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1. Purpose

The purpose of this SOP is:

- to identify the administrative process for preparing for 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 MRIN EC meetings.

Emergency meetings may be scheduled to review/approve safety / life threatening issues, new studies, additional investigators, continuing review, protocol amendments and other study activities that require full board review.

Researchers might be invited to attend the meeting to provide necessary detailed information.

3. Responsibility

The MRIN EC Chairperson may call for an emergency meeting as appropriate.


4. Flow chart

<u>No.</u>	<u>Activity</u>	<u>Responsibility</u>
1	Before the Board meeting ↓	MRIN EC Secretary
2	During the meeting ↓	MRIN EC Members and Chairperson
3	After the meeting	MRIN EC Secretariat

5. Detailed instructions

5.1 Before the Board meeting

- Decide to call an emergency meeting based on the following criteria:

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- 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
 - Suspension and or Termination of the Study
 - Other appropriate reasons.
- Contact and inform EC members, including the invited persons about the meeting.
 - A member with expertise on the item to discuss
 - Researchers participating in the protocol
 - Invite at least one consultant to look at the document, as appropriate.
 - Prepare documents for distribution to the members.
 - Attach a separate sheet with information about meeting date, time, phone numbers, the meeting ID number and an attendant confirmation form to the documents.
 - Refer to the relevant SOPs (i.e., SOP /010/2020/01.4 - Initial Review of Application Protocol, SOP /009/2020/01.4 - Expedited Review, SOP /013/2020/01.6 - Review of Protocol Amendments, etc.)

5.2 During the meeting

- Determine if there is a quorum.
 - Follow associated SOPs
 - SOP /003/2020/01.4 – Constituting an Ethics Committee
 - SOP /007/2020/01.4 – Management of Protocol Submission
 - SOP /008/2020/01.5 – Use of Assessment Form
 - SOP /009/2020/01.4 – Expedited Review
 - SOP/010/2020/01.4 – Initial Review of Application Protocol
 - SOP /011/2017/01.3 – Review of New Medical Device Studies
 - SOP /013/2020/01.6 – Review of Protocol Amendments
 - SOP /015/2020/01.5 – Continuing Review
 - SOP /021/2020/01.5 – Preparation of Meeting, Agenda, Minute and Action letters

5.3 After the meeting

- Follow the related SOPs in 5.2.

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6. Glossary

Emergency meeting A MRIN EC meeting that is scheduled outside of a normally scheduled meeting to review study activities that require full board review and approval. In order to hold an emergency meeting, a quorum must be maintained throughout the entire discussion and voting portions of the meeting.

7. Annex

Annex 1 AF/01-022/2017/01.2 Document History

8. References

- Peraturan Pemerintah Republik Indonesia Nomor 39 Tahun 1995 tentang Penelitian dan Pengembangan Kesehatan, http://www.litbang.depkes.go.id/unduh_pp
- Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization, 2000, Geneva.
- Surveying and Evaluating Ethical Review Practices, World Health Organization, 2002, Geneva.
- International Conference on Harmonisation (ICH) Harmonised Tripartite : Guideline for Good Clinical Practice E6(R1), Current Step 4 version dated 10 June 1996, November 2005.
- Undang-undang Kesehatan No. 36 Tahun 2009 pasal 44.
- Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011, World Health Organization, www.who.int.
- Pedoman Nasional Etik Penelitian Kesehatan, Komisi Nasional Etik Penelitian Kesehatan, 2011.
- SIDCER Self-Assessment Tool, <http://www.fercap-sidcer.org/selftool.php>, accessed January 2013.
- FERCAP Standard Operating Procedures (SOPs) for Ethics Committees (ECs)/Institutional Review Boards (IRBs), <http://www.fercap-sidcer.org/selftool.php>, accessed January 2013.
- Associated SOPs: SOP /003/2020/01.4, SOP /007/2020/01.4-SOP /010/2020/01.4, SOP /011/2017/01.3, SOP/013/2020/01.6, SOP /014/2020/01.5, and SOP /021/2020/01.5

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Annex 1
Form AF/01-022/2017/01.2

Document History

Author	Version	Date	Description
EC Members	01.0	2 January 2013	Final version
Ivet, Lia, Mona	01.1	11 October 2014	<ol style="list-style-type: none"> 1. Synchronize the topic number and SOP number 2. Format Document History : Author, Version, Date and Description of the main change
Lia Siti Halimah, Yan Nuryanto	01.2	1 April 2017	<ol style="list-style-type: none"> 1. Delete Komite Etik Penelitian Kesehatan (KEPK) on the header 2. Item 2 (Scope) paragraph 3: Revise the sentence to “Researchers might be invited to attend the meeting to provide necessary detailed information” 3. Item 5.1. box 2: Delete the sentence “For routine medical research studies, a physician may be invited”, and “for certain dental studies, a dentist may be invited”. Add the sentence “Researchers participating in the protocol” 4. Item 5.1. box 3: Replace the word “expert” with “consultant” 5. Item 5.1. box 4 and box 5: Replace the word “package” with “document” 6. Item 6 : Glossary : in “Emergency meeting” add the sentence “require full board review and approval”