



**Far Eastern University  
NICANOR REYES MEDICAL FOUNDATION  
Institutional Ethics Review Committee**

DOCUMENT TITLE:

**1. STRUCTURE AND COMPOSITION**

DOCUMENT CODE:  
SOP 01/04-02-2022

EFFECTIVE DATE:  
August 1, 2022

REV. NO.:  
4.2

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### Standard Operating Procedures

1. Objectives
2. Scope
3. Responsibilities
4. Constitution and Functions
5. Training of FEU-NRMF IERC Members and Personnel
6. Selection of Independent Consultants
7. Compensating Members and Consultants


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
Approval Date:	

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	<b>Far Eastern University</b> <b>NICANOR REYES MEDICAL FOUNDATION</b> <b>Institutional Ethics Review Committee</b>	DOCUMENT CODE: SOP 01/04-02-2022
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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 Falcosantos, 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 Falcosantos, Jr., DS	02	10/31/ 2014	CV template for IERC Members improved to reflect educational and work experience and birthdate; appointing authority for Independent Consultants clarified; mandate of the IERC as stated in the Introduction, Scope, Organizational Structure with regards to “Non-FEU-NRMF Primary Investigator”; references updated to include international guidelines; main subsections highlighted; appointment mechanism for Secretary clarified; “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 Falcosantos, Jr. Raquel Cariño-Mendoza, PhD	03	10/01/2017	National Ethical Guidelines (2011) included as reference in the SOP Introduction; Organogram modified to show IERC in reference to other FEU-NRMF units; additional responsibility of Vice Chair added (The Vice-Chair is responsible for ascertaining the need for new SOPs and amendment; Manages the

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			<p>review of SAE and SUSAR reports as head of the SAE Subcommittee); specified that Independent Consultants have no voting privileges; specified that the Chair assigns an Independent Consultant to review global clinical trials if member reviewers do not have the specific medical expertise; specific duration of appointment (from and to date) added in Form 1A2; RDO Chair removed from the Service Agreement (Form 2F) as one of the signatories</p>
<p>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</p>	04	03/15/2022	<ul style="list-style-type: none"> <li>• Included Policy Statement at the Overview/Introduction or at the beginning of every SOP</li> <li>• Streamlined the Responsibilities section in the SOP (duplicated in the workflow and detailed procedures) – deleted duplications (forms and number of days in workflow but maintained in detailed instructions)</li> <li>• Numbers placed in the workflow steps that correspond to the specific detailed procedures</li> <li>• Differentiated regular from alternate members in the appointment document – see From 1A2; Section 4 for definition of “alternate member”</li> </ul>

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		<ul style="list-style-type: none"> <li>• Statements added in Section 6 - Selection of Independent Consultant - Policy Statement than an engineer may be needed to explain the mechanics of a new medical device that is being proposed for a study</li> <li>• Updated references</li> <li>• Redistributed responsibilities so as not to overburden the Chair and Secretary – see shared responsibilities between Chair and Vice Chair (4.6.1.3., 4.6.1.4., 4.6.2.3., 4.6.2.4.), between Chair and Secretary (4.6.1.5., 4.6.3.6.), and between Vice Chair and Secretary (4.6.2.5., 4.6.2.6., 4.5.3.1, 4.6.3.4.)</li> <li>• Revised FEU-NMRF IERC Form 1(A2) Member Appointment to indicate whether the member is a regular or alternate member – see revised Form 1 (A2)</li> <li>• Revised Section 4.2 to define the obligations of the regular and alternate members – see 4.3.8.</li> <li>• Removed SOP 1.4.5.4.3 (minimum</li> </ul>
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			80% attendance) – see 4.6.4.3. <ul style="list-style-type: none"> <li>• Stated that the required training for all members (research ethics, GCP, SOP, update) and corresponding frequency – see 5.1. Policy Statement</li> <li>• Stated that all members should have update training once a year – see 5.1. Policy statement</li> <li>• Changed appointment of Independent consultant from 1 year to 3 years (TCT/MFN) – see 6.3. Step 3</li> <li>• Updated organizational chart and changed RDO to RCD (Research Center for Development) – see 4.2.1. for organizational chart; see 4.2.2.3. on change from RDO to RCD.</li> <li>• Changed Medical Director to Chief Medical Officer</li> <li>• Glossary revised based on PHREB SOP Workbook (2020)</li> </ul>
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"> <li>• Added SOP 1 - 4.6.4.11. The lay member reviews the informed consent process and the informed consent form.</li> <li>• Added SOP 1 – 4.6.4.12 - The non-affiliated member ensures the</li> </ul>


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			<p>independence of the FEU-NRMF IERC.</p> <ul style="list-style-type: none"> <li>Revised Form 1 (C) to specify appointment in the document as <b>&lt;CHAIR/ VICE CHAIR/ SECRETARY/ REGULAR MEMBER / ALTERNATE MEMBER / SECRETARIAT, INDEPENDENT CONSULTANT&gt;</b></li> <li>Added statement in 4.3.8 ... They receive official appointments that will cite their responsibilities.</li> <li>Added statement in 4.3.8. They will not review research proposals.</li> <li>Added 4.6.4.13. Alternate members are called to attend a meeting and substitute for regular members to comply with the quorum requirement when the latter cannot attend the meeting. They will not review research proposals.</li> <li>In all SOPs, the latest reference materials were cited and the old versions were removed.</li> </ul>
<p>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</p>	04.2	08/01/2022	<ul style="list-style-type: none"> <li>Added in Form 1(A2) 2022 under functions the SOP pertaining to the specific functions of the regular member (SOP 1 4.6.4.1 ) and</li> </ul>

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<p>Jures Mae Frias</p>		<p>alternate member (SOP 1 4.6.4.2)</p> <ul style="list-style-type: none"> <li>• Separated roles of regular and alternate members in SOP 1 4.3.8.1 (Regular Members) and 4.3.8.2 (Alternate members)</li> <li>• Separated the specific duties and functions of regular and alternate members in SOP 1 4.6.4.1 (Regular Member) and 4.6.4.2 (Alternate Member)</li> <li>• Revised role of alternate member to state that alternate members Review research proposals and accomplish assessment forms in order to participate in the decision-making of a research proposal, maintain quorum, and vote during decision-making. (SOP 1 4.3.8.2 and 4.6.4.2.2)</li> </ul>
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## **1. Objectives**

This SOP describes the Terms of Reference (TOR) which provide the organizational framework for the structure and composition of the Far Eastern University - Nicanor Reyes Medical Foundation Institutional Ethics Review Committee (FEU-NRMF IERC). This SOP also describes and provides the procedures, templates, and forms that are related to nomination, appointment, privacy and confidentiality, training, and compensation; and identifies who should read, agree to, sign, and date these forms.

## **2. Scope**

This SOP applies to the constitution of the FEU-NRMF IERC and the composition of subcommittees within the FEU-NRMF IERC, which will carry out the task of providing an independent review of research protocols involving human participants that are submitted to the FEU-NRMF IERC by members of the faculty, students, hospital staff, residents, fellows and other trainees and employees of the Far Eastern University - Dr. Nicanor Reyes Medical Foundation (FEU-NRMF), and non-FEU-NRMF principal investigators (PIs). Protocols involving non-human living vertebrates are referred to the Institutional Animal Care and Use Committee (IACUC).

This SOP describes the general ethical basis or values on which the FEU-NRMF IERC is based, the composition and appointment of FEU-NRMF IERC personnel, and duties and responsibilities of FEU-NRMF IERC personnel, including attendance, training, expected review deliverables, and disclosure of conflict of interest.

## **3. Responsibilities**

It is the responsibility of the FEU-NRMF President to constitute and establish the FEU-NRMF IERC. The FEU-NRMF President is also responsible for appointing the FEU-NRMF IERC Chair, Members, Independent Consultants, and Secretariat Staff; and providing the terms of reference for these appointments in accordance with prevailing policies, guidelines, and regulations.

It is the responsibility of the FEU-NRMF IERC Chair, Members, Independent Consultants, and the Secretariat to study, comprehend, comply with, and respect the procedures and guidelines set by the FEU-NRMF IERC as approved by appropriate officials.

It is the responsibility of all newly appointed FEU-NRMF IERC Members to read, understand, accept, and sign required appointment forms at the start of their appointment or reappointment to the FEU-NRMF IERC.

It is the responsibility of new FEU-NRMF IERC personnel to undergo training during the course of his appointment and existing FEU-NRMF IERC personnel to continuously update themselves and train on relevant knowledge and skills. The FEU-NRMF IERC Chair shall enjoin FEU-NRMF IERC personnel to attend

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trainings/seminars/ workshops as needed, and ensure that adequate resources are provided for continuing professional development. Therefore FEU-NRMF is responsible for allocating an annual budget for specific trainings and other educational activities for FEU-NRMF IERC personnel.

**4. Constitution and Functions**

**4.1. Policy Statement**

The FEU-NRMF President, as the appointing and approving officer, shall constitute the Far Eastern University – Nicanor Reyes Medical Foundation Institutional Ethics Review Committee (FEU-NRMF IERC).

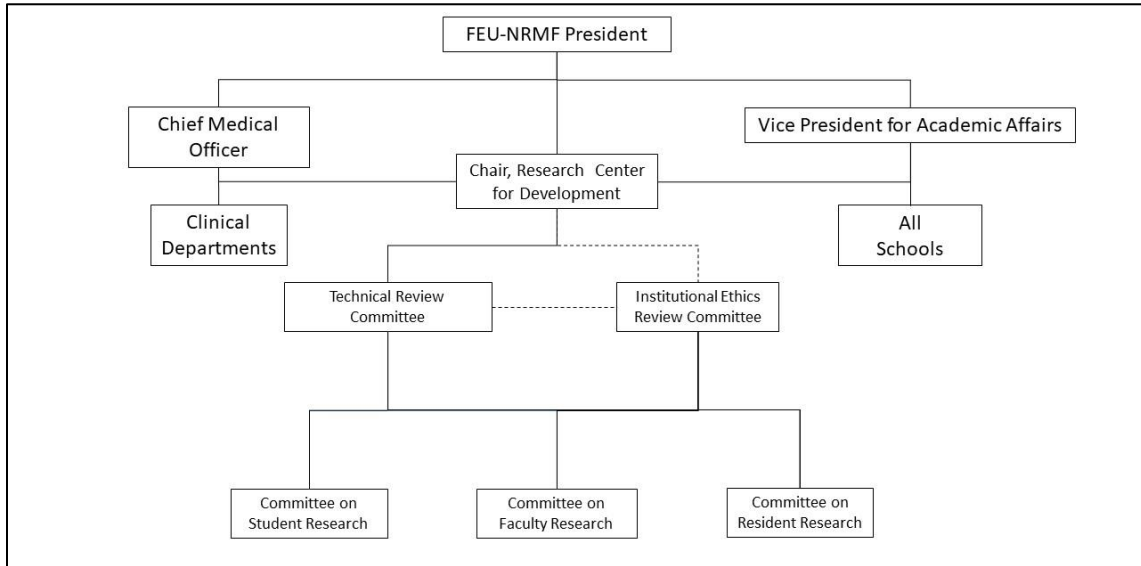
The FEU-NRMF IERC shall have a chair, vice-chair, and member-secretary. In its initiation, the chair is pre-selected by the appointing authority of FEU-NRMF, and the task of the FEU-NRMF IERC is to select the other officers. Subsequently, the officers shall be selected among the members by election in a special meeting initially presided by an outgoing officer.

Members shall be classified as regular or alternate members. Regular and alternate members receive official appointments from the institutional authority with specific terms and responsibilities including review of research proposals and attendance of meetings. The alternate members shall attend meetings whenever called to ensure that meetings are conducted with sufficient members.

**4.2. Organizational Structure of the FEU-NRMF IERC**

**4.2.1.** The FEU-NRMF President appoints the FEU-NRMF IERC Chair and Members to facilitate the discharge of functions of the FEU-NRMF IERC along the line of authority indicated by the following chart:

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**Figure 1: Organizational Chart**

**4.2.2.** The FEU-NRMF IERC is established by authorization of the FEU-NRMF President and exercises its mandate through the following structure:

- 4.2.2.1. The FEU-NRMF President, as the appointing/approving officer
- 4.2.2.2. The Vice President for Academic Affairs (VPAA) and Chief Medical Officer as endorsing officers
- 4.2.2.3. The Research Center for Development (RCD) Chair and FEU-NRMF IERC Chair as recommending officers
- 4.2.2.4. The Institutional Ethics Review Committee, as the implementing office

**4.2.3.** Only the FEU-NRMF President has the authority to dissolve the FEU-NRMF IERC after due process.

**4.3. Composition of FEU-NRMF IERC**

- 4.3.1. The FEU-NRMF IERC is composed of the Chair and the Members
- 4.3.2. The FEU-NRMF IERC can create subcommittees with their own subcommittee chair as the need arises.
- 4.3.3. The IERC is composed of at least five (5) members.
- 4.3.4. The IERC has a Secretary from among the members. The Secretary is nominated by the FEU-NRMF IERC Chair and appointed by the FEU-NRMF President.
- 4.3.5. The IERC is an independent body composed of scientific and non-scientific members wherein at least one (1) non-affiliated member and at least one (1) lay member are both present.

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**4.3.6.** The Members should have various backgrounds and should have adequate representation of members with regard to age and sex.

**4.3.7.** Members are selected according to their personal capacities; based on their interest, background, ethical, and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the work of FEU-NRMF IERC.

**4.3.8.** Members shall be classified as regular or alternate members.

4.3.8.1. **Regular members** are members constituting the research ethics committee, who receive official appointments from the institutional authority with specific terms and responsibilities including review of research proposals and attendance of meetings.

4.3.8.2. **Alternate members** are individuals who possess the qualifications of specified regular members. They receive official appointments that will cite their responsibilities. They are called to attend a meeting and substitute for regular members to comply with the quorum requirement when the latter cannot attend the meeting. They will review research proposals and accomplish assessment forms in order to participate in the decision-making of a research proposal, maintain quorum, and vote during decision-making.

**4.3.9.** Member assignments should take into consideration the appropriate mix of old and new members.

**4.3.10.** Members may be requested to participate in the meetings of other committees, upon recommendation of the FEU-NRMF IERC Chair, and in coordination with the Subcommittee Chairs.

**4.3.11.** The FEU-NRMF IERC may further be supported in its deliberation on specific protocols or requests for advice on specific ethical and / or technical issues by Independent Consultants (see **SOP 1 – 6 SELECTION OF INDEPENDENT CONSULTANTS**).

#### **4.4. Resignation, disqualification, and replacement of members**


**4.4.1.** A member may resign his/her position by submitting a letter of resignation to the FEU – NRMF President through the FEU-NRMF IERC Chair.

**4.4.2.** A member may be disqualified and/or not be reappointed for non-compliance of duties and responsibilities stated herein, and non-disclosure of conflict of interest.

**4.4.3.** A member who has resigned and members who will not be re-appointed will be replaced by new members upon recommendation of the FEU-NRMF IERC Chair and approval of the FEU-NRMF President.

#### **4.5. General Duties and Responsibilities of FEU-NRMF IERC Members and Staff**

**4.5.1.** FEU-NRMF IERC members and personnel should submit their properly signed and annually updated **CURRICULUM VITAE [FEU-NRMF IERC FORM 1(B) 2022]**, which will be filed at the FEU-NRMF IERC Membership File (contains CV, Terms of Appointment, and copies of Training Certificates of each member).

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**4.5.2.** Members are required to sign **FEU-NRMF IERC FORM 1(C) 2022: CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE** at the start of their term. The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the FEU-NRMF IERC in the course of its work.

**4.6. Specific Duties and Functions of FEU-NRMF IERC Personnel**

**4.6.1. FEU-NRMF IERC Chair**


- 4.6.1.1. Presides over IERC meetings among Members and Subcommittee Chairs
- 4.6.1.2. Ensures sufficient financial and administrative support for IERC operations
- 4.6.1.3. Assigns primary reviewers to review protocols submitted to the FEU-NRMF IERC.  
This is a shared function with the Vice Chair.
- 4.6.1.4. Decides which protocols may be expedited and assigns reviewers for expedited review. This is a shared function with the Vice Chair.
- 4.6.1.5. Prepares an annual report summarizing IERC activities and decision outcomes to the FEU-NRMF President. This is a shared function with the Secretary.
- 4.6.1.6. Forms an ad hoc committee as the need arises
- 4.6.1.7. Recommends SOP amendments and changes
- 4.6.1.8. Represents the FEU-NRMF IERC in the research organizational structure of Far Eastern University - Nicanor Reyes Medical Foundation
- 4.6.1.9. Represents FEU-NRMF IERC in national and international fora beyond the FEU-NRMF jurisdiction

**4.6.2. FEU-NRMF IERC Vice Chair**

- 4.6.2.1. Presides over meetings in the absence of the Chair
- 4.6.2.2. Ensures overall IERC compliance with GCP
- 4.6.2.3. Assigns primary reviewers to review protocols submitted to the FEU-NRMF IERC.  
This is a shared function with the Chair.
- 4.6.2.4. Decides which protocols may be expedited and assigns reviewers for expedited review. This is a shared function with the Chair.
- 4.6.2.5. Oversee FEU-NRMF IERC protocols reviewed by respective FEU-NRMF IERC members. This is a shared responsibility with Secretary.
- 4.6.2.6. Supervise the preparation and issuance of all FEU-NRMF IERC communication in respect of FEU-NRMF IERC decisions and actions. This is a shared responsibility with the Secretary.
- 4.6.2.7. Responsible for ascertaining the need for new SOPs and amendment
- 4.6.2.8. Manages the review of SAE and SUSAR reports as head of the SAE Subcommittee
- 4.6.2.9. Performs other duties as designated by the Chair

**4.6.3. FEU-NRMF IERC Secretary**

- 4.6.3.1. Oversee FEU-NRMF IERC protocols reviewed by respective FEU-NRMF IERC members. This is a shared responsibility with Vice-Chair.

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- 4.6.3.2. Oversee preparation and accuracy of the agenda and minutes of the meeting
- 4.6.3.3. Ensures good IERC documentation
- 4.6.3.4. Supervise the preparation and issuance of all FEU-NRMF IERC communication in respect of FEU-NRMF IERC decisions and actions. This is a shared responsibility with Vice-Chair.
- 4.6.3.5. Supervise the management of the FEU-NRMF IERC Office and Secretariat Staff
- 4.6.3.6. Prepares an annual report summarizing IERC activities and decision outcomes to the FEU-NRMF President. This is a shared function with the Chair.

#### **4.6.4. FEU-NRMF IERC Member**

##### **4.6.4.1. Regular Member**

- 4.6.4.1.1. Make a timely and thorough review and decision regarding protocols given to him/her for evaluation (**See SOP 2: PROTOCOL REVIEW** for timelines)
- 4.6.4.1.2. Familiarize and update him/herself with the SOPs of the FEU-NRMF IERC, his/her terms of reference, and the international and national guidelines on research ethics
- 4.6.4.1.3. Participate actively in meetings and other FEU-NRMF IERC meetings.
- 4.6.4.1.4. Assess reports and recommend appropriate action on adverse events based on monitoring reports, especially if he/she is a member of the Serious Adverse Events Subcommittee.
- 4.6.4.1.5. Participate in the review of the progress reports, final reports, and other amendments presented during the FEU-NRMF IERC meeting
- 4.6.4.1.6. Participate in Site Visits and similar activities as needed
- 4.6.4.1.7. Maintain confidentiality of the documents and deliberations of FEU-NRMF IERC meetings
- 4.6.4.1.8. Declare any conflict of interest in general and for specific protocols for review
- 4.6.4.1.9. Participate in required training as stipulated in **SOP 1 – 5: TRAINING OF FEU-NRMF IERC MEMBERS AND PERSONNEL** with proof of attendance in such training activity submitted to the Secretariat for filing.
- 4.6.4.1.10. Submit an updated and signed CV at the start of each Academic Year
- 4.6.4.1.11. The lay member reviews the informed consent process and the informed consent form.
- 4.6.4.1.12. The non-affiliated member ensures the independence of the FEU-NRMF IERC.

##### **4.6.4.2. Alternate member**

- 4.6.4.2.1. Attend meeting and substitute for regular members to comply with the quorum requirement when the latter cannot attend the meeting.
- 4.6.4.2.2. Review research proposals and post-approval submissions, and accomplish assessment forms in order to participate in the decision-making of a research proposal, maintain quorum, and vote during decision-making.

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4.6.4.2.3. Participate in required training as stipulated in **SOP 1 – 5: TRAINING OF FEU-NRMF IERC MEMBERS AND PERSONNEL** with proof of attendance in such training activity submitted to the Secretariat for filing.

4.6.4.2.4. Submit an updated and signed CV at the start of each Academic Year

4.6.4.2.5. Maintain confidentiality of the documents and deliberations of FEU-NRMF IERC meetings

4.6.4.2.6. Declare any conflict of interest in general and for specific protocols for review

#### **4.6.5. FEU-NRMF IERC Secretariat**

4.6.5.1. Manages protocol submissions

4.6.5.2. Organizes an effective and efficient tracking procedure for each protocol received

4.6.5.3. Prepare and distribute protocol files for review

4.6.5.4. Maintain the FEU-NRMF IERC Active Files and Archives, **SUBMISSIONS LOG [FEU-NRMF IERC FORM 4(L) 2022]**, references and other document files, especially their security and confidentiality

4.6.5.5. Organize FEU-NRMF IERC meetings (see **SOP 2 – 6: CONDUCT OF FULL BOARD MEETINGS**)

4.6.5.6. Prepare and maintain meeting agenda and minutes

4.6.5.7. Inform FEU-NRMF IERC members and personnel about training workshops and arrange for the latter's participation in such workshops

4.6.5.8. Organize the preparation, review, revision, and distribution of SOPs and guidelines

4.6.5.9. Provide the necessary secretariat support for FEU-NRMF IERC-related activities like Site Visits and communicating decisions to the PIs


### **4.7. Appointment/Reappointment of IERC Members**

#### **4.7.1. Policy Statement**

The selection of FEU-NRMF IERC members shall be through a nomination process that ensures representation of different disciplines (scientists and non-scientists, medical and non-medical members), sectors (male and female, older and younger age groups) and member/s who are not affiliated with the institution. The members, whether regular or alternate, shall serve for a period of 1 year initially, reappointed for a period on two years, which can be renewed for a number of terms.

#### **4.7.2. Workflow**

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
Step 1. Nomination of FEU-NRMF IERC Members	FEU-NRMF IERC Chair
Step 2. Appointment of Members	FEU-NRMF President

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Step 3. Acceptance of appointment	Member
Step 4. Submission of updated CV and accomplishment of confidentiality agreement and conflict of interest disclosure	Member
Step 5. Filing of appointment documents	Secretariat

#### 4.7.3. DETAILED INSTRUCTIONS

**Step 1 – Nomination of FEU-NRMF IERC Members:** The FEU-NRMF IERC Chair nominates or recommends the appointment/reappointment IERC Members, with a description of functions and responsibilities detailed above, using **FEU-NRMF IERC FORM 1(A1)2022: MEMBER NOMINATION**.

**Step 2 – Appointment of Members:** The nomination or recommendation by the Chair is reviewed by the FEU-NRMF President. The FEU-NRMF President appoints the members of the IERC.


Initial appointment of members, whether regular or alternate, is for a period of one (1) year and reappointment is for a period of two (2) years. Appointments may be renewed on the recommendation of the FEU-NRMF IERC Chair and upon approval of the FEU-NRMF President. The FEU-NRMF IERC Chair likewise should have a fixed term of three (3) years to ensure continuity of policy structures in place, and a reappointment period of three (3) years. A letter of appointment/reappointment is a requisite to sit as a member.

**Step 3 – Acceptance of appointment:** The nominee accepts the appointment by signing a conforme in **FEU-NRMF IERC FORM 1(A2)2022: MEMBER APPOINTMENT**.

**Step 4 – Submission of updated CV and accomplishment of confidentiality agreement and conflict of interest disclosure:** Upon acceptance of appointment, the newly appointed IERC Member submits an updated CV and **FEU-NRMF IERC FORM 1(C)2022: CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE**. A copy of **FEU-NRMF IERC FORM 1(C) 2022: CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE** must be filled out and signed by all FEU-NRMF IERC personnel. A COI does not necessarily disqualify a person from becoming a member of the FEU-NRMF IERC for as long as he/she declares it beforehand, understands his/her responsibility as a FEU-NRMF IERC member (that is, to provide an unbiased review of a protocol for the protection of research participants), and declines from participating in protocol deliberations when his/her COI could affect the result of committee decisions. The FEU-NRMF IERC personnel reads, signs the forms, and dates his/her signature on the forms then submits them to the FEU-NRMF IERC Secretariat.

**Step 5 – Filing of appointment documents:** The FEU-NRMF IERC Secretariat accepts the signed/unsigned form, makes duplicate copies of each, and files the originals together with the letter from the FEU-NRMF President about the member's appointment, his/her CV and terms of reference, in the FEU-NRMF IERC Membership Files. The Secretariat Staff gives a copy of each signed and dated form to the FEU-NRMF IERC



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Member who must keep them in his/her own personal files. The Secretariat Staff keeps one (1) copy of the signed and dated **FEU-NRMF IERC FORM 1(A1)2022: MEMBER NOMINATION, FEU-NRMF IERC FORM 1(A2)2022: MEMBER APPOINTMENT** and **FEU-NRMF IERC FORM 1(C)2022: CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE** in the FEU-NRMF IERC Membership File. The **FEU-NRMF IERC FORM 1(C) 2022: CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE** is required to be updated when appointment is renewed.

## **5. Training of FEU-NRMF IERC Members and Personnel**

### **5.1. Policy Statement**

In order to ensure a robust conduct ethics review by the FEU-NRMF IERC Members and to conduct smooth office operations by other Personnel, trainings are necessary. The FEU-NRMF IERC shall abide by the training requirements of current international and local guidelines. Institutional support is signified by providing for the means by which these trainings are received by the members and personnel. All members must undergo research ethics, GCP, and SOP training every three years. All members should have update training once a year.

### **5.2. Workflow**

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
Step 1. Set training requirements	Vice Chair
Step 2. Find available training seminars, lectures, workshops	Members, Secretariat, Vice Chair
Step 3. Signify intention to attend training or the FEU-NRMF IERC Chair instructs member/s to attend	Members, Secretariat
Step 4. Attend training and keep the training record	Members, Secretariat
Step 5. Store training record in FEU-NRMF IERC Membership Files under "Training of FEU-NRMF IERC Members"	Secretariat

### **5.3. DETAILED INSTRUCTIONS**

**Step 1 – Identification of required trainings, seminars, and workshops:** The Vice Chair periodically reviews compliance with training requirements for the FEU-NRMF IERC Chair, Secretary, Members, and Secretariat. The following are required courses:

- Basic Research Ethics & Good Clinical Practice
- FEU-NRMF IERC Standard Operating Procedures
- Continuing Ethics Education
- Other educational activities on international trends including international specialists' meetings organized for the exchange of experiences and information

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**Step 2 - Search for available training activities:** The Member/Secretariat Staff gets information about training courses, workshops, conferences, etc. which are periodically announced on websites, bulletin boards, and various media channels and selects the ones most appropriate. In-house training provided by FEU-NRMF IERC will be regularly included in the meeting agenda will be similarly documented in the **FEU-NRMF IERC FORM 1(D) 2022: TRAINING RECORD**.

**Step 3 - Communication of intention to attend training program:** The Member requesting for training informs the FEU-NRMF IERC, in writing, of intention to enroll in the course (for possible funding by FEU-NRMF IERC) and requests for funds for training. Request is made through the FEU-NRMF IERC Chair. The Member submits a copy of **FEU-NRMF IERC FORM 1(E) 2022: TRAINING REQUEST FORM** with supporting documents, including, but not limited to, *Registration Form* and *Program* at least one (1) month before the training date. The FEU-NRMF IERC Chair recommends participation of the member/s, the Chair of the Research Development Office endorses the request to the FEU-NRMF President for his final action.

**Step 4 - Attendance in the training:** The Member or Secretariat attends the training and submits proof of attendance to the Vice Chair, such as *certificate of participation or completion* and *official receipt* (for paid training courses). The Vice Chair verifies validity of submitted documents. Attendees are encouraged to echo their experience to the FEU-NRMF IERC.

**Step 5 - Storage & Filing:** The Secretariat fills out **FEU-NRMF IERC FORM 1(D) 2022: TRAINING RECORD** to document the training/workshop/conference activities in chronological order. The Secretariat makes a copy of the form and files the copy in the FEU-NRMF IERC Membership File.


## **6. Selection of Independent Consultants**

### **6.1. Policy Statement**

The FEU-NRMF IERC shall invite an independent consultant whose expertise is not represented in the current membership but is needed in a study under review. He/she need not be affiliated with the institution. Their role is to clarify technical aspects of the protocol (e.g. an engineer may be needed to explain the mechanics of a new medical device that is being proposed for a study).

### **6.2. Workflow**

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
Step 1. Invite Independent Consultants to the FEU-NRMF IERC	FEU-NRMF IERC Chair
Step 2. Sign conforme and confidentiality agreement and conflict of interest disclosure	Independent Consultant
Step 3. Appoint the roster of Independent Consultants	FEU-NRMF President

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Step 4. Store roster of Independent Consultants in the Independent Consultants File	Secretariat
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### 6.3. DETAILED INSTRUCTIONS

**Step 1 - Invitation of Independent Consultants:** The FEU-NRMF IERC Chair determines the external expertise requirements of the committee based on protocols submitted for review during previous years and the available expertise in the current FEU-NRMF IERC composition. The FEU-NRMF IERC Chair sends invitations to various professionals with specific scientific expertise to be part of the FEU-NRMF IERC roster of Independent Consultants representing expertise not present in the current members. The FEU-NRMF IERC Chair determines which protocol should be reviewed by an Independent Consultant, especially in the review of global clinical trials. Similarly, in the course of protocol review, an FEU-NRMF IERC Member may recommend that a protocol should also be reviewed by an Independent Consultant. The invitation includes the responsibilities and functions of the Independent Consultant as follows:

- Accomplish the following forms when requested:
  - **FEU-NRMF IERC FORM 1(F)2022: SERVICE AGREEMENT FOR INDEPENDENT CONSULTANTS**
  - **FEU-NRMF IERC FORM 1(C)2022: CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE**
- Review assigned protocols that concern his/her specialty using the **FEU-NRMF IERC FORM 2(C) 2022: STUDY PROTOCOL ASSESSMENT FORM** and **FEU-NRMF IERC FORM 2(D) 2022: INFORMED CONSENT ASSESSMENT FORM**.
- Attend the FEU-NRMF IERC meeting when invited where deliberations on said protocols will be made or alternatively, submit results of review to the FEU-NRMF IERC Secretariat if unable to attend the meeting.
- Return all protocol-related materials to the FEU-NRMF IERC Secretariat after review.
- Submit an updated and signed CV annually.
- NOTE: Independent consultants do not have voting privileges.

**Step 2 - Confirmation of invitation:** The Independent Consultant signifies agreement to the invitation by signing the conforme attached to the letter of invitation. The signed conforme is submitted to the FEU-NRMF IERC Secretariat.

**Step 3 - Appointment of Independent Consultants:** The FEU-NRMF IERC Chair recommends a roster of Independent Consultants who have been invited and have confirmed invitation to the FEU-NRMF President. The FEU-NRMF President appoints the roster. The appointment is for three (3) years. Appointment may be terminated by either resignation of the consultant, or by the FEU-NRMF President.

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**Step 4 - Storage of roster of Independent Consultants:** - The FEU-NRMF IERC Secretariat files the appointment-related documents in the Independent Consultants File. The Independent Consultants File contains the originally signed conforme representing the terms of reference of appointment and CV.

## **7. Compensating Members and Consultants**

### **7.1. Policy Statement**

The FEU-NRMF IERC Members and Independent consultants shall be compensated for their review of research protocols as a sign of institutional support. The compensation will cover the review of protocols, attendance of meetings, and other related FEU-NRMF IERC activities.

### **7.2. Workflow**

ACTIVITIES	RESPONSIBILITY
Step 1. Recommend honorarium	FEU-NRMF IERC Chair
Step 2. Approve honorarium	FEU-NRMF President
Step 3. Communicate honorarium information to personnel and Independent Consultants	Secretariat

### **7.3. DETAILED INSTRUCTIONS**


**Step 1 - Recommendation of honorarium:** The FEU-NRMF IERC Chair initiates the recommendation of honorarium or increase thereof, either after a dialogue with FEU-NRMF IERC members or with FEU-NRMF President. The compensation covers a fixed amount for review of protocols and a fixed amount for attending meetings and other FEU-NRMF IERC related-activities. The recommendation will be submitted to the FEU-NRMF President for Academic Affairs through the submission of the FEU-NRMF IERC budget.

**Step 2 - Approval of honorarium:** The FEU-NRMF President may approve or disapprove the recommendation. Approval or disapproval will be indicated in the approval of the FEU-NRMF IERC budget or amendment thereof.

**Step 3 - Communication of honorarium information:** The FEU-NRMF IERC Members and Independent Consultants are informed of the honorarium package both upon appointment and whenever there are changes subject to the governing rules and regulations. FEU-NRMF IERC personnel and Independent Consultants acknowledge the information upon receipt of notification.

References:

1. CIOMS Guidelines for Epidemiological Studies (2009)
2. CIOMS-WHO International Ethical Guidelines for Biomedical Research Involving Human Subjects (2016)

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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 and Health-Related 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 1: Structure and Composition. Makati Medical Center Institutional Review Board (2013)
8. Standard Operating Procedures 1: Structure and Composition. UP Manila Research Ethics Board (2012)
9. WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011