



Standard Operating Procedures (SOP -17/01)

For
Conduct of Emergency Meeting



Independent Ethics Committee (Clinical Research) India

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to identify the administrative process for preparing for an emergency meeting; and to provide instructions on the review and approval of study activities using the Emergency Meeting Procedures

2. Scope

This SOP applies to emergency Independent Ethics Committee (IEC) meetings. Emergency meetings may be scheduled to approve safety / life threatening issues, SAE and other study activities that require Full Board review.

3. Responsibility

The IEC Chairperson may call for an emergency meeting as appropriate.

4. Flow chart

<u>No.</u>	<u>Activity</u>	<u>Responsibility</u>
1	Before the Board meeting	IEC Secretariat
2	During the meeting	IEC Members and Chairperson
3	After the meeting	IEC Secretariat

5. Detailed instructions

5.1 Before the Board meeting

- The Chairperson will decide to call an emergency meeting based on the following criteria:
 - Urgent issues (if delayed will affect or have impact on patient safety, to the public benefit, national economics, etc.)
 - Occurrence of unexpected serious adverse events.



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- A matter of life and death for the patients continuing in the trial.
- Other appropriate reasons.

5.1.1 Contact and inform IEC members

- The Secretariat will contact the IEC members and inform them about the meeting especially to meet the quorum i.e.
 - At least one basic medical scientist member
 - At least one clinician member
 - At least one Legal Expert
 - At least one Social Worker/Religious person
 - At least one lay person.
- The Administrative Officer will prepare packets for distribution to the members containing the information of the SAE/other matter for which Emergency Meeting is scheduled.
- The Administrative Officer will attach a separate sheet with information about meeting date, time, phone numbers, the meeting ID number and an attendance confirmation form to the packets.
- The Administrative Officer will refer to the relevant SOPs (i.e., SOP 06/01 - Initial Review of Protocol Submission, SOP 07/01 - Expedited Review, SOP 09/01 - Review of Amended Protocol/Protocol related documents, SOP 14/01 Reviews of SAEs) as may be deemed necessary.

5.2 During the meeting

- The Chairperson/Secretary will determine if there is a quorum.
- However if after 15 minutes the quorum is not met, in view of emergency of the situation, meeting will proceed if a maximum of 3 members are present, one of which should have a scientific background.
- The IEC member will follow the related SOPs as deemed necessary.
 - SOP 02/01 - Constituting Independent Ethics Committee
 - SOP 05/01 - Management of Protocol Submission
 - SOP 06/01 - Initial Review of Protocol Submission
 - SOP 07/01 - Expedited Review
 - SOP 09/01 - Review of Amended Protocol/Protocol related documents
 - SOP 10/01 - Continuing Review of Study Protocols
 - SOP 16/01 - Agenda Preparation, Meeting procedures and recording of minutes
 - SOP 14/01 - Review of SAE



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5.3 After the meeting

- The Secretariat will follow the related SOPs as listed in 5.2.

6. Glossary

Emergency meeting An IEC meeting that is scheduled outside of a normally scheduled meeting to review study activities that require full IEC review and approval. In order to hold an emergency meeting, a quorum must be maintained throughout the entire discussion. Emergency meetings may be held via teleconference, if applicable.

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).