



Standard Operating Procedures (SOP -07/01)

For
Project Submitted to Expedited Review



Independent Ethics Committee (Clinical Research) India

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide criteria for determination of which study protocols can be reviewed through expedited process as well as instructions on 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 or informed consent changes of currently approved studies.

3. Responsibility

It is the responsibility of the Independent Ethics Committee (IEC) members to define of which study protocols should be reviewed and approved through expedited channel.

4. Flow chart

<u>No.</u>	<u>Activity</u>	<u>Responsibility</u>
1	Receive the submitted documents.	IEC Secretariat
2	Determine protocols for expedited review.	IEC Secretary/ Chairperson
3	Expedited process	IEC Members/ Chairperson
4	Communicate with the IEC and the Investigator	IEC Secretariat/ Members

5. Detailed instructions

5.1 Receive the submitted documents.

- The Secretariat will receive any of the following documents which can be submitted for Expedited Review
 1. Project Submission Application Form *AF/01/01-SOP05/01*, Protocol and protocol related documents submitted by the investigators for projects sent for review for the first time.



Independent Ethics Committee (Clinical Research) India

2. Protocol amendments and related documents
 3. Re-submitted protocol
- The Administrative Officer will get the contents of submitted package (checklist) form, as per *AF/02/01- SOP05/01* to check items received and stamp the receiving date on the documents.
 - The Administrative Officer will also sign his/her name on the receiving documents.
 - For protocol amendments and related documents instructions as per section 5 of SOP 05/01 & SOP 09/01 will be followed.
 - If it is a re-submitted protocol then instructions as per section 5 of SOP 05/01 & SOP 08/01 will be followed.

5.2 Determine protocols for expedited review.

The IEC Secretary and Chairperson will determine whether a study is qualified for expedited review according to the following criteria:

1. Proposals submitted for initial review satisfying any of the following criteria
 - Interviewing of a non-confidential nature, not likely to harm the status or interests of the individual and not likely to offend the sensibilities of the people involved.
 - Collection of data for research purposes through non-invasive procedures (not involving general anesthesia or sedation) 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.
 - Research involving data, documents or specimens that have been already collected or will be collected for ongoing medical treatment or diagnosis.
2. Modification /amendment of protocol & related documents (approved earlier) if the change involves any of the following
 - Administrative revisions
 - Addition or deletion of non-procedural items, such as the addition of study personnel names, laboratories, etc.
 - Non-significant risk research activity
 - The research activity includes only minor changes from previously approved protocol.



Independent Ethics Committee (Clinical Research) India

3. Project reviewed earlier and IEC decision was to 'Approve after the Principal Investigator incorporates the suggestions to be subjected for Expedited Review as recorded on the IEC Decision Form *AF/02/01-SOP06/01*.

5.3 *Expedited Process*

- If the protocol/protocol amendment and amended protocol related documents satisfy the criteria as listed in 5.2, the Chairperson nominates 2 or more IEC members to review the revised protocol.
- The secretariat sends the revised protocol to the selected members who will perform the expedited review on the complete proposal
- The review may be made by circulation of comments, discussion in the meeting with the Chairperson. The meeting will exclusively concern only those projects, which are subjected to expedited review and will be attended by the Chairperson, Secretary/Associate Member Secretary and 2 Independent Ethics Committee members designated to perform the expedited review. This expedited meeting will be conducted as per SOP 16/01.
- If consensus cannot be reached, the chairperson will refer the proposal back to the IEC for a full review. The IEC decision will be recorded on the IEC Decision Form *AF/02/01-SOP06/01*
- The expedited review should not take longer than 2 weeks

5.4 *Communicate with the IEC and the investigator.*

- The Secretary will inform the IEC members of the proposals approved by expedited review at its regular meetings and source documentation of the items in the meeting agenda / notes.
- The Secretariat will forward the Project approval letter/ Protocol amendment/ Document approval letter signed by the IEC Chairperson, if the Project/ Protocol amendment/ Protocol related documents are approved, to the Principal Investigator.
- If it is disapproved or requires resubmission after certain modifications, this is informed to the Principal Investigator in writing.

6. Glossary

Expedited approval An IEC approval granted only by the Chairman of the Independent Ethics Committee Board or a designated Independent Ethics Committee board member (not the full Board) for minor changes to current IEC approved research



Independent Ethics Committee (Clinical Research) India

activities and for research which involves no more than minimal risk.

Expedited review

A review process by only two designated IEC members who then report the decision to the full Board meeting. An expedited review is a *speedy* one for minor *changes to the approved protocol* and for *research proposal with minimal risk in nature*.

Expedited meeting

A meeting that will exclusively concern only those projects, which are subjected to expedited review and will be attended by the Chairperson, Secretary/Associate Member Secretary and 2 Independent Ethics Committee members designated to perform the expedited review. This expedited meeting will be conducted as per SOP 16/01.

7. References

1. WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000)- www.who.int/tdr/publications/publications/ (last accessed 24 March 2008)
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- <http://www.ich.org/LOB/media/MEDIA482.pdf> (last accessed 24 March 2008)
3. Code of Federal Regulation (CFR) 21.