Standard Operating Procedures of Institutional Ethics Committee

ICMR – NIRRCH Ethics Committee for Human Studies

Title: Management of Protocol Submissions

SOP Code: 09/V1.7 Dated: 8th November 2024 Pages: 148 to 159

9.1. Purpose

This standard operating procedure is designed to describe how the Secretariat of the Institutional Ethics Committee (IEC) manages protocol submissions to the IEC.

9.2. Scope

It is the responsibility of the Secretariat to check for the completeness of the documents to be reviewed and mark the points on the checklist and write the comments they might have after reviewing each study protocol. The Secretariat will check the project proposal submitted by the Principal Investigator and mark the points in the Checklist. The Principal Investigator needs to submit the required documents, which are not complete as per the checklist to the secretariat.
Protocol submissions may include:

1. Submission for Initial Review (for full board/ expedited/ exempt from Ethical review)
2. Resubmission of Protocols with Corrections (Revision)
3. Protocol Amendment
4. Continuing Review of Approved Protocols
5. Adverse Event/ Serious Adverse Event reports
6. Protocol deviations/violations/non-compliance
7. Protocol Termination/ Suspension/ Discontinuation
8. Request for extension of Approved Protocols
9. Protocol completion / Final reports
10. Specific application forms as follows:
    a. Application form for Clinical Trial
    b. Application form for Human Genetic Testing Research
    c. Application form for Socio-Behavioral and Public Health Research

9.3. Responsibility

It is the responsibility of the IEC secretariat to receive, record, distribute for review and get the project proposals approved by the IEC, as well as to deliver the review results by the way of discussion with / Minutes to the Principal Investigators

9.4. Flow chart

Sr. No.	**Activity**	**Responsibility**
1	Receive Submitted project proposals	IEC Secretariat
2	Check for submission items: 1. Initial Review Application 2. Resubmission of Protocols with Corrections 3. Protocol Amendment 4. Continuing Review of Approved Protocols	IEC Secretariat

	5. Adverse Event/ Serious Adverse Event reports 6. Protocol deviations/ violations/ non-compliance 7. Protocol Termination/ Suspension/ Discontinuation 8. Request for extension of Approved Protocols 9. Protocol completion/ Final reports 10. Specific application forms as follows: a. Application form for Clinical Trial b. Application form for Human Genetic Testing Research c. Application form for Socio-Behavioural & Public Health Research	
3	Assess whether proposal needs to be categorised as exempted/ expedited review/ Full Committee Review	Member Secretary & Chairperson
~~4~~	Selection of Primary Reviewers	Member Secretary in consultation with Chairperson if required
5	Sending the copies of study proposals online with study assessment form to primary reviewers at least three weeks prior to the meeting. Also sending the copies of proposals to other EC members online for deliberations during the meetings that could be virtual or physical. If review highlights major concerns, the compiled comments will be shared in advance ahead of the full board meeting with the principal investigator of the project, at the discretion of the member secretary/joint member secretary, to enable him/her to prepare responses ahead of the discussion of the project during the full board meeting.	IEC Secretariat
6	Complete the submission process	IEC Secretariat
7	Store the received documents	IEC Secretariat

9.5. Detailed instructions

9.5.1 Receive submitted documents

9.5.1.1 Initial Review Application

- Go to 9.5.2.

9.5.1.2 Resubmission of Protocols with Corrections

- Go to 9.5.2.1.2

9.5.1.3 Protocol Amendment

 Go to 9.5.2.1.3

9.5.1.4 Continuing Review of Approved Protocols including AE/SAE

 Go to 9.5.2.1.4

9.5.1.5 Protocol Termination/ Suspension/ Discontinuation

 Go to 9.5.2.1.5.

9.5.1.6 Request for extension of Approved Protocols

 Go to 9.5.2.1.6.

9.5.1.7 Project Completion/ Final

 Go to 9.5.2.1.7.

9.5.2 Check for submission items

9.5.2.1 Check the submitted documents

Receive the documents from the Scientists/ Principal Investigators after confirming that they are complete with respect to information, forms,answers to all the points in the form, approval letters, enclosures, page nos. on each page etc.

9.5.2.1.1 Initial Review

a. **Check whether Exempt from review/ Expedited/ Full Board Review (Pg. 36 ICMR Guidelines Table 6 ICMR Guidelines Table 4.2)**
b. Check for contents of a submitted project proposal as per Checklist, form **AF/1.1/06/V2.2** (see ANNEX 1of SOP 6),
c. Study assessment form **AF/01/12/V2.1** (see ANNEX 1),
d. In case of emergencies, calamities and catastrophes such as COVID19 pandemics, social strife, unrest, etc., submission of e-copy of research protocol and relevant documents through mail is permitted. This will be followed by the screening by EC Secretariat for completeness and categorization as exempt/ expedited review/ emergency full committee review depending on the urgency and need. When the situation returns to normal, hard copy of the same should reach EC office to maintain the records
e. Go to step 9.5.2.2

9.5.2.1.2 Resubmission of Protocols with corrections/ Revised protocols

a. Check for contents of a re-submitted project proposal as per Checklist, form **AF/1.1/06/V2.2** (see ANNEX 1of SOP 6),
b. Project Review form AF**/02/12/V2.1** (see ANNEX 2),
c. In case of emergencies, calamities and catastrophes such as COVID19 pandemics, social strife, unrest, etc., submission of e-copy of research protocol and relevant documents through mail is permitted. When the situation is returns to normal, hard copy of the same should reach EC office for maintaining the records.
d. Go to step 9.5.2.2

9.5.2.1.3 Protocol Amendments

a. Check for contents of a submitted project proposal as per Checklist, form **AF/1.1/06/V2.2** (see ANNEX 1.1 of SOP 6),
b. In case of emergencies, calamities and catastrophes such as COVID19 pandemics, social strife, unrest, etc., submission of e-copy of research protocol and relevant documents through mail is permitted. When the situation is returns to normal, hard copy of the same should reach EC office for maintaining the records.
c. Go to step 9.5.2.2

9.5.2.1.4 Continuing Reviews of Approved Protocols

a. Check the Continuing Review Report with the template **AF/8/06/V2.2** (see ANNEX 8) for all the points covered.
b. Take out the relevant file and check if the information given in report is same as mentioned in the file.
c. If any point/information is missing, provide Template (soft copy) to the Principal Investigator and request them to give information as per the template only.
d. In case of emergencies, calamities and catastrophes such as COVID19 pandemics, social strife, unrest, etc., submission of e-copy of research protocol and relevant documents through mail is permitted. When the situation returns to normal, hard copy of the same should reach EC office for maintaining the records.
e. Go to step 9.5.4

9.5.2.1.5 Protocol Termination/ Suspension/ Discontinuation

a. Check for contents of a submitted document, as per the format of final review **AF/11/06/V2.2** (see ANNEX 11),
b. In case of emergencies, calamities and catastrophes such as COVID19 pandemics, social strife, unrest, etc., submission of e-copy of research protocol and relevant documents through mail is permitted. When the situation returns to normal, hard copy of the same should reach EC office for maintaining the records.
c. Go to step 9.5.4

9.5.2.1.6 Request for extension of Approved Protocols

a. Check for contents of a submitted document, as per the format of Study Report Form for Extension of the Approved Study **AF/9/06/V2.2 (see ANNEX 9),**
b. In case of emergencies, calamities and catastrophes such as COVID19 pandemics, social strife, unrest, etc., submission of e-copy of research protocol and relevant documents through mail is permitted. When the situation returns to normal, hard copy of the same should reach EC office for maintaining the records.
c. Go to step 9.5.4

9.5.2.1.7 Protocol Completion/ Final

a. Check for contents of a submitted - document, as per the format of final review **AF/10/06/V2.2**(see ANNEX 10),
b. In case of emergencies, calamities and catastrophes such as COVID19 pandemics, social strife, unrest, etc., submission of e-copy of research protocol and relevant documents through mail is permitted. When the situation returns to normal, hard copy of the same should reach EC office for maintaining the records.
c. Go to step 9.5.4

9.5.2.1.8 Management of disapproved protocol

If any protocol is disapproved, the reason for the same should be conveyed to the Principal investigator in writing.

The protocol which is disapproved should be archived as per the achieving procedures set by the EC, (Refer SOP 24)

9.5.2.2 Fill in the forms:

Tick mark the points on the Checklist, form AF/1.1/06/V2.2 (see ANNEX 1.1 of SOP 6).

9.5.2.3. Verify contents of submitted project proposal

a. Covering letter
b. Checklist
c. Initial review form displaying type of project, project title, Name of the Principal Investigator & Co-investigator/Collaborator

Project Proposal should be complete as per the Checklist, form AF/1.1/06/V2.2 (see ANNEX 1.1 of SOP 6)

Participant Information Sheet: refer (ANNEX 1.4, AF/1.4/06/V2.2)

To see that all the questions are included in the Participant Information Sheet as per the given format, Informed Consent Document refer (ANNEX 1.5, AF/1.5/06/V2.2)

Detailed Study Protocol should include the following points refer (ANNEX 1.2, AF/1.2/06/V2.2)

9.5.3 Complete the Checking process

a. Check for completeness of the submitted documents
b. Notify the applicants if the package is incomplete.
c. State clearly the items missing in the package.
d. Fill up the related parts and the missing documents.
e. If the documents found to be complete, endorse with a 'Received' stamp with Date, Time & signature of Secretariat staff with the inward no. on the Covering letter. insert Protocol no., date of receipt and duration of the project on the first page of the Project document.
f. Attach the filled Checklist form **AF/1.1/06/V2.2** (see ANNEX 1.1 of SOP 6) with the copy of the Study Assessment Form **AF/01/12/V2.1** (see ANNEX 1) to the Research Protocol documents.

9.5.4 Processing the Submitted Documents

a. The Principal Investigator will be informed to make multiple copies as required for physical or e-copy for virtual meetings. If the project is to be put forth to the meeting, it will be assigned a number and the file of the project with that number will be made. The entry will be made in the 'Project Register' and an Excel sheet for writing further information. If the project is found to be incomplete, the Principal Investigator will be asked to make the corrections in the proposal.

b. Primary reviewers will be assigned and the secretariat will send the copies at least three weeks in advance of the full committee meeting with the primary reviewers and EC members.

c. The reviewers will send the comments within two weeks of receiving the projects. Comments from the reviewers will be compiled for discussion during the meeting. In case the review highlights major concerns, the compiled comments will be shared in advance ahead of the full board meeting with the principal investigator of the project, at the discretion of the member secretary/joint member secretary, to enable him/her to prepare responses ahead of the discussion of the project during the full board meeting.

9.5.5 Create a Protocol-Specific File (for Initial Review)

a. Create the 'Project' file. (Both physical and e-copy)

b. Record the name of the Principal Investigator, title, and assign number to the project.

c. Keep a copy of the submitted documents with original signatures in the respective file.

9.5.6 Store the received documents

a. Bind the documents together appropriately.

b. Store the dated and initial original protocol documents on the IEC submission shelf for review in chronological order.

9.5.7 Timelines for Procedures

Timelines for procedures will be as follows:
PI should submit protocol along with all the necessary documents at least 30 days prior to the date of the next EC meeting.
Minutes given to PI after full board meeting – Within 8 Working days
Clarifications submitted by PI – Expected within 15 days; maximum up to 60 days
Approval letter – Within 5 working days (after submission of final approved copy by Principal Investigator to the Ethics Committee office)
In the absence of any response within 120 days, the project will be declared closed for the IEC office records.

9.6. ANNEX

ANNEX 1	AF/01/09/V1.7	Approval Letter
ANNEX 2	AF/02/09/V1.7	Document Histor

ANNEX 1 **AF/01/09/V1.7**

ICMR- NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH
Jehangir Merwanji Street, Parel, Mumbai-400 012

ICMR-NIRRCH ETHICS COMMITTEE FOR Human Studies
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Recognized by: Strategic Initiative for Developing Capacity in Ethical Review (**SIDCER**),

Forum for Ethics Review Committees in Asia and the Western Pacific Region (**FERCAP**)

for its compliance with international and local standards in ethical review

CHAIRPERSON

MEMBERS

JOINT MEMBER SECRETARY

MEMBER SECRETARY

Ref.: D/ICEC/Sci-…/…/….. Date
Dr. ……
Department ……..
ICMR-NIRRCH

Subject: Name of the project Title which was approved in meeting, Version ……, dated ……..

Project No.: …… PI: Dr. ……

Dear Dr. …….,

This is with reference to the above mentioned research study proposal, Version No. dated (reviewed in the meeting) which was reviewed and approved with minor modifications/ with amendments / with revision along with the Participant Information Sheet and Informed Consent Documents (English and/ or Hindi and/or Marathi) by the ICMR-NIRRCH Ethics Committee for clinical Studies on …(meeting date)…….. with Dr. ….(Chairperson Name)… as the Chairperson. The Ethics Committee acknowledges the receipt and approves the Participant Information Sheet and Informed consent documents (English) / Hindi/Marathi on …(final copy received date)….

Please note that any changes to the proposal / Participant Information Sheet / informed consent form should have prior approval by the ethics committee before being implemented. The approval for this proposal is valid for a period of one year only.

You are requested to submit the study report for a continuing review at least 2 months before the next re-approval period / on completion of the study.

Study can be initiated only after obtaining the approval of the collaborating centers and MoU is signed between the collaborating centers.

Due date for submission of Continuing review/Completion Report:……

Sincerely,

Dr. Dr.
Member Secretary Chairperson

ANNEX 2 **AF/EC/02/09/V1.7**

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	03rd June 2013	Minor Changes in 1) Project Review Report form and 2) Study Report Form for Protocol Termination/ Completion - Inclusion of a) Date of EC Approval b) No. of Participants at each site c) Number of Participants in each of the Study Arms d) Reasons for Termination e) Whether the study samples are retained for future use f) Presentations (If any) Deletion of a) Number of Participants who received the test intervention/drug
Dr. Ragini Kulkarni	Version 1.2	24th September 2014	Changes in – Document checklist Continuing review report form Study report form for protocol termination/completion Inclusion of Study Assessment Form
Dr. Ragini Kulkarni	Version 1.3	15th April 2015	Changes in – Document checklist, addition of the point no.18 - GCP Training Certificate of Principal Investigator/ Co-Investigators/Collaborators – Attached/Not Attached
Dr. Ragini Kulkarni	Version 1.4	1st September 2016	Pg.11 - added 'Signature with date' under Study Assessment form for New Projects
Dr. Ragini Kulkarni	Version 1.5	3rd October 2017	Pg.3 Added Serious Adverse Event reports and Protocol completion reports under point 2 and in flow chart point no.2 added in point 5.1.4 AE/SAE Pg.4, point 5.1.5 deleted the word Completion

			Pg.4, point 5.2.1 deleted the word 'received' and inserted the world 'submitted' Pg.4 5.2.1.3 deleted the sentence 'Review Report form AF/EC/02/06/V1.4 (see ANNEX 2)' Pg.4 5.2.1.4 and 5.2.1.5 deleted 5.2.2 and written as 5.4 Pg.6 point 5.4 deleted the sentence 'After review of the project by the Secretariat, invite the Internal IEC members for review of project proposal and hand over the proposals for checking along with Checklist and Review Report form to internal reviewers. If the internal IEC members find the project to be technically sound and complete in all respect to be placed before the Full Board/ERC', Under Annex 1 – Checklist point 8 added point f) Does the protocol involves sending samples abroad Under point 10 added 'signed and dated' Annex 2 added point 19 MOU's with collaborating Organisation Annex 3 deleted Annual Report and written as Continuing Review *<u>Inserted in Annex 3 – added the points</u>* Budget, need of extension with justification, Risk benefit ratio and Change in risk benefit ratio: *<u>Inserted in Annex 4 – – added the points</u>* Risk benefit ratio and Change in risk benefit ratio: Deleted word termination from Annexure title Pg.15Annex 5 added new annexure for 'Study Report form for protocol Termination'

Dr. Beena Joshi	Version 1.6	1st May 2019	Formats for other review forms were relocated into their respective SOPs.
Dr. Vikrant Bhor	Version 1.7	8th November 2024	All bullets are numbered. Procedures followed in case of emergencies is added Management of disapproved protocol is added Changes in timelines and procedures of submission