary and/or Chairperson
4	Provide it to only assigned primary reviewers/full review	IEC Secretariat
5	Amendment Review Process	IEC Secretariat/EC Members /Chairperson
6	Inform the Principal Investigator	IEC Secretariat
7	Update the amendments in the database and Store Documents	IEC Secretariat

#### 14.5. Detailed instructions

##### 14.5.1 Manage the Amendment Documents/ Package

1. The amendment documents are prepared by the Principal Investigator.  
Upon receipt of the amendment documents, the Secretariat of the IEC should follow the receiving procedure in SOP/09/V1.6 (Management of Protocol Submission) and SOP/25/V1.2 (Maintaining Confidentiality of IEC Documents).

2. A request for Amendment of the Protocol by the Principal Investigator on an existing and previously approved protocol should be made in the cover letter to the chairperson. The request should:
  - a. State/describe the list of amendments
  - b. Provide the reason/clarification for the amendment
3. The Secretariat will ensure that all the required documents are submitted.

#### **14.5.2 Determine whether expedited or full review.**

After review of the materials, the Member Secretary in consultation with Chairperson will determine whether the protocol requires expedited or full review.

1. Refer to SOP/11/V3.4 for Expedited Review.
2. Refer to SOP/12/V2.1 for Initial Review.
3. Protocol amendments that increase risk to study participants, as judged by the Chairperson, such as a change in study design, which may include but is not limited to:
  - a. additional treatments or the deletion of treatments
  - b. any changes in inclusion/exclusion criteria
  - c. change in method of dosage formulation, such as, oral changed to intravenous
  - d. Significant change in sample collection procedures; eg. Type of samples, quantity of samples, Types of investigations involved
  - e. significant change in the number of participants
  - f. significant decrease or increase in dosage amount
    1. If the Chairperson decides, the protocol requires full IEC approval, the Chairperson will indicate this decision on the Checklist, sign and date the form.
    2. The Secretariat places the protocol amendment request on the agenda for the next convened meeting.

#### **The following documents are distributed:**

1. The amendment's revision documents to clearly identify each change.
2. Requested changes to the consent form, if applicable

#### **14.5.3 Send the documents to only assigned primary reviewers/full review and Chairperson of the IEC**

- a. The Secretariat should send the documents to only assigned primary reviewers/full review of the IEC.
- b. Keep "Sent" and "Received" acknowledgement as hard copy (with dated Signatures) related to the notification of the Chairperson in the protocol file under the Correspondence section.

Follow IEC SOP/22/V1.4 in preparing and distributing the documents.

#### **14.5.4 Expedited Review**

Refer to SOP/11/V3.4 for expedited review procedure.

#### **14.5.5 Full Review by the IEC**

- a. Refer to SOP/12/V2.1 for Initial Review.
- b. See section 12.5.6

#### **14.5.6 Protocol Amendment Review Process**

##### **14.5.6.1 Review amended protocols**

- a. Use the Project Review Form (see **ANNEX 2, AF/02/12/V2.1**) to review amended protocols and protocol-related documents.
- b. Note recommendations for changes to the protocol and/or informed consent requested by IEC Members in the minutes as “with modifications made by EC’ and will be communicated to the investigator.

#### **The Chairperson and the EC members can make the following decisions:**

- a. Approve the protocol amendment as is with no modification in the Participant Information Sheet and Informed Consent Document.
- b. Require a modification to the proposed amendment or informed consent documents, stating the reason and action required to sustain the study with a follow-up full IEC review
- c. Request further information regarding the amendment and the effects of the amendments on the approved study
- d. Not approve the amendment request, stating the reason – but allow the study to continue as previously approved
  1. If the IEC approves the protocol amendment, the Secretariat staff communicates this decision to the investigator.
  2. If the IEC does not approve the protocol amendment, the Chairperson notifies the investigator in writing of the decision and the reason for not approving the amendment.
  3. Keep the minutes of the meeting relevant to the discussion and the decision reached by the IEC as the official records of the amendment review process.

#### **14.5.7 Notify the Principal Investigator.**

- a. Send a signed and dated copy of the recommendation(s)/suggestions of IEC to the Principal Investigator for their records.
- b. The Principal Investigator should then submit a list of the recommendation(s)/suggestions with clarifications and page numbers indicated where changes are made. In the submitted protocol and related documents, the changes made may be indicated by highlighting the changed parts or making them bold or in italics. These changes would be checked by Secretariat and assigned reviewers as mentioned in the submitted list.

#### **14.5.8 Updating the amendments in the database and Store documents.**

The database pertaining to the amendment has to be updated along with the date of amendment and whether they were minor or major amendments. Also, the latest version of the document has to be mentioned.

Place the original completed documents, the list of clarifications and the “clean” amended version of the protocol and related documents in the protocol file with the other documents pertaining to the amendment.

#### **14.6 ANNEX**

ANNEX 1      Document History      AF/01/14/V1.4

## Document History

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1.1	24 <sup>th</sup> September 2014	<ul style="list-style-type: none"> <li>• Correction in bullet 5.3 2<sup>nd</sup> line instead of full review written as initial Review</li> <li>• Bullet 5.5 instead of full review written as initial Review</li> <li>• SOP and Annexure nos. changed</li> </ul>
Dr. Ragini Kulkarni	Version 1.2	7 <sup>th</sup> November 2017	<ul style="list-style-type: none"> <li>• Pg. 3, Responsibility 'same primary reviewers to be assigned for amendments</li> <li>• Pg. 5, 5.6.1, Decision: Deleted 3<sup>rd</sup> bullet 'suspend.....is obtained'.</li> <li>• Pg. 5, 5.6.1, Decision: Modified 3<sup>rd</sup> bullet 'Not suspend ...'.</li> <li>• Annexure 2 added for protocol amendments.</li> <li>• Change in the flow chart and accordingly in the SOPs</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 12 to 14</li> <li>• Modified ICMR common ethical review form for Application/ Notification form for Amendments added</li> <li>• Document History annexure now changed from Annex 1 to Annex 2</li> </ul>
Dr. Vikrant Bhor	Version 1.4	8 <sup>th</sup> November 2024	<p>All bullets are numbered.</p> <ul style="list-style-type: none"> <li>• 14.5.8 is added</li> </ul>