

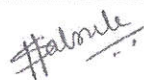

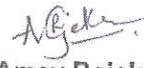



Title:	Emergency or Compassionate use of drugs.
SOP Code:	SOP 23/V1.0 dated 14 th May 2021

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
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2/7/21

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to identify the administrative process to assist treating physicians to comply with Central Drug Standard Control Organisation (CDSCO) requirements for <Emergency Uses>, <Compassionate Uses>, and <Single Patient Expanded Access>.

2. Scope

This SOP applies to emergency use of drugs. Out side review or emergency meeting may be scheduled to approve life threatening issues, and issues related to emergency drug use in practice.

3. Responsibility

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

4. Activity Table

No.	Activity	Responsibility
1	Call for an emergency meeting or review	IEC Member Secretary and Chairperson
2	Arrangement of an emergency meeting or review	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 or review

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

- Urgent issues related to emergency Uses>, <Compassionate Uses>, and <Single Patient Expanded Access>.
- Other reasons, as deemed appropriate by the Chairperson.

5.2 Arrangement of an emergency meeting or review

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 check the following required documents:
 1. Letter from clinician forwarded by Dean, Seth GSMC & KEMH regarding requirement of emergency use of drug / device.
 2. Complete drug/ device information
 3. Letter from sponsor/Clinician (clinical dilemma in case of off label use)

- Administrative Officer will prepare packets for distribution to the members containing the information and documents about the matter(s) for which review / 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.

5.3 Policy

- Whenever possible, Clinician are to notify the IEC in advance of a proposed <Emergency Use>.
- Clinician are to notify the IEC in advance of a proposed <Compassionate Uses>.
- cannot be used in a non-exempt systematic investigation designed to develop or contribute to generalizable knowledge.
- < Primary Reviewers> can inform Clinician of whether a proposed use, if carried out as described, will meet CDSCO requirements or whether a use already carried out met CDSCO/DCI requirements.
- KEMH Clinicians follow "SOP7: (continuing review)" to provide written notification to the Clinician of the results of this SOP.
- The <Emergency Use> of a drug or biologic and <Single Patient Expanded Access> are "research" as defined by CDSCO, the patient is a "subject" as defined by CDSCO, and the CDSCO may require data from an <Emergency Use> to be reported in a marketing application.
- <Single Patient Expanded Access> and <Compassionate Use> require continuing review.
- Initial and continuing review of <Single Patient Expanded Access> and <Compassionate Use> follow this procedure as well to check for any AEs /SAEs along with post trial access issues if patient benefits.

5.4 Discuss the matter and take a decision during the meeting/without meeting in circulation

- The Chairperson/Secretary will determine if there is a quorum (chairperson, secretary and one scientific member and one external member) during the meeting.
- Outside the meeting, it can be circulated to one scientific and one nonscientific person for review.
- 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.
Compassionate use of drugs	The World Health Organization defines compassionate use (CU) as a "program that is intended to provide potentially life-saving experimental treatments to patients suffering from a disease for which no satisfactory authorized therapy exists and/or who cannot enter a clinical trial.