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## **1. Purpose**

The purpose of this section is to inform the MRIN EC personnel and members why training is necessary and how the members should seek to occasionally attend training or workshop programs to up-date themselves on the progress of technology, information and ethics.

MRIN recognizes the importance of training and continuing professional development, therefore the institution will allocate an annual budget for specific training and study visits for MRIN EC personnel and members. New MRIN EC members are required to undergo a training program prior to joining the Committee.

## **2. Scope**

The SOP applies to all personnel of the EC.

## **3. Responsibility**

It is the responsibility of the EC members to have themselves educated and trained periodically.

## **4. Flow chart**

<b><u>No.</u></b>	<b><u>Activity</u></b>	<b><u>Responsibility</u></b>
1	Topics for training ↓	EC Members / Staff
2	How to get trained ↓	EC Members / Staff
3	Keeping the training record.	EC Members /staff

## **5. Detailed instructions**

### **5.1 Topics for training**

MRIN EC members should maintain competence by ensuring currency of their knowledge of:

- Good Clinical Practice (GCP)
- Declaration of Helsinki

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- Ethical Issues
- Relevant laws
- Developments in relevant science, technical and environmental, health and safety aspects
- Relevant requirements of health, safety and environmental laws and regulations and related documents
- Audit procedures.

An interchange of ideas, information and experiences with overseas institutions and organizations related to research ethics is also being carried out. International cooperation is also necessary to discuss ways of tackling harmful information distribution and joint efforts to tackle such distribution patterns. Efforts are being made to collect information on overseas trends and to attend international specialist meetings organized for the exchange of experience and information.

## **5.2 How to get trained**

- Get information about training courses, workshops, conferences, etc. which are periodically announced on websites, bulletin boards and various media channels.
- Prepare a list of Training courses, workshop, conference, etc to be attended by members (Use Annex 1)
- Select the ones you need.
- The Training submission will be approved by Chairperson of MRIN EC and The President of MRIN
- Register to attend.
- Sharing the result of Training/conference/workshop to MRIN EC

## **5.3 Keeping the training records**

- Fill in the form AF/02-005/2020/01.3 and record the training/workshop/conference activities in chronological order.
- Make a copy of the form.
- Keep the original form as your record.
- Give the copy to the administrative staff to keep in the EC file.

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## **6. Glossary**


Conference	A meeting of individuals or representatives of various organizations for the purpose of discussing and/or acting on topics of common interest.
Meeting	Deliberations between at least two (2) persons where such deliberations determine or result in the joint conduct or disposition of business.
Workshop	A group of people engaged in study or work on a creative project or subject

## **7. Annex**

Annex 1	AF/01-005/2020/01.3	Form Planning of training
Annex 2	AF/02-005/2020/01.3	Training Record Form
Annex 3	AF/03-005/2020/01.3	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,
- 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.

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**TRAINING PROPOSED FORM**

**Annex 1**

Form AF/01-005/2020/01.3


Name	Topic of Training	Schedule			Remarks
		Month	Month	Month	

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**Annex 2**  
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**Training Record Form**

First name:	Last name:
Staff / Membership since:	Status:
Education Background:	
Work Experience:	

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**Training Experience:**

#	Courses / Workshops / Conferences / Meetings Attended	Organized by:	Place	Duration	Source of Funding
1					
2					
3					
4					
5					
6					
7					
8					
9					

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**Annex 3**  
Form AF/03-005/2020/01.3

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	<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>
Ivet Suriapranata, Sintak Gunawan	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 5.2. box 6 : replace sentence to be training evaluation</li> </ol>
IS,LSH,MW, GE	01.3	02 January 2020	<ol style="list-style-type: none"> <li>1. 5.2, box 2 : Replace the statement “ Need training analyzes and master plan for training” with “ Prepare a list training courses, workshop, conference, etc to be attended by members“</li> <li>2. 5.2, Box 4: add the word of “ EC”</li> <li>3. 5.2,Box 6 : Replace the word of “ Evaluation” with “ Disseminations</li> <li>4. 5.3 : box 2 move to box 1</li> <li>5. Annex 1 ; add Training Proposed form. Annex 1 - 2 becomes Annex 2 - 3</li> <li>6. 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>