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1. Purpose

The purpose of this SOP is:

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

2. Scope

This SOP applies to emergency CHH IRB meetings.

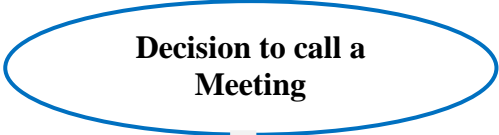


- Emergency meetings may be scheduled to review/approve safety / life threatening issues.
- For routine medical research studies, a physician may be invited to attend the meeting to provide information on medical care given to participants. For certain dental studies, it may be necessary to invite a dentist to attend the meeting as well.

3. Responsibility

The CHH IRB Chairperson may call for an emergency meeting as needed.

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4. Flowchart

No.	ACTIVITY	RESPONSIBLE PERSONNEL
I		CHH IRB Chairperson
II		CHH IRB Members and Chairperson
III		CHH IRB Secretariat

5. Detailed Instructions

5.1 Decision to call meeting

- The chair decides to call an emergency meeting based on the following criteria:
 - Urgent issues (if delay will affect or have impact to the public benefit, national economics, etc.)
 - Occurrence of unexpected serious adverse events.
 - A matter of life and death
 - Other urgent matters.
- The secretariat informs the CHH IRB members, including the invited persons about the meeting.
 - At least one medical member
 - A non-medical member
 - A non-institutional member
 - A member with expertise on the item to discussed
 - For routine medical research studies, a physician may be invited.
 - For certain dental studies, a dentist may be invited.
- Invite at least one expert to look at the document, if necessary.
- Prepare packets for distribution to the members.

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- Attach a separate sheet with information about meeting date, time, phone numbers, the meeting ID number and an attendant confirmation form to the packets.
- Refer to the relevant SOPs (i.e. SOP/006/05 - Expedited Review, SOP/012/05 - Study Protocol Amendment, etc.)

5.2 During the meeting

- Determine if there is a quorum.
- Follow the related SOPs
- Document the proceedings in the minutes of the meeting

5.3 Action/ Decision Letter

- Depending on the discussed matters the board may have an action/ decision letter if applicable

6. ANNEX: None

7. References

- ❖ World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
- ❖ International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- ❖ Associated SOPs: SOP/002/02, SOP/006/02-010/02, 012-013 and 028-029.
- ❖ National Ethical Guidelines for Health Research 2011 PNHRs