

	<b>Mochtar Riady Institute for Nanotechnology Ethics Committee (EC)/</b>	<b>SOP/004/2020/01.4</b> <b>Effective date:</b> <b>02 January 2020</b> <b>Page 1 of 11</b>
	<b><u>Title:</u></b> <b>004. Confidentiality/Conflict of Interest Agreement</b>	

## 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 Read the text carefully and thoroughly. ....	3
	5.2 Ask questions, if any. ....	3
	5.3 Sign with consent. ....	3
	5.4 Keep the agreement in mind.....	3
6.	Glossary .....	3
7.	Annex .....	4
8.	Reference .....	5
	Annex 1 Confidentiality/Conflict of Interest Agreement Form for MRIN EC Members/Independent Consultant/Ad Hoc Consultant .....	6
	Annex 2 Confidentiality Agreement Form for Guest Attendees to MRIN EC Meetings.....	9
	Annex 3 Confidentiality Agreement Form for Non members Requesting Copies of EC's Documents .....	10
	Annex 4 Document History .....	11

	<b>Mochtar Riady Institute for Nanotechnology Ethics Committee (EC)/</b>	<b>SOP/004/2020/01.4</b> <b>Effective date:</b> <b>02 January 2020</b> <b>Page 2 of 11</b>
	<b><u>Title:</u></b> <b>004. Confidentiality/Conflict of Interest Agreement</b>	

## **1. Purpose**

The purpose of this section is to provide a form of Confidentiality / Conflict of Interest Agreement and identify who should read, understand, accept, keep in mind, sign and date the form. The procedures provide details when and where to sign as well as how the signed document should be kept.

## **2. Scope**

This SOP covers the Agreements on both Confidentiality and Conflict of Interest concerning information and procedures followed by the MRIN EC

## **3. Responsibility**

It is the responsibility of all newly-appointed MRIN EC members-consultant/ guest attendees to read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form before beginning their ethical review tasks with the EC to protect the rights of study participants.

## **4. Flow chart**

<b><u>No.</u></b>	<b><u>Activity</u></b>	<b><u>Responsibility</u></b>
1	Read the text carefully and thoroughly ↓	EC Members / Guest attendees / Observers / Independent-Ad Hoc Consultant
2	Ask questions, if any ↓	EC Members / Guest attendees / Observers/ Independent-Ad Hoc Consultant
3	Sign to indicate consent ↓	EC Members / Guest attendees / Observers/ Independent-Ad Hoc Consultant
4	Keep the Agreement in mind.	EC Members / Guest attendees / Observers/ Independent-Ad Hoc Consultant

	<b>Mochtar Riady Institute for Nanotechnology Ethics Committee (EC)/</b>	<b>SOP/004/2020/01.4</b> <b>Effective date:</b> <b>02 January 2020</b> <b>Page 3 of 11</b>
	<b><u>Title:</u></b> <b>004. Confidentiality/Conflict of Interest Agreement</b>	

## **5. Detailed instructions**

### **5.1 Read the text carefully and thoroughly.**

- Newly appointed members and Independent Consultant/Ad Hoc Consultant obtain two copies of the Agreement Form ( AF/01-004/2020/01.4, AF/02-004/2020/01.4) Guest attendees should sign Confidentiality Agreement Form for Guest Attendees / Observer (Form AF/03-004/2020/01.4 )
- Read through the text of the form very carefully.
- The members fill in their names and their office on the blanks.

### **5.2 Ask questions, if any.**

- Direct questions to the Secretary, if any part or sentences is not clear.
- Let the officer explain or clarify the contents of the document.

### **5.3 Sign with consent.**

- Sign and date both copies at the document in front of a member of the Secretariat.
- Give the forms back to Secretariat to sign and date.
- The members keep a copy as their records.

### **5.4 Keep the Agreement in mind.**

- The Secretariat keeps a copy of the signed Agreement as the Institute's records.
- Keep the copies in a Confidentiality/Conflict of Interest Agreement file.
- Store the file in a secure cabinet with limited key holders.

## **6. Glossary**


Confidentiality                      The non-occurrence of unauthorized disclosure of information:

Confidentiality Agreement                      Sometimes called Secrecy or Nondisclosure agreements

An agreement designed to protect trade secrets, information and expertise from being misused by those who have learned about them.

The type of information that can be included under the umbrella of confidential information is virtually unlimited.

Most confidentiality agreements exclude certain types of information from the definition of confidential information.

	<b>Mochtar Riady Institute for Nanotechnology Ethics Committee (EC)/</b>	<b>SOP/004/2020/01.4</b> <b>Effective date:</b> <b>02 January 2020</b> <b>Page 4 of 11</b>
	<b><u>Title:</u></b> <b>004. Confidentiality/Conflict of Interest Agreement</b>	

It is very important that the recipient include these exceptions in the confidentiality agreement. This will be decided at the appropriate EC meeting. An important point that must be covered in any confidentiality agreement is the standard by which the parties will handle the confidential information.

The agreement must establish a time period during which disclosures will be made and the period during which confidentiality of the information is to be maintained.

#### Conflict of Interest

A situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties.

There are three key elements in this definition: financial interest; official duties; professional interest.

A conflict of interest occurs when:

- An individual's private interest differs from his or her professional obligations to the institute.
- Professional actions or decisions occur that an independent observer might reasonably question.
- A conflict depends upon situation and not on the character or actions of the individual.
- Potential conflicts of interest must be disclosed and managed as per policy.

#### Guest Attendees

Persons who have accessibility to documents, information, activities related to MRIN EC

### **7. Annex**

Annex 1	AF/01-004/2020/01.4	Confidentiality / Conflict of Interest Agreement Form for MRIN EC Members
Annex 2	AF/02-004/2020/01.4	Confidentiality / Conflict of Interest Agreement Form for Independent / Ad Hoc Consultants
Annex 3	AF/03-004/2020/01.4	Confidentiality Agreement for Guest / Observer Attendees to MRIN EC Meetings
Annex 4	AF/04-004/2020/01.4	Confidentiality Agreement for Non-members Requesting Copy(ies) of MRIN EC Documents
Annex 5	AF/05-004/2020/01.4	Document History

	<b>Mochtar Riady Institute for Nanotechnology Ethics Committee (EC)/</b>	<b>SOP/004/2020/01.4</b> <b>Effective date:</b> <b>02 January 2020</b>
	<b><u>Title:</u></b> <b>004. Confidentiality/Conflict of Interest Agreement</b>	<b>Page 5 of 11</b>

## **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,
- 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.
- CIOMS 2016*

	<b>Mochtar Riady Institute for Nanotechnology Ethics Committee (EC)/</b>	<b>SOP/004/2020/01.4</b> <b>Effective date:</b> <b>02 January 2020</b> <b>Page 6 of 11</b>
	<b><u>Title:</u></b> <b>004. Confidentiality/Conflict of Interest Agreement</b>	

**Annex 1**

Form AF/01-004/2020/01.4

**Confidentiality / Conflict of Interest Agreement Form for MRIN EC  
Members / Independent Consultan/Ad Hoc Consultant**

In recognition of the fact, that I.....*member's/ Independent Consultant / Ad Hoc Consultant name, and his/her affiliation.....*herein referred to as the "Undersigned", *has been appointed as a member of the Mochtar Riady Institute for Nanotechnology Ethics Committee/ (MRIN EC) has been asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines;*

Whereas, the appointment of the undersigned as a member/*Independent Consultant / Ad Hoc Consultant* of the MRIN EC is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest;

Whereas, the fundamental duty of an MRIN EC member/*Independent Consultant / Ad Hoc Consultant* is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the MRIN EC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;

The undersigned, as a member / *Independent Consultant / Ad Hoc Consultant* of the MRIN EC, is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member / *Independent Consultant / Ad Hoc Consultant* of the MRIN EC. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the MRIN EC.

	<b>Mochtar Riady Institute for Nanotechnology Ethics Committee (EC)/</b>	<b>SOP/004/2020/01.4</b> <b>Effective date:</b> <b>02 January 2020</b>
	<u><b>Title:</b></u> <b>004. Confidentiality/Conflict of Interest Agreement</b>	<b>Page 7 of 11</b>

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.

### **Conflict of Interest**

It is recognized that the potential for conflict of interest will always exist but has faith in the MRIN EC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

It is the policy of the MRIN EC that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the EC.

The Undersigned will immediately disclose to the Chairperson of the MRIN EC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that an MRIN EC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the EC member(s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict.

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the EC review or approval except to provide information requested by the Committee.

Examples of conflict of interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment.

	<b>Mochtar Riady Institute for Nanotechnology Ethics Committee (EC)/</b>	<b>SOP/004/2020/01.4</b> <b>Effective date:</b> <b>02 January 2020</b> <b>Page 8 of 11</b>
	<b>Title:</b> <b>004. Confidentiality/Conflict of Interest Agreement</b>	

**Annex 1**

Form AF/01-004/2020/01.4

**Agreement on Confidentiality and Conflict of Interest**

*Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the MRIN EC. A copy will be given to you for your records.*

In the course of my activities as a member / *Independent Consultant* / *Ad Hoc Consultant* of the MRIN EC, I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the Access to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me toward a quorum for voting.

I, ....., have read and accept the aforementioned terms and conditions as explained in this Agreement.

\_\_\_\_\_

Undersigned Signature \_\_\_\_\_  
Date

\_\_\_\_\_

Chairperson of MRIN EC \_\_\_\_\_  
Date



	<b>Mochtar Riady Institute for Nanotechnology Ethics Committee (EC)/</b>	<b>SOP/004/2020/01.4</b> <b>Effective date:</b> <b>02 January 2020</b> <b>Page 9 of 11</b>
	<b><u>Title:</u></b> <b>004. Confidentiality/Conflict of Interest Agreement</b>	

**Annex 2**

Form AF/02-004/2020/01.4

Page 1

**Confidentiality Agreement Form  
for Guest Attendees to MRIN EC Meetings**

I,....., understand that I am allowed to attend the MRIN EC meeting as a guest or an observer. In the course of the meeting of the EC, some confidential information may be disclosed or discussed. Upon signing this form, I agree to take reasonable measures to keep the information as Confidential.

Indicate the details (date and number) of the EC Meeting attended:

.....  
.....  
.....

\_\_\_\_\_  
Signature of the Guest or Observer

\_\_\_\_\_  
Date

\_\_\_\_\_  
Chairperson of MRIN EC

\_\_\_\_\_  
Date

	<b>Mochtar Riady Institute for Nanotechnology Ethics Committee (EC)/</b>	<b>SOP/004/2020/01.4</b> <b>Effective date:</b> <b>02 January 2020</b> <b>Page 10 of 11</b>
	<b>Title:</b> <b>004. Confidentiality/Conflict of Interest Agreement</b>	

**Annex 3**

Form AF/03-004/2020/01.4

**Confidentiality Agreement Form  
for Non-members Requesting Copies of MRIN EC's Documents**

I,..... as a non-member of MRIN EC, understand that the copy (ies) given to me by the EC is (are) confidential. I shall use the information only for the indicated purpose as described to the EC and shall not duplicate, give or distribute these documents to any person(s) without permission from the MRIN EC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

I have received copies of the following MRIN EC documents:

.....  
.....  
.....

\_\_\_\_\_  
Signature of the recipient

\_\_\_\_\_  
Date

\_\_\_\_\_  
Chairperson of MRIN EC

\_\_\_\_\_  
Date

	<b>Mochtar Riady Institute for Nanotechnology Ethics Committee (EC)/</b>	<b>SOP/004/2020/01.4</b> <b>Effective date:</b> <b>02 January 2020</b> <b>Page 11 of 11</b>
	<b><u>Title:</u></b> <b>004. Confidentiality/Conflict of Interest Agreement</b>	

**Annex 4**  
Form AF/04-004/2020/01.4

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	<ol style="list-style-type: none"> <li>1. Synchronize the topic number and SOP number</li> <li>2. Format Document History : Author, Version, Date and Description of the main change</li> </ol>
Budhianto Suhadi, Debbie S. Retnoningrum	01.2	1 April 2017	<ol style="list-style-type: none"> <li>1. Delete Komisi Etik Penelitian Kesehatan (KEPK) on the header</li> <li>2. Item 3 (Responsibility), Add the word of “ Guest Attendees”</li> <li>3. Item 5.1 : to add the word of “ Guest Attendees” is required to sign Confidentiality Agreement Form for Guest Attendees</li> <li>4. Item 6 : Glossary, to add the glossary of “ Guest Attendees”</li> </ol>
Mona	01.3	2 January 2019	<ol style="list-style-type: none"> <li>1. Annex 1 : Delete the word of “animal”</li> </ol>
IS,LSH,MW, GE	01.4	2 January 2020	<ol style="list-style-type: none"> <li>1. Flow Chart, Responsibility : add Independent Consultant</li> <li>2. 5.1, box 1 : add the word of “ Independent Consultant”</li> <li>3. 5.1 : after statement of “ newly appointed members” Delete the word of “ guest attendees, observer”</li> <li>4. References : <ul style="list-style-type: none"> <li>• Add ICH GCP November 2016</li> <li>• Delete link WHO</li> <li>• Delete FERCAP SOP</li> </ul> </li> </ol>