
	<b>Mochtar Riady Institute for Nanotechnology (MRIN) Ethics Committee (EC) /</b>	<b>SOP/002/2020//01.3</b> <b>Effective date:</b> <b>02 January 2020</b>
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## **1. Purpose**

This procedure describes how to prepare a new guideline or update an existing one as well as the layout and format of each guideline.

## **2. Scope**

This SOP applies to any MRIN EC guidelines and their amendment versions published and distributed by the institute.


The EC works according to internal rules that must be described in written standard operating procedures (SOPs). The SOPs are confidential but may be disclosed to authorities upon request. However, in order to maintain a transparent relationship with non-members of the MRIN EC, certain procedures will form guidelines for use by investigators, scientific experts and by the Institute personnel.

## **3. Responsibility**

It is the responsibility of the EC Secretariat or designated persons to prepare or amend the Institute guidelines as and when the need arises. The designated persons will manage the preparation/amendment of the guidelines with the assistance of the Secretariat.

## **4. Flow chart**

<b><u>No.</u></b>	<b><u>Activity</u></b>	<b><u>Responsibility</u></b>
1	Numbering of Guidelines	MRIN EC Secretariat
	↓	
2	Numbering of the Version	MRIN EC Secretariat
	↓	
3	Contents and Layout of A Guideline	MRIN EC Secretariat
	↓	
4	Approval of New and Updated Guidelines	MRIN EC Chairperson/ Members
	↓	
5	Information for Personnel	MRIN EC Members / Secretariat
	↓	
6	Distribution of Guidelines	MRIN EC Secretariat

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## **5. Detailed instructions**

### **5.1 Numbering of the Guidelines**

- When a new guideline will be created, a subsequent number should be allocated at the end of the list of existing Guidelines.
- When a guideline is no longer used, its status is changed to “inactive”. It is not allowed to reuse the guideline number of an inactive guideline.

### **5.2 Numbering of the Version**

Each guideline should be given a number and a title that is self-explanatory and is easily understood. A unique code number with the format [XX/YYYY/ZZ](#) will be assigned to each guideline by [Secretariat](#). **XX** indicates version number of the guideline. **YYYY** is the year of the guideline released. **ZZ** is a number identifying the revision of the guideline, for example 01/2020/03

### **5.3 Contents and Layout of a Guideline**

A new or updated guideline has following sections:

1. Cover Page
2. Table of Contents
3. Main text
4. References
5. Appendices

Sections 1 to 4 are mandatory. The “*Appendices*” section is not mandatory.

#### **5.3.1 Cover Page**

The cover page will have the following information:


- Logo of MRIN, and related information (address, telephone number, email address).
- Title and number of the guideline, date of implementation of the guideline
- Refer to Annex 1 ([AF/01-002/2020/01.3](#)) for an example of a cover page.

#### **5.3.2 Table of Contents**

The table of contents lists all major headers and subheadings of the guideline, including the appendices and page numbers on which these appear in the guideline.

#### **5.3.3 Main Text**

- Introduction
  - Summarize and explain the purpose of the guideline.

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- A short note on how the guideline was prepared.
- A short note on how to use the guideline.
- Detailed description
  - The final text should be short and clear.
  - Long guidelines should be split into shorter ones.
  - Wherever possible and relevant references should be added
  - Limitation of the guidelines may be mentioned

#### **5.3.4 Appendices**

- Replace long and complex descriptions.
- “Descriptions-by-example” are always recommended to avoid writing difficult and hard to understand texts.
- Glossary
- Full form of abbreviations

#### **5.4 Approval of New and Updated Guidelines**


- The members of the EC shall prepare a new guideline or update an existing guideline.
- The Chairperson of the EC should approve each new or updated guideline.
- The final version is the one to be implemented.

#### **5.5 Information for Personnel**

- All members of the MRIN EC must read and understand a new or updated guideline.
- Each member will sign a form indicating that they have read and understood each new or updated guideline.
- Refer to Annex 2 ([AF/02-002/2020//01.3](#)) for an example.

#### **5.6 Distribution of Guidelines**

- Guidelines are not confidential and may be disclosed for use by investigators, scientific experts and EC members.
- Investigators/students/institute personnel can have access to the Guidelines by accessing the MRIN website ([www.mrinstute.org](http://www.mrinstute.org))

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## **6. Glossary**


Guideline                      Any suggestion, rules, etc., intended as a guide for specific practice

## **7. Annex**

Annex 1              AF/01-002/2020/01.3 Cover page of a Guideline (2 pages)  
Annex 2              AF/02-002/2020/01.3 List of Signatures  
Annex 3              AF/03-002/2020/01.3. 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
- SIDCER Self-Assessment Tool, <http://www.fercap-sidcer.org/selftool.php>, accessed January 2013.

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Annex 1  
Form AF/01-002/2020/01.3

**Cover page of a Guideline**

**Guideline for**

.....

.....


*XX/YYYY/ZZ*  
*Effective from MM/YYYY*



**Mochtar Riady Institute for Nanotechnology**

**Address:**

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**Annex 1**  
 Form AF/01-002/2020/01.3  
 Page 2

**Information on the Back of the Cover Page**

Number of Copies Printed

Title of the Guideline

Version No.


Month/Year of Publication

ISBN:

Author: MRIN EC

Editor: MRIN EC

Computer Record (file name and location)

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**Annex 2**  
Form AF/02-002/2020/01.3



**LIST OF SIGNATURES**


**Title of the Guideline:** .....

**Number of the Guideline :** GL .....

The following listed persons with their signatures have read this guideline.

No.	Full Name of MRIN EC members	Signature	Date




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Annex 3  
 Form AF/03-002/2020/01.3

Document History

Author	Version	Date	Description
EC Members	01.0	2 January 2013	<b>Final version</b>
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
Suryani As'ad, Ivet Suriapranata	01.2	1 April 2017	1. Delete Komisi Etik Penelitian Kesehatan (KEPK) on the header 2. Item 5.5 : replace sentences in box 4 to: "Investigators/students/institute personnel can have access to the Guidelines by accessing the MRIN website ( <a href="http://www.mrinstitute.org">www.mrinstitute.org</a> )" 3. Item 5.6 replace sentence to "Guidelines are not confidential and may be disclosed for use by investigators, scientific experts and EC members"
IS,LSH,MW, GE	01.3	2 January 2020	1. 5.1, box 1 : Delete 2. 5.1, Box 2 – 3 becomes box 1 – 2 3. Replace content 5.2 with Each guideline should be given a number and a title that is self-explanatory and is easily understood. A unique code number with the format <a href="#">XX/YYYY/ZZ</a> will be assigned to each guideline by <a href="#">Secretariat</a> . <a href="#">XX</a> indicates version number of the guideline. <a href="#">YYYY</a> is the year of the guideline released. <a href="#">ZZ</a> is a number identifying the revision of the guideline, for example 01/2017/01 4. 5.3 : Replace the word of "has four" with " has following" 5. 5.3.1,box 1 : Delete the word of " fax

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			number” 6. 5.3.1, box 3 : DELETE 7. 5.3.1, box 4 becomes box 3 8. Annex 1 : Cover page of guideline : Replace numbering of “version month/year” with “ XX/YYYY/ZZ, effective from MM/YY” 9. References : <ul style="list-style-type: none"> <li>• Add ICH GCP November 2016</li> <li>• Delete Link WH</li> <li>• Delete FERCAP SOP</li> </ul>
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