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1. Purpose

The purpose of this SOP is to provide criteria for determination of which study protocols can be reviewed through exempted or expedited process as well as instructions on management, review and approval of the expedited or exempted review

2. Scope

This SOP applies to the review and approval of study proposals with minimum risk to participants, protocol amendments or informed consent changes of currently approved studies.

3. Responsibility

It is the responsibility of the Chairperson/Vice chairperson/Secretary of MRIN EC to define of which study protocols should be reviewed and approved through expedited or exempted channel.

4. Flow chart

4.1. Exempted

No.	Activity	Responsibility
1	Receive the submitted documents. ↓	EC Secretariat
2	Determine protocols for exempt review. ↓	EC Chairperson/Vice chairperson/Secretary
3	Exempt process. ↓	Chairperson/Vice chairperson/Secretary EC
4	Communicate with the MRIN EC and the Investigator.	EC Secretariat Members

4.2. Expedited

No.	Activity	Responsibility
1	Receive the submitted documents. ↓	EC Secretariat
2	Determine protocols for expedited review. ↓	EC Chairperson/Vice chairperson/Secretary
3	Expedite process ↓	Chairperson/Vice Chairperson/ Secretary/ reviewers
4	Communicate with the MRIN EC and the Investigator.	EC Secretariat Members

5. Detailed Instructions

5.1 Detailed Instructions Exempted Review

5.1.1 Receive the submitted documents

- ☐ Receive the application documents submitted by investigators.
- ☐ Write the receiving date on the letter and the documents.
- ☐ Sign the receiver's name on the receiving documents.
- ☐ Hand the received documents to the MRIN EC secretariat.

5.1.2 Determine protocols for exempted review.

MRIN EC Chairperson/Vice chairperson/Secretary determines whether a study is qualified for exempted review according to the following criteria:

- ☐ Research conducted in an established or commonly accepted medical educational settings which involve normal educational practices, such as:
  a. Research on regular or special education instructional strategies, or
  b. Research on the effectiveness of or comparison between teaching techniques, curricula, or classroom management methods.

- ☐ Research involving the use of a variety of educational tests (cognitive, diagnostic, aptitude, achievement), various survey procedures, various interview procedures or observation of public behavior, unless:

a. The information obtained is recorded in such a way so that human subjects can be identified, directly or indirectly, and
b. A disclosure of the subjects' responses outside the research could put the subjects at risk of criminal or civil liability, or be detrimental to the subjects' financial standing, working ability, or reputation

☐ Research involving the use of educational tests (cognitive, diagnostic, proficiency, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt if:
a. The human subjects are elected public or appointed public officials or candidates for public office, or

b. Constitution requires without exception that the confidentiality of personally identifiable information will be maintained during the period of research and thereafter.

☐ Research involving secondary data, documents, records, pathological specimens, or existing diagnostic specimens, if these sources are publicly available or if the information is recorded by the researcher in a way that the subject cannot be identified directly or indirectly.

☐ Research study which are conducted by or subject to the approval of department or agency which are designed to study, evaluate, or review
a. public health programs;
b. Procedures for obtaining benefits or services under the programs
c. Possible changes in or alternatives to the program or procedure ; or
d.Possible changes in methods or levels of payment for benefits or services under the programs

☐ **Taste and food quality evaluation and consumer acceptance studies:**
- **a. If healthy foods without additives are consumed or**
- **b. If the food is safe to consume with respect to chemical, agricultural pollutants (pesticides residues etc.), as determined by The National Agency of Food and Drug Control (Badan POM).**

5.1.3 Exempted Process

☐ Chairperson or Vice chairperson or Secretary of MRIN EC members to review the protocol.

- ☐ Carry out the exempted review on the complete proposal (study protocol with all the attached documents as mentioned in the guidelines for submission of proposals - see AF/01-007/2020/01.4
- ☐ The review may be made either by circulation of comments, electronic communication discussion or meeting
- ☐ Inform the MRIN EC of the proposals approved by exempted review at its regular meetings.

5.1.4 Communicate with the MRIN EC and the Investigator.

- ☐ The reviewers forward their comments to the Secretary.
- ☐ Full Board notification of items approved through expedited review by the Chairperson or the designee is accomplished by providing notification and source documentation of the items in the meeting agenda/notes.
- ☐ The MRIN EC Secretariat communicates the decision to the investigator. (SOP/008/2020/01.5)

5.2 Detailed instructions Expedited Review

5.2.1 Receive the submitted documents

- ☐ Receive the application documents submitted by investigators.
- ☐ Write the receiving date on the letter and the documents.
- ☐ Sign the receiver's name on the receiving documents.
- ☐ Hand the received documents to the MRIN EC secretariat.

5.2.2 Determine protocols for expedited review.

MRIN EC Chairperson/Vice chairperson/Secretary determines whether a study is qualified for expedited review according to the following criteria:

- ☐ Modification /amendment of protocol
  - ☐ ***administrative revisions***, such as correction of types
  - ☐ addition or deletion of ***non-procedural items***, such as the addition of study personnel names, laboratories, research population , etc.
  - ☐ ***non-significant risk*** research activity
  - ☐ The research activity includes only ***minor changes*** from previously approved protocol.
- ☐ Proposals involve interviewing of a ***non-confidential nature*** (not of a private eg. relate to sexual preference *etc.*), ***not likely to harm*** the status or interests of the individual and ***not likely to offend*** the sensibilities of the people involved.

- ☐ Those that involve ***collection of small amounts of blood samples*** (and not too frequent) e.g. by finger, heel or ear stick.
- ☐ Those that involve collection of biological specimens for research purposes by ***non-invasive means*** (e.g. collection of body fluids or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non-threatening manner).
- ☐ Collection of data for research purposes through ***non-invasive procedures*** (not involving general anesthesia or sedation) routinely employed in clinical practice and using medical devices which have been already approved for use. Examples of such procedures include collection of data through application of EEG or ECG electrodes, acoustic testing, tests using the Doppler principle, non-invasive blood pressure and other routine clinical measurements, exercise tolerance etc. However procedures involving the ***use of x-rays or microwaves are NOT recommended for expedited review***.

- ☐ Research involving data, documents or specimens that have been already collected or will be ***collected for ongoing medical treatment*** or diagnosis.
- ☐ Continuing review of research previously approved with no modifications to the original protocol and studies have taken place and ***no additional risks*** have been ***identified***.

If the protocol satisfied any of the criteria for **expedited** review, the secretariat will send the protocol to Chairperson.

5.2.3 Expedited Process

- ☐ Chairperson or Vice chairperson or Secretary appoints 2 or more MRIN EC members to review the revised protocol.
- ☐ The selected members are normally those who reviewed and recommended the previous version of that protocol, if it is not submitted for the first time.
- ☐ The secretariat sends the revised protocol to the selected members.
- ☐ Carry out the expedited review on the complete proposal (study protocol with all the attached documents as mentioned in the guidelines for submission of proposals - see AF/01-007/2020/01.4 & SOP/010/2020/01.4
- ☐ The review may be made either by circulation of comments, electronic communication discussion or meeting.
- ☐ If consensus can not be reached, the chairperson will refer the proposal back to the MRIN EC for a full review
- ☐ The expedited review should not take longer than 2 weeks

- ☐ Inform the MRIN EC of the proposals approved by expedited review at its regular meetings.
- ☐ If any committee member raises concern about any of the proposals presented to it as expedited review, then that proposal shall undergo a regular review.

5.2.4 Communicate with the MRIN EC and the Investigator.

- ☐ The reviewers forward their comments to the Secretary.
- ☐ Full Board notification of items approved through expedited review by the Chairperson or the designee is accomplished by providing notification and source documentation of the items in the meeting agenda/notes.
- ☐ The MRIN EC Secretariat communicates the decision to the investigator. (SOP/008/2020/01.5)

6. Glossary

Administrative Documents	Documents include official minutes of Board meetings as described in Standard Operating Procedures, both historical and Master Files as described in SOP/027/2017/01.2
Expedited approval	An MRIN EC approval granted only by the Chairman of the MRIN Board or a designated MRIN. board member (not the full Board) for minor changes to current MRIN EC approved research activities and for research which involves no more than minimal risk.
Expedited review	A review process by only two or more designated MRIN EC members who then report the decision to the Full board meeting. An expedited review is for *research protocol* with *minimal risk in nature* and with minor *changes to the approved protocol*.
Exempted approval	EC approval granted only by the Chairman of the MRIN Board or a designated MRIN. board member (not the full Board) for research which involves no more than minimal risk and follow the exempted criteria.
Exempted review	A review process by the MRIN EC Secretary who then report the decision to the full Board meeting. An exempted review is a speedy one for research proposal with no more than minimal risk in nature.

7. Annex

Annex 1 AF/01-009/2020/01.4 Document History

8. References

- ☐ 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, November 2016
- ☐ Undang-undang Kesehatan No. 36 Tahun 2009 pasal 44.
- ☐ Standards and Operational Guidance for Ethics Review of Health-Related
- ☐ 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.
- ☐ International Ethical Guidelines for Health – related Research Involving Humans. CIOMS, 2016, Geneva
- ☐ Associated SOPs: SOP/007/2020/01.4, SOP/008/2020.01.5 and SOP/027/2017/01.2

Annex 1

Form AF/01-009/2020/01.4

Document History

Author	Version	Date	Description
EC Members	01.0	2 January 2013	**Final version**
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 3. Purpose : study protocols can be reviewed through exempted or expedited process 4. Add a section about exemption in SOP 9 (expedited review), and provide criteria for exemption - Section 4.1. Flowchart Exempted - Section 4.2. Flowchart Expedited - Section 5.3. Determine protocols for exempted review. - Section 5.5. Exempted Process - Section 6. Glossary
Liliana Kurniawan, Lia Siti Halimah	01.2	1 April 2017	1. Delete Komite Etik Penelitian Kesehatan (KEPK) on the header 2. Item 4.2. : revise flowchart no. 3; responsibility. Add "Secretary" and replace : designated MRIN EC/KEPK MRIN Members related to topic of research" with " reviewers" 3. Item 5.1 box 3: replace the word of stamp with write 4. Item 5.1 box 2 : delete the sentence of "Get a contents of submitted package (checklist) form, AF/01-007/2017/01.2 to check items received." 5. Item 5.4. box 1 : replace the word of nominates with appoints 6. Glossary : Change the sentence " An expedited review is speedy one for minor changes to the approved protocol and for reserach with minimal risk in nature " to "An expedited review is for reserach protocol with minimal risk in nature and with minor changes to the approved protocol " in the expedited review"

LSH/MW/IS	01.3	2 January 2019	1. Item 5.5 Box 2 : to exclude SOP/010/2018/01.3 2. Item 3, Item 4, Item 5.2 and 5.3 : to add Vice chairperson
MW,IS,LSH, GE	01.4	02 January 2020	1. 5.1 Detailed Instructions : Separate between detailed instruction exempted review and expedited review 2. References : • Delete link WHO • Delete FERCAP SOP • Add ICH 2016