

CHAPTER 8.2

EMERGENCY MEETING

SOP NUMBER: SOP/023/01



INSTITUTIONAL REVIEW BOARD (IRB)

Khesar Gyalpo University of Medical Sciences of Bhutan

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1. PURPOSE

The purpose of this SOP shall be:

- 1.1. to identify the administrative process for preparing for an emergency meeting;
- 1.2. To provide instructions on the review and approval of study activities using the Emergency Meeting Procedure.

2. SCOPE

This SOP shall apply to emergency IRB meetings. Emergency meetings may be scheduled to review/approve safety / life threatening issues, new studies, and additional investigators, continuing review, protocol amendments and other study activities that require full Committee review. An independent consultant may be requested to attend the meeting to provide expert information on the relevant topics. E.g. For certain dental studies, it may be necessary to invite a dentist to attend the meeting as well.

3. RESPONSIBILITY

The IRB Chairperson may call for an emergency meeting as appropriate.

4. FLOW CHART

No.	Activity	Responsibility
1	Before the Committee meeting ↓	IRB Secretariat IRB Chairperson
2	During the meeting ↓	IRB Members and Chairperson
3	After the meeting	IRB Secretariat

5. DETAILED INSTRUCTIONS

5.1. Before the Committee meeting

- 5.1.1. The IRB Chairperson shall decide to call an emergency meeting based on the following criteria:
 - 5.1.1.1. Urgent issues (if delay will affect or have impact to the public benefit, national interest, etc.)
 - 5.1.1.2. Occurrence of unexpected serious adverse events.
 - 5.1.1.3. A matter of life and death
- 5.1.2. The IRB Secretariat shall contact and inform IRB members and the following representatives must be present within the quorum to conduct the Emergency meeting
 - 5.1.2.1. At least one scientific member
 - 5.1.2.2. A non-scientific member
 - 5.1.2.3. A member with expertise on the item to discussed
 - *E.g. for routine medical research studies, a physician may be invited.*
- 5.1.3. The IRB Secretariat shall prepare packets for distribution to the members.
 - 5.1.3.1. Attach a separate sheet with information about meeting date, time, phone numbers, the meeting ID number and an attendant confirmation form to the packets.
- 5.1.4. Refer to the relevant SOPs (SOP/011/01 - Initial Review of Application Protocol, SOP/010/01- Expedited Review, SOP/015/01 - Review of Protocol Amendments)

5.2. During the meeting

5.2.1. Determine if there is a quorum.

5.2.2. Follow the related SOPs:

- 5.2.2.1. SOP/003/01 – Constituting an Ethics Committee
- 5.2.2.2. SOP/008/01 – Management of Protocol Submission
- 5.2.2.3. SOP/012/01 – Use of Study Assessment Form
- 5.2.2.4. SOP/009/01 – Expedited Review
- 5.2.2.5. SOP/010/01 – Initial Review of Application Protocol
- 5.2.2.6. SOP/011/01 – Review of New Medical Device Studies
- 5.2.2.7. SOP/014/01 – Review of Protocol Amendments
- 5.2.2.8. SOP/015/01 – Management of protocol continuing Reviews
- 5.2.2.9. SOP/022/01 – Preparation of Meeting, agenda, minutes & action letters

5.3. After the meeting

5.3.1. Follow the related SOPs in 5.2.

6. GLOSSARY

Emergency meeting	An IRB meeting that is scheduled outside of a normally scheduled meeting to review study activities that require full IRB review and approval. In order to hold an emergency meeting, a quorum shall be maintained throughout the entire discussion and voting portions of the meeting. Emergency meetings may be held via teleconference, if applicable.
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7. REFERENCES

- 7.1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
- 7.2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996 & 2016.
- 7.3. World Health Organization, Standards and operational guidance for ethics review of health-related research with human participants, 2011.
- 7.4. Associated SOPs: SOP/003/01, SOP/009/01, SOP/012/01, SOP/013/01, SOP/015/01, SOP/016/01, and SOP/023/01.