Table of Contents

<table>
<thead>
<tr>
<th>No.</th>
<th>Content</th>
<th>Page No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Table of Contents</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>Purpose</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>Scope</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>Responsibility</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>Flow chart</td>
<td>2</td>
</tr>
<tr>
<td>5</td>
<td>Detailed instructions</td>
<td>2</td>
</tr>
<tr>
<td>5.1</td>
<td>Before the Board meeting</td>
<td>2</td>
</tr>
<tr>
<td>5.2</td>
<td>During the meeting</td>
<td>3</td>
</tr>
<tr>
<td>5.3</td>
<td>After the meeting</td>
<td>3</td>
</tr>
<tr>
<td>6</td>
<td>Glossary</td>
<td>3</td>
</tr>
<tr>
<td>7</td>
<td>Annex</td>
<td>4</td>
</tr>
<tr>
<td>8</td>
<td>Reference</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Annex 1 Document History</td>
<td>5</td>
</tr>
</tbody>
</table>
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**

<table>
<thead>
<tr>
<th>No.</th>
<th>Activity</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Before the Board meeting</td>
<td>MRIN EC Secretary</td>
</tr>
<tr>
<td>2</td>
<td>During the meeting</td>
<td>MRIN EC Members and Chairperson</td>
</tr>
<tr>
<td>3</td>
<td>After the meeting</td>
<td>MRIN EC Secretariat</td>
</tr>
</tbody>
</table>

5. **Detailed instructions**

   5.1 **Before the Board meeting**

   - Decide 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
- 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.
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**

<table>
<thead>
<tr>
<th>Annex</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>AF/01-022/2017/01.2 Document History</td>
</tr>
</tbody>
</table>

8. **References**

- Undang-undang Kesehatan No. 36 Tahun 2009 pasal 44.
- 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
Annex 1
Form AF/01-022/2017/01.2

Document History

<table>
<thead>
<tr>
<th>Author</th>
<th>Version</th>
<th>Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC Members</td>
<td>01.0</td>
<td>2 January 2013</td>
<td>Final version</td>
</tr>
</tbody>
</table>
| Ivet, Lia, Mona      | 01.1    | 11 October 2014  | 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     | 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” |