Independent
Ethics Committee
(Clinical Research) India

Standard Operating Procedures

(SOP -08/01)

For

Review of Resubmitted Protocols

Independent Ethics Committee (Clinical Research) India

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how resubmitted study protocols are managed, re-reviewed and approved by the Independent Ethics Committee (IEC).

2. Scope

This SOP applies to study protocols that have been reviewed earlier with recommendations from IEC for some corrections in the initial review process.

3. Responsibility

It is the responsibility of the IEC Secretariat to ensure the completeness of the resubmitted documents and to notify the Chairperson that a protocol previously approved with conditions for revision has been resubmitted to the IEC for reconsideration.

A re-submitted protocol may be reviewed and approved by either the Chairperson or some IEC members designated by the Chairperson, or full IEC as per IEC decision determined by the IEC at the time of the initial review of the project during the full board IEC meeting. This information can be found on the IEC Decision Form (*AF/02/01-SOP06/01*) by the Secretariat.

4. Flow chart

No.	Activity	Responsibility
1	Receive protocol resubmitted package and distribution	IEC Secretariat
2	Review the revised protocol	IEC Members/ Chairperson
3	IEC Meeting	IEC Members / Chairperson
4	Written communication of the IEC decision	IEC Secretariat/ Chairperson

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5. Detailed instructions

5.1 Receive protocol resubmitted package and distribution.

- The Secretariat will check the protocol resubmitted packages for the following items:
  - Reply to the query letter addressing the corrections,
  - Verify if the Principal Investigator has forwarded the reply within 90 days of receipt of the letter
  - Revised version of protocol and related documents such as the informed consent document, data collection or case report forms, diary sheets, etc are included as part of the package with the changes made to the documents are underlined or highlighted.
- The Secretariat will refer the IEC Decision Form *AF/02/01-SOP06/01* on the given protocol and distribute the protocol package accordingly to the decision taken for the resubmitted protocol. The administrative officer will distribute this package containing the copy of the reply to the query letter, modified protocol and related documents along with Assessment Form for resubmitted protocol *AF/01/01-SOP08/01*to all the IEC members, if the decision on the protocol was 'Resubmission of the protocol subjected to full board'. The packet will be distributed to any (at least two) IEC members if the decision on the protocol was 'resubmission of the protocol subjected to expedited review'. The selection of the two or more IEC members will be done by the chairperson. The packet will contain Assessment of resubmitted protocol Form. The packet will be sent only to the Chairperson if the decision on the protocol was 'Approved with recommendations subjected to review by Chairperson only' as per IEC Decision Form *AF/02/01-SOP06/01*.

5.2 Review the revised protocol.

- The IEC member/ Chairperson will refer to the query letter as guidance for the review and consider whether the recommendations of the IEC have been followed.
- The member will make further comments where appropriate, in the Assessment Form for resubmitted protocol *AF/01/01-SOP08/01*.
- The member will sign and date the reviewer's name and notify the IEC Secretariat.

5.3 IEC meeting

- The Secretariat receives the Assessment Form for resubmitted protocol *AF/01/01-SOP08/01* from the members/Chairperson.
- The Secretary prepares for the Full Board/Expedited meeting as per instructions in SOP 16/01

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- The Secretary presents a brief oral summary of the study design and the comments of the IEC members/Chairperson in the IEC Full Board/Expedited meeting.
- The Chairperson entertains discussion on the protocol revision from all the IEC members.
- The Chairperson calls for a consensus on the revision to take any of the following decision:
  a. Approve the study to start as presented with no modifications: *Approved*
  b. Require modifications to items noted at the convened meeting and follow-up by the Chairperson/IEC member designated by the Chairperson in Full Board/Expedited meeting after receipt of the requested modifications: *Approved with modification*
  c. Disapproved
- This IEC decision will be recorded by the Secretariat in the IEC Decision Form (*AF/02/01-SOP06/01*).

5.4 Written communication of the IEC decision.

- The Administrative Officer will place the original completed documents along with the completed Form *AF/01/01-SOP08/01*, the Assessment Form and the Initial Review Application Form *AF/01/01-SOP06/01* as well as the others in the protocol package.
- The Secretariat then prepares the Approval Letter and gets the Chairperson's signature.
- If the study is approved, the Committee determines the frequency of Continuing Review for each study site.
  - The Secretariat sends an Approval Letter to the investigator notifying the IEC decision and schedule of continuing review.
  - The letter contains, at a minimum, a listing of each document approved, the date set by the Committee for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study.
  - The approval and expiration date is written on the approval letter along with the list of IEC members approving the project
- If the Committee requires modifications to any of the documents, the Secretariat sends a written repeat query letter to the Principal Investigator mentioning the specific changes and request the Principal Investigator to make the necessary modifications and resubmit the documents to the IEC office. The answer to the repeat query letter must be received within 30 days.

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6. Glossary

Document	All kinds of evidence to include paper documents, electronic mail (e-mail), fax, audio or video tape.
Completed Assessment Form	An official record of the review decision along with comments and dated signature of the reviewer.

7. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)- *www.who.int/tdr/publications/publications/* (lastaccessed 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)

8. Annex

ANNEX 1 AF/01/01-SOP08/01 Assessment of Resubmitted Protocol

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Annex 1
AF/01/01-SOP08/01

Assessment of Resubmitted Protocol

Protocol No.:		
Protocol Title:		
Total Participants :		☐ 2nd Review ☐ 3rd Review ☐ 4th Review
Principal Investigator:		Tel.:
Initial Review Date:		Last Review Date:
Type of Review : Expedited Full board		
IEC Decision recorded in the meeting minutes :		
Opinion of the reviewer: — Revision or Modification according to the recommendation — Additional comments:	☐ Yes ☐ No : Explain:…….. …….. ……	

SIGNATURES:

_____Date:……
Protocol Reviewer