Standard Operating Procedures of Institutional Ethics Committee

ICMR – NIRRCH Ethics Committee for Human Studies

Title: Expedited Review

SOP Code: 11/V3.4 Dated: 8th November 2024 Page Nos: 167 to 173

Expedited review

A review process by minimum of 3 Ethics Committee members and Chairperson who report the decision to the Ethics Committee during full board. The proposals with minor changes to the approved study proposals and those presenting no more than minimal risk to research participants may be subjected to expedited review.

11.1. Purpose

The purpose of this SOP is to provide criteria for determination of which study *proposals* can be reviewed through expedited process as well as instructions on composition of ERC (Expedited review consideration), appointment of members, management, review and approval of the expedited review.

11.2. Scope

This SOP applies to the review and approval of study proposals with minimum risk to participants, protocol amendments, changes in the Participant Information Sheet and/ or Informed Consent Document of currently approved studies.

11.3. Nature of Study Proposals considered for expedited review process:

Proposals that pose no more than minimal risk may undergo expedited review, for example;

a. Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples
b. If the samples are some left-over clinical samples of previous study, then ICF records of the same needs to be cross checked.
c. Research involving clinical documentation materials that are non-identifiable (data, documents, records)
d. Modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s)
e. Revised proposals previously approved through expedited review, full review or continuing review of approved proposals
f. Minor deviations from originally approved research causing no risk or minimal risk
g. Progress/ annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee; and
h. For multicenter research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review.
i. Research during emergencies and disasters (Check Section 12 of National Ethical Guidelines for Biomedical & Health Research involving Human Participants for further details).

11.4. Flow chart

Sr. No.	Activity	Responsibility
1	Receive the submitted documents.	IEC Secretariat
2	Determine protocols for expedited review. Agenda will be tabulated with titles of study proposals and reasons for IEC referral as heading	Member Secretary or Joint Member Secretary with consultation and concurrence from the Chairperson.
3	Expedited review process	Ethics Committee members, Chairperson and secretariat
4	Communicate with the IEC- full board and the Investigator.	Member Secretary and IEC Secretariat

11.5. Detailed instructions

11.5.1 Receive the submitted documents.

a. Receive the application documents submitted by investigators.
b. Fill the relevant checklist to check items received.
c. Inward Stamp which includes the receiving date on the letter and the documents.
d. Sign the receiver's name on the receiving documents.
e. Hand over the received documents to the IEC secretariat.
f. 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. The screening by EC Secretariat for completeness will follow this.
g. The member secretary in consultation with the chairperson will determine, if the protocol is appropriate to be reviewed under the expedited review category or needs to be reviewed as regular/ emergency full committee review depending on the criteria below.
h. In case of projects reviewed under emergency situations, upon return to normalcy, , hard copy of the project should reach EC office for maintaining the records
i.

11.5.2 Determine protocols for expedited review.

IEC Secretariat determines whether a study is qualified for expedited review according to the following criteria:

11.5.2.1 Modification /amendment of protocol with minimal changes

a. *Administrative revisions*, such as correction of typos
b. Addition or deletion of *non-procedural items*, such as the addition or deletion of study personnel names, laboratories, etc.
c. *Non-significant risk* research activity

11.5.2.2 Proposals involve interviewing of a *non-confidential nature* (not of a private e.g. relate to sexual preference *etc.*), *not likely to harm* the status or interests of the individual and *not likely to offend* the sensibilities of the people involved.

11.5.2.3 Collection of data for research purposes through *non-invasive procedures* routinely employed in clinical practice and using medical devices that have been already approved for use.

Examples of such procedures include collection of data through application of EEG or ECG electrodes, acoustic testing, tests using the Doppler principle, non-invasive blood pressure and other routine clinical measurements, exercise tolerance etc.

However, procedures involving the use of x-rays or microwaves are NOT recommended for expedited review.

11.5.2.4 Research involving data, documents or specimens that have been already collected or will be *collected for ongoing medical treatment* or diagnosis.

11.5.2.5 Health Systems Research with no more than minimal risk such as collecting the information on health problems with non-identifying personal information etc.

If the protocol satisfies any of the criteria for expedited review, the secretariat will send the protocol to Chairperson and the designated members.

11.5.2.6 Research during humanitarian emergencies and disasters can be reviewed through an expedited review/scheduled/unscheduled full committee meetings and this may be decided by the Member Secretary on a case-to-case basis depending on the urgency and need. If an expedited review is done, full ethical review should follow as soon as possible.

11.5.2.7 If not fitting in the above criteria, secretariat will decide for full committee review. The same should be communicated to the Principal Investigator through mail/ letter.

11.5.3 Expedited Process

Nomination procedure for expedited reviewers

a. In case of new proposals, the member secretary in consultation with the Chairperson will decide the reviewers, depending on the nature of protocol and the expertise in the committee.
b. in case of amendments/ resubmitted proposal they will be reviewed by the reviewers who had initially reviewed it.
c. The secretariat sends the revised protocol to at least 3 Ethics Committee members and Chairperson for review.
d. Carry out the expedited review on the new projects as per Study Assessment Form, **ANNEX 1 (AF/01/12/V2.1)** (study protocol with all the **attached** documents as mentioned in the guidelines for submission of proposals) and the Project Review form for expedited process – refer to **ANNEX 2 (AF/02/12/V2.1).**

e. The expedited review should not take longer than 2 weeks from the date of submission.
f. Inform the IEC- full committee of the proposals approved by expedited review at its regular meetings for ratification.
g. If any committee member raises concern about any of the proposals presented to it as expedited review, then that proposal shall undergo a full committee review.

11.5.4 Communicate with the IEC and the investigator.

a. Full committee notification of items approved through expedited review by the Chairperson or the designee is accomplished by providing notification and source documentation of the items in the meeting agenda / notes.
b. Decision will be documented as Approved/ Not approved/Referred for full committee Review. The IEC Secretariat communicates the decision to the investigator signed by the Member Secretary and the Chairperson/Alternate Chairperson.

11.6. ANNEX

ANNEX 1	AF/01/11/V3.4	Approval letter for Expedited Review
ANNEX 2	AF/02/11/V3.4	Document History

ANNEX 1 **AF/01/11/V3.4**

Approval letter for Expedited Review

ICMR-NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH (ICMR-NIRRCH)

Jehangir Merwanji Street, Parel, Mumbai-400 012

ICMR-NIRRCH ETHICS COMMITTEE FOR Human Studies

Tel: 91-22-24192000/2043/2147, Fax No. 91-22-24139412

E-mail: ethics@nirrch.res.in

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:

Name of the PI
Department ……
ICMR-NIRRCH

Subject: Reference to the project "……, Version … dated …….
Project No.: …….. PI: ……

Dear Dr. ……,

This is with reference to the study proposal version …. dated ….. which was submitted to the Ethics Committee Secretariat on ……. for granting approval.. The research study proposal has been reviewed through Expedited process.

The Ethics Committee acknowledges the receipt and approves the proposal version … dated …… (English, Hindi and /or Marathi) with waiver of Informed Consent on ……..

Please note that any changes to the proposal 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 continuing review report at least 2 months before the next re-approval period.

You are requested to submit the Completion report within 2 months of the completion of study.

Ethics Committee approval of the collaborating centers should be obtained.
Project can be initiated only after signing MoU between collaborating centers.
Due date for submission of Continuing review/ completion report: ……

Sincerely,

Dr. Dr.
Member Secretary Chairperson

ANNEX 2 **AF/02/11/V3.4**

Document History

Author	Version	Date	Description of the Change
Dr. Lalita Savardekar	Version 1	10th June 2009	First approved copy
Dr. Lalita Savardekar	Version 2	21st July 2011	Inclusion of protocols on Health Systems Research with no more than minimal risk such as collecting the information on health problems with non-identifying personal information etc. Teleconference system adopted for discussion on and approval of project
Dr. Ragini Kulkarni	Version 3	20th March 2013	Addition in point no.2, minor revisions suggested in full board
Dr. Ragini Kulkarni	Version 3.1	24th September 2014	• Board meeting not required/no quorum required (revised 5.3 bullet 6) on page no.6 • PMS goes to full board review – removed 5.4a on page no.3 • Remove bullet 4 of 5.2.1 (PIs translations) on pg.5 • Included nomination procedure for expedited reviewers on page no.5
Dr. Ragini Kulkarni	Version 3.2	3rd October 2017	● 1st sentence modified ● Pg. 3, point 3, subpoint 2 word 'Minor deviation' replaced with "Minor modifications'. ● Pg. 3, point 3, subpoint 3 Deleted 'or continuing review ….. data analysis. ● Deleted from sub point 5 - word 'or specimens' & sentence 'have been collected for non- research (clinical) purposes. ● Pg.3 Added sub point no.6 ● Pg. 4, 5.2.3 deleted 'not involving GA or sedation' ● Pg.5, section 5.2.5 deleted
Dr. Beena Joshi	Version 3.3	1st May 2019	● SOP no. changed from 7 to 11 ● Modified as per ICMR guidelines 2017 & ICMR common ethical review forms 2018
Dr. Vikrant Bhor	Version 3.4	8th November 2024	● All bullets are numbered. ● Nomination for expedited review of New proposals is modified