


<b>TAGORE MEDICAL COLLEGE &amp; HOSPITAL</b> 	<b>Conduct of Emergency Meeting</b>		<b>Institutional Ethics Committee</b>
			<b>TMCH/IEC/SOP/8</b>
<b>Amendment No: 00</b>	<b>Issue No: 01</b>	<b>Issue Date: 02/11/2020</b>	<b>PAGE 1 OF 4</b>

## Conduct of Emergency Meeting

For Institutional Ethics Committee




Tagore Medical College and Hospital




Melakkottaiyur, Rathinamangalam, Chennai-127

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**Issue No** : 01  
**Issue Date** : 02.11.2020  
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**Copy Holder Name and Designation** : Dr. R. Geetha, Member Secretary, IEC

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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



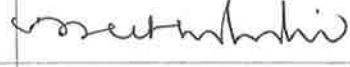
This SOP applies to emergency Institutional Ethics Committee (IEC) meetings. Emergency meetings may be scheduled to approve safety / life threatening issues, SAE and other study activities that require Full Board review.


### 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

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## 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:




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


### 5.2 Arrangement of an emergency meeting

#### 5.2.1 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 (in case 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.

#### 5.2.2 Discuss the matter and take a decision during the meeting



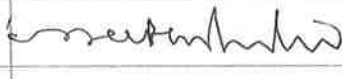
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- The Chairperson/Secretary will determine if there is a quorum.
- If a quorum is not met, the meeting will be postponed for 15 minutes. However, if there is no quorum at the end of 15 minutes; the meeting would be held without a quorum provided at 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. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)-  
<https://www.who.int/tdr/publications/documents/ethics.pdf> (last accessed 22<sup>nd</sup> October 2020).
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996-<http://www.ich.org/LOB/media/MEDIA482.pdf> (last accessed 22<sup>nd</sup> October 2020).
3. National Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR 2017

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