



Standard Operating Procedures (SOP -09/01)

For
**Review of Amended Protocol/Protocol Related
Documents**



Independent Ethics Committee (Clinical Research) India

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how amended protocol/ protocol related documents are managed and reviewed by the Independent Ethics Committee (IEC).

2. Scope

This SOP applies to previously approved study protocols but later being amended and submitted for approval to the IEC. Amendments made to protocols will not be implemented until reviewed and approved by the IEC.

3. Responsibility

It is the responsibility of the IEC Secretariat to manage protocol amendments. Investigators may amend the contents of protocols from time to time. Protocol amendments may be submitted for either “expedited” review or full board IEC review by the Chairperson.

4. Flow chart

<u>No.</u>	<u>Activity</u>	<u>Responsibility</u>
1.	Receive the Amendment Package and Verify the contents	IEC Secretariat
2.	Notify the Chairperson of the IEC	IEC Secretariat
3.	Determine whether expedited or full review.	IEC Secretariat / Chairperson
4.	Distribution to IEC members	IEC Secretariat
5.	Protocol Amendment Review Process	IEC Secretariat / members / Chairperson
6.	IEC Decision	IEC Secretariat / members / Chairperson
7.	Communication of the Decision to the Principal Investigator	IEC Secretariat / members / Chairperson
8.	Store documents	IEC Secretariat



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5. Detailed instructions

5.1 Receive the Amendment Package and Verify the contents.

- The amendment package forwarded by the Principal Investigator is received by the Secretariat.
- The Secretariat of the IEC should follow the procedures as in SOP05/01 (Procedures for Management of protocol submission) and SOP 20/01 (Procedure for Maintaining Confidentiality of IEC Documents).
- The Secretariat will confirm the **request for Amendment Memorandum** of the Protocol/Protocol related documents from the Principal Investigator on an existing and previously approved Protocol/Protocol related documents. The memorandum should:
 - State/describe the amendment
 - Provide the reason for the amendment
 - State any untoward effects with original protocol
 - State expected untoward effects because of the amendment
- The Secretariat will check for completeness of Document Checklist for the contents of protocol amendment submission package i.e. *AF/02/01-SOP05/01*
- The Administrative Officer will confirm the presence of the following documents:
 - The amended version of the protocol and related documents
 - The changes or modifications should be underlined or highlighted.

5.3 Notify the Chairperson of the IEC.

- Upon receipt of the amendment package, the Secretariat will inform the Chairperson of the IEC verbally.
- The Secretariat will send the request for amendment memorandum and the protocol and related documents to the Chairperson within one working day of receipt of the package with the Protocol Amendment Assessment Form *AF/01/01-SOP09/01*.

5.3 Determine whether expedited or full review.

- After review of the materials, the Chairperson and Secretary will determine whether the protocol requires expedited review as per SOP 07/01 or full board review.
- The amended protocol/ protocol related document will require Full Board review if any of the following criteria are met:



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- The Protocol amendment which increase risk to study participants, as judged by the Chairperson and Secretary, such as a change in study design, which may include but is not limited to:
 - a. additional treatments or the deletion of treatments any changes in inclusion/exclusion criteria.
 - b. change in method of dosage formulation, such as, oral changed to intravenous
 - c. significant change in the number of subjects if the decrease/increase in the number of subjects alters the fundamental characteristics of the study, it is significant
 - d. significant decrease or increase in dosage amount
- If the Chairperson decides the protocol requires full board IEC or expedited approval, the Chairperson will indicate this decision on the Protocol Amendment Assessment Form *AF/01/01-SOP09/01*.

5.4 Distribution to IEC members

- The following documents are distributed to each IEC member if full board review; at least 2 IEC members if expedited review by the Secretariat:
 - the amendment's revision documents to clearly identify each change.
 - Protocol Amendment Assessment Form *AF/01/01-SOP09/01*.
- The Secretariat places the protocol amendment request on the agenda for the next convened meeting.

5.5 Protocol Amendment Review Process

- The IEC member will utilize the process outlined in the SOP for Initial Review of Submitted Protocol (SOP 06/01) to review amended protocols and protocol-related documents.
- The Chairperson / IEC members performing the expedited/full board review must sign and date the form i.e. *AF/01/01-SOP09/01* and return this to the Secretariat after the review.

5.6 IEC Decision

- The Secretary will read the comments on the amended protocol/protocol related documents in the Full Board/Expedited meeting
- The Chairperson or designee calls for a consensus on the proposed amendment to:
 - Approve the protocol amendment
 - Require a modification to the proposed amendment or informed consent documents, stating the reason and action required to sustain the study with a follow-up full IEC review/Expedited IEC review.
 - Suspend the entire study, until further information is obtained



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- Not approve the amendment request, stating the reason – but allow the study to continue as previously approved.
- The Chairperson signs the Decision Form (AF/02/01-SOP06/01) after the IEC has reached its decision.

5.7 *Communication of the Decision to the Principal Investigator*

- If the IEC approves the protocol amendment, the Secretariat staff communicates this decision to the investigator. The Secretariat sends a signed and dated Amendment Approval letter (i.e. AF/02/01-SOP09/01) to the Principal Investigator (P.I.) for their records no later than 10 working days of the meeting of the IEC
- If the IEC does not approve the protocol amendment, the Secretary immediately notifies the investigator in writing of the decision and the reason for not approving the amendment.
- If the IEC requires modifications to any of the documents, or the protocol amendment, the Secretariat sends a written request about the specific changes to the investigator asking him or her to make the necessary changes and resubmit the documents to IEC

5.8 *Store documents.*

- The Secretariat will keep the forms, minutes of the meeting relevant to the discussion and the decision reached by the IEC as the official records of the amendment review process.
- The Administrative Officer will place the original completed documents, the amended version of the protocol and related documents in the protocol file with the other documents pertaining to the amendment.
- The Amendment assessment form along with the protocol amendment and related documents are filed in the same project file sequentially

6. Glossary

Amendment protocol package	A package of the amended parts and related documents of the protocol, previously approved by the IEC/IRB. In the course of the study, the PI may decide to make changes in the protocol.
Expedited approval	An IEC approval granted only by the Chairperson of the IEC (not the full IEC) for minor changes to current IEC approved research activities and for research which involves no more than minimal risk, as stated in the SOP 07/01



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7. References

1. World Health Organization, Operational Guidelines for Ethics Committees 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 §56.110, The United States of America, 1998

8. Annexure

ANNEX 1	AF/01/01-SOP09/01	Protocol Amendment Assessment Form
ANNEX 2	AF/02/01-SOP09/01	Project Amendment/Document Amendment Approval letter



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Annex 1
AF/01/01-SOP09/01

Protocol Amendment Assessment Form

Protocol Number:		
Protocol Title:		
Principal Investigator:		
Institute:		Telephone:
Approved date:		No. of amendment:
Reason for the amendment:		
Type of review :- (Decision by Chairperson/Secretary) EXPEDITED (Minor changes) FULL REVIEW BY IEC (More than minor changes or that amendment "materially" affects risks to subject)		
Comments :-		
Provisional Decision:	<input type="checkbox"/> Approved <input type="checkbox"/> Approved with Recommendation <input type="checkbox"/> Disapproved	
Signature of IEC member reviewing the project:		Date:



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Annex 2
AF/02/01-SOP09/01

Project Amendment/Document Amendment Approval letter

To

PI Address

Ref :- Project title

Dear Dr.----

We have received from you the following document.

1.

At the Independent Ethics Committee meeting held on ---- the above mentioned documents were reviewed. After consideration, the committee has decided to approve the aforementioned study-related documents

The members who attended this meeting held on ---- at which the above mentioned document was discussed, are listed below.

1.

2.

3.

It is to be noted that neither you nor any of your proposed study team members were present during the decision-making procedures of the Independent Ethics Committee.

Yours truly,

Dr.-----.

Chairperson.

Independent Ethics Committee (IEC)