Standard Operating Procedures

1. **Objectives**
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11. **Single Joint Research Ethics Board (SJREB) Workflow for Initial Review**
12. **Management of Appeals**

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:	

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 and Makati Medical Center 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	mandate of the IERC as stated in the Scope with regards to "Non-FEU-NRMF Primary Investigator"; references updated to include international guidelines; main subsections highlighted; responsibility of primary reviewers included; criteria for Expedited Review and Full Board Review for "Amendments/Reports" moved to SOP 3; "Present review by the Primary Reviewers" included in the workflow; "Conduct clarificatory interview" qualified as "only when necessary"; "Review" in "Review report of results of expedited review" deleted in the workflow; "A matter of life and death" which is already included in unexpected SAEs deleted; In section 2.2. [PI qualifications] of Form 2 (C) [Study Protocol Assessment Form], COI declaration included as example of "relevant certifications"; in Form 2 (G) [Meeting Agenda], 6.1.3. [Study Protocols for Clarificatory Interview] incorporated as part of both 6.1.1. [Study Protocols for Initial Review] and 6.1.2. [Resubmissions or Study Protocols for Modification]; Approval letter of study protocol form moved

			from SOP 4 to SOP 2; "workflow" in the title of each main subsection deleted and made as the first subtopic under each main subsection; subsection on "Protocol Review Decision Notification" detailing the instructions for notifying the PI about the IERC decision added
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	Provided separate SOPs on Management of Protocol Submissions, Full Board Review Process, Expedited Review Process, Preparation for IERC Meeting, and Conduct of Meeting; Included criteria for Major or Minor Modification; Included section for Exemption from review; Revised flow chart for Full Board and Expedited Review, including Exempt from review; Incorporated timelines in the flow chart for review process; Provided letter template for Notification of Ethics Review Exemption, Disapproval, Request for Waiver of Informed Consent; Clarified schedule of regular meeting; Included in the SOP the timeline when notification will be received by the PI for Expedited Review; Designated official signatory for all communications for Form 2(J) and 2(K) as the Chair; Form 2(L) modified to state that Continuing Review application should be 30 days prior to expiration; Included risk assessment procedures in the Full board Meeting; Meeting Agenda Form 2(G) modified to include onsite SAE reports for full board review, onsite SAE reports for expedited review, and quarterly SAE reports; Secretariat included as signatory of meeting agenda; Approval Letter modified to state that application for renewal of approval is 30 days prior to expiration; Member Secretary summarizes the discussion prior to board decision; Risk assessment included in the Study

			Protocol Assessment form and during the Full board meeting; recusal of IERC member with COI clarified – member needs to leave the room and is not allowed to take part in deliberation or voting

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	04	03/15/2022	• Included Policy Statement at the Overview/Introduction or at the beginning of every SOP
			• Defined clearly the conditions when FEU-NRMF IERC can review external protocols (outside stakeholders) (scope of authority of review) – see Section 2 – Scope
			  ○ No institutional REC in the site
			  ○ No willing REC at the site of the study (PI has to declare)
			  ○ FEU-NRMF IERC has the expertise to review the protocol and exercise oversight
			  ○ FEU-NRMF IERC review is in accordance with relevant guidelines and regulations (PHREB, DOH, FDA, etc.)
			• Required MOA with research sites when FEU-NRMF IERC provides review, specifying FEU-NMRF IERC accountability – see Section 2 Scope; revised Form 2A Review Checklist
			• Deleted PI responsibilities in the SOP
			• Provided SOP on Management of Appeals – see Section 12 – Management of Appeals; Form 2Q – Decision Letter on Appeal

			• Included SOP on Joint Review with SJREB (Section 11) and appended the SJREB SOP (Appendix A) • added statements in SOP 2 – 4.3 Management of protocol submissions - Step 3 Assignment of Primary Reviewers and Independent Consultants and SOP 2 - Conduct of Full Board Meeting that an engineer may be needed to explain the mechanics of a new medical device that is being proposed for a study. • Created an SOP on Preparing the Meeting Agenda – see Section 8 Preparation for IERC Meeting, Step 2 in Workflow and Detailed instructions • Updated references • Section 4.1.1 – Included Research Ethics training in the Basic Documents required – see 4.3. Step 1 – Receipt and management of study protocol submission Basic Documents; see revised Form 2A Review Checklist • Section 4.1.3 – Gave a detailed procedure on how a code is assigned or derived - see section 2: Management of study protocol submissions – Detailed instructions – Step 1 referring to SOP 4 – 7: Active Study Files – Detailed Instructions – Step 1 • Included SJREB number to their protocol number to be able to crosscheck with SJREB review – see Section 11 SJREB Workflow for Initial Review and the coding system section in SOP 4 – 7: Active Study Files

			– Detailed Instructions – Step 1 • Section 4.2.1 - Included protocols with more than minimal risk under full board review – see 4.3. Step 2 Classification of Review • Section 8.4.1 - Included review of Progress Reports before Continuing Review – see section 9: Conduct of Full Board Review, Step 6; see also created section on Progress Reports in SOP 3 Section 6; also created Form 3(L) 2022: Progress Report Form; also added field for Progress Report in Meeting Agenda (Form 2G) and Minutes of the Meeting (Form 4A) • Section 4.3.1 – Specified that a medical/scientist member is assigned for the technical & ethical issues and the non-scientist for the ICF review – see 4.3 Step 3 Assignment of Primary Reviewers and Independent Consultants • Rearranged the sequence: EXEMPT FROM REVIEW, EXPEDITED, then FULL REVIEW before discussing preparation and conduct of the Full Review board meeting – see Section 4 Management of Protocol Submission – Step 2 Classification of Review • Section 5 Workflow 8.1 - Included Approval of Agenda to be consistent with Section 8.3.5 wherein the Chair declares the approval of the Meeting Agenda – see Section 9 Workflow and Detailed Instructions - Step 3

			• Included the conduct of ONLINE meetings in the SOP detailed procedures – see added statements in the Sections 8: Preparation for IERC Meeting, and 10: Special Meetings that meetings may be conducted through a secure video conferencing platform provided by the institution under the following circumstances: inclement weather, government regulations and institutional memoranda that preclude physical meetings, disasters, and exigent situation. Attention must be given to ensure privacy and confidentiality. Meetings may also be held in a hybrid format, with some members present physically, and others present via video conference. • Section 4.2.5 – Created an assessment checklist to justify Exempt from Review – see Form 2 (P) – Exemption checklist; added statement in detailed instruction in Section 4 on Classification of Review • Required a Final Report for protocols prior to archiving and include this requirement in the Exemption Letter – see Form 2 (M); also deleted parts in SOP 4 pertaining to exempt files as immediately archived; added "submit an annual notification letter if your study is still ongoing. Failure to submit will result in archiving of the study" in the exemption letter • Provided a section for Review Resubmission of protocols.

			These usually have minor or major modification decisions. Protocols with Minor modifications can be by expedited review while major modifications are by full review. – See Section 5 – Management of Protocol Resubmissions • Included a procedure of checking version number of resubmitted documents – see Section 5 Management of Protocol resubmission – Detailed Instructions - Step 1 • Included a statement that resubmissions will be reviewed by the same primary reviewers – see SOP 2 Section on Resubmissions - Policy Statement • Changed definition of quorum and comply with NEGHHR 2017 rule of 50% + 1 for the number of members to be present and to include the presence of the non-scientist and non-affiliated members (age and genders considered) – see Section 9 Conduct of Full Board Meeting - Detailed Instructions Step 1 and Section 10 – Special Meetings - Detailed Instructions Step 2 • Revised fields in Minutes of Meeting on the Section of Withdrawals – no decision needed; will be reported but essentially approved since the study has not yet been implemented. Appropriate changes made in the Sections on Full board and Expedited review in SOP 2. • Added Minutes of Special Meeting Template – to

			delineate process for regular meeting and special meeting – see revised Form 4A heading to provide option to choose between regular or special meeting • FEU-NRMF IERC FORM 2(G) 2017 Meeting Agenda - revised to determine if Special or Regular Meeting • Implemented primary reviewer system for efficiency (no need to send documents to all members) • Form 2B – modified type of study to align with PHREB annual report form • Updated risk stratification in study protocol assessment form • Added type of review in action letter - see revised Form 4 (B) • Added section on report of study protocols classified as exempted from review in the full board meeting • Added field on SJREB review in the Form 2B: Application form • Deleted fields on Onsite SAEs/SUSARs and Quarterly Off-site SAEs in the section of Expedited review in the Minutes of the Meeting • Added statement that the Chair may assign a second scientist member as a Primary Reviewer, especially in Sponsored Clinical Trials – see Section 4: Management of Protocol Submission – Detailed Instructions Step 3 • Glossary revised based on PHREB SOP Workbook (2020)

			• Removed "Registration" in the Application Form – see revised Form 2B • Harmonized the discrepancy between the application for review form 2(B) and the SOP regarding the institution outside of FEU doing the oversight of the protocol reviewed by FEU-NMRF IERC – included conditions for review of studies of outside stakeholders; see revised Form 2B Section IV • Included MOA/MOU for research done outside FEU or non-FEU researcher in the checklist for required documents – see revised Form 2A and 2B • Stated the date of effectivity to the date of expiration for the ethical clearance – see revised Form 2(L) • Form 2(M) – Ethics Review Exemption - Stated that any change or alteration to the exempted protocol will invalidate the exemption given and the submission of a final report is required. – see revised Form 2(M) • 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	• Divided Section 4 step 2 to two separate steps: Step 2. Classification of submission if qualified for exemption or not qualified for exemption and Step 3. Classification of submission not qualified for exemption if for expedited of full board review to clearly show sequence (see SOP 2 –

			4.2 Workflow and 4.3 DETAILED INSTRUCTIONS
			• Indicated Primary Reviewer in the following assessment forms
			  ○ 2B – Study Protocol Assessment Form
			  ○ 2C – Informed Consent Assessment Form
			  ○ 2H – Review of Resubmitted Protocol Form
			• In section 27 of Form 2B, added a space to indicate SJREB Code if the protocol will undergo SJREB Review
			• Added FEU-NRMF Data Privacy Office (DPO) Research Clearance Form (for studies involving FEU-NRMF students, faculty, employees, or patients as participants or data source) in Form 2A
			• In all SOPs, the latest reference materials were cited and the old versions were removed.

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1. Objective

This SOP aims to describe the initial review procedures of the Institutional Ethics Review Committee from initial submissions of the protocol until the time the approval letter is sent to the Principal Investigator.

2. Scope

The FEU-NRMF IERC reviews research conducted by members of the faculty, students, employees, consultants, residents and fellows of FEU-NRMF Medical Center and Institute of Medicine, as well as clinical trials by pharmaceutical companies and non - FEU-NRMF principal investigators (PIs).
The FEU-NRMF IERC can accept review from outside stakeholders when:

- There is no institutional research ethics committee in the site
- There is no willing REC at the site of the study upon declaration of the PI
- FEU-NRMF IERC has the expertise to review the protocol and exercise oversight
- FEU-NRMF IERC review is in accordance with relevant guidelines and regulations (PHREB, DOH, FDA, etc.)
- A memorandum of agreement/understanding (MOA/MOU) between FEU-NRMF and the research site is provided

3. Responsibilities

It is the responsibility of the Secretariat to manage study protocol submissions to the FEU-NRMF IERC and process the submission.

It is the responsibility of the FEU-NRMF IERC Chair to decide whether the study protocol is for full board review or for expedited review.

It is the responsibility of the Secretary to ensure that the deliberations and discussions are adequately documented.
It is the responsibility of the FEU-NRMF IERC Members to check the completeness of the study protocol package delivered to them, systematically review the study protocol before the scheduled meeting, write their comments after each item listed in the study protocol assessment forms and informed consent checklist, include consideration of relevant guidelines when doing the review. It is the responsibility of the Primary Reviewers to present findings in the full board meeting (for full review study protocols).

4. Management of Protocol Submission

4.1. Policy Statement

The FEU-NRMF IERC shall require the submission of a set of pertinent documents for an application for ethical review to be accepted. Submissions may be in the form of physical or digital documents. A preliminary evaluation shall determine whether a research proposal is exempted from or needs to undergo ethical review based on the NEGHHR 2017 The Research Ethics Review Process Guideline 3.1. Subsequent amendments to a protocol that was exempted from review shall be submitted for a preliminary evaluation to determine whether the revised protocol can still be exempted from review.

4.2. Workflow

ACTIVITY	RESPONSIBILITY
Step 1. Receipt and management of study protocol submissions	Secretariat
Step 2. Classification of submission if qualified for exemption or not qualified for exemption	FEU-NRMF IERC Chair
Step 3. Classification of submission not qualified for exemption if for expedited of full board review	FEU-NRMF IERC Chair
Step 4. Assignment of Primary Reviewers and Independent Consultants	FEU-NRMF IERC Chair
Step 5. Sending of study protocol package to Primary Reviewers and Independent Consultants	Secretariat, FEU-NRMF IERC Chair

4.3. DETAILED INSTRUCTIONS

Step 1 - Receipt and management of study protocol submission: A study protocol package for initial review must be received together with duly signed and accomplished forms and documents (as applicable) as enumerated in **FEU-NRMF IERC FORM 2(A) 2022 REVIEW CHECKLIST**:

Basic Documents (must submit)

- Review Checklist **[FEU-NRMF IERC FORM 2(A) 2022]**
- Printed Registration and Application Form **[FEU-NRMF IERC FORM 2(B) 2022]**
- Study Protocol Assessment Form **[FEU-NRMF IERC FORM 2(C) 2022]**
- FEU-NRMF Form 1A Proposal Review Form
- Study protocol
- Data collection forms (including CRFs)
- CV of PI and study team members
- Proof of payment – Ethics Review Fee (if applicable)
- Research Ethics Training

Study-specific Documents (submit as needed)

- Investigator's Brochure (for clinical trials phase I, II, III) or Basic Product
- Information Document (for clinical trials phase IV)
- Informed Consent Assessment Form (for studies with human participants) **[FEU-NRMF IERC FORM 2(D) 2022]**
- Informed consent form in English (for studies with human participants)
- Informed consent form in local language (for studies with human participants)
- Assent form in English (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)
- Assent form in local language (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)
- Request to Waive of Written and Verbal Informed Consent **[FEU-NRMF IERC FORM 2(N) 2022]**
- Good Clinical Practice (GCP) Training Certificate of PI, Co-I and the rest of the study team (for clinical trials)
- Recruitment advertisements (as needed by the study protocol)
- Other information or documents for participants (such as diaries, etc.)
- Material Transfer Agreement (for any research involving transfer of biological specimens)
- Memorandum of Agreement (for collaborative studies)
- RCD-endorsed Clinical Trial Agreement (for clinical trials done in FEU-NRMF Medical Center; processed separately by the FEU-NRMF Legal Office and to be submitted to RDO upon receipt of notification of ethical approval from FEU-NRMF IERC)
- Site Resources Checklist for Clinical Trial Outside FEU-NRMF By FEU-NRMF Personnel **[FEU-NRMF IERC FORM 2(E)2022]** or by Non-FEU-NRMF Personnel
- National Commission for Indigenous People Clearance (NCIP) (for studies with indigenous populations; can be processed while IERC review is ongoing)
- Memorandum of Agreement/Understanding (for outside stakeholders)

The Secretariat ensures completeness of submitted forms and documents using the above checklist. The Secretariat receiving the study protocol assigns a code to the package and stamps it onto to all the forms and documents submitted. The Secretariat acknowledges receipt of study protocol and communicates to the PI the assigned code and date of full board meeting in which the study protocol will be reviewed using **FEU-NRMF IERC FORM 2(K) 2022: ACKNOWLEDGEMENT LETTER.** The Secretariat includes the SJREB code with FEU-NRMF IERC Code to cross-check with SJREB review, if necessary. Detailed procedure on coding is on SOP 4 – 7: Active Study Files – Detailed Instructions – Step 1. The Secretariat signs **FEU-NRMF IERC FORM 2(A) 2022 REVIEW CHECKLIST** to document the receipt of study protocol package and gives one copy of duly signed form to the PI or designated representative submitting the package, and attaches another duly signed form to the study protocol package. The Secretariat logs the submission using **FEU-NRMF IERC FORM 4(L) 2022 SUBMISSIONS LOG**. The Secretariat informs the IERC Chair within **two (2) calendar days** of the receipt of the study protocol package.

Step 2 - Classification of submission if qualified for exemption or not qualified for exemption: The IERC Chair classifies study protocols as Exempted from ethics review, facilitated through the use of **FEU-NRMF IERC FORM 2(P) 2022: CHECKLIST FOR EXEMPTION FROM ETHICAL REVIEW** if they fulfill the following criteria:

- Protocol is not considered to be 'research'
    - Performance reviews
    - Testing within normal education requirements
    - Literary or artistic criticism
    - Service evaluation
        - Service is undertaken to benefit those who use a particular service and is designed and conducted solely to define or judge current service or deliver it. It involves an intervention where there is no change to standard service being delivered (eg. no randomization of service users into different groups). This does not require ethics approval.
        - It is possible to use data collected from participants during a service evaluation for later research as long as:
        - The data is completely anonymous
        - It is not possible to identify participants from any resulting report
        - Use of data will not cause substantial damage and distress
    - Quality assurance/audit
        - Audit is defined as assessing the level of service being provided against a set of pre-determined standards. This generally involves analyzing existing data with results usually being used/distributed locally in order to effect change to improve/change the level of service currently being provided. It does not require ethical approval.
- Researches involving animal subjects or specimens; these are reviewed by the Institutional Animal Care and Use Committee
- Researches with biosafety issues or pose hazards to the environment (including those involving animals and plants); these are reviewed by the Biosafety Committee
- The following researches involving human participants, specimen, or collection of personal information do not require ethical approval unless the research requires approval by an external funding body or other external body, or involves vulnerable participants (eg. children and young people, those with a learning disability or cognitive impairment, individuals in a dependent or unequal relationship, etc.):
    - Research involving information freely available in the public domain (eg. published biographies, newspaper accounts of an individual's activities and published minutes of a meeting whilst under the Data Privacy Act of 2012
    - Research involving anonymized records and data sets that exist in public domain, where appropriate permissions have already been obtained and is not possible to identify individuals from the information provided

- Studies of public behavior that are purely observational (non-invasive and non-interactive), unless the recorded observations identify individuals (names, photographs) which could place them at risk of harm, stigma, or prosecution
- Research involving the use of non-sensitive, completely anonymous educational tests, survey and interview procedures when the participants are not defined as "vulnerable" and participation will not induce undue psychological stress or anxiety
- Research involving the use of educational tests, survey, and interview procedures on human participants in the public arena (eg. elected or appointed public officials, candidates for public office, artists)
- Taste and food quality evaluation and consumer acceptance studies, if the food consumed is:
  - Wholesome without additives, or
  - Contains a food ingredient, agricultural, chemical or environmental contaminant, for a purpose and a level declared safe by the relevant national food safety agency

The Chair returns the exempted protocols to the Secretariat in **two (2) calendar days**. The Secretariat sends a notification to the PI on the exemption in **two (2) calendar days**, facilitated with **FEU-NRMF IERC FORM 2 (M) 2022: NOTIFICATION OF ETHICS REVIEW EXEMPTION.** Exempt studies must be closed out when completed or if the Principal Investigator/s are no longer affiliated with the institution. Faculty mentors are responsible for oversight of student projects and should ensure that exempt studies are completed. If the protocol is not qualified for exemption, the Chair proceeds with the next step.

Step 3. Classification of submission not qualified for exemption if for expedited of full board review: The Chair classifies the study protocol that is not qualified for exemption as to whether it will undergo Expedited Review or Full Board Review, using the following criteria:

INITIAL SUBMISSION/RESUBMISSION	
EXPEDITED REVIEW	**FULL BOARD REVIEW**
▪ The research poses no more than minimal risk. ▪ The study does not involve vulnerable populations. ▪ The study does not involve the collection of stigmatizing information. ▪ The study uses anonymized or archived samples. ▪ Continuing review of clinical trials that do not involve further recruitment of participants. ▪ Continuing review of studies previously classified under expedited review. ▪ Study protocol amendments that are administrative in nature and do not affect the study protocol.	▪ Clinical trials about investigational new drugs, biologics or device in various phases (Phase 1, 2, 3) ▪ Phase 4 Intervention research involving drugs, biologics or device ▪ Protocols including questionnaires and social interventions that are confidential in nature. ▪ Protocols involving vulnerable subjects. ▪ Protocols that involve collection of identifiable biological specimens for research ▪ Protocols with more than minimal risk

Step 4 – Assignment of Primary Reviewers and Independent Consultants: The Chair assigns appropriate Primary Reviewers (one scientist members and one non-scientist member) based on expertise and clinical background. The Chair may assign a second scientist member as a Primary Reviewer, especially in Sponsored Clinical Trials. A medical/scientist member is assigned for the technical & ethical issues and the non-scientist for the informed consent form review, and its compliance with the requirements of international and national ethical guidelines, as well as national and institutional policies. If needed, the Chair also assigns appropriate Independent Consultants to aid in the review of study protocols when none of the members possesses sufficient qualifications to make a thorough review. This is especially true for, but not limited to, Sponsor-Initiated clinical trials. An engineer may be needed to explain the mechanics of a new medical device that is being proposed for a study. The Chair classifies the review, assigns Primary Reviewers, and informs the Secretariat of his decisions within **two (2) calendar days** of receipt of information about the study protocols for review.

Step 5 – Sending of Study Protocol Package to Reviewers: The Secretariat sends study protocols with **FEU-NRMF IERC FORM 2 (J) 2022: TRANSMITTAL LETTER,** prepared by the Secretariat and signed by Chair, to Primary Reviewers within **two (2) calendar days** after classification of review and assignment of Primary Reviewers by the Chair. Only studies received by the Secretariat fifteen **(15)** calendar days before the full board meeting which were classified as requiring full board review are included in the agenda.

5. Management of Protocol Resubmission

5.1. Policy Statement

Management of resubmission ensures that the researcher addressed the required modifications before approval of the protocol. The FEU-NRMF IERC shall require a resubmission of a protocol that requires either minor or major modification. For protocols that initially underwent full board review, minor modifications shall undergo expedited review while major modifications shall undergo full review. For protocols that initially underwent expedited review, minor and major modifications shall undergo expedited review. Resubmissions will be reviewed by the same primary reviewers.

5.1.1. Workflow

ACTIVITY	RESPONSIBILITY
Step 1. Receipt and Entry in the Logbook	Secretariat
Step 2. Coding of Resubmitted Protocol Documents	Secretariat
Step 3. Notification of Chair and Reviewers	FEU-NRMF IERC Chair and Secretariat
Step 4. Review of the Resubmission	Primary Reviewers

5.2. Detailed Instructions

Step 1 – Receipt and Entry in the Logbook: The Secretariat receives study document, checks the nature of the document, the correctness of its version, and ensures that the submission is properly logged.

Step 2 – Coding of Resubmitted Protocol Documents: The Secretariat stamps/indicates the code assigned to the protocol when it was initially submitted and the date of receipt on all the documents.

Step 3 – Notification of the Chair and Reviewers: The staff retrieves the **FEU-NRMF IERC FORM 4(B) 2022 ACTION LETTER TO STUDY PROTOCOL SUBMISSIONS, RESUBMISSIONS, AND AMENDMENTS** that pertains to the original protocol and informs the Chair about the resubmission and about the nature of the modifications required from the researcher. Given the necessary information, the Chair either evaluates the resubmitted protocol at his/her level or directs the staff to inform the reviewers concerned and to forward to them the necessary documents.

Step 4 – Review of the Resubmission: The primary reviewers conduct review of the resubmitted protocol by referring to the resubmission form noting the different recommendations made by the FEU-NRMF IERC and evaluating whether these were satisfactorily addressed in the resubmitted protocol. The reviewers submit the report to the Chair for inclusion in the next regular meeting.

6. Full Board Review

6.1. Policy Statement

A full review shall be conducted when a proposed study entails more than minimal risk to study participants or when study participants belong to vulnerable groups or when a study generates vulnerability to participants. Only protocols submitted for, at least, 2 weeks before a scheduled meeting shall be included in the agenda for full review. Full review shall be conducted through a primary reviewer system. If necessary, independent consultants and or the proponents shall be invited during the meeting to clarify certain issues. The decision shall be communicated to the proponent within 1 week after deliberation of the study in the full board meeting. The communication document shall include clear instructions/recommendations for guidance of the researcher, must be written on an official stationery of the IERC and signed by the chair.

6.2. Workflow

ACTIVITY	RESPONSIBILITY
Step 1. Study Protocol Review	Primary Reviewers
Step 2. Inclusion of protocol in the agenda of the next full board meeting	Secretariat
Step 3. Presentation of review findings during full board meeting	Primary Reviewers
Step 4. Committee deliberation on full board action on the protocol	Members
Step 5. Protocol decision notification	Secretariat, Member Secretary, Chair

6.3. Detailed Instructions

Step 1 - Study Protocol Review: Primary reviewers accomplish **FEU-NRMF IERC FORM 2(C) 2022: STUDY PROTOCOL ASSESSMENT FORM** and **FEU-NRMF IERC FORM 2(D) 2022: INFORMED CONSENT ASSESSMENT FORM** completely and comprehensively, and check for completeness of the documentation and information about the PI/s, study sites, and other documents as required by the study protocol under review such those listed in **SOP 2 - 4 Step 1 - RECEIPT AND MANAGEMENT OF STUDY PROTOCOL SUBMISSIONS** applicable to the study. The Primary reviewers review the study protocol and informed consent documents in accordance with the assessment points and elements detailed in **FEU-NRMF IERC FORM 2(C) 2022: STUDY PROTOCOL ASSESSMENT FORM** and **FEU-NRMF IERC FORM 2(D) 2022: INFORMED CONSENT ASSESSMENT FORM.** The primary reviewers and members accomplish the aforementioned forms and return them to the Secretariat in **ten (10) to twelve (12) days**.

In addition to the review elements described above, the primary reviewers should ensure study protocol compliance with the ***National Ethical Guidelines for Health and Health-Related Research 2017*** on:

- Use of biological materials
- Appropriate contracts or memoranda of understanding especially in collaborative studies
- Community involvement and impact/benefit of the study to community and/or the institution are examined and if relevant, noting the following if applicable: community consultation, involvement of local researchers and institutions in the study protocol design, analysis and publication of the results, contribution to development of local capacity for research and treatment, benefit to local communities, availability of study results, and benefit sharing.

The primary reviewers signify their decision by marking the appropriate section of the aforementioned forms and affixing their signature in the space provided. Decision points are: **APPROVAL, MINOR MODIFICATIONS, MAJOR MODIFICATIONS, and OR DISAPPROVAL.** The criteria for Major and Minor Modifications are as follows:

- Major Modification – there are substantive changes to the informed consent document; or inadequacy of scientific basis for the study and scientific design and therapy changes
- Minor modification - do not involve significant changes to:
    - scientific design and therapy (minor scientific changes; eg. changes in targeted sample size, accrual objectives, minor changes to inclusion/exclusion criteria)
    - content of informed consent document (typographical errors, formatting)

Step 2 - Inclusion of protocol in the agenda of the next full board meeting: The Secretariat includes the protocol in the agenda of the next full board meeting as described in **SOP 2 – 8 Step 2: Preparing the Meeting Agenda.**

Step 3 - Presentation of review findings during full board meeting: The primary reviewers present their findings in the full board meeting where committee action is deliberated. See **SOP 2 – 9: CONDUCT OF FULL BOARD MEETING.** For decisions on resubmissions and post approval submissions, the committee may request information or clarificatory interview from the PI, as the need arises. In the event that a PI decides not to continue the application for ethics review, the PI must write a letter requesting for withdrawal of study protocol from the FEU-NRMF IERC. All requests for withdrawal will be reported during full board meetings regardless of initial review classification. Since the study protocol has not yet been implemented, it will be archived as stipulated in **SOP 4 – 8: ARCHIVED (EXEMPTED/INACTIVE/ COMPLETED/ TERMINATED) FILE.**

Step 4 - Committee deliberation on full board action on the protocol: The members deliberate on full board action on the protocol as described in SOP 2 – 9: CONDUCT OF FULL BOARD MEETING.

Step 5: Protocol Review Decision Notification: After full board review, the Secretariat and the Member Secretary prepare the protocol review decision – related documents, and the Chair signs and endorses the same to the Secretariat. The Secretariat notifies the PI of the protocol review decision within **seven (7) calendar days** after the full board meeting, noting the following:

- **Approval:** Send notification of decision to PI
- **Minor modification**: send notification with recommendations to PI; process resubmission by expedited review
- **Major modification**: Send notification with recommendations to PI; process resubmission by full board review
- **Disapproval:** Send notification of decision to PI with justification

Notification may be accomplished via hand-carried mail, courier service, or e-mail.

7. Expedited Review

7.1. Policy Statement

An expedited review shall be conducted for study protocols that (1) do not entail more than minimal risk to the study participants, and (2) do not have study participants belonging to a vulnerable group, and (3) the study procedures do not generate vulnerability. The results of the initial review shall be released to principal investigator within two weeks after the submission of all the required documents. The communication document shall include clear instructions/recommendations for guidance of the researcher, must be written on an official stationery of the REC and signed by the chair. The study protocol that underwent expedited review and approved shall be reported in the subsequent regular committee meeting.

7.2. Workflow

ACTIVITY	RESPONSIBILITY
Step 1. Study Protocol Review	Primary Reviewers
Step 2. Protocol decision notification	Secretariat, Member Secretary, Chair

7.3. Detailed Instructions

Step 1 - Study Protocol Review: Primary reviewers accomplish the **FEU-NRMF IERC FORM 2(C) 2022: STUDY PROTOCOL ASSESSMENT FORM** and **FEU-NRMF IERC FORM 2(D) 2022: INFORMED CONSENT ASSESSMENT FORM** completely and comprehensively, and check for completeness of the documentation and information about the PI/s, study sites, and other documents as required by the study protocol under review such those listed in **SOP 2- 4 Step 1**: **RECEIPT AND MANAGEMENT OF STUDY PROTOCOL SUBMISSIONS** applicable to the study. The Primary reviewers review the study protocol and informed c**ons**ent documents in accordance with the assessment points and elements detailed in **FEU-NRMF IERC FORM 2(C) 2022: STUDY PROTOCOL ASSESSMENT FORM** and **FEU-NRMF IERC FORM 2(D) 2022: INFORMED CONSENT ASSESSMENT FORM.** The primary reviewers accomplish the aforementioned forms, and returns them to the Secretariat within **seven (7)** calendar days from receipt of package.

In addition to the review elements described above, the primary reviewers should ensure study protocol compliance with the ***National Ethical Guidelines for Health and Health-Related Research 2017*** on:

- Use of biological materials
- Appropriate contracts or memoranda of understanding especially in collaborative studies
- Community involvement and impact/benefit of the study to community and/or the institution are examined and if relevant, noting the following if applicable: community consultation, involvement of local researchers and institutions in the study protocol design, analysis and publication of the results, contribution to development of local capacity for research and treatment, benefit to local communities, availability of study results, and benefit sharing.

The primary reviewers signify their decision by marking the appropriate section of the aforementioned forms and affixing their signature in the space provided. Decision points are: **APPROVAL, MINOR MODIFICATIONS, MAJOR MODIFICATIONS, and OR DISAPPROVAL.** The criteria for Major and Minor Modifications are as follows:

- Major Modification – there are substantive changes to the informed consent document; or inadequacy of scientific basis for the study and scientific design and therapy changes
- Minor modification - do not involve significant changes to:
    - scientific design and therapy (minor scientific changes; eg. changes in targeted sample size, accrual objectives, minor changes to inclusion/exclusion criteria)
    - content of informed consent document (typographical errors, formatting)

Expedited study protocols that are disapproved by any primary reviewer are referred for full board review.

For decisions on resubmissions and post approval submissions, the committee may request information or clarificatory interview from the PI, as the need arises. In the event that a PI decides not to continue the application for ethics review, the PI must write a letter requesting for withdrawal of study protocol from the FEU-NRMF IERC. All requests for withdrawal will be reported during full board meetings regardless of initial review classification. Since the study protocol has not yet been implemented, it will be archived as stipulated in **SOP 4 – 8: ARCHIVED (EXEMPTED/INACTIVE/ COMPLETED/ TERMINATED) FILE.**

Step 2 - Protocol Review Decision Notification: After expedited review, the Secretariat and the Member Secretary prepare the protocol review decision – related documents (see SOP 4 – 4.4.2), and the Chair signs and endorses the same to the Secretariat, noting the following:

- **If approved:** Send notification to PI
- **If major or minor modification**: Send notification with recommendations to PI then process resubmission by expedited review
- **If disapproved**: Send to full board review and process accordingly

The Secretariat notifies the PI of the protocol review decision within **three (3) calendar days** after receipt of decision by the Primary Reviewers. Notification may be accomplished via hand-carried mail, courier service, or e-mail. Outgoing communications are recorded in the **OUTGOING COMMUNICATIONS LOG [FEU-NRMF IERC FORM 4(M) 2022**.

8. Preparation for IERC Meeting

8.1. Policy Statement

The FEU-NRMF IERC shall have a regular schedule of meetings every last Friday of the month. All meetings shall ideally be held within the premises of the institution. However, in certain circumstances, meetings may be conducted through a secure video conferencing platform provided by the institution**.**

8.2. Workflow

ACTIVITY	RESPONSIBILITY
Step 1. Setting regular meeting schedule	Chair, Secretary, Members, Secretariat
Step 2. Preparing the Meeting Agenda	Secretary, Secretariat
Step 3. Distribution of Meeting Agenda and Minutes of the previous meeting	Secretariat
Step 4. Preparation of Meeting Materials	Secretariat

8.3. Detailed Instructions

Step 1 - Setting regular meeting schedule: The IERC sets its regular **monthly** meeting during the **last Friday of the month** to facilitate preparations and regular attendance of Members. In case the IERC cannot meet during the last Friday of the month due to work or class suspensions, inclement weather, holidays, conflict of schedule among members, anticipated lack of quorum, and other unforeseeable reasons, the Secretariat ensures that another more appropriate meeting date is set through proper coordination and notification with the Members with due acknowledgement. The Secretariat confirms venue reservation for the scheduled meeting date and time **one (1) week** before the meeting. The Secretariat ensures that the venue, equipment, and facilities are made available and in good working condition prior to the meeting day to allow ample time for equipment replacement or purchase of necessary supplies.

Meetings may be conducted through a secure video conferencing platform provided by the institution under the following circumstances: inclement weather, government regulations and institutional memoranda that preclude physical meetings, disasters, and exigent situations. Attention must be given to ensure privacy and confidentiality. Meetings may also be held in a hybrid format, with some members present physically, and others present via video conference.

Step 2 - Preparing the Meeting Agenda: The Secretariat, under the supervision of the Member Secretary prepares the draft agenda two (2) weeks before the scheduled meeting, using **FEU-NRMF IERC FORM 2(G) 2022: MEETING AGENDA**. The agenda includes the following:

- Call to order
- Determination of quorum and presence of non-institutional members
- Disclosure of Conflict of interest
- Reading and approval of the Minutes of the last meeting
- Business arising from the Minutes of the last meeting
- Protocol review
    - FULL REVIEW
        - Study Protocols for Initial Review and Clarificatory Interview
        - Resubmissions or Study Protocols for Modification and Clarificatory Interview
        - Withdrawal of Study Protocol Applications
        - Study Protocol Amendment Applications
        - Progress Reports
        - Continuing Review Applications
        - Final Reports
        - Study Protocol Non-Compliance (Deviation or Violation) Reports
        - Early Study Termination Application
        - Queries or Complaints
        - Onsite SAE and SUSAR Reports
        - Quarterly Offsite SAE and SUSAR Reports
        - Site Visit Reports:

- REPORT OF PROTOCOL SUBMISSIONS FOR EXPEDITED REVIEW AND FULL BOARD PROTOCOLS WITH MODIFICATION EXPEDITED AT THE LEVEL OF THE CHAIR
- REPORT OF PROTOCOL SUBMISSIONS CLASSIFIED AS EXEMPTED FROM ETHICS REVIEW

- Other Matters

Step 3 - Distribution of the Meeting Agenda and Minutes of the Previous Meeting: The Secretariat distributes the **FEU-NRMF IERC FORM 2(G) 2022: MEETING AGENDA** together with the related study protocols or study protocol synopses to meeting attendees (members, invited PIs, independent consultants, and others) and minutes of the previous meeting at least **five (5) days** before the meeting through email and messenger or courier service. Members should confirm their attendance within **three (3)** days before the meeting. The Secretariat sends meeting reminders to all persons who will be in attendance, through mobile phone, email, or regular telephone the day before the meeting. Non-members who will be attending only specific portions of the meeting should be informed accordingly, as specified in their formal invitation to attend the meeting.

Step 4 - Preparation of Meeting Materials (members' meeting folders, study protocols, and study protocol-related submissions scheduled for review): The Secretariat makes copies of the approved Minutes **[FEU-NRMF IERC FORM 4(A) 2022: FORMAT OF THE MINUTES OF THE MEETING]** of the previous meeting, for all members attending the meeting. For details regarding preparation of the Minutes refer to **SOP 4 – 4: MINUTES OF THE MEETING.** The Secretariat provides copies of the agenda and minutes of the meeting at least 5 days before the meeting. The Secretariat distributes the folders containing meeting materials such as agenda and minutes at the start of the meeting. The folders are collected afterwards. The Committee Members must bring all meeting-related materials sent to them during the actual meeting to serve as their reference during the review.

9. Conduct of Full Board Meeting

9.1. Policy Statement

Meetings shall be presided by the chair or designated substitute, shall proceed only when quorum is declared, and shall be guided by the approved agenda. The presence of a conflict of interest among the members shall be disclosed prior to the discussion of protocols for review. The FEU-NRMF IERC IERC shall communicate its decisions to the researcher within 1 week after the full board meeting. The communication document shall include clear instructions/recommendations for guidance of the researcher, must be written on an official stationery of the FEU-NRMF IERC and signed by the Chair.

9.2. Workflow

ACTIVITY	RESPONSIBILITY
Step 1. Determine quorum	Secretariat
Step 2. Call the meeting to order and completion of required	Chair, Secretary

procedures prior to meeting proper	
Step 3. Approval of Agenda	Chair, Members
Step 4. Declaration of conflict of interest	Chair, Secretary, Members
Step 5. Reading and approval of the minutes of the previous meeting	Chair, Members
Step 6. Discussion of initial study protocol submissions and resubmissions	Chair, Members, Primary Reviewers
Step 7. Conduct clarificatory interview (only when necessary)	Chair, Members
Step 8. Review post-approval submissions	Chair, Members
Step 9. Report of results of expedited review	Chair, Members
Step 10. Report of study protocols exempted from ethics review	Chair
Step 11. Adjournment of the meeting	Chair
Step 12. Collection and storage or disposal of meeting materials	Secretary, Secretariat
Step 13. Protocol Review Decision Notification	Chair, Secretary, Secretariat

9.3. Detailed Instructions

Step 1 - Determination of quorum: Quorum is defined as:

- Presence of at least five (5) members if the committee consists of five to nine members
- Presence of 50% + 1 of the number of members If the committee consists of at least ten (10) members
- Presence of scientist member(s) with expertise on the study protocols being reviewed
- At least one (1) non-scientist member
- At least one (1) member independent of the institution (who can be represented by the non-scientific member as the case may be)
- Representation of both female and male members
- Representation of varied age groups

In studies involving children, a pediatrician or child development expert should be present. In case of anticipated lack of quorum, an administrative meeting will be held instead of the Protocol Review. On the appointed meeting time, the Member Secretary determines quorum viability and informs the Chair to indicate readiness to call the meeting to order. Members may be present physically or through a secure online video conferencing platform provided by the institution, ensuring privacy and confidentiality.

Step 2 - Calling the meeting to order and completion of required procedures prior to review proper: The Chair, or the Vice-Chair in the Chair's absence, calls the meeting to order upon confirmation of quorum by the Secretary. The IERC also allows, at the discretion of the Chair, guests (such as auditors or surveyors) or observers (such as students or trainees) to observe FEU-NRMF IERC meetings. Non-members (who are not PIs) attending any FEU-NRMF IERC Committee Meeting are required to sign a **CONFIDENTIALITY AGREEMENTFOR GUESTS/OBSERVERS [FEU-NRMF IERC FORM 2(I): 222]**. The Secretary documents the proceedings of the meeting, as soon as the meeting is called to order by the Chair, noting the time. The Secretary documents the development of the agenda, specifically all board

opinions and action with respective reasons, for inclusion in the meeting minutes, and subsequent communication with the principal investigator. For details regarding preparation of the **Minutes of the Meeting,** refer to **SOP 4 – 4: MINUTES OF THE MEETING.** The Chair calls upon the Secretary to formally confirm quorum by citing the attendance requirements.

Step 3 - Approval of the Meeting Agenda: The Secretary presents the Meeting Agenda, the Chair asks if any member has an item that they would like to be added and decides if to be added to the agenda or can be added to the next meeting's agenda. Any member can declare a motion for approval, which any member can second. The Chair then declares **approval of the Meeting Agenda.**

Step 4 – Declaration of Conflict of Interest: The Chair calls for declaration of Conflict of Interest (COI) in respect of any study protocol or submission scheduled for review. Members declaring COI are documented by the Secretary. The Chair instructs the members who declared COI to recuse themselves from the deliberation of the respective study protocol for which the COI declaration was made**.** The Member with COI should step out of the room during deliberation. If the Member with COI is present via video conferencing platform, or if the meeting is conducted via video conferencing platform, the member with COI must leave the meeting during deliberation. Clarificatory interview may be done on the Member if he/she is the PI, but again, should step out of the room again during deliberations. They **are not** allowed to take part in the consensus or voting.

Step 5 – Reading and Approval of the Minutes of the Previous Meeting: The Chair presides over the review of the Minutes of the previous meeting. Any member can declare a motion for approval, which any member can second. The Chair then declares approval of the Minutes of the previous meeting. The Chair proceeds to facilitate discussion of matters arising from the minutes, the results of which are noted by the Secretary for inclusion in the Minutes of the current meeting.

Step 6 - Discussion of initial study protocol submissions and resubmissions: Full board review of study protocol and study protocol-related submissions typically includes review of the following in sequence:

- Initial Study Protocol Submissions
- Resubmission or Study Protocols for Modification
- Clarificatory Interview
- Withdrawal of Study Protocol Applications
- Study Protocol Amendment Applications
- Progress Reports
- Continuing Review Applications
- Final Reports
- Serious Adverse Event Reports
- Site Visit Reports
- Study Protocol Noncompliance (Deviation or Violation) Reports
- Early Study Termination Applications
- Queries from Various Stakeholders

The Chair may allow some modifications of the sequence of review in exigent circumstances. For example, if a clarificatory interview is included in the agenda, the committee may opt to move this up in the review sequence. The Chair instructs the member who had previously declared conflict of interest (COI) to recuse himself/herself from ensuing study protocol deliberation just before the respective study protocol is presented for deliberation. Such members must step out of the room during deliberations but may be asked to, in a clarificatory interview if he/she is the PI, assist in the board in arriving at a board action, but should step out again during deliberation and when the board makes a decision. If the Member with COI is present via video conferencing platform, or if the meeting is conducted via video conferencing platform, the member with COI must leave the meeting during deliberation.

For initial review, the Chair calls the primary reviewers to present findings on respective study protocols based on study protocol assessment points specified in **FEU-NRMF IERC FORM 2(C) 2022: STUDY PROTOCOL ASSESSMENT FORM** and elements detailed in **FEU-NRMF IERC FORM 2(D) 2022: INFORMED CONSENT ASSESSMENT FORM.** The scientific primary reviewer is instructed to focus presentation of findings on scientific soundness and its impact on human subject protection, while the non-scientific primary reviewer is instructed to focus presentation of findings on the informed consent process and informed consent form (ICF) and its compliance with the requirements of international and national ethical guidelines, as well as national and institutional policies. The Members deliberate on the study assessment points and informed consent elements as detailed in the aforementioned forms.

For review of resubmissions, the Chair calls the Primary Reviewers to present findings on the response of the PI to the previous recommendations of the committee summarized in **FEU-NRMF IERC FORM 2(H) 2022: REVIEW OF RESUBMITTED STUDY PROTOCOL.**

In case of unavailability of the Primary Reviewers to attend the meeting, said members are required to forward the completed assessment forms to the Secretariat three **(3)** days before the meeting. The findings summarized therein will be presented by the Chair or his designee when the study protocol is deliberated on.

Prior to making a board decision, the Chair calls upon the Members to state their risk assessment of the protocol being discussed, and the Secretary notes the number of members who made their decisions per risk assessment level. The reviewer looks into the risks to research subjects posed by participation, conditions that make a situation dangerous, including inherent risks of known procedures, and if these are justified by the anticipated benefits to the subjects or society.

In assessing risk against the benefit:

- determine whether the risks are reasonable in relation to anticipated benefits; and/or if the risks can be minimized
- Participants are selected equitably especially if randomization is not to be used. Participant's information sheets should be clear and adequate

- There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data, where appropriate
- There are appropriate safeguards included to protect vulnerable participants
- There is clear justification for the use of biologic materials

The risk assessment levels are defined as:

- **Minimal –** the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during routine physical and psychological examinations or tests (ex. ECG, DEXA Scan, anthropometrics)
- **Low –** involves minor increase over minimal risk; risks commensurate with those inherent in actual or expected physiological, psychological, social or educational situations; healthy volunteers performing low-risk research procedures (ex. IV infusion or euglycemic clamp); minimal risk studies that involve special populations (ex. mentally handicapped); studies that involve sensitive information; post-marketing studies (phase IV drug/device studies as defined by FDA)
- **Moderate** – risks are greater than low risk, but their surveillance and protection are adequate to identify adverse events promptly and keep their effects minimal (i.e. risks can be controlled); reasonable risks in relation to anticipated benefits to research participants and the importance of the knowledge that may reasonably be expected to result from the study; benefits are greater than the risks
- **High –** involves greater-than-low risk without prospect of direct benefit to research participants, but the study is likely to yield generalizable knowledge about the disorder or condition studied; in situations where the prospect of direct benefit to study participant exists, the risks associated with study procedures are considered substantial

If the protocol is more than minimal risk, reviewers must look for justification based on literature review and rationale. If justified, the reviewers must look for safeguards against the risks.

The Member Secretary summarizes the discussion prior to decision making. For decision on both initial study protocol submission and resubmission, the Chair calls for a consensus for any of the following actions:

- Approval
- Minor Modification, which can be resolved at the level of the Chair
- Major Modification, which require full board deliberation
- Disapproval

If a consensus cannot be reached, board action is settled by a vote, with the Secretary noting the number of votes per action. A decision is arrived at based on a simple majority.

If in case one primary reviewer is absent and has not submitted his/her review, discussion of the study protocol may still proceed at the discretion of the Chair. If the Chair assesses that the present Committee

composition does not have the expertise to proceed with the review, the discussion of the study protocol may be deferred until the next meeting. Also, the Committee may request comments or clarificatory interview from the PI.

The IERC allows investigators and other resource persons (such as an Independent Consultant commissioned by the IERC or the technical reviewer who endorsed the study protocol) of highly specialized areas to attend the part of the Committee meeting related to specific studies for purposes of clarifying issues related to the study protocol only (and not to present the study protocol to the board). For example, an engineer may be needed to explain the mechanics of a new medical device that is being proposed for a study.

Step 7 - Conduct of Clarificatory Interview: The Committee conducts, if any, clarificatory interviews with PIs and/or study team members whose submissions raise ethical issues that are better addressed by the PI himself/herself. The Secretariat sends **FEU-NRMF IERC FORM 4(D 2022): LETTER FOR CLARIFICATORY INTERVIEW** to PIs called for interview**.** PIs may also request a clarificatory interview with the Committee by formally expressing their intention in writing. PI's or study team members to be interviewed by the Committee must sign **FEU-NRMF IERC FORM 2(I) 2022: CONFIDENTIALITY AGREEMENT FOR GUESTS/OBSERVERS** prior to the interview. They are allowed inside the meeting room only during the actual interview, after which they will be requested to leave. Clarificatory interviews may be conducted in person or through the secure video conferencing platform provided by the institution. The Chair calls for action depending on the type of submission (**See SOP 2 – 6 and SOP 2 - 7)**. Decisions are based on the Committees assessment of the PI's response to their queries.

Step 8 - Discussion of post-approval submissions: For a detailed instruction on the conduct of review of post approval submissions during the Full Board Meeting, see **SOP 3: POST APPROVAL REVIEW**

Step 9 - Review of results of Expedited Review: The Chair reports all the study protocols and study protocol-related submissions that were processed under expedited review. The submissions are reported in the same sequence as full board review with similar corresponding actions (see **SOP 2 - 6**). In the event that there is no scheduled meeting, the Secretariat will notify all members regarding the results of expedited review through email/courier for information or comments.

Step 10 - Report of study protocols exempted from ethics review: The Chair reports, if any, all the study protocols classified as exempted from ethics review.

Step 11 - Adjournment of the meeting: Before closing the meeting, the Chair calls for any non-study protocol matters that need attention or action, as the need arises. With no further matters for discussion, the Chair formally adjourns the meeting, with the time noted by the Secretary who is documenting the meeting.

Step 12 - Collection and storage or disposal of meeting materials: The Secretary collects all meeting materials, including the documentation collected for the Minutes of the meeting; mindful that these

materials are confidential and must be handled in accordance with **SOP 4 – 9: MAINTENANCE OF CONFIDENTIALITY OF STUDY FILES AND IERC DOCUMENTS**. The Secretary files all meeting materials that must be stored in the relevant study files in a manner prescribed by instruction found in **SOP 4 – 7: ACTIVE FILES** and **SOP 4 – 8 ARCHIVED (INACTIVE/ COMPLETED/TERMINATED) FILES.**

Step 13 - Protocol Review Decision Notification: After full board review, the Secretariat and the Member Secretary prepare the protocol review decision – related documents (see SOP 4 – 4.4.2), and the Chair signs and endorses the same to the Secretariat. The Secretariat notifies the PI of the protocol review decision within **seven (7) calendar days** after the full board meeting. Notification may be accomplished via hand-carried mail, courier service, or e-mail. Outgoing communications are recorded in the **OUTGOING COMMUNICATIONS LOG [FEU-NRMF IERC FORM 4(M) 2022**.

10. Special Meetings

10.1. Policy Statement

The FEU-NRMF shall hold special meetings to resolve issues that require immediate attention, e.g. safety of participants, protocol violation that impact research integrity. All meetings shall ideally be held within the premises of the institution. Meetings may be conducted through a secure video conferencing platform provided by the institution under the following circumstances: inclement weather, government regulations and institutional memoranda that preclude physical meetings, disasters, and exigent situation. Attention must be given to ensure privacy and confidentiality.

10.2. Workflow

ACTIVITY	RESPONSIBILITY
Step 1. Preparation for conduct of special meeting	Secretary, Secretariat
Step 2. Conduct of special meeting	Chair/Members
Step 3. Collection and storage or disposal of meeting materials	Secretary, Secretariat

10.3. Detailed Instructions

Step 1 - Preparation for Conduct of Special Meeting: A special meeting may be called by the Chair or is proposed by a member of the FEU-NRMF IERC or the Chair of the RCD. The Secretariat informs the FEU-NRMF IERC members, including the invited persons, about the special meeting. The decision to call a special meeting is based on the following criteria:

- Urgent issues (if delay will affect or have impact on the public benefit, national economy, etc.)
- Occurrence of unexpected serious adverse events
- Other similar situations

Step 2 - Conduct of Special Meeting: Quorum is defined as:

- Presence of at least five (5) members if the committee consists of five to nine members
- Presence of 50% + 1 of the number of members If the committee consists of at least ten (10) members
- At least one scientist member
- A non-scientist member
- At least one non-institutional member
- Representation of both female and male members
- Representation of varied age groups
- A member/or invited guest with expertise on the item to be discussed

Meetings may be conducted through a secure video conferencing platform provided by the institution under the following circumstances: inclement weather, government regulations and institutional memoranda that preclude physical meetings, disasters, and exigent situations. Attention must be given to ensure privacy and confidentiality. Meetings may also be held in a hybrid format, with some members present physically, and others present via video conference. The meeting is conducted in the same sequence as full board review with similar corresponding actions.

Step 3 - Collection and storage or disposal of meeting materials: The Secretary, aided by the Secretariat, collects all meeting materials, including the documentation collected for the Minutes of the meeting; mindful that these materials are confidential and must be handled in accordance with **SOP 4 - 9: MAINTENANCE OF CONFIDENTIALITY OF STUDY FILES AND IERC DOCUMENTS**. The Secretary files all meeting materials that must be stored in the relevant study files in a manner prescribed by instruction found in **SOP 4 - 7: ACTIVE FILES** and **SOP 4 - 8: ARCHIVED (INACTIVE/ COMPLETED/ TERMINATED) FILES.**

11. Single Joint Research Ethics Board (SJREB) Workflow for Initial Review

11.1. Policy Statement

The Single Joint Research Ethics Board (SJREB) conducts the institutional joint ethics review process in the Department of Health (DOH) (see **APPENDIX A: SINGLE JOINT RESEARCH ETHICS BOARD – STANDARD OPERATING PROCEDURES ver. 1**). It is a joint review mechanism among Philippine Health Research Ethics Board (PHREB) duly accredited Research Ethics Committees (RECs) of DOH hospitals and may include other non-DOH RECs from both public and private organizations that will accept the results of SJREB.

11.2. Workflow

ACTIVITY	RESPONSIBILITY
1. Receive study protocols qualified for SJREB review	Secretariat
2. Receive request from SJREB for reviewers	Secretariat

3. Coordinate with SJREB Secretariat Staff regarding reviewers and UPMREB representative	Secretariat
4. Notify primary reviewer for review and request to attend SJREB meeting	FEU-NRMF IERC Chair, Secretariat
5. Accept or decline invitation for SJREB review	FEU-NRMF IERC Chair, FEU-NRMF IERC Members or Independent Consultants
6. Obtain minutes of the meeting and decision letter from SJREB	Secretariat
7. Conduct of study protocol review	FEU-NRMF IERC Members or Independent Consultants
8. Notify Principal Investigator of the decision	Secretariat

11.3. Detailed instructions

Step 1 - Receive study protocols qualified for SJREB review: Multi-site protocols involving at least three (3) sites in the Philippines with at least one (1) DOH hospital are endorsed for single joint review. FEU-NRMF IERC receives an invitation from SJREB to participate in the review of a specific protocol and submits the letter of intent signed by the FEU-NRMF IERC Chair to the SJREB Secretariat. Study protocols qualified for SJREB is processed by FEU-NRMF IERC through expedited review.

Step 2 - Receive request from SJREB for reviewers: SJREB may request primary reviewers for study protocols included for SJREB review. These requests are coursed through the Secretariat. SJREB may request for primary reviewers that are not yet members of FEU-NRMF IERC. For study protocols for initial review, the requested reviewers are invited as independent consultants. Meanwhile, non-members who are requested as additional reviewers to a previously reviewed study protocol by FEU-NRMF IERC are invited as an SJREB Independent Consultant.

Step 3 - Coordinate with SJREB Secretariat Staff regarding reviewers and FEU-NRMF IERC representative: The Secretariat coordinates with the SJREB Secretariat regarding the request for reviewers and representatives. Study protocols may be assigned to an independent consultant if there are no available experts among the regular members. In these cases, the FEU-NRMF IERC Chair serves as the primary scientific reviewer.

Step 4 - Notify primary reviewer for review and request to attend SJREB meeting: The Chair assigns primary reviewers to the study. The Secretariat notifies the assigned reviewers and forwards the complete FEU-NRMF IERC and SJREB package. The Secretariat invites the reviewer to attend the SJREB full board meeting.

Step 5 - Accept or decline invitation for SJREB review: The primary reviewer accepts or declines request for review through the Secretariat. In the event that the reviewer agrees to review but cannot attend the meeting, the FEU-NRMF IERC Chair assigns a representative to present the reviewer's assessment during the SJREB meeting.

Step 6 - Obtain SJREB minutes of the meeting: The Secretariat will obtain the decision letter and minutes of the meeting from SJREB to be filed in the protocol folder. The Secretariat will send the excerpt of the SJREB minutes of the meeting to the reviewer who failed to attend the discussion of a particular protocol.

Step 7 - Conduct of study protocol review: The Secretariat notifies the Primary Reviewers for protocol assignments within **three (3) calendar days** from receipt of protocol submission. The Primary reviewer acknowledges receipt of study protocol package for review and agrees to review within the time frame. Otherwise, the protocol will be re-assigned to another primary reviewer if there is no response within three days. The primary reviewers review the study protocol and informed consent documents in accordance with the assessment points and elements detailed in **FEU-NRMF IERC FORM 2(C)2022: STUDY PROTOCOL ASSESSMENT FORM** and **FEU-NRMF IERC FORM 2(D)2022: INFORMED CONSENT ASSESSMENT FORM.** Primary reviewers will review site-specific issues while SJREB is ongoing. FEU-NRMF IERC accepts the decisions made by SJREB. The primary reviewer consolidates SJREB and site-specific recommendations, accomplishes the aforementioned forms, completely signed and dated, forwards the electronic form through e-mail, or returns the signed paper-based review to the Secretariat within **seven (7)** calendar days from receipt of package.

Step 8 - Notify Principal Investigator of the decision regarding protocol submission: Upon SJREB approval of the protocol submission, FEU-NRMF IERC Secretariat receives endorsement of approval from SJREB. FEU-NRMF IERC Secretariat informs PI to submit the revised documents and address any site-specific concerns raised by FEU-NRMF IERC. Upon favorable recommendation, FEU-NRMF IERC issues **FEU-NRMF IERC FORM 2(L) 2022: APPROVAL LETTER TO STUDY PROTOCOL** of the site-specific documents and cites the documents SJREB has approved. Outgoing communications are recorded in the **OUTGOING COMMUNICATIONS LOG [FEU-NRMF IERC FORM 4(M) 2022**.

12. Management of Appeals

12.1. Policy Statement

The FEU-NRMF IERC shall consider the perspective of the researcher regarding the feasibility and acceptability of REC recommendations including its disapproval. Appeals of researchers shall undergo full review and shall be resolved within six weeks (24 working days) upon receipt of the fully documented appeal. Management of appeals ensures fairness, transparency and comprehensiveness of ethics review that takes into consideration the perspective of the researcher.

12.2. Workflow

ACTIVITY	RESPONSIBILITY
Step 1. Receipt of an appeal	Secretariat
Step 2. Retrieval of pertinent protocol file	Secretariat

Step 3. Notification of Chair and Primary Reviewer/s	Secretariat
Step 4. Inclusion in Agenda of the next regular meeting	Chair and Primary Reviewer
Step 5. Discussion of and deliberation on the appeal	Chair and FEU-NRMF IERC Members
Step 6. Communication of committee action	Chair, Secretariat

12.3. Detailed Instructions

Step 1 - Receipt of an Appeal: The Secretariat receives the letter of appeal and enters the pertinent information into the **FORM 4(L) 2022: SUBMISSIONS LOG.**

Step 2 - Retrieval of pertinent protocol file: The Secretariat retrieves the pertinent file for reference in the review. The file includes the initially submitted protocol, ICF, research tools and other related documents.

Step 3 - Notification of Chair and Primary reviewers: The Secretariat notifies the Chair and the primary reviewers about the letter of appeal and awaits further instructions.

Step 4 - Inclusion in the Agenda of the next regular meeting: The Chair instructs the Secretariat to include the appeal in the agenda of the next meeting, to ensure that the retrieved protocol and related documents are available during the meeting and to inform the researcher to be available on the scheduled meeting in case there is a need for further clarification.

Step 5 - Discussion of and Deliberation on the Appeal: The Primary reviewer summarizes the protocol and the previous discussion of the issues in the protocol as background to the appeal. The Chair presents the contents of the appeal and leads discussion. The researcher may be called in for further clarification of issues. The researcher is asked to step out after the committee has taken up the issues for clarification. The committee then decides (by consensus) whether to accept any or all of the points raised in the appeal.

Step 6 - Communication of Committee Action: Based on the deliberations, the Chair summarizes the decision points and instructs the Secretariat to prepare the draft decision letter using **FEU-NRMF IERC FORM 2(Q): DECISION LETTER ON APPEAL** for his/her finalization and forwarding to the researcher within a week after the full board meeting. Outgoing communications are recorded in the **OUTGOING COMMUNICATIONS LOG [FEU-NRMF IERC FORM 4(M) 2022**.

References:

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3. CIOMS-WHO International Ethical Guidelines for Biomedical Research Involving Human Subjects (2016)
4. Declaration of Helsinki, World Medical Association (2013)

5. ICH Harmonized Guideline – Integrated Addendum to ICH E6 (R1) Guideline for Good Clinical Practice E6 (R2) Current Step 4 version (2016)
6. National Ethical Guidelines for Health Research. Philippine National Health Research System (2017)
7. Philippine Health Research Ethics Board - A Workbook for Developing Standard Operating Procedures - "The SOP Workbook" (2020)
8. Standard Operating Procedures 2: Initial Review Procedures. Makati Medical Center Institutional Review Board (2014)
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10. University College London – Research Ethics Committee – Exemptions (2000) – retrieved from https://ethics.grad.ucl.ac.uk/exemptions.php
11. WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011