Title: Expedited Review

SOP Code : SOP/07/V3.2

Effective date: 07/11/2017

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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.

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, appointment of members, management, review and approval of the expedited review.

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.

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

The study proposals considered for the ERC include

1. Study proposals approved with minor modifications before final approval
2. Minor modifications from originally approved research during the period of approval (usually of one year duration). Examples: addition/relieving of a collaborator.
3. Revised proposal previously approved through full review by the IEC.
4. Research activities that involve only procedures listed in one or more of the following categories :
   - Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or
   - Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.
5. Research involving clinical documentation materials (data, documents, records) that are non-identifiable.
6. Research involving non-identifiable specimen and tissue from sources like blood bank, tissue banks and left over clinical samples.
6. When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and the same participants should not be included in the clinical trial that may be initiated later based on the findings of the pilot study.

4. Flow chart

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 ERC referral as heading ↓	Members 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

5. Detailed instructions

5.1 Receive the submitted documents.

- Receive the application documents submitted by investigators.
- Fill the relevant checklist to check items received.
- Inward Stamp which includes the receiving date on the letter and the documents.
- Sign the receiver's name on the receiving documents.
- Hand over the received documents to the IEC/IRB secretariat.

5.2 Determine protocols for expedited review.

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

5.2.1 Modification /amendment of protocol with minimal changes

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

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.

5.2.3 Collection of data for research purposes through *non-invasive procedures* routinely employed in clinical practice and using medical devices which 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*.

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

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.

5.3 Expedited Process

Nomination procedure for expedited reviewers

- The study proposal will be reviewed by the reviewers who had initially reviewed the proposal in case of amendments and resubmitted proposals.
- In case of new proposals, the member secretary in consultation with the Chairperson will decide the reviewers only in case of emergency, depending on the nature of protocol and the expertise in the committee.
- The secretariat sends the revised protocol to the 3 Ethics Committee members and Chairperson for review.
- Carry out the expedited review on the complete proposal as per the review report form for expedited process – refer to ANNEX 2 (AF/EC/02/06/V1.5) Study Assessment Form for New Projects (study protocol with all the attached documents as mentioned in the guidelines for submission of proposals).
- The expedited review should not take longer than 2 weeks.
- Inform the IEC- full board of the proposals approved by expedited review at its regular meetings.
- If any committee member raises concern about any of the proposals presented to it as expedited review, then that proposal shall undergo a regular review.

5.4 Communicate with the IEC and the investigator.

- Full Board 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.
- Decision will be documented as Approved/ Referred for Regular full Review. The IEC Secretariat communicates the decision to the investigator signed by the Member Secretary and the Chairperson/Alternate Chairperson.

6. Glossary

Expedited approval - An IEC approval granted only by the Chairman of the IEC (not the full Board) for minor changes to current IEC approved research activities and for research which involves no more than minimal risk.

7 References

7.1 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.

7.2 International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

7.3 Code of Federal Regulation (CFR) 21.

7.4 Ethical Guidelines for Biomedical Research on Human Participants, ICMR, 2006

7.5 National Ethical Guidelines for Biomedical and Health involving Human Participants, ICMR, 2017

8. ANNEX

ANNEX 1	AF/EC/01/07/V3.2	Document History
ANNEX 2	AF/EC/02/07/V3.2	Checklist
ANNEX 3	AF/EC/03/07/V3.2	Approval letter for Expedited Review

ANNEX 1 **AF/EC/01/07/V3.2**

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) purpose. • 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

ANNEX 2 **AF/EC/02/07/V3.2**

Checklist of Documents for Expedited Review

S. No.	Documents	Y/No/NA
1	Covering letter	
2	Study proposal	
3	Justification for consideration under Expedited Review (Refer to Point 7.2 Pg.5)	

ANNEX 3 **AF/EC/03/07/V3.2**

Approval letter for Expedited Review

NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE HEALTH (NIRRH-ICMR)
Jehangir Merwanji Street, Parel, Mumbai-400 012

NIRRH ETHICS COMMITTEE FOR CLINICAL STUDIES
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E-mail: nirrh.cliethics@gmail.com

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

Ref.:D/ICEC/Sci-…/../ …. Date

Name of the PI
Department ……
NIRRH

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 study report for continuing review at least 2 months before the next re-approval period/ on completion of study.

You are requested to submit the Completion report within 3 months of the completion of study.

Due date for submission of Continuing review: ……

Sincerely,

Dr. Ragini Kulkarni
Member Secretary

Dr. Usha Saraiya
Chairperson