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1. Purpose

The MRIN EC is established in October 2012 in order to provide independent guidance, advice, and decision (in the form of “approval/recommendation/stipulation/disapproval”) on health research or other specific research protocols involving human subjects and experimental animal.

The MRIN EC is composed of both scientists and lay persons. It is independent in its reflection, advice, and decision.

These standard operating procedures describe the Terms of Reference (TOR) which provide the framework for constitution, responsibilities and activities of the MRIN EC. The TOR is further supported by the Standard Operating Procedures of MRIN EC

2. Scope


The SOP applies to all activities under MRIN EC.

3. Responsibility

It is the responsibility of the MRIN EC members, Secretariat to read understand and respect the rules set by the EC

4. Flow chart

<u>No.</u>	<u>Activity</u>	<u>Responsibility</u>
1	Ethical basis / Guidelines ↓	EC Members, Secretariat
2	Composition of the MRIN EC ↓	EC/KEPK MRIN Members and Secretariat
3	Membership Requirements ↓	EC Members and Secretariat
4	Resignation, Disqualification, Replacement of Members ↓	EC Members and Secretariat
5	Independent Consultants ↓	Chair of MRIN EC
6	Conditions of Appointment ↓	EC Members and Secretariat
7	Officers ↓	EC Chairperson and Secretary


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8	Secretariat ↓	EC Secretary
9.	ROLES AND RESPONSIBILITIES OF MRIN EC MEMBERS ↓	EC Members
10	Quorum Requirements ↓	EC Members and Secretariat
11	Dissolving of the MRIN EC	Chairman MRIN

5. Detailed Instructions

5.1 Ethical basis

- The MRIN EC recognizes that the protocols it approves may also be approved by ethics committees prior to their implementation in specific localities.
- In evaluating protocols and ethical issues, the MRIN EC is aware of the diversity of laws, cultures and practices governing research and medical practices in various countries around the world.
- It attempts to inform itself where possible of the requirements and conditions of the various localities where proposed MRIN research is being considered.
- The MRIN EC also seeks to be informed, as appropriate, by national/local ethics committees and researchers of the impact of the research it has approved.
- The MRIN EC is guided in its reflection, advice, and decision by the ethical principles expressed in the Declaration of Helsinki (1964 and subsequent revisions).
- It makes further reference to the National and International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS), the Belmont Report, and the European Convention on Human Rights and Biomedicine.
- The MRIN EC establishes its own standard operating procedures based on the Operational Guidelines for Ethics Committees That Review Biomedical Research (WHO), the WHO & ICH Guidelines for Good Clinical Practice and the local regulations.
- The MRIN EC seeks to fulfill the requirements for international assurances and is established and functions in accordance with the national law and regulations.


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5.2 Composition of the MRIN EC

- The MRIN EC is composed of at least 5 members
- The members shall include at least one member whose primary concerns are in medical science, at least one member whose primary concerns are in non-medical areas (lay person), and at least a member from outside the institute (non affiliated member).
- The members should have various backgrounds to promote complete and adequate review of research activities commonly conducted by the institute.
- Professional qualifications may include physician, pharmacist, nurse, social scientist, lawyer, statistician, paramedic, etc.
- The MRIN EC cannot consist entirely of men or entirely of women.
- The MRIN EC should have representatives from the older and younger generations.

5.3 Membership requirements

- Chairperson and Vice Chair will be appointed by the Chairman of MRIN Foundation based on recommendation from the EC Members, except the first MRIN EC Chairperson who was directly appointed by the Chairman of MRIN Foundation
- Members are selected in their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the MRIN EC's work.
- Members must disclose any interest or involvement – financial, professional or otherwise – in a project or proposal under consideration.
- MRIN EC members accept and sign the agreement contained in the Confidentiality / Conflict of Interest form before beginning their ethical review tasks
- The MRIN EC will decide the extent to which members that might have a conflict of interest may participate in bringing out an advice/decision, refer to SOP/004/2020/01.4 - Confidentiality / Conflict of Interest Agreement.
- Members will be required to sign a confidentiality agreement at the start of their term.

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- The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the MRIN EC in the course of its work.
- Members are appointed for a period of 3 years
- Their appointments may be renewed by the Chairman of MRIN Foundation based on recommendation of MRIN EC Chair and Members.
- The Ethics Committee will include some members replacement to ensure continuity within the MRIN EC.

5.4 Resignation, Disqualification, Replacement of Members


- Members may resign their positions by submitting a letter of resignation to the Chairperson.
- Members may also be disqualified from continuance should the Chairperson provide written arguments to the (other) members and there is unanimous agreement.
- Members that have resigned or have been disqualified may be replaced by appointing authorities.
- Members will be disqualified and replaced by the new member when he/she is in decease condition
- Penerimaan anggota akan dilakukan sesuai kebutuhan kondisi (recruitment of the members will be selected with regards to the need of ethics committee)

5.5 Independent Consultants

- The MRIN EC may be further supported in its reflections on specific protocols or requests for advice on specific ethical issues by Independent Consultants.
- Independent Consultants are appointed by the Chairperson of the MRIN EC based on MRIN EC Members recommendation.
- Their professional qualifications may be in the areas of community and/or patient representation, medicine, statistics, social science, law, ethics, and religion. Independent Consultants are appointed for the duration of the period when needed (see SOP/006/2020/01.3)

5.6 Conditions of Appointment

- Members and Independent Consultants are appointed to the EC under the following conditions:
- Willingness to publicize his/her full name, profession, and affiliation;

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- All financial accountability, reimbursement for work and expenses, if any, within or related to the EC should be recorded and made available to the public upon request;
- All EC Members and Independent Consultants must sign Confidentiality / Conflict of Interest Agreements regarding meeting deliberations, applications, information on research participants, and related matters.

5.7 Officers


- The following officers through their respective responsibilities contribute to the good functioning of the EC:

Chairperson	responsible to chair the meetings and liase directly with the Director or President of MRIN, report the meeting outcomes to the Director, invite independent consultants to provide special expertise to the EC on proposed research protocol.
Vice-Chairperson	responsible to chair the meetings in the absence of the Chairperson and act as vice-chair during meetings with the Chairperson,
Secretary/Vice Secretary	responsible for the administrative aspect of the EC (see 5.8 - below)

- The officers are elected by the EC members for three-year terms. They may be re-elected but not for more than three consecutive terms. Should they resign or be disqualified, the EC members elect a replacement until the completion of the normal term.

5.8 Secretariat

- The Secretariat is composed of the EC secretary and the administrative supporting staff.
- The supporting staff are staff members of the MRIN appointed by the MRIN Director or President.
- The Secretariat shall have the following functions:
 - Organizing an effective and efficient tracking procedure for each proposal received (SOP/007/2020/01.4 and SOP/025/2020/01.3).
 - Preparation, maintenance and distribution of study files (SOP/024/2020/01.3)
 - Organizing EC/ meetings regularly (SOP/021/2020/01.5).
 - Preparation and maintenance of meeting agenda and minutes (SOP/021/2020/01.5)

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- Maintaining the EC's documentation and Archive (SOP/010/2020/01.4 and SOP/025/2020/01.3)
- Communicating with the EC members and applicants (SOP/023/2020/01.4)
- Arrangement of training for personnel and EC members (SOP/005/2020/01.3)
- Organizing the preparation, review, revision and distribution of SOPs and guidelines (SOP/001/2020/01.3 and SOP/025/2020/01.3)
- Providing the necessary administrative support for EC related activities to the Chairperson of the Committee (e.g. communicating a decision to the applicant – SOP/007/2020/01.4 – SOP/021/2020/01.5)
- Providing updates on relevant and contemporary issues related to ethics in health research, as well as relevant contemporary literature to the Committee members.

5.9 Roles and responsibilities of MRIN EC members


- Participate in the EC meeting
- Review, discuss and consider research proposals submitted for evaluation
- Monitor serious adverse event reports and recommend appropriate action(s) (SOP/019/2020/01.3)
- Review the progress reports and monitor ongoing studies as appropriate
- Inspect research facilities as directed by MRIN EC.
- Evaluate final reports
- Maintain confidentiality of the documents and deliberations of EC meetings (SOP/026/2017/01.2)
- Declare any conflict of interest
- Participate in continuing education activities in biomedical ethics and biomedical research

5.10 Quorum Requirements

- A minimum of 50% plus one (1) of the EC members must be present at a meeting in order to issue a valid advice and/or decision.
- Professional qualifications of the quorum requirements should consist of: At least one lay person, one medical scientist and at least one member who is nonaffiliated of the institution/research site (non affiliated member).

5.11 Dissolving of the MRIN EC/KEPK MRIN

- At any point in time, the Chairman of the MRIN can dissolve MRIN EC.

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6. Glossary


Confidentiality	Prevention of disclosure, to other than authorized individuals, of MRIN EC's information and documents
MRIN EC	Independent Ethics Committee / Institutional Review Board is an independent body (either a review board or committee) whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection.
Scientists	Professionals with advanced training and expertise in the medical or non-medical areas related to the protocol being reviewed
Layperson	a person who is not qualified in a given profession and/or does not have specific knowledge of the certain subject, should have no vested interest in the research
Non Affiliated members	members are not employed under Medical Science Group and/or UPH

7. Annex


Annex 1	AF/01-003/2020/01.5 Organizational Structure
Annex 2	AF/02-003/2020/01.5 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
- Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011, World Health Organization,

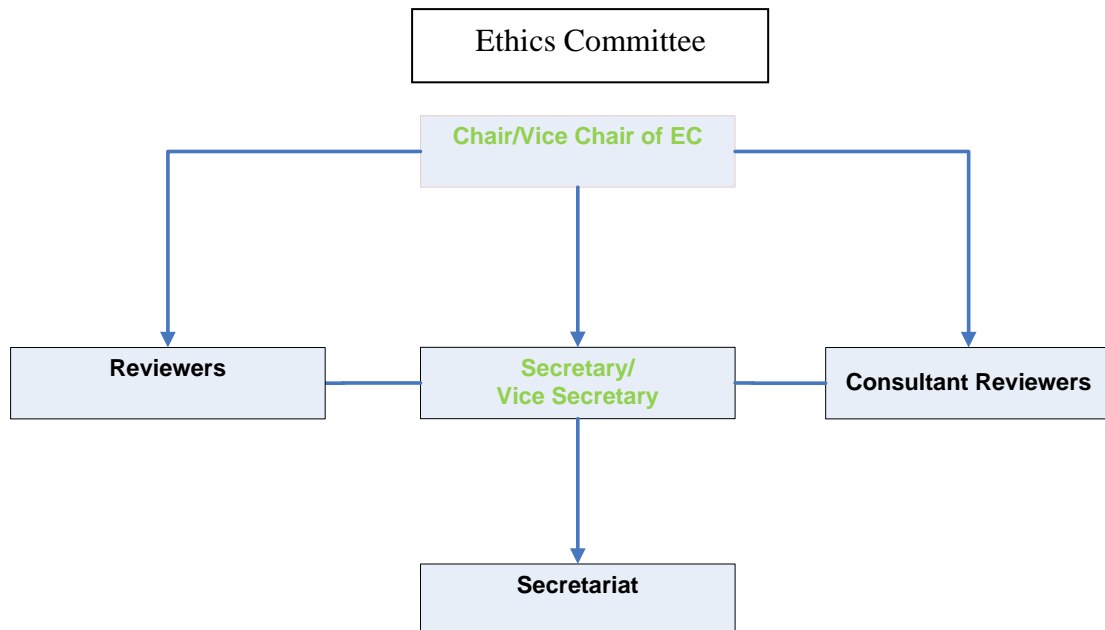
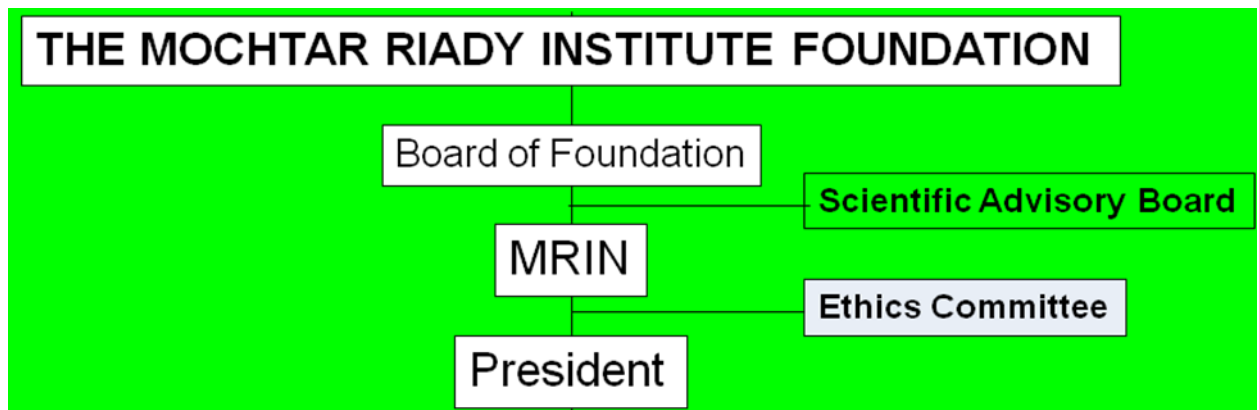
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- Pedoman Nasional Etik Penelitian Kesehatan, Komisi Nasional Etik Penelitian Kesehatan, 2011.
- SIDCER Self-Assessment Tool, <http://www.fercap-sidcer.org/selftool.php>, accessed January 2013.
- .Associated SOPs: SOP/001/2020/03., SOP/004/2020/01.4, SOP/005/2020/01.3, SOP/007/2020/01.4-SOP/010/2020/01.4, and SOP/012/2020/01.5, SOP/025/2020/01.3.

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Annex 1
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**Mochtar Riady Institute for Nanotechnology Ethics Committee (MRIN EC)
Organizational Structure**




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Annex 2
Form AF/02-003/2020/01.5

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 : 3. Author, Version, Date and Description of the main change' Scope of coverage of EC review functions to include researches done in Siloam Hospitals, UPH, and research institutes of Lippo group (and reconsider the name of the EC) 4. Section 5.3 : Membership requirement 5. Section 5.10 : to define quorum as 50% + 1 6. Annex I : Organization Chart
Ivet, Lia, Mona	01.2	15 November 2014	<ol style="list-style-type: none"> 1. Section 5.11 : Replace reference from MRIN Director to MRIN Chairman 2. Annex I : Organization Chart
Dondin Sajuthi, George Mathew. Monalisa	01.3	1 April 2017	<ol style="list-style-type: none"> 1. Delete Komisi Etik Penelitian Kesehatan (KEPK) on the header 2. Item 2 : Scope, to delete the teaching project 3. Item 5.2 : to add laboratory animal veterinarian in the professional qualification 4. Item 5.2. box 2 : delete non scientific 5. Item 5.2 box 3 : to add non affiliated member 6. Item 5.5 box 3 : to add veterinary medicine in the professional qualification 7. Item 5.5. box 4 : replace the duration of the period sought to period when needed

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			8. Item 5.9 : to add inspect research facilities including animal research as directed by the MRIN EC 9. Item 5.10 : to add non affiliated member 10. Item 5.10 : box 2, to change Professional qualification 11. Item 5.10 : box 2 to add the word of EC in the sentence plus one of the members 12. Item 5.11 box 2 : Delete the sentences of dissolved by “President” and the following written notification to each of the members becomes the MRIN EC may also be dissolved at any time by the Chairman of the MRIN 13. Annex 1 : revise organizational structure without name and period 14. Glosarry : to add lay person
LSH, IS, MW	01.4	2 January 2019	1. Definition of a members non affiliated are added in the Glossary 2. Item 5.5. Box 3 Delete Veterinary medicine 3. Item 5.7 To add vice secretary 4. Item 5.7 To revise the maximum of terms of members appointment from 2 terms to be 3 terms 5. Item 5.9.Box5 : Delete including Animal research 6. Annex 1 : to add vice person/vice chair
IS,MW,LSH, GE	01.5	2 January 2020	1. SCOPE : Replace the statement of “the SOP applies.....conducted elsewhere” with “The SOP applies to all activities under MRIN EC” 2. Flowchart : to add “ role dan responsibility” and Delete President 3. Flow Chart : step 9 & 10 becomes 10 & 11 4. 5.2,box 4 : delete the word of “ Laboratory Animal, Veterinarian and/or layperson 5. 5.3,box 1 : replace “the head of

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			<p>...members” with the “Chairperson...MRIN Foundation”</p> <ol style="list-style-type: none"> 6. 5.3, box 3 : Delete the word of “ in writing” 7. 5.3, : add box 4 : MRIN EC members accept and sign the agreement contained in the Confidentiality / Conflict of Interest form before beginning their ethical review tasks 8. 5.3 , box 8 : Revised statement “renewed by the president...consecutive terms” with “the chairman of MRIN Foundation... and members“ 9. 5.3, box 10 : replace the statement “ The Ethics Committee will include some rotation after a period of three year for up two consecutive terms, but it will also strive..... within the MRIN EC” with ”The Ethics Committee will include some members replacement to ensure continuity within the MRIN EC 10. 5.4, box 5 : add statement of “Penerimaan anggota akan dilakukan sesuai kebutuhan kondisi (recruitment of the members will be selected with regards to the need of ethics committee) 11. 5.5, box 2 : add the sentences of “ based on MRIN EC Members recommendation” 12. 5.9, box 6 : delete the word of “outcomes” 13. Structure Organization : Replace Consultant Reviewer with Independent Consultant 14. References : <ul style="list-style-type: none"> • Add ICH GCP November 2016 • Add Declaration Helsinki • Delete link WHO • Delete FERCAP SOP
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