

Title: Conduct of Emergency Meeting **SOP**

Code: **SOP 17/V1 dated 18th February 2017**

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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 Institutional 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

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

5. Detailed instructions

Before the Board meeting

The Chairperson/ Member Secretary will decide to call an emergency meeting for any one or more of the following reasons:

- Urgent issues (which, if not decided upon early could adversely affect or have adverse impact on patient safety, public safety or national economy etc.)
- Occurrence of unexpected serious adverse event(s).
- A matter of life and death for the patients continuing in the trial.
- Other reasons, as deemed appropriate by the Chairperson.

Contact and inform IEC members

- The Secretariat will endeavor to contact each and every IEC member and inform about the date, time and venue of the meeting as well as the reason for calling for the meeting. For the purpose of calling an emergency meeting, contact by telephone or email to the email address provided by the member would be considered as sufficient.
- The Secretariat/ Administrative Officer will prepare packets for distribution to the members containing the information and documents about the matter(s) for which Emergency Meeting is scheduled or send the relevant details (incase the documents are too many) via email.

- 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 and act according to the relevant SOPs depending upon the matter under consideration.

During the meeting

- The Chairperson/Secretary will determine if there is a quorum.
- If a quorum is not met, the meeting will be postponed for 15 minutes. However, if there is no quorum at the end of 15 minutes; the meeting would be held without a quorum provided at least three members (other than Chairperson and including at least one scientific member) are present, given the urgency of the matter under consideration. The IEC member will follow the related SOPs as deemed necessary.
 - SOP 02/V1 - Constituting Ethics Committee for Research on Human Subjects.
 - SOP 05/V1 - Management of Protocol Submissions.
 - SOP 06/V1 - Initial Review of Submitted Protocol.
 - SOP 07/V1 - Expedited Review.
 - SOP 09/V1 - Review of Amended Protocol/Protocol related documents.
 - SOP 10/V1 - Continuing Review of Study Protocols.
 - SOP 16/V1 - Agenda Preparation, Meeting procedures and recording of minutes.
 - SOP 14/V1 - Review of SAE.
 - SOP 12/V1- Review of protocol deviations/violations

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.
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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 31st August 2013)
- [2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- <http://www.ich.org/LOB/media/MEDIA482.pdf> (last accessed 31st August 2013)