
	Far Eastern University NICANOR REYES MEDICAL FOUNDATION Institutional Ethics Review Committee	DOCUMENT CODE: SOP 05/04-02-2022
		EFFECTIVE DATE: August 1, 2022
	DOCUMENT TITLE:	REV. NO.: 4.2
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Standard Operating Procedures

- 1. Policy Statement**
- 2. Objectives**
- 3. Scope**
- 4. Responsibilities**
- 5. Preparing Standard Operating Procedures**


Supersedes	04.1
Version:	04.2
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Version Date:	08/01/2022
Approved by:	Atty. Antonio H. Abad President Far Eastern University – NICANOR REYES MEDICAL FOUNDATION
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FAR EASTERN UNIVERSITY – NICANOR REYES MEDICAL FOUNDATION
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Document History

Author	Version	Date	Description of main change
Milagros F. Neri, MD, MA, MPH, MS Abraham Daniel C. Cruz, MD, MSc (cand.) Trina C. Tan, RN, MAN Macario F. Reandelar, Jr., MD, MSPH Nimfa R. Baria, MD Joselito C. Matheus, MD Mr. Jesse Emmanuel Bacon II Fr. Leoncito Angelo Falcasantos, Jr., DS (Adapted from UPMREB SOP)	01	05/02/2014	NONE
Milagros F. Neri, MD, MA, MPH, MS Abraham Daniel C. Cruz, MD, MSc (cand.) - editor Trina C. Tan, RN, MAN Macario F. Reandelar, Jr., MD, MSPH Nimfa R. Baria, MD Joselito C. Matheus, MD Mr. Jesse Emmanuel Bacon II Fr. Leoncito Angelo Falcasantos, Jr., DS	02	10/31/2014	References updated to include international guidelines; main subsections highlighted; "Preparing SOPs Workflow" started with "Constituting the SOP Team", described as the composition of the SOP Team; "workflow" in the title of each main subsection deleted and made as the first subtopic under each main subsection
Milagros F. Neri, MD, MA, MPH, MS Abraham Daniel C. Cruz, MD, MS - editor Trina C. Tan, RN, MAN Macario F. Reandelar, Jr., MD, MSPH Nimfa R. Baria, MD Joselito C. Matheus, MD Mr. Jesse Emmanuel Bacon II Fr. Leoncito Angelo Falcasantos, Jr. Raquel Cariño-Mendoza, PhD	03	10/01/2017	No change
Milagros F. Neri, MD, MA, MPH, MS Abraham Daniel C. Cruz, MD, MS – editor Trina C. Tan, RN, MAN Nimfa R. Baria, MD Joselito C. Matheus, MD Priscila Doctolero, EdD Lorelie Ann C. Rivera, MD Jures Mae Frias	04	03/15/2022	<ul style="list-style-type: none"> Included Policy Statement at the Overview/Introduction or at the beginning of every SOP Updated references Glossary revised based on PHREB SOP Workbook (2020)

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			<ul style="list-style-type: none"> Reformatting of Workflow and Detailed Instructions
Milagros F. Neri, MD, MA, MPH, MS Abraham Daniel C. Cruz, MD, MS – editor Trina C. Tan, RN, MAN, EdD Nimfa R. Baria, MD Joselito C. Matheus, MD Priscila Doctolero, EdD Lorelie Ann C. Rivera, MD Jures Mae Frias	04.1	06/01/2022	<ul style="list-style-type: none"> In SOP 5.2 Step 2 – in the SOP Code, ZZZZ was changed from “year it was first drafted” to “year it was approved” In SOP 5.2 Step 2, deleted the section stating that the URL will be included in the footer of the SOP Modified SOP Template (SOP 5.2 Step 2 and Form 5A) based on institutional requirements for ISO Accreditation - formatting and addition of revision number, change “SOP” to “Document” In all SOPs, the latest reference materials were cited and the old versions were removed.
Milagros F. Neri, MD, MA, MPH, MS Abraham Daniel C. Cruz, MD, MS – editor Trina C. Tan, RN, MAN, EdD Nimfa R. Baria, MD Joselito C. Matheus, MD Priscila Doctolero, EdD Lorelie Ann C. Rivera, MD Jures Mae Frias	04.2	08/01/2022	<ul style="list-style-type: none"> NONE

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1. Policy Statement

The FEU-NRMF IERC shall designate a team to regularly review its set of SOPs to determine its continuing relevance and effectiveness to its operations.

2. Objectives

This Standard Operating Procedure (SOP) defines the process for writing, reviewing, distributing, amending, and storing FEU-NRMF IERC SOPs.

3. Scope

This SOP applies to any FEU-NRMF IERC SOPs and their amended versions as published and distributed by the FEU-NRMF IERC.

4. Responsibilities

The FEU-NRMF IERC Vice Chair is responsible for ascertaining the need for new SOPs and amendments to existing ones based on changes in international and national s and policies or requests from various stakeholders including FEU-NRMF IERC Members.

The FEU-NRMF IERC Chair is responsible for designating an SOP Team, chaired by the FEU-NRMF IERC Vice Chair, which drafts new SOPs and amends them as needed. The team is responsible for proposing design and format as well as the substantial contents of the SOP.


FEU-NRMF IERC Members are responsible for FEU-NRMF IERC consensus action on the proposed SOP, the outcome of which is submitted by the FEU-NRMF IERC Chair to the Research Development Office Committee Chair, who in recommends it to the Vice President for Academic Affairs and Medical Director, who endorse it to the FEU-NRMF President for approval.

The FEU-NRMF IERC Secretariat is responsible for storing and distribution.

5. Preparing Standard Operating Procedures

5.1. **Workflow**

ACTIVITY	RESPONSIBILITY
Step 1. Constituting the SOP Team	FEU-NRMF IERC Vice Chair and Members
Step 2. Designing the SOP format, coding, and layout	SOP Team
Step 3. Writing and review of new SOP	SOP Team

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Step 4. Presentation of new/revised SOP/ to the FEU-NRMF IERC	Vice Chair, Chair
Step 5. Decision of FEU-NRMF IERC action on new/revised SOP	Members
Step 6. Approval of new/revised SOP for implementation	Research Center for Development Chair, Vice President for Academic Affairs, Chief Medical Officer, FEU-NRMF President
Step 7. Distribution and storage of new/revised SOP	Secretariat
Step 8. Amendment of existing SOP	Members, Vice Chair, SOP Team


5.2. Detailed Instructions

Step 1 – Constituting the SOP Team: Upon determination of the need to prepare an SOP, the SOP Team is constituted. It is composed of the IERC Vice Chair and appointed Members.

Step 2 - Designing the format, coding (using an identifier), and layout: An SOP follows the format:

- **Number and version**, which follows the SOP on coding of SOPs
- **Title**, which is descriptive of contents
- **Policy Statement**, which states institutional or committee policies upon which the activity and procedures are based, and/or specific provisions from international and national guidelines pertinent to the activity
- **Objectives**, which defines the purpose and intended outcome
- **Scope**, which defines the extent of coverage of the SOP and its limitations
- **Responsibilities**, which delineates tasking and accountabilities for SOP implementation
- **Workflow** when necessary, which provides a graphic representation of the essential steps to implement the SOP
- **Detailed instructions**, which elaborates the steps outlined in workflow
- **FEU-NRMF IERC FORM 5(D): DOCUMENT HISTORY**, which tabulates the different versions (from draft to final versions) of the document by author, version, date, and description of main changes
- **Forms**, which are documents to be filled out or accomplished by different parties as required by the SOP, with a **list of forms**
- **References**, which lists the instruments used to draft the SOP, such as other SOPs or policies
- **Appendices** which provide elaborations or clarifications of specific sections including glossary and list of abbreviations

Each SOP is alphanumerically coded: **FEU-NRMF IERC SOP XX/YY-WW-ZZZZ**, where **XX** is a two-digit number corresponding to the SOP chapter, **YY** is a two-digit number identifying the version of the SOP, and **WW** is a two-digit number identifying the version of SOP with minor changes in the SOP, and **ZZZZ**

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refers to the year the SOP was approved. **YY** (version) starts from 01 and **W** starts with 0. Thus, the SOP on writing of SOPs is identified with the code **FEU-NRMF IERC SOP 05/03-00-2017**, signifying that this SOP can be seen in Chapter 5, it is the second version (05/02), and has no minor changes, (05/02-00) as of 2017 (when it was approved).

The layout of a typical SOP page [**FEU-NRMF IERC FORM 5(A) 2022: SOP TEMPLATE**] uses a **header** with the following elements:

- Institutional seal or logo
- Name of institution
- Document code
- Document title
- Effective date
- Page number
- Revision Number
- SOP content


The SOP is introduced by a cover page [**FEU-NRMF IERC FORM 5(B) 2022: SOP COVER PAGE**] laid out as a typical SOP or page with the following additional items included:

- Summary content after the title
- Institutional contact details (address, telephone numbers, facsimile number, email address)
- Date of the previous version; if not applicable, the date of previous issue is indicated by “N/A” (not applicable)
- Name of the authors/editors
- Approval information such as approving authorities and offices

Step 3 - Writing and review of new SOP: SOPs are issued by the FEU-NRMF IERC in order to facilitate transparent, clear, and systematic implementation of its functions. New SOPs may be issued in not less than three-year intervals; unless regulations on which these documents are based have significantly changed in the interim. Existing SOPs are reviewed every three (3) years; unless regulations on which these documents are based have significantly changed in the interim.

Step 4 - Presentation of new/revised SOP/ to the FEU-NRMF IERC. The draft version is submitted by the SOP Team to the FEU-NRMF IERC Vice Chair. The FEU-NRMF IERC Vice Chair organizes a FEU-NRMF IERC forum, which is expected to be attended by at least 3/4 of the FEU-NRMF IERC Members. The FEU-NRMF IERC Chair presents the new/revised SOP to the FEU-NRMF IERC during this forum and presides over deliberation.

Step 5 - Decision of FEU-NRMF IERC action on new/revised SOP: The FEU-NRMF IERC members will deliberate on the proposed draft and arrive at a consensus action. If a consensus cannot be achieved, the matter is put to a vote. Favorable action by voting requires a vote of **two-thirds plus one** of the

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members present in the meeting. Action can be deferred if recommendations for further amendments or revisions are lodged during the forum, in which case, the FEU-NRMF IERC Vice Chair will supervise the documentation of requested amendments or revisions and call for a subsequent meeting, no more than thirty (30) days from the date of the aforementioned forum.

Step 6 - Approval of new/revised SOP for implementation: Upon favorable action by FEU-NRMF IERC, the approved SOP is submitted by the FEU-NRMF IERC Chair to the Research Center for Development (RCD). The new/revised SOP is recommended by the RCD Chair, endorsed by the Vice President for Academic Affairs and Medical Director, and approved by FEU-NRMF President. The approval is indicated by the dated signature of the FEU-NRMF President on the cover page of the document. The effective date of the document is reckoned as the date when the FEU-NRMF President signs the document. However, in the interest of continuity of FEU-NRMF IERC work, SOP and documents may be regarded as functionally approved as of the date of favorable action by FEU-NRMF IERC (see step 5 above).


Step 7 - Distribution and storage of new/revised SOP: The printed copy of the approved SOPs will be distributed to FEU-NRMF IERC Members within **thirty (30)** days of approval by the FEU-NRMF President. An electronic copy of the SOP will be made available in the FEU-NRMF IERC website. One (1) complete originally signed set of current SOPs is maintained by the FEU-NRMF IERC Secretariat, which can be reproduced as needed.

Step 8 - Amendment of Existing SOP: Any request for amendment or revision must be written and submitted to the FEU-NRMF IERC Vice Chair for processing by the FEU-NRMF IERC in preparation for the next round of SOP review. A request for amendment or revision is accomplished by filling out **FEU-NRMF IERC FORM 5(C) 2022: REQUEST FOR AMENDMENT OF AN SOP**. The FEU-NRMF IERC Vice Chair is responsible for initial review of the request, procurement of relevant information, recommendation of further action as follows:

- Confirm need for amendment or revision, forward to SOP Team
- Request further information (state)
- Forward to content expert for opinion

When the need for a new Chapter has been identified and agreed on, the FEU-NRMF IERC Vice Chair will organize the writing process whereby a draft will be written by the SOP Team designated by the Chair. The draft is regarded as a consensus issuance by the SOP Team, and may be a result of consultation with other stakeholders prior to completion.

When an amended or revised SOP is in place, the old version will undergo archiving procedures by the Secretariat. The word “SUPERSEDED” is stamped on all pages of one complete set of the old version, after which it is stored separately from the current version.

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Superseded versions are indicated in the **FEU-NRMF IERC FORM 5(D) 2022: DOCUMENT HISTORY** of the new version by Secretariat Staff prior to storage.

References:

1. CIOMS Guidelines for Epidemiological Studies (2009)
2. CIOMS-WHO International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
3. Declaration of Helsinki, World Medical Association (2013)
4. ICH Harmonized Guideline – Integrated Addendum to ICH E6 (R1) Guideline for Good Clinical Practice E6 (R2) Current Step 4 version (2016)
5. National Ethical Guidelines for Health Research. Philippine National Health Research System (2017)
6. Philippine Health Research Ethics Board - A Workbook for Developing Standard Operating Procedures - “The SOP Workbook” (2020)
7. Standard Operating Procedures 5: Preparing Standard Operating Procedures and Guidelines. UP Manila Research Ethics Board (2012)
8. Standard Operating Procedures 5: Writing and Revising SOPs. Makati Medical Center Institutional Review Board (2013)
9. WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011