



**Independent Ethics Committee (IEC)**  
Regd. No. 1433/1999 G.B.B.S.D

## **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**

<b><u>No.</u></b>	<b><u>Activity</u></b>	<b><u>Responsibility</u></b>
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.



**Independent Ethics Committee (IEC)**  
**Regd. No. 1433/1999 G.B.B.S.D**

- 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



**Independent Ethics Committee (IEC)**  
Regd. No. 1433/1999 G.B.B.S.D

**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/](http://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).