Standard Operating Procedures of Institutional Ethics Committee

ICMR – NIRRCH Ethics Committee for Human Studies

Title: Initial Review of Project Proposal

SOP Code: 12/V2.1 Dated: 8th November 2024 Page Nos:174 to 187

12.1. Purpose

This SOP describes how the ICMR-NIRRCH Ethics Committee for Human Studies will review the initially submitted project proposal for approval by the Ethics Committee by using the Study Assessment Form (see Annex 1, AF/EC/01/10/V2.0) & Project Review Form (see Annex 2, AF/EC/02/10/V2.0).

12.2. Scope

This SOP applies to the assessment of all protocols submitted for review and approval from the IEC.

12.3. Responsibility

It is the responsibility of the Assigned/primary Reviewer to check the contents of project for there suitability as per the the Study Assessment Form (see Annex 1, AF/EC/01/12/V2.0) & Project Review Form (see Annex 2, AF/EC/02/12/V2.0). Assigned reviewer can mark their comments in the forms & sent the same to the EC secretariat at least 21 days prior to the Ethics committee meeting or within 1 week span when the document is to be reviewed by expedited procedure.

12.4. Flow chart

Sr. No.	Activity	Responsibility
1	**Assign the primary reviewers- Scientific & Ethical Review**	**Member Secretary**
2	Review of the protocol with associated documents and communicating the comments/suggestions to the ethics secretariat using Study assessment form duly signed & dated	Primary reviewers
3	Compilation of the comments given by primary reviewers	Secretariat and Member Secretary
4	Place the study proposal in the IEC meeting for review	Secretariat and Member Secretary
5	Record the IEC's Decision	IEC Secretariat

12.5. Detailed instructions

12.5.1 Choosing primary reviewers and roles of the assigned primary reviewers

a. The Member Secretary chooses the primary reviewers based on the topic of the proposal and expertise available within the committee.
b. A legal person is made a primary reviewer to assess issues pertaining to rights of vulnerable populations and assess if MOUs or compensation issues are adequately addressed.
c. Similarly social and or gender issues have to be assessed by the social science expert.
d. A layperson is designated as a primary reviewer in every proposal where there is a PIS as the language and content need to be reviewed by lay person for understanding and clarity of description.
e. Apart from primary reviewers all members will have access to all proposals that would be discussed in the meeting agenda.
f. The primary reviewers provide written feedback on the proposal using the appropriate template within two weeks of the receipt of the project and approximately one week ahead of the full board meeting. This will help the Member Secretary to compile the comments and present them 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.

Placing the proposal before the Ethics Committee Meeting

Member Secretary will provide brief summary and compiled comments of Primary Reviewers. However, in case any major concerns are noted and highlighted during the review by the primary reviewers, the respective PIs of the projects will make a brief presentation of the project instead of the member secretary, followed by the provision of responses/clarifications to the major comments of the reviewers. Following this, any additional comments will be provided by primary reviewers followed by the chairperson inviting other members for their comments on the relevance/ deficiencies of the protocol, if any. The Member Secretary and reviewers will ensure that the comments given by the SRC/SAC are included in the protocol. The Principal Investigator/Co-Investigator will be requested to provide clarifications on the study protocol if required, even if no major concerns are noted as above. The Member Secretary (assisted by the Secretarial staff) shall record the discussions and minute it.

In case of emergencies, calamities, and catastrophes such as COVID-19 pandemics, social strife, unrest, etc., submission of an e-copy of the research protocol and relevant documents through mail is permitted. When the situation returns to normal, hard copy of the same should reach EC office to maintain the records.

12.5.2 Decision-making on submitted protocols.

The EC members will discuss and clarify the comments and suggestions. The Member secretary (assisted by the Secretarial staff) shall record the discussions and minute it.

a. Member(s) of the committee who is/are listed as investigator(s) on a research proposal or have conflict of interest shall declare it and will not vote on the proposal and will opt out from all discussion on the proposal by leaving the meeting room. PI/ Co-investigator is called for only for providing clarifications.
b. An investigator or study team member invited for the meeting will not vote or participate in the decision-making procedures of the committee if she/he happens to be IEC member.
c. An independent consultant invited for the meeting to provide opinion will not participate in the decision-making procedures of the committee. She/ he is required to provide comments in writing (sent as email/ hard copy)
d. Specific patient groups invited for the meeting to give comments on the study will provide their views/comments on the appropriateness of methodology for recruitment, sample collection, compensation for study-related injuries, patient information sheet etc. However, they will not participate in the decision-making procedures of the committee.
e. The decision on the project will be recorded as follows:
    1. **Approved**
    2. **Minor revision: Answers to be reviewed by Member- Secretary and /or primary reviewers by circulation**
    3. **Major revisions: PI's response to be reviewed by primary reviewers first and placed at the next full-board meeting for further review..**
    4. **Disapproved**

f. If the EC decision is 'Approved', it implies the approval of the study as it is presented with no modifications and the study can be initiated.
g. If the EC decision is minor modification for expedited review, it implies that the items noted at the convened meeting will be reviewed through an expedited review process as per SOP/11/V3.3.
h. If the EC decision is a major modification, the proposal will have to be reviewed by primary reviewers and submitted for the full committee meeting.
i. If the EC decides to disapprove the protocol, it should give reasons for the same, and the principal investigator should be asked to respond with justification for reconsideration of the protocol.
j. If the study is approved, the Committee will determine the frequency of continuing review for each protocol. Usually, approval is given for one year.
k. If the study is disapproved, the PI may be called in person for discussion and informed about the reason for disapproval. The same should be communicated to him/her in written form. The PI may make suitable changes and resubmit the protocol as a new proposal. The protocol documents should be archived as per the routine archival procedure.
l. The Secretariat will list participating members in the meeting and summarize the discussion and decision reached by the EC members and minute it.

m. It should also be recorded if the decision needs to be taken at the next full committee meeting or can be communicated earlier, based on the assessment by members of the IEC, member secretary and Chairperson. The decision if taken before the next EC meeting, should be put on the agenda of the next meeting and conveyed to the Committee at its next meeting.

12.5.3 Final communication of the Ethics Committee decision taken on the project to the Principal Investigator

a. The Secretariat will prepare minutes indicating a decision of the EC meeting on the submitted protocol. The minutes will be circulated to all members for approval. Following this the Chairperson and the Member Secretary will sign the minutes.

b. The minutes will then be sent to the PIs mentioning

i Date, Project No., Project title, Name of the PI
ii Date of the meeting when the project is placed before the meeting and approved and version numbers of the project
iii Suggestions/comments of the members
iv Decision of the committee

c. The Secretariat will hand over the minutes within 15 days without disclosing the names of primary reviewers. The PI will be asked to make the necessary corrections in the project proposal, if required and resubmit it to the ethics secretariat for consideration of the Ethics Committee.

d. Principal Investigator will be asked to respond to the comments given through the minutes within 60 days of the receipt of the letter by the investigator. In the absence of any response, the project will be declared closed and archived.

e. The Chairperson and Member Secretary will sign the approval letter, and the Secretariat will send it to the Principal Investigator. In cases when the Member Secretary is unavailable for the meeting, or she/he is the PI on the project, the joint Member Secretary will sign the letter instead. The approval will be provided only after all requirements are fulfilled including comments about the translated PIS and ICD, questionnaires, patient dairy etc.

12.6. ANNEX

ANNEX 1	AF/EC/01/12/V2.1	Study Assessment Form
ANNEX 2	AF/EC/02/12/V2.1	Project Review Form
ANNEX 3	AF/EC/03/12/V2.1	Document history

ANNEX 1 **AF/01/12/V2.1**

Study Assessment Form for New Projects

Protocol Number: Date (D/M/Y):

Protocol Title:

Name of Principal Investigator:

Reviewer's name:

Mark and comment on whatever items are applicable to the study.

Sr. No.	**Points**	**Comments**
Section A - Scientific Assessment		
1	Objectives of the Study	Clear/ Unclear
What should be improved?		
2	Background and Rationale	Sufficient/ insufficient
Comment:		
3	Methodology	Clear/ Unclear
What should be improved?		
4	Need for diagrammatic representation	Yes/ No
Comment :		
5	If diagrammatic representation given:	Clear/ Unclear
What should be improved?		
6	Study Design and Sample size	Appropriate/ Inappropriate
Comment:		
7	Inclusion Criteria	Appropriate/ Inappropriate
Comment:		
8	Exclusion Criteria	Appropriate/ Inappropriate
Comment:		
9	Withdrawal /intervention Criteria	Appropriate/ Inappropriate
Comment:		
10	Use of control group or placebo	Appropriate/ Inappropriate
Comment:		
11	Use of medical devices	Appropriate/ Inappropriate
Comment:		

12	Procedure used in research	Appropriate/ Inappropriate
Comment:		
13	Blood/other specimen (frequency and amount of collection)	Appropriate/ Inappropriate
Comment:		
14	If Blood/other specimen will be sent to other lab/ abroad	Not applicable / Clear/ Unclear
Comment:		
15	Duration and number of follow up	Appropriate/ Inappropriate
Comment:		
16	Statistics used in analysis	Appropriate/ Inappropriate
Comment:		
17	Risk Benefit (Efficacy / Safety) assessment	Appropriate/ Inappropriate
Comment:		
18	Monitoring of complications and solutions	Appropriate/ Inappropriate
Comment:		
19	Data Collection & Method Tool	Appropriate/ Inappropriate
Comment:		
20	Draft MoU/ MTA submitted	Yes/ No
Comment:		
Section B - Ethical Issues		
1	Type of Vulnerable population	
a	Identification of vulnerability	Clear/ Unclear
b	Justification for use of vulnerable participants	Clear/ Unclear
c	Protections of vulnerable groups (if applicable)	Clear/ Unclear
Comment:		
2	Risk assessment of the protocol	Tick the appropriate
a	Research not involving more than minimal risk	
b	Research involving greater than minimal risk but presenting the prospect of direct benefit to the participants	

c	Research involving greater than minimal risk and no prospect of direct benefit to individual participant, but likely to yield generalizable knowledge about the participant's disorder or condition	
3	Risks to the health of participants	
a	Identification of the risk, physical, phychological, legal, risk due to invasion of privacy and breach of confidentiality	Clear/ Unclear
b	If all the risks are identified in the protocol	Clear/ Unclear
c	If the risks are reasonable	Clear/ Unclear
d	Are the risks clearly stated in the protocol	Clear/ Unclear
e	Are these risks properly stated in the PIS	Clear/ Unclear
f	Are the risk minimization strategies described in the protocol	Clear/ Unclear
g	Are the risk minimization strategies sufficient or any additional measures are suggested?	Clear/ Unclear
Comment:		
4	Risk to the health of embryo / unborn child / spouse	Not applicable/ Clear/ Unclear
Comment:		
5	Risks to the research community	Not applicable/ Clear/ Unclear
Comment:		
6	Direct benefits to participants	Appropriate/ Inappropriate/ Clear/ Unclear
a	During the study	
b	After study (post-study benefits)	
Comment:		
7	Benefits to the research community	Not applicable/ Clear/ Unclear
Comment:		
8	Benefits to society	Clear/ Unclear
Comment:		
9	Favorable benefit/risk ratio	Clear/ Unclear
Comment:		
Section C - Qualification of Investigators		
1	Are Qualification and experience of the Participating Investigators appropriate?	Yes/ No
Comment:		
2	Disclosure or Declaration of Potential Conflicts of Interest	Yes/ No
Comment:		

3	Facilities and infrastructure of Participating Sites	Appropriate/ Inappropriate
Comment:		
4	Involvement of Local Researchers and Institution in the Protocol Design, Analysis and dissemination of Results	Yes/ No
Comment:		
5	Contribution to Development of Local Capacity for Research and Treatment	Yes/ No
Comment:		
6	Community consultation where needed	Not applicable/ Yes/ No
Comment:		
7	Benefit to Local Communities	Not applicable/ Yes/ No
Comment:		
Section D - Participation Information Sheet and Informed Consent Documents		
S N	Points	Comments
1	Are procedures for obtaining Informed Consent appropriate?	
a	Person who obtained informed consent	Yes/ No
b	Time when obtained informed consent	Yes/ No
c	Place where informed consent was obtained	Yes/ No
Remarks:		
2	Appropriateness of type of Consent/ Assent forms	Yes/ No
Remarks:		
3	Contents of the Informed Consent Document	Clear/ Unclear
Remarks:		
4	Language of the Informed Consent Document	Clear/ Unclear
Remarks:		
5	Voluntary participation	Clear/ Unclear
Remarks:		
6	Right to withdraw from the study	Clear/ Unclear
Remarks:		
7	Alternatives in case of non-participation	Clear/ Unclear
Remarks:		
8	Risks/ inconveniences mentioned clearly	Yes/ No
Remarks:		
9	Risk benefit analysis assessment	Yes/ No Appropriate/ Inappropriate
Remarks:		
10	Mention about tests to be performed if any	Yes/ No
Remarks:		

11	Period of storage of biological samples	Yes/ No
Remarks:		
12	Are possible benefits for participants and others mentioned	Yes/ No
Remarks:		
13	Contact details of investigators for Participants	Yes/ No
Remarks:		
14	Privacy & Confidentiality	Yes/ No
Remarks:		
15	Inducement for Participation	Unlikely/ Likely
Remarks:		
16	Provision for Medical / Psychosocial Support	Appropriate/ Inappropriate
Remarks:		
17	Provision for Treatment of Study Related Injuries	Appropriate/ Inappropriate
Remarks:		
18	Provision for reimbursement or payment	Yes/ No
Remarks:		
19	Provision for Compensation	Yes/ No
Remarks:		

Opinion of the Reviewer

( ) Approve

( ) Minor Modification

( ) Major modification

( ) Disapprove

please provide reasons: _____

Duration of progress report:

☐ 3 Months

☐ 6 Months

☐ 12 Months

Any other comment:

Signature of reviewer with date: _____

ANNEX 2 **AF/02/12/V2.1**

Project Review Form for other submissions

Name of Principal Investigator:

Study no:

Revision/ Amendment/ Continuing Review Report/ Completion Report/ Translated Version of Informed conent form

"Title of the project", Version & Date (in case of Revised/ Amended Project)

Assigned Reviewer:

Received date and sign: _____

Comments on pages nos:_____

_____

Comments on Participant Information Sheet and Informed consent documents:_____

_____

Handed over to Ethics Committee with signature and date: _____

ANNEX 3 **AF/03/12/V2.1**

Document History

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1.0	20th March 2013	First approved Copy
Dr. Ragini Kulkarni	Version 1.1	3rd June 2013	Inclusion of the sentences: " I give/ do not give permission to preserve my samples to be used for any extension or modification of this study that may be decided in the future with the appropriate permission of the Ethics Committee" in Informed Consent Form
Dr. Ragini Kulkarni	Version 1.2	24th September 2014	• Removed the bullet 5.2 - Invite internal members to review the project on page no.4 • Minor correction in bullet 5.3, 5.4, 5.5 and 5.6 from page 4 to page 6 • Inclusion of the following Annexures : Annex 7: Assent form template, page no.21 Annex 9 : Guidance of Protocol Submission, page no.25 Annex 10 : Approval letter, page no.27
Dr. Ragini Kulkarni	Version 1.3	12th January 2015	Inclusion in the face sheet "Duration of the study" and addition of the sentence in Informed Consent form "I am informed that I will be/will not be given any compensation/reimbursement for participation in the study."
Dr. Ragini Kulkarni	Version 1.4	15th April 2015	Addition of the sentence in the approval letter "Due date for submission of Continuing review/Completion Report: …" and addition of the point in Enclosure list "GCP Training Cetificate of Principal Investigator/Co-Investigators/Collaborators". Changes in the name of the members of the Ethics Committee in Approval letter
Dr. Ragini Kulkarni	Version 1.5	4th March 2016	Addition of the words 'wherever relevant' after the words 'Legal Authorised Representative' in Informed Consent Form Insertion of Annex 7 : Informed Consent form for future use of stores samples on page 21
Dr. Ragini Kulkarni	Version 1.6	24th September 2016	Pg.6, Time for respond to comments changed to '90 days' instead of '180 days' Pg.20,21- deletion of the word 'Collaborator' from Informed Consent Form.
Dr. Ragini Kulkarni	Version 1.7	7th November 2017	Extensive revision of the SOP has been done as per SIDCER/FERCAP recommendations and the ICMR guidelines 2017.

Dr. Beena Joshi	Version 2.0	1st May 2019	SOP no. changed form 8 to 12 SOP has been modified to describe procedure followed for Reviewing of Protocol related documents
Dr. Vikrant Bhor	Version 2.1	8th November 2024	All bullets are numbered. 12.5.1 Choosing primary ….. reviewers is added Timelines are given to reviewers for reviewing and providing comments before the meeting is added. If the review highlights major concerns the comments are compiled and shared with the Principal Investigator. The PI is allowed to present the project in response to comments during the EC meeting is now being implemented. 12.5.2 Decision-making on submitted protocols modified. Annex 1 Study assessment form modified as per the SIDCER FERCAP survey form