
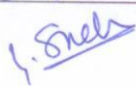
	Institutional Ethics Committee (IEC) Seth G.S. Medical College and K.E.M. Hospital, Parel, Mumbai – 400 012. Web: www.kem.edu	SOP 14/V5 Effective from 1st Aug 2017, Valid up to 30th July 2019
	Conduct of Emergency Meeting	


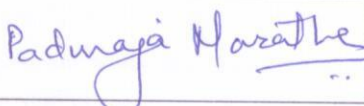
Title: Conduct of Emergency Meeting

SOP Code: SOP 14/V5 dated 26th July 2017

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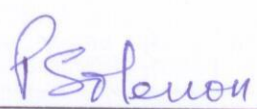


 Dr. Padmavathy Menon, Chairperson, IEC-I (Signature with Date)	 Dr. Alan Almeida, Chairperson, IEC - II (Signature with Date)
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1. Purpose

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

It is responsibility of the Member Secretary in consultation with Chairperson to call an emergency meeting. It is responsibility of the IEC secretariat to arrangement of an emergency meeting. It is responsibility of the Chairperson/Secretary to conduct the meeting and discuss the matter with the IEC members for the decision making.

4. Flow chart

No.	Activity	Responsibility
1	Call for an emergency meeting	IEC Member Secretary and Chairperson
2	Arrangement of an emergency meeting	IEC Secretariat
3	Discuss the matter and take a decision	IEC Members, Member Secretary and Chairperson

5. Detailed instructions

5.1 Call for an emergency 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.

5.2 Arrangement of an emergency meeting

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.

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- 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.

5.3 Discuss the matter and take a decision 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 members will act according to the relevant IEC SOPs (Expedited Review, SAE review, Review of Protocol deviations/violations etc.) for discussion and decision-making on the matter under consideration. The minutes of the emergency meeting would be prepared, distributed, approved and filed as described in the steps above for regular full board meeting.

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 July 2017)
- [2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- <http://www.ich.org/LOB/media/MEDIA482.pdf> (last accessed 31st July 2017)