
	Mochtar Riady Institute for Nanotechnology Ethics Committee (MRIN EC)	SOP/017/2017/01.2 Effective date: 1 April 2017 Page 1 of 6
	<u>Title:</u> 017. Response to Research Participants Requests	

Table of Contents

<u>No.</u>	<u>Content</u>	<u>Page No.</u>
	Table of Contents	1
1.	Purpose	2
2.	Scope	2
3.	Responsibility	2
4.	Flow chart.....	2
5.	Detailed instructions.....	3
5.1	Receive the request.....	3
5.2	Take action	3
5.3	File the request document	3
6.	Glossary.....	3
7.	Annex	4
8.	References	4
	Annex 1 Request Record Form	5
	Annex 2 Document History	6

	Mochtar Riady Institute for Nanotechnology Ethics Committee (MRIN EC)	SOP/017/2017/01.2 Effective date: 1 April 2017
	<u>Title:</u> 017. Response to Research Participants Requests	Page 2 of 6

1. Purpose

Since the EC considers protection of the rights and welfare of the subjects participating in a clinical investigation/research approved by the EC as its primary responsibility, Informed Consent documents reviewed by the EC may routinely contain the statement, “Questions regarding the rights of a participant/patient may be addressed to the EC Secretary with the MRIN address and/or phone number. On some occasions the first contact a participant/patient may have would be the EC Secretary.

This procedure provides guidelines for dealing with and accommodating requests by participants/patients regarding their rights as a participant in any approved research study.

2. Scope

This SOP applies to all requests concerning the rights and well-being of the research participants participating in studies approved by the EC.

3. Responsibility

The Institute’s policy designates the Secretary of the EC as the person responsible for communicating with participants/patients regarding their rights as study participants. Delegation of this responsibility to another EC member is acceptable as long as the delegation is documented (in writing). Delegation to non-IEC members is not permitted.

It is the responsibility of all Staff and EC members acting on behalf of the MRIN EC to facilitate participant/patient requests within the scope of their responsibilities.

4. Flow chart

<u>No.</u>	<u>Activity</u>	<u>Responsibility</u>
1	Receive the request ↓	EC Members and Secretary
2	Take action ↓	EC Members and Chairperson
3	File the request document	EC Secretariat

	Mochtar Riady Institute for Nanotechnology Ethics Committee (MRIN EC)	SOP/017/2017/01.2 Effective date: 1 April 2017 Page 3 of 6
	<u>Title:</u> 017. Response to Research Participants Requests	

5. Detailed instructions

5.1 Receive the request.

- The MRIN EC secretariat receives the inquiry or requests from research participants/patients.
- Record the request and information in the request record form (Form AF/01-017/2017/01.2)
- Communicate with the MRIN EC members about study participant rights for instruction.
- Refer the inquiry to the MRIN EC Chairperson/ Secretary in writing.
- MRIN EC Secretariat may provide assistance in contacting the Chairperson/ Secretary, but will not provide comments/opinions about the inquiry.
- The Chairperson/ Secretary shall
 - document the communication for the MRIN EC study file,
 - request follow-up information,
 - provide advice as required,
 - inform the other MRIN EC members about the inquiry,
 - follow-up at the next MRIN EC meeting or
 - delegate these tasks to MRIN EC members.

5.2 Take Action

- Appoint EC members to investigate the fact.
- Record information and any action or follow-up taken in the form AF/01-017/2017/01.2.
- Sign and date the form.
- Report to the MRIN EC Chairperson/ Secretary about the action taken to address the concerns of the subject directing them to the PI and monitoring the outcomes.

5.3 File the request document

- Keep the record form in the “response” file.
- Keep a copy in the study file.
- Store the file in the appropriately labeled shelf.

6. Glossary

Participants'rights Recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world. It is essential that Human Rights should be protected by the rule of law.

	Mochtar Riady Institute for Nanotechnology Ethics Committee (MRIN EC)	SOP/017/2017/01.2 Effective date: 1 April 2017
	<u>Title:</u> 017. Response to Research Participants Requests	Page 4 of 6

7. Annex

Annex 1	AF/01-017/2017/01.2	Request Record Form
Annex 2	AF/02-017/2017/01.2	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.

	Mochtar Riady Institute for Nanotechnology Ethics Committee (MRIN EC)	SOP/017/2017/01.2 Effective date: 1 April 2017 Page 5 of 6
	<u>Title:</u> 017. Response to Research Participants Requests	

Annex 1
Form AF/01-017/2017/01.2

Request Record Form

Date Received:	
Received by :	
Request from :	<input type="checkbox"/> Telephone call No..... <input type="checkbox"/> Fax No..... <input type="checkbox"/> Mailed letter / Date..... <input type="checkbox"/> E-mail / Date..... <input type="checkbox"/> Walk-in / Date / Time..... <input type="checkbox"/> Other, specify
Participant's Name:	
Contact Address: Phone:	
Title of the Participating Study	
Starting date of participation :	
What are requested?	
Action taken: Outcome:	

	Mochtar Riady Institute for Nanotechnology Ethics Committee (MRIN EC)	SOP/017/2017/01.2 Effective date: 1 April 2017 Page 6 of 6
	<u>Title:</u> 017. Response to Research Participants Requests	

Annex 2
 Form AF/02-017/2017.01.2

Document History

Author	Version	Date	Description
EC Members	01.0	2 January 2013	Final version
Ivet, Lia, Mona	01.1	11 October 2014	1. Synchronize the topic number and SOP number 2. Format Document History : Author, Version, Date and Description of the main change
Ivet Suriapranta, Sintak Gunawan	01.2	1 April 2017	1. Delete Komisi Etik Penelitian Kesehatan (KEPK) on the header