Independent
Ethics Committee
(Clinical Research) India

Standard Operating Procedures

(SOP -16/01)

For

Agenda Preparation, Meeting Procedures and Recording of Minutes

Independent Ethics Committee (Clinical Research) India

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to identify the administrative process and provide instructions for the preparation, review, approval and distribution of meeting agenda, minutes and action, invitation, and notification letters of Independent Ethics Committee (IEC) meetings.

2. Scope

This SOP applies to administrative processes concerning the preparation of the agenda for all regular IEC meetings, divided into three stages: before, during and after the meeting.

3. Responsibility

It is the responsibility of the Secretariat staff to prepare the agenda for the IEC meeting and to ensure the quality and validity of the minutes after the meeting is over. The Chairperson should review and approve the agenda and the minutes sent to him/her.

4. Flow chart

No.	Activity	Responsibility
1	Before each Board Meeting & Preparation of meeting agenda	IEC Secretariat
2	During the Meeting	IEC Secretariat, Members and Chairperson
3	After the Board Meeting & Preparing the minutes	IEC Secretariat / Chairperson
4	Approval of minutes	IEC Secretariat / Chairperson
5	Filing the minutes	IEC Secretariat

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5. Detailed instructions

5.1 Before each Board meeting and Preparation of meeting agenda

- The Secretariat will prepare the agenda to include:
  1. All projects submitted for initial review (follow instructions as in SOP 06/01 Procedures for Initial Review of Submitted protocol)
  2. All resubmitted protocols wherein IEC decision was Full Board review
  3. Review of Amended protocol/protocol related documents wherein decision was Full Board review
  4. Continuing review of study protocols
  5. Review of Study Completion Reports
  6. Review of premature study termination
  7. Review of Site Monitoring Visit Reports
  8. SAE reports/CIOMS forms/Safety letters
- The Secretariat will collect and verify all forms/documents for completeness to keep all these papers in the meeting.
- The Secretariat will prepare the meeting agenda, according to the format in *AF/01/01-SOP16/01*.
- The Administrative Officer will schedule protocols in the agenda on a first-come first-serve basis.
- The Secretary will schedule the meeting either at the time of the previous scheduled meeting or within 4 weeks after new project submission and consult the Chairperson/IEC members to schedule and reconfirm the meeting date.
- Prepare invitation letters to all the members for the IEC meeting at least 2 weeks in advance.
- Circulate the agenda of the meeting to inform all the IEC members via email at least 4 days in advance of the scheduled meeting.
- Make a room reservation on the scheduled meeting date and time.
- Make sure that the room, equipment and facilities are available in good running conditions and cleaned for the meeting day.

5.2 During the meeting

- The committee will hold regular meetings at least once every four (4) weeks. When there are no research proposals to review, the meeting may be held less frequently, but no less than once every twelve (12) weeks.
- Meeting will be held as scheduled provided there is quorum. A quorum will be defined as one-half of the current regular members of the committee rounded off to the next higher whole number (e.g. 6 out of 12). As per the schedule Y(dated

20th Jan 2005) the quorum must include members with the following representations;

- One Basic medical scientist (preferably one pharmacologist)
- One Clinician
- One Legal expert.
- One Social scientist/representative of non-governmental voluntary agency/Philosopher/ethicist/theologian or a similar person.
- One Lay person from the community.

- At the discretion of the Chairman, guests may be allowed to observe the Board meetings.
- These guests may include a potential client, students and are required to sign a confidentiality agreement (*AF/02/01-SOP03/01*).
- The Secretariat will obtain signatures on the Confidentiality /Conflict of Interest Agreement Form from newly appointed members/Guests/observers /Independent Consultants prior to the start of the meeting.
- The Secretariat will also obtain the signatures of all the IEC members on the attendance register.
- The Chairperson will initiate the meeting once the quorum has been met.
- The Secretary then reports on the minutes of the previous meeting and presents the agenda for discussion.
- The meeting proceeds in the order organized in the agenda; however, the Chairperson may allow some switching depending on the situation.
- During the approval process a member of the Secretariat gives the briefing about the study by reading the comments and evaluation of the reviewers.
- The other members give their comments right after the presentation and the discussion about the study takes place.
- Investigators may be allowed to present their projects in brief and attend the IEC meeting to clarify any questions related to their project that the IEC members may have.
- The Secretariat records the discussions and the decisions made during the meeting in the IEC Decision Forms.

5.3 After the Board meeting and Preparing the Minutes

- The Secretariat will compose the summary of each meeting discussion and decision in a concise and easy-to-read style in the minutes.

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- The Secretariat will make sure to cover all contents in each particular category to include the following:
  - Name of person preparing the minutes
  - Location where the meeting was held (city, state)
  - Meeting date/duration of the meeting
  - Names of the attending board members and guests
  - Name of the individual serving as Chairperson of the meeting
  - Determination of a duly constituted quorum by the Chairperson to proceed with the meeting
- Requirements for each study or activity requesting Approval:
  - Sponsor's name;
  - Protocol number/date/version of protocol, when available;
  - Investigator's name;
  - Discussion as deemed appropriate by the Chairperson
  - Reference to the investigator approval letter that lists all changes requested by the board;
  - Determination of the next requested continuing review.
- Requirements for each study or activity requesting Expedited Review:
  - Sponsor's name;
  - Protocol number, if applicable
  - Investigator's name;
  - Lists of expedited approval requests and outcomes.
- Required for each Continuing Review Report:
  - Sponsor's name;
  - Protocol number, if applicable;
  - Investigator's name;
  - Indication of the Board's determination to continue, terminate, or amend the study;
  - Lists of recommendations or actions to be taken up with the investigator, if applicable.
- Required for each Adverse Event notification and Final Report:
  - Sponsor's name;
  - Protocol number, if applicable;
  - Investigator's name;
  - Actions deemed appropriate by the Board's review.
- Required for Termination of Approval:
  - Sponsor name's;
  - Protocol number, if applicable;
  - Investigator's name; reason for termination

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5.4 Approval of the minutes

- The Secretariat will check the correctness and completeness of the minutes and prepare it within 10 days of the meeting held.
- The Secretariat will request the Chairperson of the IEC to sign and date the minutes of the IEC meeting.

5.5 Filing the minutes

- The Secretariat will place the original version of the minutes in the minutes file.
- The Administrative Officer will file the IEC Decision Forms in the project files and place all correspondence in the appropriate files.

6. Glossary

Agenda	A list of things to be done; a program of business at a meeting
Minutes	An official record of the business discussed and transacted at a meeting, conference, etc.
Quorum	Number of IEC members required to act on any motion presented to the Board for action.
Majority vote	A motion is carried out if one half plus one member of the required quorum votes in its favor.

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. Annexure

ANNEX 1 AF/01/01-SOP16/01 Agenda format

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Annex 1
AF/01/01-SOP16/01

Agenda Format

Agenda of the IEC Meeting
No……./year Location
of the meeting Date
Meeting time

The Board meeting will proceed in the following sequences:

Period 1 Issues to be informed to the members.

Period 2 Approval of the last meeting minute

Period 3 New Protocol Presentation, Review, Discussion and reaching a consensus to approve/raise queries,
Review the responses forwarded by the PI to the query letter/resubmitted protocols
Approve protocol amendment and related documents.
To approve additional sites for project already approved.
To review the annual report and consider the application for Extension of approval.
To review trial completion/ Premature termination reports.
To review Monitoring reports.
To review SAE/Safety reports.

Period 4 Issues to be reported for Consideration

Period 5 Other issues of interest to the members