Standard Operating Procedures

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Supersedes	04.1
Version:	04.2
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Approved by:	 Atty. Antonio H. Abad President Far Eastern University – NICANOR REYES MEDICAL FOUNDATION
Approval Date:	

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 Falcosantos, Jr., DS (Adapted from UPMREB SOP)	01	05/02/2014	NONE
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Milagros F. Neri, MD, MA, MPH, MS Abraham Daniel C. Cruz, MD, MS - editor Trina C. Tan, RN, MAN	03	10/01/2017	Contents of onsite and offsite SAE database differentiated; Form 4(A) Format of the Minutes of the Meeting modified to include onsite SAE reports

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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	• Included Policy Statement at the Overview/Introduction or at the beginning of every SOP • Updated references • Included exempted protocols in the template of the Agenda and Minutes – see revised Form 2G and 4A • Included procedure for outgoing communications – kinds of documents, fields/columns of particulars in the logbook – see added procedure on logging outgoing communications in the section 5: Study Protocol Communication Records – Detailed Instructions Step 2; see Form 4(M) Outgoing Communications Log; see additional statements in SOP 2 and SOP 3 in all sections pertaining to Communication of Results • Included membership files in the confidential list – see Section 9: Confidentiality of Study Files and FEU-NRMF IERC Documents – Detailed Instructions – Step 1 • FORM 4(A) Format of the Minutes of the Meeting – removed "reasons" in the last row of Study Protocol Review boxes • Added section for Summary of Reviewed Protocols in the last part of the FEU-NRMF IERC

			FORM 4(A) Format of the Minutes of the Meeting • Changed Study File Code to IERC Code in FORM 4(G) Borrowers Log • Changed Date in to Date Returned in FORM 4(I) Log of Request for Copies of Documents • Glossary revised based on PHREB SOP Workbook (2020) • Form 4(A) - Included in Format of the Minutes of Meeting the following: Approval of the Agenda after Quorum and before COI; Report of exempted protocols – see revised Form 4(A) • Glossary revised based on PHREB SOP Workbook (2020) • 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	• 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	• NONE

1. Objectives

This SOP describes how the FEU-NRMF IERC manages documentation and communication of review, such as how the minutes of the meetings are to be prepared, used, distributed, and filed; how to ensure proper completion, distribution, and filing of written study protocol- or review-process-related communication, how administrative records and FEU-NRMF IERC administrative documents (exclusive of study protocol files) are processed, stored, or disposed of; how active and inactive or archived study protocol files are maintained, including their amendments and/or modifications; and how to handle original documents and copies of documents in order to protect confidentiality of documents.

2. Scope

This SOP applies to minutes of the meeting, all communication records related to study protocols with FEU-NRMF IERC approval or undergoing FEU-NRMF IERC review; to administrative documents, active study protocol files, and inactive study protocol files that are retained or archived for at least three (3) years after completion of the research so that the records are accessible for auditors and inspectors. This SOP applies to all kinds of handling, distribution, and storage of submitted study protocols, FEU-NRMF IERC documents, and correspondences.

3. Responsibilities

The Secretariat, under the supervision of the Secretary, has the primary responsibility for study protocol and administrative documentation and archiving. The Chair is responsible for final approval of documents.

4. Minutes of the Meeting
4.1. Policy Statement

The meeting minutes shall be based on the approved agenda and shall be the basis of the decision letter on protocols.

4.2. Workflow

ACTIVITY	RESPONSIBILITY
Step 1. Preparation of the template of the Minutes of the Meeting	Secretariat
Step 2 Prepare draft of Minutes	Secretariat, Secretary
Step 3. Approval of the Minutes	Secretary, Chair
Step 4. Storage of the approved Minutes	Secretariat

4.3. DETAILED INSTRUCTIONS

Step 1 - Preparation of the template of the Minutes of the Meeting: The Secretary and Secretariat uses the **FORMAT OF THE MINUTES OF THE MEETING [FEU-NRMF IERC FORM 4(A) 2022]** to organize a template of the minutes ahead of the meeting date. All the relevant identifying information should be filled out such as standard text in the regular sections and relevant study protocol information. The minutes of the meeting is generated as the meeting progresses. The Secretariat in charge of documentation notes all board opinions and actions in all specific sections of the agenda, as the agenda is developed and discussed, with respective reasons in the case of study protocol-related actions. The development of the minutes during the meeting is displayed in a multimedia screen to allow members to make immediate corrections.

Step 2 - Preparation of the draft of the Minutes: Opinions and actions included in the minutes are understood to be collective and need not be attributed to specific members, unless in the case of administrative or operational queries from members who require follow-up information or action. The Secretariat submits a complete draft of the minutes to the Secretary within **seven (7) days** after the meeting for form and content corrections and finalization. The finalized draft is sent to the Chair immediately for approval. The following information must be indicated in the minutes:
- Date and venue of meeting
- Members' attendance (members present and absent)
- Guests and observers' attendance
- Time when the meeting was called to order
- Presiding officer
- Items discussed per Meeting Agenda
- Name and signature of person who prepared the Minutes
- Date of completion
- Name and signature of the Secretary to indicate that the contents have been verified and corrected
- Name and signature of the Chair to indicate approval
- Date of approval by the Chair

Step 3 - Approval of the Minutes: The Chair approves the Minutes by affixing his/her signature and the date the minutes was signed. Upon approval of the minutes, the contents of the Conclusions and Recommendations section (per study protocol discussed) are transferred into a/an:
- **APPROVAL LETTER TO THE STUDY PROTOCOL [FEU-NRMF IERC FORM 2(L)],** or
- **Any of the following, as the case may be**
  - **ACTION LETTER TO STUDY PROTOCOL SUBMISSIONS, RESUBMISSIONS AND AMENDMENTS [FEU-NRMF IERC FORM 4(B) 2022]**
  - **LETTER FOR CLARIFICATORY INTERVIEW [FEU-NRMF IERC FORM 4(C) 2022]**

- o **APPROVAL LETTER TO THE STUDY PROTOCOL AMENDMENT [FEU-NRMF IERC FORM 4(D) 2022]**
- o **NOTIFICATION LETTER (INFORMATION OR FURTHER ACTION) TO PROGRESS REPORT, CONTINUING REVIEW APPLICATION, FINAL REPORT, DEVIATION, SAE, SITE VISIT [FEU-NRMF IERC FORM 4(E) 2022]**
- o **ARCHIVING NOTIFICATION [FEU-NRMF IERC FORM 4(F) 2022]**
- o **NOTIFICATION LETTER (UPHOLD APPROVAL) TO PROGRESS REPORT, CONTINUING REVIEW APPLICATION, DEVIATION, AE, SITE VISIT [FEU-NRMF IERC FORM 4(K) 2022]**
- **CERTIFICATION OF BOARD ACTION [FEU-NRMF IERC FORM 4(J) 2022]** is issued to study protocols that are classified as Sponsor-Initiated clinical trials.

Step 4 -Storage of the Approved Minutes: The Secretariat files the original copy of the Minutes in the Minutes Folder. The Secretariat makes copies of the minutes approved by the Chair and files a copy in the members' meeting folders. The Minutes approved by the Chair is distributed to the members within **fifteen (15)** days after the meeting. The approved minutes will be presented in the next full board meeting for approval.

5. Study Protocol Communication Records

5.1. Policy Statement

All communications shall be recorded accurately and appropriately in a physical log book and electronic database. Protocol-related communications are separated from administrative communications. Incoming communications shall be acted upon promptly.

5.2. Workflow

ACTIVITY	RESPONSIBILITY
Step 1. Sorting of all communications received and issued by the FEU-NRMF IERC	Secretariat
Step 2. Recording of the details of the incoming and outgoing communication	Secretariat
Step 3. Storage of communication records	Secretariat

5.3. Detailed Instructions

Step 1 - Sorting of all communications received and issued by the FEU-NRMF IERC: Communications can come in the form of letters, official memoranda, or emails. The Secretariat sorts all communications received and prepares them for recording.

Step 2 - Recording of the details of the incoming and outgoing communication: Incoming study protocol-related communications received by the FEU-NRMF IERC are recorded in the **SUBMISSIONS LOG** [**FEU-NRMF IERC FORM 4(L) 2022**]. This form is updated as each submission is received. The record should contain, but is not limited to, the following:

- Date Received
- Study Code
- Title
- PI
- Submitting Person
- Receiving Person
- Date of Document
- Type of Submission
- Content of Submission
- Mode of Delivery
- Action
- Further Action Required

Outgoing communications are recorded in the **OUTGOING COMMUNICATIONS LOG [FEU-NRMF IERC FORM 4(M) 2022**. This form is updated as each communication is sent out. The record should contain, but is not limited to, the following;

- Date
- Nature of document (Decision Letter, Approval Letter, Invitation, Notice of Meeting, etc.)
- FEU-NRMF IERC Code (if applicable)
- Signatory
- Addressee
- Received by (Name and Signature of Recipient)
- Delivered by (Name and Signature)

Step 3 - Storage of communication records: Upon completion of the **SUBMISSIONS LOG [FEU-NRMF IERCFORM 4(L) 2022]** and **the OUTGOING COMMUNICATIONS LOG [FEU-NRMF IERC FORM 4(M) 2022,** the Secretariat files a copy of the communication in the study file. The Secretariat then writes in the protocol folder contents index as each communication is filed.

6. Administrative Records

6.1. Policy Statement

The FEU-NRMF IERC shall maintain administrative documents used its daily operations in physical as well as electronic files.

6.2. Workflow

ACTIVITY	RESPONSIBILITY
Step 1. Compilation of administrative records	Secretariat, Members, Chair
Step 2. Sorting and storage documents	Secretariat
Step 3. Dispose unnecessary copies	Secretariat

6.3. Detailed Instructions

Step 1 - Compilation of administrative records: The Secretariat maintains administrative documents not related to specific study protocols, but used in daily operations of the FEU-NRMF IERC such as:

- Reference materials and guidelines
- Standard Operating Procedures
- Communications issued to and received from persons other than principal investigators, on matters that are not related to any study protocols
- FEU-NRMF IERC members and files (CVs, Appointment letters, Signed **CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE [FEU-NRMF IERC FORM 1(C) 2022]**, **TRAINING RECORDS [FEU-NRMF IERC FORM 1(D) 2022]**
- Certificates of training
- Log of copies of documents requested by non-members **[FEU-NRMF IERCFORM 4(G) 2022: BORROWERS LOG]**
- Forms

These documents are maintained separately from study protocol-related documents.

Step 2 - Sorting and storage of documents: The Secretariat labels and files administrative documents sequentially. Guidelines are filed numerically by subject and by subject alphabetically. SOP Manuals are filed chronologically. Important communications are filed in the communications folder and recorded chronologically in the **SUBMISSIONS LOG** [**FEU-NRMF IERC FORM 4(L) 2022**] and **OUTGOING COMMUNICATIONS LOG [FEU-NRMF IERC FORM 4(M) 2022.** Members' and other personnel's files are filed alphabetically by last name. Only the most recently updated **CURRICULA VITAE [FEU-NRMF IERC FORM 1(B) 2022]** are filed in the individual member's folder. Signed **CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURES** [**FEU-NRMF IERC FORM 1(C) 2022]** and training certificates are filed chronologically under every member's or other personnel's file. **TRAINING RECORDS [FEU-NRMF IERC FORM 1(D) 2022]** must be updated as each training certificate is submitted by the member or personnel for filing. Active FEU-NRMF IERC blank forms are kept in individually labelled folders or envelopes. The folders or envelopes are filed numerically with a list or index of forms written as:

- Form number
- Subject of form

Step 3 - Disposal of documents: Spare protocol files are removed from the files. Closed protocol files are retained for three (3) years and are then removed from the files. Guidelines and references that have been superseded or outdated for three (3) years are also removed from the files. Removed document files are shredded and permanently deleted from electronic and physical files.

7. Active Files

7.1. Policy Statement

Active files shall be kept in a secured cabinet, arranged in an orderly manner that shall allow easy identification and retrieval. Access to the active files shall be governed by SOP on Access to Confidential Files

7.2. Workflow

ACTIVITY	RESPONSIBILITY
Step 1. Creation of a coding system for active files	FEU-NRMF IERC
Step 2. Organization of contents of the active study files	Secretariat
Step 3. Maintenance of active study files	Secretariat
Step 4. Maintenance of electronic database back-up file	Chair

7.3. Detailed Instructions

Step 1 - Creation of coding system for active study files: Active files are study protocols that have been received by the FEU-NRMF IERC Secretariat and are either undergoing review (full board or expedited) or approved by the FEU-NRMF IERC. Active study files are coded as **FEU-NRMF IERC-YYYY-NNNN**, where **YYYY** represents the year and **NNNN** represents sequential study protocol number (as received by the FEU-NRMF IERC Secretariat). Study protocol files that are also processed by SJREB are coded similarly, with the **SJREB code** placed after FEU-NRMF IERC code, written as **FEU-NRMF IERC-YYYY-NNNN-SJREB-YYYY-NNNN.**

CODES FOR ELECTRONIC DATABASE are indicated below.
- FEU-NRMF IERC Review Codes:
  - **CT1 -** Clinical trials from pharmaceutical companies
  - **CT2 –** Clinical trials conducted by fellows, residents, nursing , and other research at the FEU-NRMF Medical Center
  - **NCT -** Basic research, applied research, or translational research

- FEU-NRMF Institute of Medicine/Medical Center Unit or Department Codes:
    - MED – School of Medicine
    - MLS – School of Medical Laboratory Science
    - NUR – School of Nursing
    - PT – School of Physical Therapy
    - RT – School of Radiologic Technology
    - RTH – School of Respiratory Therapy
    - ND – School of Nutrition and Dietetics
    - PHA – School of Pharmacy
    - GEN – General Education
    - ANA – Anatomy
    - BIO – Biochemistry and Molecular Biology
    - PHA – Pharmacology
    - PHY – Physiology
    - ANES – Anesthesiology
    - CFM – Community and Family Medicine
    - LAB – Clinical Laboratories
    - PAT – Pathology
    - IMED – Internal Medicine
    - OBG – Obstetrics and Gynecology
    - OPH – Ophthalmology
    - ORL – Otorhinolaryngology
    - PED – Pediatrics
    - RAD – Radiology
    - SUR – Surgery
    - PAR – Paramedical

The study file code should appear prominently on the study protocol folder.

Step 2 - Organization of contents of active study files: Study files are encoded into the Study Protocol Database, which contains the following information:
- FEU-NRMF IERC Code
- Date Received
- Study Title
- Principal Investigator
- Paper/Investigator Category
- Study Category
- Type of Study
- Purpose of Study
- Study Site

- Endorsing College/Institution
- Use of Special Populations or Vulnerable Groups
- Total Budget
- Funding Agency
- Technical Review
- Previous Ethics Approval or Clearance Issued by Other Sites
- Type of Review
- Dates of Meeting
- Dates of Onsite SAE/SUSAR Reports
- Dates of Offsite SAE/SUSAR Reports
- Primary Reviewers
- Date of Approval
- Due Date of Progress Report
- Date of Inactivation
- Status

The elements included in the Study Protocol Database are linked to the following sub-databases, with respective contents:

- Principal Investigators Database
  - Name
  - Sex
  - Birthday
  - Institution
  - College/Unit
  - Department
  - Telephone
  - Mobile
  - Fax No.
  - Email Address
  - Highest Educational Attainment
  - School
  - Specialization
  - Sponsors
  - Declaration of Conflict of Interest of PI

- Reviewers Database
  - Reviewer No.
  - Name
  - Home Address
  - Mailing Address

- o Contact Number
- o Institution
- o Birthday
- o Date of Appointment
- o Classification (Regular or Alternate; Scientist or Non-Scientist; Affiliated or Non-Affiliated)
- o Area of Expertise
- o Ethics or GCP Trainings Attended

- Onsite Serious Adverse Events/SUSAR Database
    - o Report No.
    - o Event No.
    - o FEU-NRMF IERC Code
    - o Date of Submission of AE
    - o Date of AE
    - o Type of Report
    - o Reporter's Name
    - o Patient Initials
    - o Country
    - o Date of Birth
    - o Age
    - o Sex
    - o Narrative of the AE
    - o Suspected drug
    - o Dose of drug
    - o Route of administration of drug
    - o Concomitant Drugs
    - o Dose of Concomitant Drugs
    - o Comorbidities
    - o Causality
    - o Nature of SAE
    - o Action
    - o Outcome

- Offsite Serious Adverse Events/SUSAR Database
    - o Date of Report
    - o Date Received
    - o SAE
    - o SAE count
    - o Nature of each SAE

- Institution and Study Site Database
  - Name
  - Classification
  - Address
  - Telephone Number
  - Fax
  - Email Address
  - Website
  - Administrator

The Secretariat puts study protocol files in file folders upon processing of the submission of the study protocol, ensuring that one folder contains documents for one study protocol and labelled with the title and code of the study protocol. Folders are then kept in secure cabinets labelled as "Active Files". Cabinets labelled as "Active Files" should only contain study file folders classified as "active."

A study file folder contains the following documents, as applicable:
- Index
- All versions of study protocol
- Related documents that came with the study protocol
- Principal investigator and co-investigators' CVs and other similar documents
- Reviewers' assessment forms
- Action in the form of excerpts from minutes
- Amendment reports
- Progress Reports
- Continuing review applications
- Final report
- Serious Adverse Event Reports or Safety Notifications
- Non-compliance (Deviation or Violation) reports
- Participant Queries
- Site Visit Reports
- Approval letters
- Action Letter/Notification of FEU-NRMF IERC Decision
- Miscellaneous communication

Step 3 - Maintenance of active study protocol files: The Secretariat files all the aforementioned documents in the study folder as they come. The Secretariat stamps the receiving date on all documents before putting them in the folders. All Active File folders are maintained in the "Active Files" cabinet until the **FINAL REPORT FORM [FEU-NRMF IERC FORM 3(C) 2022]** is approved by the FEU-NRMF IERC. The Secretariat maintains individual Active Files cabinets under the supervision of the Secretary.

Step 4 - Maintenance of electronic database back-up file: A back-up file of the electronic database is maintained by the Chair. It is stored in an external hard drive and kept in a fixed and secure place by the Chair.

8. Archived (Inactive/Completed/Terminated) Files

8.1. Policy Statement

Files of studies which have been terminated or completed or declared inactive shall be kept in a separate storage for 3 years. Studies of Researchers who have not resubmitted their proposals within seven (7) months after receiving the Notification Letter shall be considered inactive.

8.2. Workflow

ACTIVITY	RESPONSIBILITY
Step 1. Management of inactive/completed/terminated study files	Secretariat
Step 2. Sorting of administrative documents to be archived	Secretariat
Step 3. Retrieval of documents	Secretariat

8.3. Detailed Instructions

Step 1 - Management of Archived (inactive/completed/terminated) study files: Archived (Inactive/Completed/Terminated) study files are study protocols:
- with approved (by the FEU-NRMF IERC) final reports, or
- declared Inactive by the review if no communication is received from study team for a period of seven months.

Upon receipt of **FEU-NRMF IERC FORM 3(C) 2022: FINAL REPORT FORM**, the FEU-NRMF IERC reviews it in accordance with **SOP 3 - 8: FINAL REPORTS.** Upon approval of the **FEU-NRMF IERC FORM 3(C) 2022: FINAL REPORT FORM,** the Secretariat removes the contents of the entire file from the active study filing area and verifies that all documents are present in an organized manner. An archive number is assigned to the document by adding the year of archiving to the original code of the study file. Correspondingly, the data about the study and the year when archived should be entered on the Study Protocol Database.

Step 2 - Sorting of archived administrative documents: The Secretariat should perform inventories of miscellaneous administrative documents yearly. Administrative documents that are related to any fund released by FEU-NRMF are required to be archived in a manner that allows easy retrieval for audit purposes. These include documents that specify appointment of personnel, issuance of honorarium, approved annual budget, financial reports, as well as financial/funding policies. One set of such documents are stored in the appropriate storage container/cabinet for archived administrative files.

Unnecessary copies are disposed of accordingly (see **Section 6: Administrative Records - Detailed Instructions – Step 3** above).

Step 3 - Retrieval of documents: Only authorized FEU-NRMF IERC Secretariat can retrieve documents either from active study files or from the archives. Active or inactive study files can be borrowed, upon written request by the PI or the FEU-NRMF IERC personnel, and only for room use. The Secretariat places the borrower's information in a file folder using the **BORROWERS LOG [FEU-NRMF IERC FORM 4(G) 2022]** and contains the following information:
- Study file code
- Date when borrowed
- By (borrower)
- Signature of borrower
- Date when returned
- Signature of Secretariat upon return of document

9. Confidentiality of Study Files and FEU-NRMF IERC Documents

9.1. Policy Statement

Access to the FEU-NRMF IREC confidential files shall be regulated and limited to FEU-NRMF IREC members and staff. Other persons with legitimate interest in these files (e.g. institutional authorities, regulatory agencies, sponsors) shall be allowed to access specific files with proper justification. Researchers/Investigators shall be allowed access only to their own protocol files upon request.

9.2. Workflow

ACTIVITY	RESPONSIBILITY
Step 1. Classification of documents as confidential	FEU-NRMF IERC
Step 2. Access to FEU-NRMF IERC documents	Members, non-members
Step 3. Reproduction of confidential documents	Secretariat
Step 4. Maintenance of log of copies	Secretariat

9.3. Detailed Instructions

Step 1 - Classification of documents as confidential: Access to confidential documents is restricted by the FEU-NRMF IERC to members and secretariat, but limited access can be provided to non-members who have a legitimate purpose to access the documents. The FEU-NRMF IERC considers the following as confidential:
- Study protocols
- Study protocol-related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)

- Meeting Minutes
- Decisions, action letters/notification of FEU-NRMF IERC decision, approval letters
- Study protocol-related communications
- Membership files

Mechanisms for the maintenance of confidentiality are implemented. Physical files are kept in the IERC office with a lock and key. The files are kept in cabinets with lock and key as well. The Secretary and the Secretariat hold the keys to the locks. Electronic files are password-protected and are stored in a computer inside the IERC office.

Step 2 - Access to confidential FEU-NRMF IERC documents: All FEU-NRMF IERC members and Secretariat staff with a signed **CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE** [**FEU-NRMF IERC FORM 1(C) 2022**] can have access to FEU-NRMF IERC confidential documents upon request. Non-members can access specific documents upon formal request and completion/signing of **CONFIDENTIALITY AGREEMENT FOR NONMEMBERS [FEU-NRMF IERC FORM 4(H) 2022]**. The form requires the approval of the FEU-NRMF IERC Chair. Regulatory authorities have access to FEU-NRMF IERC files provided it is within the mandate of the said authority, and upon reasonable notice to make the files available. All requests for access are recorded by the Secretariat in the **LOG OF REQUEST FOR COPIES OF DOCUMENTS [FEU-NRMF IERC FORM 4(I) 2022]** before the documents are released.

Step 3 - Reproduction of confidential documents: The Secretariat makes only the exact number of copies requested. The recipient signs for the copies requested in the **LOG OF REQUEST FOR COPIES OF DOCUMENTS [FEU-NRMF IERC FORM 4(I) 2022]** upon receipt of the copies.

Step 4 - Maintenance of log of copies: The Secretariat ensures the diligent recording of all document copies issued in the **LOG OF REQUEST FOR COPIES OF DOCUMENTS [FEU-NRMF IERC FORM 4(I) 2022].** This log is filed in a separate folder labelled Log of Copies Issued.

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 4: Documentation and Archiving. Makati Medical Center Institutional Review Board (2013)

8. Standard Operating Procedures 4: Documentation and Archiving. UP Manila Research Ethics Board (2012)
9. WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011