Independent
Ethics Committee
(Clinical Research) India

Standard Operating Procedures

(SOP -10/01)

For

Continuing Review of Study Protocols

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1. Purpose

The purpose of this Standard Operating Procedure is to describe how continuing reviews of previously approved protocols are managed by the Independent Ethics Committee (IEC). Tension notice

The purpose of the continuing review is to monitor the progress of the entire study, not just the changes in it, to ensure continuous protection of the rights and welfare of research participants. Continuing review of the study may not be conducted through an expedited review procedure, unless 1) the study was eligible for, and initially reviewed by, an expedited review procedure; or 2) the study has changed such that the only activities remaining are eligible for expedited review.

2. Scope

This SOP applies to conducting any continuing review of study protocols involving Clinical subjects at intervals appropriate to the degree of risk. All the projects approved by the Independent Ethics Committee will be reviewed atleast once a year. Depending upon the degree of risk to the participants, the nature of the studies, and the vulnerability of the study participants and duration of the study, the IEC may choose to review or monitor the protocols more frequently.

3. Responsibility

It is the responsibility of the Independent Ethics Committee Secretariat to remind the Independent Ethics Committee and the principal investigators regarding study protocols that should be continuously reviewed. All the approved protocols will be reviewed annually. The Chairperson is responsible for determining the date of continuing review if the project will be reviewed more frequently in the year. This decision is taken during the Independent Ethics Committee meeting wherein the project is finally approved.

The IEC is responsible for reviewing the progress made in the protocol, the occurrence of unexpected events or problems, and the rate of accrual of participants. The protocol, informed consent documents and assent documents are examined to ensure that the information remains accurate.

The IEC has the same options for decision making on a continuing review package as for an initial review package. The decision is made as approval to continue the study; approval with recommendations; or disapproval. All Principal Investigators

along with the submission of the annual project progress report will also apply for extension of approval of the project.

4. Flow chart

No.	Activity	Responsibility
1	Determine the date of continuing review	IEC Secretariat and Chairperson
2	Notify the Principal Investigator or study team	IEC Secretariat
3	Manage continuing review package upon receipt	IEC Secretariat
4	Notify the members of the IEC	IEC Secretariat
5	Prepare meeting agenda	IEC Secretariat and Chairperson
6	Protocol review process	IEC Secretariat, Members and Chairperson
7	Store original documents	IEC Secretariat
8	Communicate the IEC decision to the Principal Investigator	IEC Secretariat

5. Detailed instructions

5.1 Determine the date of continuing review.

- The Administrative Officer will look through the document archives/master chart of projects approved by the Independent Ethics Committee for the due date of continuing reviews.
- The Secretariat will plan for continuing review of annual progress reports to be discussed in the forthcoming Independent Ethics Committee meeting at least one month ahead and as close as possible to the due date or the anniversary of the effectivity date, (date of original approval) of the protocol.
- The Secretary will consult the Chairperson for inclusion of annual project reports in the forthcoming Independent Ethics Committee meeting.

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5.2 Notify the Principal Investigator or the study team

- The Secretary will inform the Principal Investigator at least **one month in advance** of the due date for the continuing review in writing, requesting for 12 copies of the annual / periodic progress report to allow the Study Team sufficient time to collate the information and to prepare a report package required for the continuing review.
- The Secretariat will mail a Continuing Review Application Form *AF/01/01-SOP10/01* (available at the IEC office or IEC website www.iecindia.org) to the Study Team to fill it up and keep the informed notice in the project file.

5.3 Manage continuing review package upon receipt.

- The Secretariat will receive a package submitted by the Study Team of continuing review for each approved protocol.
- Upon receipt of the package, the Secretariat of the IEC will perform the following (as per instructions in SOP 05/01 for procedures on receipt of submitted packages).

5.3.1 Verify the contents of the package.

- The Secretariat will make sure that the contents of the package include the following documents:

  1. Continuing Review Application Form (*AF/01/01-SOP10/10)*
  2. The Progress Report with:
     - Information about the number of participants enrolled to date and since the time of the last review, an explanation for any "yes" (ticked on the Continuing Review Application Form *AF/01/01-SOP10/10*) answers on the application form and a discussion of scientific development, either through the conduct of this study or similar research that may alter risks to research participants.
     - The progress report summary of the protocol since the time of the last review (12 copies).
  3. Request letter for extension of approval of the project, if the project is ongoing.

- The Secretariat will check for complete information and for the presence of the required signatures of the Principal Investigator in the Continuing Review Application Form (*AF/01/01-SOP10/01*).

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5.3.2 Store the continuing review package.

- The Administrative Officer store the original package in the protocol specific file.

5.4 Notify the Members of the IEC

- The Secretariat will distribute the protocol progress report to all the members of the IEC along with continuing review application form (*AF/01/01-SOP10/01*).

5.5 Prepare meeting agenda.

- The Secretariat will see SOP 16/01 for procedures on the preparation of meeting agenda and place the forwarded Annual Progress Report on the agenda for the meeting of the IEC, which is near to/coincides, with the anniversary of the protocol effective date (original approval date).

5.6 Protocol Review Process

- The IEC members will use the Continuing Review Application Form (*AF/01/01-SOP10/01*) to guide the review and deliberation process. The IEC members could arrive at any one of the following decisions at the IEC meeting:
  1. Approved – Project continues without any modification, extension letter will be issued.
  2. Approved with recommendations. Protocols that have been *approved with recommendations* by the IEC may not proceed until the conditions set by the IEC in the decision have been met. Protocols should be amended and submitted to the IEC within *one* month for re-review
  3. Disapproved.

  This decision is recorded by the Member Secretary on *AF/02/01-SOP10/01*.
- The IEC Chairperson will sign and date the IEC decision on Continuing Review Report after a decision has been reached.
- The completed IEC decision on Continuing Review Report is the official record of the decision reached by the IEC for the protocol.
- The IEC Secretariat will maintain and keep the IEC Decision forms and minutes of the meeting relevant to the continuing review as part of the official record of the review process.
- The IEC Secretariat will also collect the Continuing Review Application Form signed and dated by all the IEC Members.

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5.7 Store original documents.

- Place the original completed documents *AF/01/01-SOP10/01* with the other documents in the Continuing Review Package in the protocol file.

5.8 Communicate the IEC Decision to the Principal Investigator

- The Secretariat will notify the Principal Investigator if the decision is approved and distribute notification letter to the Principal Investigator within **10** working days and forward project extension approval letter *AF/03/01-SOP10/01* of the project for one more year
- If the decision is approved with recommendations, the recommendations will be notified to the Principal Investigator and he/she will be requested to resubmit the protocol/protocol related documents as amendment within 1 month for approval. Till then the project is suspended.
- If the decision is disapproved, then this decision will be notified to the Principal Investigator.
- These letters must be sent to the Principal Investigator within 10 working days.

6. 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)

7. Annexure

ANNEX 1 AF/01/01-SOP10/01 Continuing Review Application Form

ANNEX 2 AF/02/01-SOP10/01 IEC Decision on Continue Review Report

ANNEX 3 AF/03/01-SOP10/01 Project Approval Extension letter

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Annex 1
AF/01/01-SOP10/01

Continuing Review Application Form

Date:

PROTOCOL No.:	ASSIGNED No.: FFF / FF-FF
PROTOCOL TITLE:	
PI : Institute :-:	

HAVE THERE BEEN ANY AMENDMENTS SINCE THE LAST REVIEW?
‰ NO
‰ YES (Describe briefly in attached narrative)

WERE THESE PROTOCOL AMENDMENTS APPROVED BY IEC
‰ NO
‰ YES
If no mention the amendments not approved
_____

Which protocol amendment is the site following at this date
_____

SUMMARY OF PROTOCOL PARTICIPANTS:
_____Accrual ceiling set by IEC
_____New participants accrued since last review
_____Total participants accrued since protocol began

ACCRUAL EXCLUSIONS
‰ NONE
‰ MALE
‰ FEMALE
‰ OTHER (specify: _____)

IMPAIRED PARTICIPANTS
‰ None
‰ Physically
‰ Cognitively
‰ Both

HAVE THERE BEEN ANY CHANGES IN THE PARTICIPANT POPULATION, RECRUITMENT OR SELECTION CRITERIA SINCE THE LAST REVIEW?

‰ NO
‰ YES (Explain changes in attached narrative)

WERE THESE ICD AMENDMENTS APPROVED BY IEC
‰ NO
‰ YES
If no mention the amendments not approved
_____

Which ICD amendment is the site following at this date
_____

HAS ANY INFORMATION APPEARED IN THE LITERATURE, OR EVOLVED FROM THIS OR SIMILAR RESEARCH THAT MIGHT AFFECT THE IEC/IRB'S EVALUATION OF THE RISK/BENEFIT ANALYSIS OF CLINICAL SUBJECTS INVOLVED IN THIS PROTOCOL?

‰ NO
‰ YES (Discuss in the attached narrative)

HAVE ANY UNEXPECTED COMPLICATIONS OR SAE BEEN NOTED SINCE LAST REVIEW AT YOUR SITE?
‰ NO
‰ YES (Discuss in the attached narrative)

HAVE ANY PARTICIPANTS WITHDRAWN FROM THIS STUDY DURING THE LAST ONE YEAR?
‰ NO
‰ YES (Discuss in the attached narrative)

HAVE ANY PARTICIPATING INVESTIGATORS BEEN ADDED OR DELETED SINCE LAST REVIEW?
‰ NO
‰ YES (Identify all changes in the attached narrative)

HAVE ANY NEW COLLABORATING SITES (INSTITUTIONS) BEEN ADDED OR DELETED SINCE THE LAST REVIEW?
‰ NO
‰ YES (Identify all changes and provide an explanation of changes in the attached narrative)

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	HAVE ANY INVESTIGATORS DEVELOPED AN EQUITY OR CONSULTATIVE RELATIONSHIP WITH A SOURCE RELATED TO THIS PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST? ‰ NO ‰ YES (Append a statement of disclosure)

SIGNATURES:

_____Date: ……..

Principal Investigator

- Assessment of project progress report
  - Comments: ……
  - Reviewed By ----------
- Action requested
  - Renew-New participant accrual to continue
  - Renew-Enrolled participant follow up only
  - Terminate- protocol discontinued
  - Renew after recommendations are incorporated

Sign/date of IEC member

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Annex 2
AF/02/01-SOP10/01

IEC Decision on Continue Review Report

Project Title :-

PI:- Site:-

Review a) Annual Progress Report

b) Other

Date of IEC meeting:-

Decision

- Approval

- Approval with recommendations requiring protocol resubmission

  Approved with recommendations is subjected to:
  - Reviewed by Chairperson only in Full Board/Expedited meeting
  - Reviewed by any 2 IEC members in Full Board/Expedited meeting

1. Name of IEC member: _____ Sign: _____

2. Name of IEC member: _____ Sign: _____

   - Reviewed in Full Board IEC meeting

   State the recommendations:

- Disapproved

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Extension permitted (Yes/No)

If yes from-------- to --------

Chairperson signature with date

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Annex 3
AF/03/01-SOP10/01

Project Approval Extension letter

PI Name :-

PI address :-

Ref :- Project Title

This is with reference to your letter dated ----- regarding the application for one year extension of the above mentioned project. The Annual Study Status Report was discussed and noted in the Independent Ethics Committee meeting held on ------. The Independent Ethics Committee has noted the progress report and grants an extension for the referenced study from ----- to ---------.

Chairperson