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RESEARCH MANUAL

The FEU-NRMF RESEARCH MANUAL
Third Edition – 2022

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Research Center for Development
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This manual is a general reference on various guidelines and proceduresin the conduct of research and research related activities in FEU-NRMF Institute of Medicine and FEU-NRMF Medical Center, West Fairview, Quezon City

For specific information about topics contained in this Manual, direct queries to the Publisher.

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Abbreviations/Acronyms

ACU Animal Care Unit

ACUP Animal Care and Use Program
ADR Adverse Drug Reaction
APA American Psychological Association
AVPAA Associate Vice President for Academic Affairs BMJ British Medical Journal
CONSORT Consolidated Standards of Reporting Trials / Conversational System with On-Line Remote Terminals
FEU-NRMF Far Eastern University-Nicanor Reyes Medical Foundation IACUC Institutional Animal Care and Use Committee ICH International Conference on Harmonisation
ICH GCP International Conference on Harmonisation – Good Clinical Pract
ICH GCP E6 International Conference on Harmonisation – Good Clinical Practice E6 D
ICMJE International Committee of Medical Journal Editors
IERC Institutional Ethics Review Committee
IMRAD Introduction, Methods, Results, and Discussion MRL Mycobacterium Research Laboratory
NLM National Library of Medicine
ORCID Open Researcher and Contributor Identification
PCHRD Philippine Council for Health Research and Development PHREB Philippine Health Research Ethics Board PI Principal Investigator
PRISMA Preferred Reporting Items for Systematic Reviews and Meta-Analy
RCD Research Center for Development
SAEs Serious Adverse Events
STARD Standards for Reporting of Diagnostic Accuracy
STROBE Strengthening the Reporting of Observational Studies in Epidemiol
SUSARs Suspected Unexpected Serious Adverse Reactions vi

1.0 RESEARCH CENTER FOR DEVELOPMENT

The Research Center for Development (RCD) is the overall center for all

research activities conducted at the FEU- Nicanor Reyes Medical Foundation. It is directly under the Office of the President through the Chief Operating Officer and the Vice President for Academic Affairs.

In compliance with the VISION and MISSION statements of the FEU-NRMF, the RCD is geared towards the pursuit and completion of relevant research activities that will uphold the health and health-related needs of Filipinos. To accomplish this mission, the RCD has set up goals and specific objectives.

1.1 GENERAL OBJECTIVES

1.1.1 Develop a strong research arm by providing an optimal atmosphere to carry out the process, provide research opportunities and possible funding.

1.1.2 Encourage the faculty, residents, students, and employees to do research projects through a system of recognition, rewards and incentives.

1.1.3 Formulate a continuing series of policies and guidelines in support of any research undertaking.

1.2 SPECIFIC OBJECTIVES

1.2.1 Maintain a dynamic research center (Research Center for Development) to be in charge of coordinating all research activities.

1.2.2 Establish linkages with other agencies to strengthen logistical support.

1.2.3 Identify exemplary research protocols and assist researchers in the technical preparations and requirements.

1.2.4 Establish a regular research fund and generate other sources of funding for research activities and projects.

1.2.5 Provide avenues for publications, presentations, and disseminations of research outputs, both locally and internationally.

1.2.6 Offer training courses, workshops, and programs to ensure continuity of quality research endeavors and activities.

2.7 Establish a coordinated system of database storage of all research outputs and data.

2.8 Continuously revise rules, regulations, and guidelines in research to suit the needs of the times.

1.3 ESSENTIAL PREREQUISITES FOR EFFECTIVE IMPLEMENTATION OF RESEARCH PROGRAMS

To ensure optimal performance, the following are essential prerequisites for the effective implementation of the research program in accordance with the general and specific objectives:

1.3.1 RESEARCH COMMITTEE COMMITMENT AND STATUS - Each member of the committee must be committed to actively participate in all research-related activities as may be envisioned by the committee. The committee must have an annual budget and should be given some degree of autonomy in the exercise of its functions.

1.3.2 STRONG ADMINISTRATIVE SUPPORT – The administration must be fully supportive of the activities of the committee to ensure effective implementation of its programs. It should assist the committee by providing the necessary logistical and moral support that may be needed.

1.3.3 FACULTY SUPPORT AND COMMITMENT – The full cooperation and commitment of the faculty members are very vital for the success of the various research programs since most of the supervision of the research projects particularly on content analysis shall be done by them.

1.3.4 RESIDENTS' AND STUDENTS' INTEREST AND COMMITMENT – Faculty and committee members must instill interest and commitment from residents and students with regard to their attitude towards research. They must serve as role models so the residents and students can develop interest in producing good quality research projects.

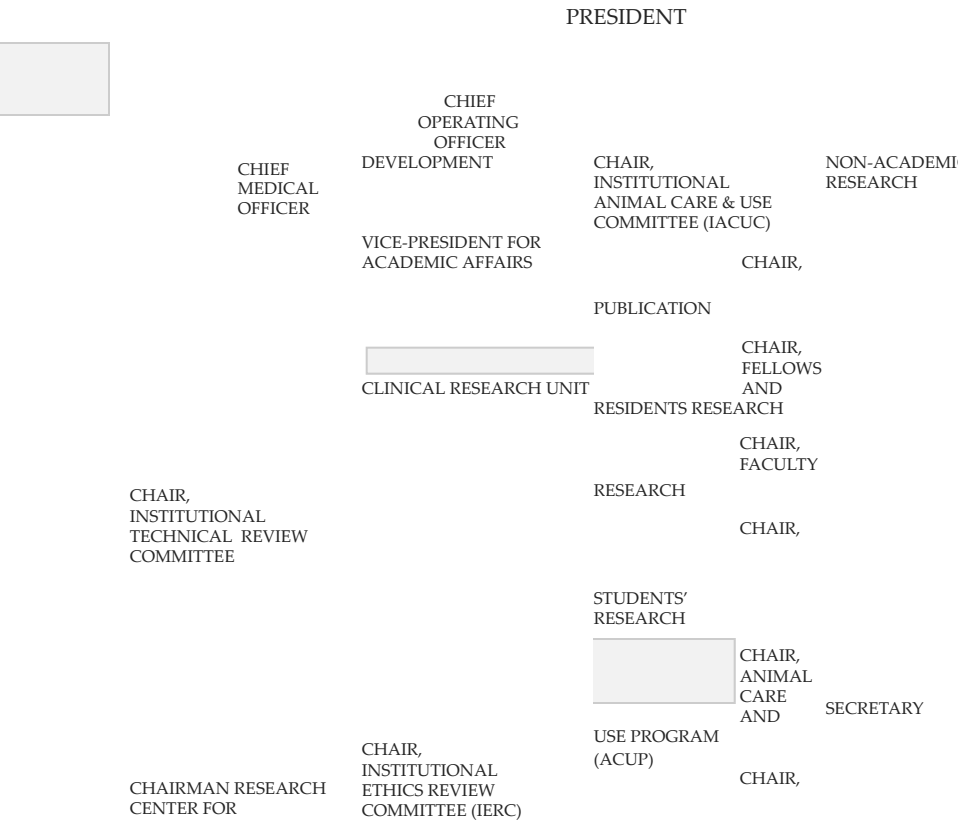
1.3.5 GOOD RESEARCH FACILITIES – There must be good research facilities

that will serve as venues for literature search as well as provide the researchers the necessary technical support especially on content analysis, choice of research methodology and statistical tests. There must also be a good and adequate source of materials and opportunities to conduct observational and clinical/experimental researches.

1.3.6 NETWORKING WITH OTHER DEPARTMENTS AND RESEARCH AGENCIES The entire research program can be better realized if good relations with the various research-oriented schools and universities as well as government and private research organizations such as the Department of Health, Philippine Council for Health Research and Development, etc. are in place.

1.4 ORGANIZATIONAL CHART

The organizational chart of the RCD is formulated to demonstrate the different levels of authority and coordination to ensure the smooth flow of the different functions of the various offices and committees involved in the operations of the RCD



2.0 RCD INSTITUTIONAL COMMITTEES

The RCD shall be composed of 3 institutional committees that shall serve specific independent functions that shall have jurisdiction over all researches to be done under the RCD.

2.1 INSTITUTIONAL ETHICS REVIEW COMMITTEE (IERC)
2.2 INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) 2.3 INSTITUTIONAL TECHNICAL REVIEW COMMITTEE (ITRC)

3.0 RCD STANDING COMMITTEES

The RCD shall be composed of various standing committees that shall have their specific functions and activities which are all geared towards achieving the various research programs and activities of the Center.

3.1 FACULTY RESEARCH COMMITTEE
3.2 FELLOWS AND RESIDENTS RESEARCH COMMITTEE
3.3 STUDENT RESEARCH COMMITTEE
3.4. CLINICAL RESEARCH UNIT COMMITTEE
3.5 NON-ACADEMIC RESEARCH COMMITTEE
3.6 ANIMAL CARE AND USE PROGRAM COMMITTEE
3.7 PUBLICATIONS COMMITTEE

4.0 COMPOSITION AND FUNCTIONS OF INSTITUTIONAL COMMITTEES

4.1 INSTITUTIONAL ETHICS REVIEW COMMITTEE (IERC)

The committee is directly responsible for evaluating all research proposals involving human subjects as to whether they are in compliance with the ethical standards in research.

4.1.1 **Composition**

The committee shall be composed of a chairman, and members, among which shall be included a lay member and a specialist/ scientist.

4.1.2 **Functions**

4.1.2.1 The FEU – NRMF Institutional Ethics Review Committee (IERC) addresses ethical issues in research involving human participants.

4.1.2.2 The committee reviews all research protocols by principal investigators (PI), including PI-Initiated (FEU – NRMF faculty, consultant, resident/fellow-in-training, student) studies and sponsor-initiated studies done in this institution prior to implementation. For PI initiated studies, a technical review approval from this institution is required prior to ethics review.

4.1.2.3 The FEU-NRMF IERC may also review studies where the research site is outside the scope of authority of FEU-NRMF and the PI is a non-FEU-NRMF personnel, provided that a technical review of the study has been accomplished in their institution and an official of the institution signifies capability to provide oversight in research site.

4.1.2.4 For purposes of organization, the FEU – NRMF IERC is a subcommittee of the RCD, which coordinates

researches from both the FEU – NRMF Medical Center and the FEU- NRMF Institute of Medicine. However, it must be emphasized that the committee's actions, including composition, procedures, and decision making, are independent of political, institutional, professional, and market influences, as embodied in the World Health Organization – Operational Guidelines for Ethics Committees that Review Biomedical Research (2011). It utilizes the World Medical Association (WMA) Declaration of Helsinki as its guiding principle in reviewing research protocols.

4.2 INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

The committee is directly responsible for evaluating research proposals involving the use of animals as to whether they are in compliance with the ethical standards in animal research.

4.2.1 **Composition**

4.2.1.1 The committee shall be composed of a chairman, a veterinarian, an external member and an institutional committee member or scientist.

4.2.2 **Functions**

4.2.2.1 Evaluates and approves the Animal Care and Use Program (ACUP) and the protocols of scientific procedures

4.2.2.2 Monitors and reviews the implementation of the ACUP and scientific procedures

4.2.2.3 Submits an annual report on the status and implementation of the ACUP

4.2.2.4 Provides necessary technical recommendations and guidelines/references (e.g., a list of recommended anesthetics, analgesics, and tranquilizers with dose ranges)

4.2.2.5 Revokes any approval on the basis of non-compliance to the approved program/protocol despite repeated appeals on its violations.

4.3 INSTITUTIONAL TECHNICAL REVIEW COMMITTEE

The committee is responsible for evaluating the technical soundness of all research proposals for the Faculty members and determine whether they are in compliance with generally accepted principles and methodology in conducting research.

4.3.1 **Composition**

4.3.1.1 The committee shall be composed of a chairman and regular members who are all proficient in the technical
evaluation of research proposals.

4.3.2 **Functions**

4.3.2.1 Provides overall support to the Committees on Student Research, Resident/Fellow Research and Faculty/ Consultant Research

4.3.2.2 Reviews Research Protocols submitted by the faculty members, consultants, and non-medical employees of FEU-NRMF

4.3.2.3 Provides technical support to all individuals making/ doing Research.

4.3.2.4 Provides trainings/seminars related to research activities.

5.0 COMPOSITION AND FUNCTIONS OF STANDING COMMITTEES

5.1 FACULTY RESEARCH COMMITTEE

This committee is responsible for all research development programs as well as researches done or published by the faculty from all schools in the FEU-NRMF

5.1.1 **Composition**

The committee shall be composed of a chairman as well as Faculty Research Representatives for Basic and Clinical departments of School of Medicine and representatives of the schools of Nursing, Physical Therapy, Medical Laboratory Science, Respiratory Therapy, RadiologicTechnology, Pharmacy, Nutrition and General Education.

5.1.2 **Functions**

5.1.2.1 Encourages all faculty to engage actively in creative output like research.

5.1.2.2 Organizes seminar-workshops for research capacity building for all faculty and consultants.

5.1.2.3 Coordinates and facilitates the process of awarding of research grants and protected time to deserving faculty and consultants with research proposal.

5.1.2.4 Coordinates and facilitates the process of granting publication research incentives to qualified faculty and consultants.

5.1.2.5 Monitors the conduct of faculty research activities.

5.1.2.6 Organizes the Annual Faculty Research Contest.

5.1.2.7 Attends the monthly meeting of RCD.

5.1.2.8 Attends meeting, seminar-workshop, convention organized by PCHRD, MMHRDC, DOH, CHED, DOST

5.2 FELLOWS AND RESIDENTS RESEARCH COMMITTEE

This committee is responsible for all research development programs as well as researches done or published by the Fellows and Residents of the various training programs under the FEU-NRMF Medical Center

5.2.1 **Composition**

5.2.1.1 This committee shall be composed of a chairman and

the research coordinators or representatives of the various training programs under the FEU-NRMF Medical Center

5.2.2 **Functions**

5.2.2.1 Guides and actively engaged in training residents of each department in research.

5.2.2.2 Widens research perspectives/topics by organizing seminars/workshops to improve research capability of the residents.

5.2.2.3 Provides avenues for quality research by organizing case/research contests bi-annually for publication in the FEU-NRM Medical Journal as well as in other local and international journals.

5.2.2.4 Ensures that all residents fulfill the research paper requirements of each specialty board.

5.3 STUDENTS RESEARCH COMMITTEE

This committee is responsible for all research development programs and researches done and published by the students of the different schools under the FEU-NRMF.

5.3.1 **Composition**

5.3.1.1 The committee is composed of a chairman and research coordinators or representatives from each of the different schools under the FEU-NRMF.

5.3.2. **Functions**

5.3.2.1 Coordinates and sends for ethics approval the research papers made by students, both in the medical and undergraduate studies.

5.3.2.2 Directs activities of the students holding their research colloquia via their respective committees.

5.3.2.3 Oversees the activities of the medical and undergraduate students during Institutional Research Day.

5.4 NON-ACADEMIC RESEARCH COMMITTEE

This committee is responsible for all research development programs and researches done and published by the non-academic or non

teaching personnel of FEU-NRMF

5.4.1 **Composition**

5.4.1.1 The committee is composed of a chairman and representatives from the various non-academic or non-teaching departments and sections under the FEU-NRMF.

5.4.2 **Functions**

5.4.2.1 Encourages non-teaching staff to actively engage in producing creative output like research.

5.4.2.2 Organizes seminar-workshop for research capacity building for all non-teaching staff.

5.4.2.3 Coordinates and facilitates the process of awarding of research grants and protected time from work load to deserving non-teaching staff with research proposals.

5.4.2.4 Coordinates and facilitates the process of granting publication research incentives to qualified non teaching staff

5.4.2.5 Monitors the conduct of non-teaching staff research activities.

5.4.2.6 To attends the monthly meeting of the Research Center for Development

5.4.2.7 Attends meetings, seminar-workshops, and conventions on research-related topics.

5.5 ANIMAL CARE AND USE PROGRAM COMMITTEE

This committee is responsible for the overall management of the animal care facility and its personnel.

5.5.1 **Composition**

8.5.2.1 The committee is composed of a chair, a veterinarian and all the animal care personnel of the animal facility.

5.5.2 **Functions**

5.5.2.1 Considers alternatives (in vitro systems, computer simulations, and/or mathematical models) to reduce or replace the use of animals.

5.5.2.2 Designs and performs procedures on the basis of relevance to human or animal health, advancement of knowledge, or the good of society.

5.5.2.3 Uses appropriate species, quality, and number of animals.

5.5.2.4 Avoids or minimizes discomfort, distress, and pain of animals.

5.5.2.5 Uses appropriate sedation, analgesia, and anesthesia.

5.5.2.6 Establishes humane endpoints.

5.5.2.7 Provides adequate veterinary care.

5.5.2.8 Provides appropriate animal transportation and husbandry directed and performed by qualified persons.

5.5.2.9 Conducts experimentation on living animals exclusively by and/or under the close supervision of qualified and experienced personnel.

5.6 PUBLICATIONS COMMITTEE

This committee shall be responsible for all matters regarding the selection of researches for publication in the FEU-NRMF Medical Journal as well as in other local and international journals.

5.6.1 **Composition**

5.6.1.1 The committee shall be composed of the Editor-in Chief, Associate Editor, Editorial Board coming from representatives of the various schools, departments, and sections under the FEU-NRMF, Editorial Consultants made up of the Deans of all Schools, the Chairman of RCD, and the Chief of Clinics of FEU-NRMF Medical Center, and a Circulation Manager.

5.6.2 **Functions**

5.6.2.1 Selects and screens all researches for publication in the FEU-NRMF Medical Journal.

5.6.2.2 Maintains a list of well-selected peer reviewers.

5.6.2.3 Ensures that all researches selected for publication are peer reviewed.

5.6.2.4 Ensures that all researches for publication have

undergone the anti-plagiarism (Turnitin) program.

5.6.2.5 Ensures that the FEU-NRMF Medical Journal is published regularly bi-annually.

5.6.2.6 Ensures that the FEU-NRMF Medical Journal gets the necessary accreditation from local and international accrediting bodies.

5.6.2.7 Screens and gives clearances to researches to be presented for publication in other journals, local or international, making sure that the authors carry the name of FEU-NRMF.

6.0 DUTIES AND RESPONSIBILITIES OF THE COMMITTEE CHAIRMAN AND SUPPORT STAFF

6.1 CHAIRMAN, RESEARCH CENTER FOR DEVELOPMENT

The Chair of the RCD

6.1.1 Calls and presides the monthly meetings.

6.1.2 Oversees and runs administratively the RCD.

6.1.3 Supervises the activities of the RCD secretary.

6.1.4 Recommends members of the committee and the subcommittees to the Vice-President for Academic Affairs for appointment. 6.1.5 Maintains an inventory of the equipment, supplies and furnishings in the RCD.

6.1.6 Makes requisitions for supplies, equipment, etc. from administration for use in the RCD.

6.1.7 Prepares the annual programs and activities of the committee.

6.1.8 Ensures that the research committee and all its subcommittees are meeting regularly and functioning effectively.

6.1.9 Coordinates and networks with other research agencies, whether private or government.

6.1.10 Prepares the annual budget of the committee.

6.1.11 Oversees the fund-raising activities of the committee. 6.1.12 Maintains the account of the committee in a reputable bank. 6.1.13 Disburses diligently the funds of the committee in the pursuit of its programs and obligations.

6.1.15 Submits a detailed annual report on the finances of the committee.

6.1.16 Prepares an annual accomplishment report on the programs

and activities of the committee.

6.2 CHAIRMAN, INSTITUTIONAL ETHICS REVIEW COMMITTEE The Chair of the Institutional Ethics Review Committee:

6.2.1 Attends monthly RCD meetings.

6.2.2. Heads the review of all research proposals that need ethical review, presides at the IERC meetings, and liaises directly with the VPAA.

6.2.3 Gathers all reviewed proposals by the members of the Institutional Ethics Review Committee.

6.2.4 Reports important outcomes of a meeting to the VPAA through the RCD Chairman.

6.2.5 Communicates with the investigator of the proposals that need to be revised or that are disapproved.

6.2.6 Gives the final approval for the proposals that have passed the committee's approval.

6.2.7 Coordinates with the Chief Medical Officer in all researches that are performed in the hospital.

6.2.8 Makes the final decision on resubmitted protocols, amendments, and documents that have been reviewed.

6.2.9 Represents the IERC in all national and international meetings concerning research ethics.

6.2.10 Invites independent consultants as the need arises, to provide special expertise to the IERC on relevant research protocols.

6.2.11 Assists the RCD chair in budget planning and the preparation and submission of annual reports to be submitted to the VPAA of the Institution and the Philippine Health Ethics Board (PHREB) of which the IERC is a member.

6.2.12 Performs other IERC-related tasks that may be assigned to her/ him by the VPAA or the Chair of the RCD.

6.3 CHAIRMAN, INSTITUTIONAL ANIMAL CARE AND USE PROGRAM COMMITTEE

The Chair of the Institutional Animal Care and Use Program Committee: 6.3.1 Oversees the coordination and implementation of effective, efficient systems for protocol review and program review by the IACUC in compliance with the RA 8485 Animal Welfare act of

1998 as amended by RA 10631.

6.3.2 Ensures that the IACUC has a quorum present at all meetings.

6.3.3 Declares the loss of a quorum resulting in the end of official business if a sufficient number of members depart.

6.3.4 Prepares and/or oversees the preparation of meeting minutes, agendas and reports and submit appropriate documents to the Institutional Official (IO).

6.3.5 Reports to the IO any activities which have been suspended by the IACUC for non-compliance.

6.3.6 Ensures the establishment of a written system of communication for the IACUC with the investigators concerning the approval status of protocols and the steps necessary to secure approval.

6.3.7 Stays abreast of the most recent regulatory trends and interpretations.

6.3.8 Has regular interaction with other institutional committees, occupational health and safety, physical plant, human resources. 6.3.9 Assigns designated reviewers for protocols.

6.3.10 Participates in facility inspections.

6.3.11 Communicates regularly with the IO, Attending Veterinarian, IACUC members and staff.

6.4 CHAIRMAN, INSTITUTIONAL TECHNICAL REVIEW COMMITTEE The Chair of the Technical Review Committee:

6.4.1 Attends monthly Research Committee meetings.

6.4.2 Acts as technical expert and chief spokesperson in matters pertaining to medical statistics and trends.

6.4.3 Represents RCD in meetings and projects with specialists in other departments.

6.4.4 Coordinates with the members of the technical support group to assist in the preparation and/or review of proposals, reports, and articles.

6.4.5 Serves on professional committees and panels.

6.4.6 Establishes and maintains affiliation with professional organizations.

6.4.7 Maintains a knowledge base that enables RCD to provide a high degree of expertise to students, trainees and faculty seeking information on diverse medical research-related topics and data

needs.

6.4.8 Meets with a technical support group to discuss, assist in developing and/or evaluating methods for measuring and analyzing medical research data, characteristics, impacts and trends.

6.4.9 Coordinates with the RCD secretary the scheduling of presentations, conferences, workshops, and seminars for the Technical Support Group.

6.4.10 Works towards the general improvement and advancement of medical research methods and standards, and

6.4.11 Develops effective outreach strategies, activities and products that will include dialogues, briefings, presentations, interaction with the media, articles for specialist publications and scientific papers in peer-reviewed journals.

6.5 CHAIRMAN, FACULTY RESEARCH COMMITTEE

The Chair of the Faculty Research Committee:

6.5.1 Attends monthly RCD meetings.

6.5.2 Coordinates with the committee all researches done or being done by faculty.

6.5.3 Assists in the planning of research-related continuing education programs.

6.5.4 Participates in RCD activities.

6.5.5 Holds meetings with basic department/school coordinators.

6.5.6 Reminds faculty every semester to submit proposals, progress reports and or manuscripts.

6.5.7 Reviews proposals, progress reports and manuscripts of faculty.

6.5.8 Recommends to the Chair of RCD and the VPAA for protected time in teaching load, points for promotion, and publishing in the FEU-NRMF Medical Journal for research output of faculty.

6.5.9 Reviews proposals of other subcommittee under research when called upon by the RCD secretary to do so.

6.5.10 Acts as a liaison between the faculty and the administration in research-related matters.

6.5.11 Ensures proper filing of faculty research at RCD.

6.6 CHAIRMAN, RESIDENT AND FELLOW RESEARCH COMMITTEE The Chair of the Resident and Fellow Research Committee: 6.6.1 Attends monthly RCD meetings.

6.6.2 Coordinates with the committee all researches done or being done by the residents of the FEU-NRMF Medical Center. 6.6.3 Assists in the planning of research related continuing education programs.
6.6.4 Participates in RCD activities.
6.6.5 Reminds residents and department research coordinators every year to submit proposals, progress reports and / or manuscripts. 6.6.6 Reviews proposals, progress reports and manuscripts of the residents.
6.6.7 Recommends to the Chair of RCD and the Chief of Clinics and the Chief Medical Officer scientific papers worthy of financial sponsorship from the Research Committee.
6.6.8 Reviews proposals of other subcommittees under research when called upon by the RCD secretary to do so.
6.6.9 Acts as a liaison between the residents and department research coordinators and the administration in research-related matters. 6.6.10 Ensures proper filing of resident research at RCD.

6.7 CHAIRMAN, STUDENT RESEARCH COMMITTEE
The Chair of the Student Research Committee:
6.7.1 Attends monthly RCD meetings.
6.7.2 Reports to the Research Committee all student research activities.
6.7.3 Participates in Research Committee activities.
6.7.4 Reviews proposals of other subcommittees when called upon to do so.
6.7.5 Acts as a liaison between the student and the administration in research-related matters.
6.7.6 Recommends students to participate in research forums outside the institute.

6.7.7 Reviews proposals, progress reports and manuscripts of students.
6.7.8 Submits one copy of finished researches done by students to the RCD.
6.7.9 Ensures proper filing of student researches at RCD. 6.7.10 Recommends to the Chair of RCD and the VPAA for publishing student research outputs to the FEU-NRMF Medical Journal.

6.8 CHAIRMAN, NON-ACADEMIC RESEARCH

COMMITTEE The Chair of the Non-Academic Research Committee:

6.8.1 Attends monthly RCD meetings.

6.8.2. Coordinates with the committee all researches done or being done by the non-teaching staff.

6.8.3 Assists in the planning of research.

6.8.4 Participates in RCD activities.

6.8.5 Holds meetings with the auxiliary area representatives and other non-teaching staff from the Institute of Medicine.

6.8.6 Reminds and encourages staff to submit proposals, progress reports, and/or manuscripts.

6.8.7 Reviews proposals, progress reports, and/or manuscripts. 6.8.8 Recommends to the Chair of the RCD, VPAA, Department Head for protected time in workload and for publishing in FEU-NRMF Medical Journal for research output of staff.

6.8.9 Acts as a liaison between staff and administration in research related matters.

6.8.10 Ensures proper filing of staff research in the RCD office.

6.9 CHAIRMAN, ANIMAL CARE AND USE PROGRAM COMMITTEE The Chair of the Animal Care and Use Program Committee: 6.9.1 Supervises the day-to-day and overall management of laboratory animal care personnel and the animal facility.

6.9.2 Assists in the procurement of animals for research and teaching purposes, supervision of animal laboratory technicians and other part-time personnel, control of animal holding facilities and helping to obtain proper veterinary care for the animals.

6.9.3 Ensures that conditions vital to the well-being of animals continuously are met in accordance with the Animal Care and Use Program and Animal Welfare Act.

6.9.4 Implements and evaluates new procedures.

6.9.5 Monitors experiments to ensure research study protocols are being followed and notifying proper personnel if deviations are noted.

6.9.6 Participates in Institutional Animal Care Use Committee (IACUC) meetings.

6.9.7 Coordinates facility inspections.

6.9.8 Maintains all required facility records, including daily inspection logs, health records, protocols, censuses, and facility records, in computer databases.

6.10 CHAIRMAN, PUBLICATIONS COMMITTEE

The Chair of Publications Committee:

6.10.1 Attends monthly RCD meetings.

6.10.2 Calls meetings of the Editorial Board.

6.10.3 Reviews and makes revisions in the editorial policies, and recommends them to the Chair of the RCD.

6.10.4 Recommends to the Chair, RCD the composition of peer reviewers.

6.10.5 Sees to it that the Editorial Board members are carrying out their duties.

6.10.6 See to it that the journal is published on time.

6.10.7 Develops and maintains exchange publication programs with other journals.

6.10.8 Coordinates with the Circulation Manager the circulation list and updates it accordingly.

6.10.9 Sees to it that a set of reprints are given to the contributors.

6.10.10 Coordinates with the chairs of faculty, residents, and student research in the collection of materials for publication.

6.10.11 Edits the materials and assigns the editorial board their specific tasks.

6.10.12 Prepare index at the end of each volume.

6.10.13 See to it that all published articles are in conformity with the policy or viewpoint of the organization. In cases of articles which may be controversial in nature, the Editor-in-Chief should seek the Committee on Research approval before such Articles are published in the Journal.

6.11 DEPARTMENT/SCHOOL RESEARCH COORDINATORS

Department / School Coordinators:

6.11.1 Regularly attend meetings called for by the RCD. 6.11.2 Encourage research output from their respective department.

6.11.3 Review, evaluate and coordinate research activities of their respective department/school.

6.11.4 Monitor the progress of all research work of their respective department/school.

6.11.5 Set up a research group in their respective department/ school.

6.11.6 Assure implementation of standard format for proposals/ manuscripts.

6.11.7 Select a panel of reviewers for proposals/manuscripts. 6.11.8 Formulate guidelines for research and proposal presentations.

6.11.9 Formulate and monitor a research plan for the department.

6.12 SECRETARY, RESEARCH CENTER FOR DEVELOPMENT The Secretary of the RCD:

6.12.1 Collects proposals and papers.

6.12.2 Assigns reference numbers, and file them accordingly.

6.12.3 Informs respective chairs of submitted proposals/papers.

6.12.4 Coordinates meetings between investigators and subcommittees.

6.12.5 Takes the minutes of the department meeting.

6.12.6 Files and updates all records of the committee.

6.12.7 Prepares materials for the monthly meeting of the Research Committee such as –

6.12.7.1 Memos to the different departments/ subcommittees.

6.12.7.2 Reminders for the meeting.

6.12.7.3 Requisition of food.

6.12.7.4 Office supplies needed in the RCD meeting.

6.12.7.5 Be responsible for all clerical jobs- typing and record keeping.

6.12.8 Performs other related duties assigned by the chair from time to time.

7.0 RESEARCH FACILITIES

The RCD has various facilities to ensure that all its research development programs and activities can be carried on expediently and efficiently.

7.1 RESEARCH CENTER FOR DEVELOPMENT (RCD) OFFICE The RCD Office is located at the third floor of the Institute of Medicine building. It holds copies of researches done by students, residents, faculty, and employees. Materials necessary for the researcher such as: guidelines, manuals and forms are also available at this office. Documents and records of all research related activities are likewise found therein. In addition, it provides adequate working space for meetings, group discussions and consultations.

The secretary is available from 7 AM to 4 PM, Monday to Friday to assist investigators with research needs such as: processing of proposals and research manuscripts, literature search, coordinating the use of research facilities, scheduling of reviews, and setting appointments with RCD members, and technical support group. She can be contacted thru the FEU-NRMF phone at local 1223.

7.2 MYCOBACTERIUM RESEARCH LABORATORY

The Mycobacterium Research Laboratory is located on the Fifth floor of the Institute of Medicine building. It was also created through a grant from PCHRD. In 2001, it was turned over to the Department of Clinical Laboratory and was renamed Microbiology Extension Laboratory. Although it is now used for processing clinical specimens of the hospital, it can also be used for investigations involving microorganisms, especially Mycobacterium tuberculosis.

7.3 INSTITUTE LABORATORY

The Institute Laboratory is located on the Upper Ground floor of the Institute of Medicine building. Although it mainly functions as a training facility of the School of Laboratory Science, it may be used for the conduct of investigations requiring the equipment and manpower of a medical clinical laboratory. It now houses the cancer research equipment granted by PCHRD.

7.4 ELECTRONIC JOURNAL LIBRARY

The e-Journal section of the library is connected to an electronic journal provider allowing the investigator to access over 1,000

full text journals. The library staff assigned to this area may assist researchers in downloading, copying, and printing materials.

7.5 CLINICAL RESEARCH UNIT

The FEU-NRMF Clinical Research Unit is located at Josephine Cojuangco Reyes (JCR) Building. The establishment of the clinical research unit has been the brainchild of President Atty. Antonio Abad Jr. and former Medical Director, Dr. Policarpio Joves Jr. In 2015, it came to reality when Dr. May Emmeline B. Montellano spearheaded the set-up of the clinical research unit to cater the required areas in the conduct of clinical trials.

The unit has several rooms for the conduct of disease awareness, informed consent, physical examination room, laboratory unit, vaccination room, investigational product (IP) room, document room, and storage area. It is equipped with a Pharmaceutical Bio-refrigerator, -20°C and -70°C Freezer. Several medical and paramedical professionals including subspecialists, nurses, medical technologists, pharmacists, midwives, and encoders are part of the research team.

In 2016, the first vaccine clinical trial of Sanofi Pasteur CYD66 Dengue vaccine (Dengvaxia) was conducted at the site. Subsequently, the clinical research unit has been involved and sought by different clinical research organizations (CRO) and pharmaceutical companies in several vaccine and drug trials such as Abbott for Flu vaccine, Synermore for Rabies vaccine, Pfizer antimicrobial, MSD for RSV vaccine and the most recent, Clover Biopharmaceuticals Inc. for COVID-19 vaccine.

The clinical research unit has been cited already in the Pediatric Infectious Disease Journal for the conduct of Dengue vaccine.

7.6 ANIMAL CARE UNIT

The FEU-NRMF Animal Care Unit (ACU) is an animal facility under the Research Center for Development (RCD) currently located at the 2nd Floor of the FEU-NRMF Institute of Medicine Building. It is utilized by faculty researchers from the different schools of the Institution. The FEU-NRMF ACUP manages the animal facility, which can hold approximately 60 rodents at any given time. It

is equipped to handle research protocols classified under the current Animal Biosafety Level 1.

The animal house has a total floor area of 12 square meters for a preparation room separated from the animal room 24 square meters with a glass sliding door.

8.0 THE RESEARCH PROPOSAL

8.1 GUIDELINES FOR WRITING THE RESEARCH PROPOSAL 8.1.1 **Title**: Appropriate description of the study; avoid talking of 'A Study of', 'An Investigation of', "A Comparative Study of".

8.1.2 **Introduction**: Use the 3-paragraph rule

8.1.2.1 First paragraph: Background of the problem, magnitude of the problem, rationale of the study

8.1.2.2 Second paragraph: Previous studies that addressed the problem, Deficiencies/gap in the previous studies

8.1.2.3 Third paragraph: Hypothesis, aim of the study, significance of the study

8.1.3 **Literature Review** – Appropriate and comprehensive

8.1.4 **Objectives**: Clear and specific

8.1.5 **Methodology**

(Should be described in sufficient details such that other competent researchers will be able to repeat the study. Details are important! Use verbs in the present or future tense. Don't use verbs in the past tense!)

8.1.5.1 **Research Design** – what research design is used in the study? Is it a Descriptive study or an Analytic study? Is it an observational or experimental study? If observational, specify if it's Cross-sectional, Case-control or Cohort. If Experimental, specify.

8.1.5.2 **Study Population and Study Site** – This is the population where you will get your samples. Define/Describe your study population, the place, and the time period you will do the study. If your sampling population involves

patients with a disease, define the criteria for making a diagnosis of the disease. If your study is a case-control, describe/define as well who is the control, and how will they be diagnosed.

8.1.5.3 **Eligibility Criteria** – these are attributes a respondent must possess to qualify in the study.

(From the eligibility criteria, we will know if the participants selected are representative of the target population).

8.1.5.3a **Inclusion criteria** – characteristics that the prospective participants must have to be included in the study; describe who will be included in the study.

8.1.5.3b **Exclusion criteria** – characteristics that disqualify prospective participants from being included in the study; describe who will be excluded. (This is not the opposite of the inclusion criteria). Exclude the participants who have fulfilled the inclusion criteria but have characteristics that can influence or affect the outcome/results of the study. Do not put those who refuse to sign the informed consent, those who are not willing to participate!

8.1.6 **Study Procedure For Interventional/Experimental Studies**:

8.1.6.1 **Recruitment of participants** – how will participants be recruited? When do you ask them to participate in the study? When will informed consent be obtained?

8.1.6.2 **Method of assignment to study groups** – how do you assign the treatment? Will you do randomization? If so, describe specifically how.

8.1.6.3 **Description of procedure for the experimental and control group** – describe how treatment and control is given.

8.1.6.3a **Laboratory procedure** – will there be laboratory exams to be requested? Where, when, and how often? If blood will be extracted, specify amount of blood per extraction.

8.1.6.3b **Follow-up procedure** – will there be follow up? Specify where, when and how often.

8.1.6.3c **Method of dealing with adverse events and/or serious adverse events** – should there be adverse events, describe how to deal with them, e.g., hospitalization., giving of drugs specifying the name, manner of administration, strength, dosage, frequency, duration, etc.

8.1.6.3d **Blinding procedure** – are participants and/or investigators or observers blinded? Describe how.

8.1.6.3e **Data to be collected** – How will data be collected? What are the data to be collected?

8.1.6.3f **Criteria for withdrawal of subjects** – specify when do you withdraw the participants?

8.1.6.3g **Criteria for stopping the study as a whole** – when do you decide to stop the study as a whole?

8.1.7 **Study Procedure For Observational Studies** 8.1.7.1 **Sampling methodology** – how will you select your participants? Describe specifically the type of sampling methodology to be used.

8.1.7.2 **Recruitment of participants** – how will participants be recruited? When do you ask them to participate in the study? When will informed consent be obtained?

8.1.7.3 **Data collection method** – how will data be collected? What method will you use? Do you review of records, use a questionnaire, or do

observation? Describe in detail how they will be done.

8.1.7.4 **Data to be collected** – what are the data to be collected? Specify all data or variables that you will collect, demographic characteristics, exposure variables, outcome variables, etc.

8.1.7.5 **Instrument/s to be used for measuring an exposure and/or an outcome (if applicable)** – what instruments will you use to measure the exposure and/or the outcome? Is/are the instrument/s used validated?

8.1.7.6 **Laboratory procedure (if applicable)** – do you do laboratory procedure? What, when, where and how frequent? Do you do blinding of Laboratory personnel? (If applicable).

8.1.7.7 **Follow-up (if applicable)** – do you follow up participants? When, where and how frequent? 8.1.7.8 **Biosafety Clearance** (if applicable, attach Clearance in the Appendix).

8.1.7.9 **Variable description/Operational definition** – define only the variables you will collect! Don't define the participants of the study here. (They would have been defined under the Study population.) Definition should be operational so you can classify your participants as to what classification they belong. For example, if the variable is quality of life (QOL), state that QOL is defined using a validated questionnaire. Then state how it will be measured. Do you measure it using the actual score, or do you categorize/ classify it into meaningful categories?

8.1.7.9a **Dependent variable/s** – define operationally. If categorical, provide codes for the categories.

8.1.7.9b **Independent variable/s and**

confounders – define operationally. If categorical, provide codes for the categories.

8.1.7.9c **Confounders/Control variables** – identify each of them and define each too.

8.1.8 **Sample Size Calculation** – calculate sample size based on the objectives. Give the assumptions.

8.1.9 **Data Management and Analysis**

8.1.9.1 **Data Processing and Encoding** – where do you process and encode data? What statistical software will be used?

8.1.9.2 **Data Analysis** - Identify statistical test/s to be used for each objective. What is the Level of significance?

8.1.10 **Dummy Tables** – make dummy tables for objective.

8.1.11 **Ethical Consideration** – Describe Conflict of Interest, or if there is none, assurance of confidentiality and anonymity, Informed Consent process, Assent for minors, Vulnerability issues, in anticipated risks and discomforts and risk assessment, expected benefits to the subjects, Incentives and/or Compensation, Community considerations including issues like stigma or draining of local capacity, sensitivity to cultural traditions, and involvement of the community in decisions about the conduct of study.

8.1.12 **Informed Consent** – get a template of an informed consent from the WHO.

8.1.13 **Schedule of Activities** – better presented as a Gantt chart

8.1.14 **Budgetary Requirement**

8.1.15 **References**

8.1.16 **Appendix** - Data collection tool (Coding Manual) o Questionnaire o Biosafety Clearance, Informed Consent

8.2 PROCESS OF SUBMISSION OF PROTOCOL FOR TECHNICAL REVIEW

8.2.1 **Purpose**

8.2.1a. The purpose of this policy is to standardize the processes for efficient and timely submission of Research Protocols.

8.2.1b. To decrease the probability of errors and protect the FEU-NRMF from risks associated with Protocol making.

8.2.2 **Scope**

8.2.2a This policy covers Research Protocols of Students, Residents, Fellows Faculty members, Consultants, and other Employees of the Foundation.

8.2.3 **Steps in Details**

Steps	Responsible	Details
1. Writing of the research proposal	Investigator (Student, Resident/Fellow Faculty member, Consultant, or an Employee)	· Investigator makes a final write-up of his/her Research Protocol after consultation with an Adviser.
2. Submission of the Research Protocol	Investigator (Student, Resident/Fellow, Faculty member, Consultant, or an Employee)	· Investigator submits the Research Protocol to the Department/School Adviser/Faculty Adviser using RCD Technical Review Form 1A (See attached Form)
3. Evaluation of the submitted Research Protocol	Research Coordinator / School Adviser / Faculty Adviser	· Using the form, evaluator reviews the submitted Research Protocol and gives an Outcome of the evaluation as either, Approved, With Minor Revision, With Major Revision. If Outcome is 'Approved', Investigator proceeds to Step 5; otherwise, he goes to the next step.

4. Revision of the Research Protocol	Investigator	• Investigator revises the Protocol accordingly as indicated in the RCD Technical Review Form 1A and goes back to Step 3 until the Outcome of the evaluation is 'Approved'.
5. Submission of the Research Protocol to the RCD	Investigator	• Investigator submits to the RCD via email at research@feu-nrmf.edu.ph the RCD Technical Review Form 1A with the Outcome 'Approved'.

6. Submission of the Research Protocol to the applicable Committee Chair
Secretary of the RCD • The Secretary of the RCD submits via email to the applicable Committee Chair depending on the category of the investigator; if Student, to the Chair of the Student Research Committee; if Faculty/Consultant, to the Chair of the Faculty Research Committee or to the Resident/Fellow, to the Chair of the Resident/Fellow Research Committee; if

5. Submission of the Research Protocol to the RCD
Investigator • Investigator submits to the RCD via email at research@feu-nrmf.edu.ph the RCD Technical Review Form 1A with the Outcome 'Approved'.

6. Submission of the Research Protocol to the applicable Committee Chair	Secretary of the RCD	• The Secretary of the RCD submits via email to the applicable Committee Chair depending on the category of the investigator; if Student, to the Chair of the Student Research Committee; if Resident/Fellow, to the Chair of the Resident/Fellow Research Committee; if Faculty/Consultant, to the Chair of the Faculty Research Committee or to the Chair of the Technical Review Committee; if employee, to the Chair of the Technical Review Committee.

7. Submission of the Approved Protocol to the RCD	Applicable Committee Chair	· Applicable Committee Chair sends the Approved Research Protocol to the RCD via email using the RCD Technical Review Approval Form 1B. (See attached Form)
8. Submission of the Approved Research Protocol to the Investigator	Secretary of the RCD	· Secretary of the RCD sends back to the Investigator via email the approved Research Protocol.
9. Submission of the Research Protocol to the Institutional Ethics Review Committee (IERC)	Investigator	· Investigator submits to the IERC the approved Research Protocol and all other IERC requirements.

8.2.4 **Process Flow Chart**

Investigator formulates a research problem

Shows to Adviser

No

Approved by the Adviser

Yes

Investigator writes research proposal using format as described in **Format of Research Proposal**

Investigator asks for Technical Review Form, (**RCD Technical Review Form 1A**) at the RCD.

Secretary gives the **RCD Technical Review Form 1A** to the Investigator: Dept. /Sch.

The investigator gives the **RCD Technical Review Form 1A** to the Dept. Research Coordinator who reviews the Proposal.

Outcomes of the Review by the Research Coordinator

Minor Revision Major Revision

Approval

The investigator then SUBMITS to the RCD the completed RCD Technical Review Form 1A, and the Research Proposal placed in a brown envelope labeled with the Authors' name and the Department/School.

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The secretary receives from the investigator RCD Technical Review Form 1Aand the Research Proposal. She keeps a file of the accomplished RCD Technical Review Form 1A and the copy of the Research Proposal or in a hard drive for soft copy.

The Secretary of the RCD fills up the Technical Review Approval with information for the submitted protocol and gives the same to the respective Chair of the Technical Review who affixes its signature.

The Secretary sends to the Investigator via email the signed Technical Review Approval which will serve as an endorsement of the RCD to the IERC.

Investigator applies for an Ethics Review

9.0 INSTITUTIONAL ETHICS REVIEW COMMITTEE REVIEW PROCESS

The Far Eastern University – Nicanor Reyes Medical Foundation Institutional Ethics Review Committee (FEU-NRMF IERC) is tasked to review all protocols that involve human participants and obtain protected or sensitive information that are conducted in FEU-NRMF. It can also review protocols from other institutions that may not have an ethics review committee, provided that there will be sufficient oversight of the study by officials where the study will be conducted. The FEU-NRMF IERC utilizes the Primary Reviewer system, where the Chair assigns two (2) Primary Reviewers per protocol (1 scientific, 2 lay member). Protocols may undergo Full Board Review (requires deliberation and en banc decision by the IERC during the monthly meeting) or Expedited Review (Primary Reviewers and Chair make the decision). Some protocols are exempted from ethics review. There are three major areas that the FEU NRMF IERC reviews: Initial, Post-Approval, and Serious Adverse Events. Complete details of the review processes are found in the FEU-NRMF IERC Standard Operating Procedures Version 3 (2017).

9.1 INITIAL REVIEW

9.1.1 Prior to submission to the FEU-NRMF IERC, all protocols must have undergone technical review by their respective committees. The Principal Investigator (PI) is responsible for submitting a complete set of documents to the FEU-NRMF IERC. These include (see Complete Instructions for the Initial Review Application at the Appendices):

12.1.1a. Review Checklist
12.1.1b. Registration and Application Form
12.1.1c. Study Protocol Assessment Form
12.1.1d. Informed Consent Assessment Form
12.1.1e. Other protocol-related documents

9.1.2 The Secretariat manages study protocol submissions to the FEU-NRMF IERC and processes the submission. The FEU-NRMF IERC Chair then decides whether the study protocol is for full board review or for expedited review, or is exempted, and then assigns Primary Reviewers

based on expertise and experience. (In some cases, an Independent Consultant may be called upon in case none of the IERC Members have sufficient training to make a thorough review of a particular protocol.) The type of review is based on the following criteria:

INITIAL SUBMISSION/RESUBMISSION		
EXPEDITED REVIEW	FULL BOARD REVIEW	EXEMPTED (Unless required by an external body or utilize vulnerable participants)
▪ The research poses no more than minimal risk. ▪ The study does not involve vulnerable populations. ▪ The study does not involve the collection of ▪ Clinical trials about investigational new drugs, biologics, or device in various phases (Phase 1, 2, 3) ▪ Phase 4 Intervention nvove vulnerable populations. ▪ The study does not involve the collection of stigmatizing information. ▪ The study uses anonymized or archived samples. researc nvovng	research involving drugs, biologics, or device ▪ Protocols including 31 questionnaires and social interventions that are confidential Researches that involve: ▪ animal subjects or specimens (review c/o IACUC) ▪ biosafety issues or pose hazards to the environment (review c/o Biosafety Committee) ▪ information freely available in the public ▪domain ▪ anonymized records	

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

▪ information freely available in the public domain
▪ 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
▪ public behavior that are purely observational
(non-invasive and non interactive), unless the recorded
observations identify individuals
(names, photographs) ▪ 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
▪ use of educational tests, survey, and
interview procedures on human participants in the public
arena
▪ Taste and food quality evaluation and
consumer acceptance studies if the food
consumed is:
- Wholesome
without
additives, or
- Contains a food
tests, survey, an
interview procedures
on human participants
in the public arena
▪ 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

9.1.3 The decision on exempted protocols is finalized at the level of the Chair. For protocols requiring Full Board Review, the decision may be any of the following: 9.1.3a. Approved
9.1.3b. Minor Modification (PI must make revisions and resubmit protocol; protocol undergoes
Expedited Review)
9.1.3c. Major Modification (PI must make revisions and resubmit protocol; protocol undergoes
Full Board Review)
9.1.3d. Disapproved (PI may submit a new protocol)

9.1.4 For protocols that undergo Expedited Review, the decisions are the same. However, whether the protocol needs Minor and Major Modification, subsequent submissions will undergo Expedited Review. The decisions are made known to the PI by the IERC in a timely manner. The Initial Review process is illustrated
below:

9.1.4a. Protocol Submission

<table>
<tr><td colspan="2">Secretariat receives and manages study protocol submissions (2 days) ↓</td></tr>
<tr><td colspan="2">Chair classifies submission as expedited review, full board review, or exempted
↓</td></tr>
<tr><td>Expedited or Full Board Review</td><td>Exempted</td></tr>
</table>

Chair assigns Primary Reviewers and Independent Consultants and returns protocol submissions to Secretariat (2 days) ↓	Chair returns protocol submissions to Secretariat (2 days) ↓
Secretariat Sends study protocol package to primary reviewers, IERC members, and Independent Consultants for review (STUDY PROTOCOL ASSESSMENT FORM, INFORMED CONSENT ASSESSMENT FORM, TRANSMITTAL LETTER) (2 days)	Secretariat Notifies the PI of exemption with NOTIFICATION OF EXEMPTION FROM ETHICS REVIEW (2 days)

9.2 FULL BOARD REVIEW

Primary Reviewers and Members review the protocol and return accomplished STUDY PROTOCOL ASSESSMENT FORM, INFORMED CONSENT ASSESSMENT FORM to the Secretariat (10 – 12 days) ↓
Secretariat Includes the protocol in the agenda of the next full board meeting ↓
Primary Reviewers present review findings during full board meeting ↓
Members deliberate on full board action on the protocol ↓
If approved: IERC sends notification of decision to PI If minor modification: IERC sends notification with recommendations to PI; process resubmission by expedited review If major modification: IERC sends notification with recommendations to PI; process resubmission by full board review If disapproved: IERC sends notification of decision to PI with justification (7 days)

9.3 EXPEDITED REVIEW

Primary Reviewers review the protocol and return accomplished STUDY PROTOCOL ASSESSMENT FORM and INFORMED CONSENT ASSESSMENT FORM to the Secretariat (7 days) ↓
If approved: IERC sends notification to PI If major or minor modification: IERC sends notification with recommendations to PI then process resubmission by expedited review If disapproved: IERC sends to full board review and process accordingly (3 days)

Note: After the initial review, the Principal investigator resubmissions can only be accepted within 90 days from the date of the action letter. Failure to respond within 90 days from the date of the letter will inactivate the application and study protocol will be archived. Subsequent submissions will be processed as initial review.

9.4 POST-APPROVAL REVIEW

9.4.1 The FEU-NRMF IERC processes post approval submissions by the Principal Investigators. Depending on the nature of the submissions, they may be processed by either "expedited" or full board review. These submissions are the following:

9.4.1a. Requests for amendments
9.4.1b Continuing review
9.4.1c. Final reports
9.4.1d. Non-compliance (deviation or violation) reports
9.4.1e. Early study termination
9.4.1f. Queries from stakeholders
9.4.1g. Serious adverse events (SAEs) and suspected unexpected serious adverse reactions (SUSARs) reports
9.4.1h. Site visit reports

9.4.2 The PI must comply with post-approval review requirements, including the submission of required reports listed in the approval letter.

9.4.3 After the PI submits the relevant forms and other

protocol-related documents, the Secretariat receives and processes them. The Chair decides whether the

submission requires Full Board or Expedited Review. This is based on the following criteria:

AMENDMENTS / REPORTS	
EXPEDITED REVIEW	FULL BOARD REVIEW
Proposed continuing reviews, protocol amendments and end of study reports that have minor modifications and no significant risk to study participants, such as: ▪ Administrative revisions, such as correction of typing errors ▪ Addition or deletion of non procedural items, such as the addition of study personnel names, laboratories, etc. ▪ Research activity includes only minor changes from previously approved protocol. ▪ Minor protocol amendments that do not change the risk/benefit assessment. ▪ Progress/final reports that do not deviate from approval given by the IERC ▪ Offsite SAEs.	▪ Major revisions of the protocol and informed consent after initial review. ▪ Amendments that involve major changes from previously approved protocol or consent form ▪ Major amendments that change the risk/benefit ratio ▪ Major protocol violations ▪ Progress/Final reports that deviate from original approval given by the FEU-NRMF IERC ▪ Onsite SAEs or SUSARs that may require protocol amendment or reconsent of participants

9.4.4 Original Primary Reviewers are responsible for reviewing these post- approval submissions. After the review, the decision may be any of the following:

9.4.4a. Uphold original approval with no further action

9.4.4b. Request further information

9.4.4c. Recommend further action

9.4.5 The decisions are made known to the PI by the IERC in a timely manner. The Post-Approval Review process is illustrated below:

Secretariat receives and manages documents submission (2 days) ↓
Chair classifies submissions as full board review, expedited review, or exempted (2 days) ↓
Secretariat forwards submissions to Primary Reviewers and Members ↓
Reviewers review submissions and return the same to the Secretariat (10 – 12 days for full board review; 7 days for expedited review) ↓
Chair and Members deliberate full board study protocols in committee meeting ↓
Secretariat communicates results to PI/Participant (7 days after full board meeting for full board review; 3 days after review of Primary Reviewers)

9.5 SERIOUS ADVERSE EVENTS REVIEW

9.5.1 SAE and SUSAR reports are submitted by investigators and sponsors to the FEU-NRMF IERC to comply with ICH GCP. ICH GCP E6 defines a serious adverse event (SAE) or a serious adverse drug reaction (ADR) as any untoward

medical occurrence at any dose:

9.5.1a. Results in death

9.5.1b. Is life threatening

9.5.1c. Requires hospitalization or prolongation of existing hospitalization

9.5.1d. Results in persistent or significant disability or incapacity

9.5.1e. Results in a congenital anomaly or birth defect

9.5.1f. Any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

9.5.2 A suspected unexpected serious adverse reaction (SUSAR) is a serious event the nature and severity of which is not consistent with the applicable product information. In the case of an unapproved investigational product, the event is not consistent with the Investigator's Brochure (or its equivalent). In the case of a licensed product, the event is not consistent with the approved package insert or summary of product characteristics.

9.5.3 The FEU-NRMF IERC receives and reviews SAE and SUSAR reports, which is a form of post-approval submission, from its own site and takes the necessary action to ensure the safety of participants. In multicenter studies, the IERC also receives SAE and SUSAR reports from other sites within and outside the country. The FEU NRMF IERC must be updated about safety issues related to studies that it has approved.

9.5.4 The FEU NRMF IERC can suspend or terminate approval of research at its site when the safety of participants is no longer assured. When FEU NRMF IERC takes such action, it must provide the reasons for its action and must promptly report such decision to the investigator, the sponsor, the institution, and relevant regulatory authorities.

9.5.5 The FEU-NRMF IERC Vice Chair is designated as the head

of the SAE Subcommittee, which is tasked to manage SAE and SUSAR reports. The SAE Subcommittee is defined as the Vice Chair and the Primary Reviewers of the study protocol with SAE/SUSAR submission. All onsite SAEs and SUSARs undergo Expedited Review (unless the SAE subcommittee recommends that the issue be deliberated on in a full board meeting) in order to hasten the decision-making, especially when the safety of study participants are involved. All offsite SAEs and SUSARs are collated and reported to the board quarterly.

9.5.6 When the IERC receives SAE and SUSAR reports, the Secretariat receives all the necessary documents

and forwards them to the SAE Subcommittee. The subcommittee reviews the report, and the Vice Chair makes any of the following recommendations to the Chair:

9.5.6a. Uphold original approval with no further action

9.5.6b. Request further information

9.5.6c. Recommend further action

9.5.7 The decision is then finalized at the level of the Chair, after which the PI is informed of the decision in a timely manner. The SAE Review Process is illustrated below:

<table>
<tr><td colspan="2">Investigators and/or Sponsor Report SAE and SUSAR
↓</td></tr>
<tr><td colspan="2">Secretariat receives SAE and SUSAR reports
↓</td></tr>
<tr><td>(Onsite SAEs)
Secretariat Informs Chair and forwards reports to the Vice Chair and Primary Reviewers
(2 days)
↓</td><td>(Offsite SAEs)
Secretariat Informs Chair and Vice Chair; Encodes and collates data in database
↓</td></tr>
</table>

Vice Chair and Primary Reviewers review SAE and SUSAR reports and make a recommendation to the Chair (2 days) ↓		↓
Chair refers to full board as needed ↓	Chair finalizes action ↓	↓
Chair and Vice Chair summarize and report to full board ↓	↓	Chair and Vice Chair summarize and report to full board quarterly ↓
Chair and Members deliberate on board action ↓	↓	↓
Secretariat informs Investigator, sponsor & other officials about IERC decision Onsite: Full board - 7 days after full board meeting; Expedited: 3 days Offsite: as needed		

9.6 PROCESS FLOW CHART

NOTE:
Please note that resubmissions can only be accepted within 90 days from the date of this letter. Failure to respond within 90 days from the date of this letter will inactivate the application and study protocol will be archived. Subsequent submissions will be processed as initial review.

INITIAL REVIEW

SPONSOR INITIATED STUDY PROTOCOL
PRINCIPAL INVESTIGATOR- INITIATED STUDY PROTOCOL
(Consultant, Faculty, Fellow, Resident, Students)

Department/School Research Coordinator who reviews the Research Proposal using the RCD Technical Review Form 1A

PRINCIPAL INVESTIGATOR submits duly accomplished forms to the IERC Secretariat who forwards it to the Chair
(2days) ▪ REVIEW CHECKLIST FORM 2(A)
▪ REGISTRATION & APPLICATION FORM 2(B)
▪ STUDY PROTOCOL ASSESSMENT FORM 2(C)
▪ INFORMED CONSENT ASSESSMENT FORM 2(D) - Follow WHO format for studies requiring informed consent
▪ REQUEST TO WAIVE WRITTEN OR VERBAL INFORMED CONSENT FORM2 (N) – Protocols with review of records

(and other protocol - related documents as enumerated in the checklist)

IERC Chair classifies submission as full board,

A
expedited or exempt from
D

review **(2days)**

FULLBOARD REVIEW:
IERC deliberates on fullboard action & decision during monthly

fullboard meeting

B

0 **EXEMPTED:**
Finalized at the

Primary reviewers recommend action;
C
level of the Chair

EXPEDITED REVIEW:

the Chair **(7days)**

IERC notifies PI of

finalized at the level of

exemption **(2days)** **Approved:**
IERC Notifies PI of decision **(7days after full Disapproval:**

board meeting) **Archived**

IERC Notifies PI of decision with justification **(7days after full board meeting)**

Approved:
IERC Notifies PI of decision **(3days)**

Disapproval:
Study protocol will be sent to full board review and

accordingly

Minor/ Major Modification:

D 1

IERC Notifies PI of recommendations; resubmission expedited review **(3days)**

Archived 1

Major Modification:
IERC notifies PI of recommendations; resub is processed by full board review **(7days after full**

processed

Min or Mod ification: IERC notifies PI of recommendations; resubmissions is processed by

board meeting) **C** **A** **B**

ing)

NOTE:
*Application for renewal of ethical clearance thirty **(30) days** before the expiration date of approval*

10.0 THE RESEARCH PAPER / MANUSCRIPT

10.1 FORMAT OF THE MANUSCRIPT

10.1.1 The Research Paper / Manuscript to be submitted shall

follow a Medical Journal Format specifically, the IMRaD format.

10.1.2 IMRaD is an Acronym that stands for:

I - Introduction
M - Methods
R - Results
A - and
D - Discussion

10.1.3 IMRaD format does not have a separate section on the Review of Literature and the Objective/s. The Review of Literature is discussed in the Introduction in the second paragraph and in the Discussion section. The Objective/s is/are written in the third paragraph of the Introduction section.

10.1.4 The Introduction is written using the three-paragraph rule

10.1.5 Write up of the Methods, Results and Discussion sections should follow the STROBE checklist guidelines for Observational Studies or the CONSORT checklist guidelines for Clinical Trials.

10.1.6 Format for Tables and Figures, In-text Citation and Reference list shall follow the American Psychological Association (APA) style.

10.1.7 Paper size, Font size, Spacing and Margins:

Paper size Letter (8 ½ x 11) white bond paper
Font Arial - size 12
Line Double spaced
Margin 1 inch all around

Note: Format of the International Committee for Medical Journal Editors (ICMJE) may also be followed.

10.2 Submission of the Manuscript for Residents, Fellows, Consultants/ Faculty Members and Office Staff

Residents, Fellows, Consultants/Faculty Members and Office

Staff submit to the RCD the following documents:
10.2.1 Approved and signed RCD Manuscript Review Form 3A
10.2.2 Signed RCD Research Registry Form 3B
10.2.3 Ethics Approval (before data collection)
10.2.4 Research Manuscript with Turnitin Summary Results in the Appendix, each one fastened in a short sliding folder.
o Five (5) copies from the Residents
o Five (5) copies from the Fellows, Consultants/Faculty members
10.2.5 Research Manuscript with Turnitin Summary Results in the Appendix emailed to research@feu-nrmf.edu.ph
10.2.6 Final Report Letter

Note: Place all documents in a long brown envelope labelled with the Name of the Investigator and the Department

10.3**Submission of the Manuscript for Students** Submission of the Manuscript for Students

STEPS	RESPONSIBLE	DETAILS
1. Submission of 2 hard copies of approved manuscript to the RCD.	Student	The final manuscript must contain the approval sheet and the final grade of the student. The 2 copies are for student's personal copy and library copy.
2. Sealing of the submitted manuscript.	RCDO administrative clerk	The RCDO administrative clerk seals the submitted manuscript to signify its receipt and registration to the database.

3. Submission of the pdf file to the research@feu nrmf.edu.ph and medicallibrary@feu nrmf.edu.ph	Student	The student shall take picture of the sealed page to be appended i the pdf fil. The pdf file will be submitted to research@feu nrmf.edu.ph and medicallibrary@feu nrmf.edu.ph
4. Submission to the library	RCDO administrative clerk	Th RCDO administrative clerk forwards the sealed manuscript to the library.

5. Issuance of clearance Chief Librarian The chief librarian nr h h

nrmf.edu.ph and
medicallibrary@feu
nrmf.edu.ph

4. Submission to the library	RCDO administrative clerk	Th RCDO administrative clerk forwards the sealed manuscript to the library.
5. Issuance of clearance	Chief Librarian	The chief librarian counter checks the submitted manuscript with the pdf file submitted. Once verified, the library shall issue clearance to the student.

The file name shall contain the following format:
SchoolCode_Year_Reseach Title i.e SPH_2023_Hypoglycemic Effects

11.0 THE CASE REPORT

11.1 CHARACTERISTICS OF CASE REPORT

A case report is a documentation of a unique, unusual, or newsworthy scientific observation for education and research

purposes. Cases should possess a notable departure from current clinical understanding. Cases should strive to advance the general understanding of the disorder, improve clinical skills, and/or introduce suggested research.

11.1.1 **Unique Case** – appears to represent a previously undescribed syndrome or disease.

11.1.2 **Case of Unexpected Association** – two or more diseases or disorders in a patient which may represent a previously unsuspected causal relation.

11.1.3 **Outlier Case** – representing a new and important variation from an expected pattern

11.1.4 **Case of Unexpected Event** – case with an unexpected evolution suggesting a therapeutic or adverse drug effect.

11.1.5 **Innovation Case** – case that utilizes a new or modified surgical technique.

11.2 FORMAT OF CASE REPORT

11.2.1 **Abstract** – In one paragraph make statements about the objectives, the salient features of the case and highlights of the discussion. Include a brief explanation of the clinical questions or problems being addressed in the case report. In addition, a statement summarizing why this case is unusual and noteworthy should be included.

11.2.2 **Introduction** – In less than three paragraphs briefly describe the salient clinical features of the disease being addressed (e.g., epidemiological background of the disease, unique presentations/signs/symptoms). Present the topic of the case report as well as a justification (objective) of why the case is worthy of discussion. Relevant background information obtained through a review of the literature should also be

included.

11.2.3 **Case Presentation** – The presentation should include the chief/presenting complaint, the pertinent history, medications, habits, allergies, history of present illness, family history, personal history, systems review, clinical examination, laboratory investigations, and other diagnostic tests or studies performed (e.g., radiology, biopsy, etc.) Introduce the patient and provide a history of present illness in chronological order. Only pertinent findings from the physical exam and laboratory/imaging studies should be included. List reference values for less commonly ordered tests.

11.2.4 **Discussion** - Discussion of the case should seek to enlighten the reader about the approaches used toward the clinical scenario presented to highlight recent advancements in the field of diagnosis and treatment of the condition, and to generally include points of clinical learning. Restate the significance of the particular case and discuss the unusual and striking features of the case. Back up your discussion with additional information obtained from your literature review to support your arguments. Address any contradictory evidence. Emphasize the importance and educational value of the case.

11.2.5 **Summary, Conclusion, Recommendation** - In one para graph, the summary should include recommendations for therapy/diagnosis, significance to the practice of medicine and opportunities for research State the take home message. You may also address what you would do differently the next time. Provide recommendations to other clinicians and researchers and consider suggest ing possibilities for further study.

11.2.6 **References**, **Acknowledgements, Illustrations** - Site sources for all historical information discovered by your literature search. Never transfer a reference cited in another article to your own list without reading the cited article critically.

11.3 DOCUMENT FORMAT FOR THE CASE REPORT

The Case Report should follow this prescribed format:

14.3.1 Letter size (8 ½ x 11) white bond paper

14.3.2 Margin 1" on all sides

14.3.3 Font - Arial 12

14.3.4 Folder with side slide

11.4 SUBMISSION OF A CASE REPORT FOR RESIDENTS

Residents submit to the RCD the following documents:

14.4.1 Approved RCD Case Report Review Form 4

14.4.2 Case Report, five (5) copies, each one fastened in a short sliding folder.

14.4.3 Case Report emailed to research@feu-nrmf.edu.ph

14.4.4 Informed Consent from the patient

Note: Place all documents in a long brown envelope labelled with the Name of the Investigator and the Department

12.0 FACULTY REWARDS AND INCENTIVES

The Faculty Research Committee may recommend the granting of various rewards and incentives to the faculty members who may be involved in the various research development programs of the RCD or may have completed publications of researches in the name of FEU-NRMF.

12.1 TEACHING LOAD

In order for a faculty to be given teaching load for research, the following guidelines should be followed:

12.1.1 The approved proposal, following guidelines of this

manual, should be submitted to the RCD on or before the first day of the semester.

12.1.2 The RCD in coordination with the Chair on Faculty Research will review the proposal and determine the number of teaching load credits to be allotted. Teaching load will be in the form of laboratory hours; thus 2 hours of research work is equivalent to 1 credit hour.

12.1.3 The RCD will send a letter stating the recommended teaching load credit to the Chairman of the department concerned and to the Dean.

12.1.4 On or before the last day of the said semester, the final paper or a progress report must be submitted to the RCD.

12.1.5 If the research is not completed in one semester, the RCD will determine, based on the progress report, whether teaching load credit will be given for another semester.

12.2 PROMOTION

In order for a research to be used for promotion, the following guidelines will be followed:

12.2.1 Two (2) paper copies and one (1) electronic copy of the finished research must be submitted to the RCD. The paper must follow the recommended format. The author will be asked to accomplish an RCD Research Registry Form 3B

12.2.2 The RCD, in coordination with the Committee on Faculty Research, will review the paper using RCD Manuscript Review Form 3A and will determine if it will be accepted for promotion purposes.

12.2.3 A letter of acceptance will be completed in triplicate. Copies will be sent to the author, the Chairman of the department concerned and the Dean.

12.2.4 If the Committee on Publications would like to publish the paper in the FEU-NRMF Medical Journal, it will communicate with the author(s) asking for permission to do so.

12.2.5 In order to increase the output of Research Papers from Faculty members, Research Papers done outside FEU

NRMF can be accepted as a Research Output of the Faculty member as long as they are published locally or internationally in medical journals and can be accessed from the internet or from a hard copy of the journal.

12.2.6 Thesis from doctorate or master's papers cannot be used for teaching load or promotion purposes.

12.2.7 Research papers done outside of the institution may be given points for promotion.

13.0 RCD REWARDS, INCENTIVES AND GRANTS FOR PUBLICATIONS

13.1 REWARDS AND INCENTIVES FOR PUBLISHED PAPERS

As per Academic Policy No. 2016-011 approved on November 10, 2016

13.1.1 Research papers published in Information Science Institute (ISI) Journals shall receive PhP15,000.00.

13.1.2 Research papers published in non-ISI Journals shall receive PhP5,000.00.

13.1.2 Research papers published in the FEU-NRMF Medical Journal shall be given PhP2,000.00.

13.2 REWARDS AND INCENTIVES FOR PAPERS PRESENTED IN RESEARCH FORA

As per Academic Policy No. 2016-011 approved on November 10, 2016

13.2.1 Faculty members whose research work has been accepted for presentation and publication to conference/s abroad shall be given 100% travel grant

13.2.2 Faculty members whose research work has been accepted for presentation to conference/s abroad shall be given 50% travel grant

13.3 GRANTS FROM RCD BASED ON RESEARCH DESIGN As per approved 2022 budget, the following grants may be given to help fund researches depending on the Research Design:

13.3.1 Descriptive Research PhP20,000.00 13.3.2 Action Research PhP15,000.00 13.3.3 Meta-analysis PhP30,000.00 13.3.4 Animal Experimental Research PhP40,000.00 13.3.5 Randomized Clinical Trial

PhP60,000.00

13.4 PROCESS FOR APPLICATION FOR RCD GRANTS FOR RESEARCH PAPERS

13.4.1. **Purpose**

This policy covers the process in availing research grant from FEU-NRMF.

13.4.2 **Definition of Terms**

13.4.2.i Researcher–Principal investigator/ Co-investigator who conducts research in an organized and systematic investigation.

13.4.2.ii IERC – Institutional Ethics Review Committee is tasked to review all protocols that involve human participants and obtain protected or sensitive information that are conducted in FEU-NRMF.

13.4.2.iii Institutional Animal Care and Use Committee (IACUC) - the committee is responsible for assessment and oversight of the institution's Program components and facilities. It should have sufficient authority and resources (e.g., staff, training, computers, and related equipment) to fulfill this responsibility.

13.4.2.iv FEU-NRMF Research Agenda - refer to research priorities of FEU-NRMF from 2017-2022 which is compiled and edited by the RCD.

13.4.3 **Steps in Details**

Steps	Responsible	Details

1. Submit a Filled- up RCD Research Funding Form 2	Researcher	Accomplish 01-RDC-F-03-REV0-06-01-22. Submit the filled-up form to the RCD office or thru online: https://www.feu-nrmf.ph research@feu-nrmf.edu.ph
2. Submit the FF: a. Letter of Intent to apply for necessary clearance/permits b. Curriculum Vitae of Principal Investigator, Co Investigator and other senior researchers c. Duties and responsibilities of project personnel/ research assistant d. Copy of Research Proposal e. Copy of tools to be used in the research project f. Declaration of NO Conflict of Interest g. Official endorsement of School/Department	Researcher RCD Secretariat	a. Letter of Intent to apply for necessary clearance/ permits (e.g., IERC, IACUC) b. CVs of Principal Investigator, Co Investigator and other senior researchers. Include the following in the CVs, the List of Researches (Completed and Ongoing), title of Research, Role in the research (PI, Co-PI, etc.), list of Publications of Article. c. Duties and responsibilities of project personnel/ research assistant d. Copy of research proposal that adheres to FEU-NRMF Research Agenda,2017-2022 Submit all the requirements to the RCD office or thru online: https://www.feu-nrmf.ph research@feu-nrmf.edu.ph RCD secretariat checks all the submitted requirements and endorses to the Chairman of Faculty research committee

3. Endorsement of the research proposal for research funding to the RCD	Chairman of Faculty Research Committee	The Chairman of Faculty research committee check all the submitted requirements and endorses to the RCD.

4. Recommending Approval of research grant by RCD Director for Research — Center for During the monthly meeting of RCD members, the research proposal for funding will be

submitted requirements and endorses to the Chairman of Faculty research committee

3. Endorsement of the research proposal for research funding to the RCD	Chairman of Faculty Research Committee	The Chairman of Faculty research committee check all the submitted requirements and endorses to the RCD.
4. Recommending Approval of research grant by RCD	Director for Research Center for Development	During the monthly meeting of RCD members, the research proposal for funding will be deliberated and approval of the research protocol is recommended.
5. Endorsement of the research protocol to Vice-president for Academic affair (VPAA)	RCD Director	The Director of Research Center for Development endorses the research proposal to the Administration thru the Vice-President of Academic Affair
6. Endorsement of the research protocol to the Chief Operating officer and President for final approval	VPAA	The Vice-President for Academic affairs endorses and recommend the approval of the research proposal to the President and Chief Operating Officer for final approval

7. Release of research grant to the Researcher thru the RCD	RCD	The Research Center for Development releases the financial grant in the form of check under the name of the principal investigator and properly acknowledged by the principal investigator.
8. Submit a quarterly progress report on the conduct of research	Researcher	The researcher submits a quarterly progress report on the status of research project
9. Submit the final research paper and liquidation report.	Researcher	The researcher submits the final research paper and liquidation report to the RCD.

13.5 PROCESS FOR APPLICATION FOR EXTERNAL GRANTS FOR RESEARCH PAPERS

13.5.1 **Purpose**

13.5.1.i. The purpose of this procedure is to provide assistance in applying research grant to outside institution like MMHRDC, PCHRD, DOH and CHED to all faculty members, consultants, residents, students, non- teaching employees. This policy will guide the researcher/ investigator in applying for research grant from outside institutions like MMHRDC, PCHRD, DOH and CHED.

13.5.1.ii To ensure the efficiency of the plans in relation to the policies and goals of FEU-NRMF.

13.5.2 **Scope**

13.5.2.i This procedure covers the process in availing supplementary research grant from outside institution.

13.5.3 **Definition of Terms**

13.5.3.i Researcher – Principal investigator/Co-investi gator who conducts research in an organized

and systematic investigation.

13.5.3.ii IERC – Institutional Ethics Review Committee is tasked to review all protocols that involve human participants and obtaining protected or sensitive information that are conducted in FEU-NRMF.

13.5.3.iii Institutional Animal Care and Use Committee (IACUC)- the committee responsible for assessment and oversight of the institution's Program components and facilities. It should have sufficient authority and resources (e.g., staff, training, computers and related equipment) to fulfill this responsibility.

13.5.3.iv MMHRDC - Metro Manila Health Research Development Consortium

13.5.3.v PCHRD- Philippine Council for Health Research and Development

13.5.3.vi DOH- Department of Health

13.5.3.vii CHED – Commission of Higher Education

13.5.4 **Steps in Details**

Steps	Responsible	Details
1. Submit a Filled- up Form from other institution	Researcher	Accomplish Institutional research form Submit the filled-up form to the RCD office or thru online: https://www.feu-nrmf.ph research@feu-nrmf.edu.ph

2. Submit the FF: a. Letter of Intent to apply for necessary clearance/permits b. Curriculum Vitae of Principal Investigator, Co Investigator and other senior researchers c. Duties and responsibilities of project personnel/ research assistant d. Copy of Research Proposal e. Copy of tools to be used in the research project f. Declaration of NO Conflict of Interest g. Official endorsement of School/Department	Researcher	a. Letter of Intent to apply for necessary clearance/permits (e.g., IERC, IACUC) b. CVs of Principal Investigator, Co-Investigator, and other senior researchers. Include the following in the CVs, the List of Researches (Completed and Ongoing), title of Research, Role in the research (PI, Co-PI, etc.), list of Publications of Article. c. Duties and responsibilities of project personnel/research assistant d. Copy of research proposal that adheres to FEU-NRMF Research Agenda,2017-2022 Submit the filled-up form to the RCD office or thru online: https://www.feu-nrmf.ph research@feu-nrmf.edu.ph
3. Endorsement of the research proposal for research funding by RCD to outside institution	Chairman of RCD	The Chairman checks all the submitted requirements and endorses to outside institution for external research grant.

14.0 RESEARCH REQUIREMENTS FOR RESIDENCY CERTIFICATION

14.1.1 Each resident shall be required to attend a seminar on EVIDENCE BASED MEDICINE and submit a CASE REPORT and an analytical or descriptive (must be relevant) RESEARCH PAPER prior to finishing his/her training program. A certificate of completion of residency shall not be released unless these two research papers are submitted.

14.1.2 It is recommended that first year residents attend the Evidence Based Medicine seminar.

14.1.3 The interesting Case Report shall be required prior to being promoted to the second year of residency.

14.1.4 To ensure the quality of the analytical or descriptive paper, the proposal should be submitted to the RCD for approval on the second year of residency. Progress reports should be given to the research coordinator every 6 months until completion of the study.

14.1.5 The resident should work closely with the department's Research Coordinator. The Research Coordinator is a consultant appointed by the Department Chairman to provide guidance and help so that the resident completes all research requirements for certification

14.1.6 An analytical or descriptive research approved by the RCD is required for certification of training given by the Chief of Clinics.

14.1.7 The various departments are encouraged to form their own committee on research to guide their residents in the formulation of protocols and in the final drafting of their papers. The different departments may optionally require their residents to prepare research papers prior to be being promoted to the next level of residency.

14.1.8 The guidelines and format for the case reports and research papers should always be followed.

14.1.9 The submission of Case Reports for First year residents and submission of Research Proposals for Second year residents will be 6 months after issuance of their SO.

14.1.10 Third year residents should submit an analytical or descriptive study as a requirement for graduation and in his residency program.

14.1.11 The deadlines were set to ensure that output could be included in the Annual Case Report Presentation in September of each year and the Annual Research Paper Presentation Contest in January of each year.

14.1.12 Research paper without a previously approved proposal will not be accepted.

14.1.13 Research papers not following the proper sequence of protocol submission and obtaining IERC approval

shall not be allowed to be included in the research presentation contests.

14.1.14 Departments that do not have a representative for the

case report/research contest will be fined.

15.0 PROCESS FOR SUBMISSION OF FELLOWS AND RESIDENTS' RESEARCHES

15.1 PURPOSE

15.1.1 The purpose of this procedure is to guide and inform those concerned with the requirements of Residents and Fellows in completing their training programs by submitting their research papers. Their finished papers are important to maintain one of the pillars of Far Eastern University - Dr. Nicanor Reyes Medical Foundation which is Research.

15.1.2 To ensure the process of producing quality and relevant research papers pursuant to their respective fields of training.

15.2 SCOPE

15.2.1 This procedure covers the information, functions, and processes of making the research papers of Residents and Fellows in training in FEU-NRMF Medical Center.

15.3 DEFINITION OF TERMS

15.3.1 Residents – qualified physicians (board certified MD) who are undergoing training at FEU-NRMF MC to obtain certification of their specialty of choice.

15.3.2 Fellows in training – these are physicians who completed their residency program and continue to pursue further training in a sub-specialty.

15.3.3 Case Papers – this is a study of an interesting disease of a patient which the resident encountered during his 1st year.

15.3.4 Research paper – this is a study paper using an in depth analysis of a topic using statistical data, previous researches, and ethical considerations.

15.4 STEPS IN DETAILS

Steps	Responsible	Details
1. Submit a Case Report	All 1st year Residents, Research coordinators	• Submit finished Case report and Ethics form to RCD • A representative paper by each department will be chosen to participate in the Annual Case presentation contest. The 3 winners will be published in the FEU-NRMF Journal.
2. Submit a Research paper	All Senior Residents, Fellows in training, co authors, Research coordinators, Ethics committee	• Senior Residents/Fellows in training must submit a research proposal to the RCD. • The RCD thru the Research coordinator will check and approve the proposal. This will be sent to the Ethics committee for review and approval before starting the Research. Once finished, the final paper is submitted to the RCD. • A representative paper chosen by the department will participate in the Annual Research Paper presentation contest. The winners will be published in the FEU-NRMF Journal

16.0 FEU-NRMF CLINICAL RESEARCH UNIT

16.1 PURPOSE

16.1.1 The purpose of this document is to detail the composition and function of the clinical research unit (CRU) as a physical facility to conduct clinical research from within

and outside the FEU-NRMF.

16.1.2 To ensure the efficiency of the plans in relation to the policies and goals of FEU-NRMF.

16.2 SCOPE

16.2.1 This document enumerates the clinical research unit composition and their responsibilities, clinical research conducted at the CRU, and the application process for use of the facility.

16.3 RESEARCH UNIT COMPOSITION

Members	Responsibilities
President of the Foundation	Reviews and approves agreements for clinical research from within FEU-NRMF and collaborative local and international studies.
Chief Operating Officer (COO)	Reviews and approves agreements for clinical research from within FEU-NRMF and collaborative local and international studies.
Vice-President for Academic Affairs (VPAA)	Reviews and approves clinical research from within FEU-NRMF.
Chairman of the Research Development Office (RDO)	Reviews and approves clinical research applications from within FEU-NRMF and collaborative local and international studies.
Chairman of the Clinical Research Unit (CRU)	Reviews and approves clinical research application from within FEU-NRMF and collaborative local and international studies.
Study Coordinator (SC)	Facilitates applications of clinical research from within FEU-NRMF and collaborative local and international studies for review

	and approval.

16.4 TYPES OF CLINICAL RESEARCH CONDUCTED AT THE CRU AND ITS DEFINITION

1. Interventional	On-site	Clinical studies conducted within the premises of FEU-NRMF-CRU.
	Community-based	Clinical studies conducted within the community of FEU-NRMF and the community it serves.
	Hospital-based	Clinical studies conducted within the FEU NRMF Medical Center.
2. Observational	Epidemiological	Clinical studies conducted within FEU NRMF-CRU and collaborative local and international studies.

16.5 STEPS IN DETAILS

16.5.1 **Clinical Studies within FEU-NRMF**

STEPS	RESPONSIBLE	DETAILS
1. Study protocol approval	Investigator, VPAA, COO, President	• Investigator submits IERC and RDO approved study protocol to the VPAA for review • VPAA approves study protocol • Investigator submits study protocol to COO and President for approval

2. Execution of the Clinical study at the CRU	Investigator, SC, Chair-CRU	• Investigator submits approved study protocol to the CRU-SC for review and coordination of studies. • CRU-SC submits the study protocol to the Chair-CRU for notification of approval. • Written acknowledgement sent to the Investigator • Upon receipt of acknowledgement, investigator initiates first subject first visit (FSFV).
3. Study Close out	Investigator, SC, Chair-CRU, COO, President	• Investigator submits study close-out letter addressed to the Chair-CRU, COO, and President

16.5.2 **Clinical Studies from International or Local Collaboration**

STEPS	RESPONSIBLE	DETAILS
1. Feasibility Study	Principal investigator (PI), SC	• Clinical Research Organization (CRO) thru the Clinical Research Associate (CRA) sends Feasibility studies to the PI • PI signs Confidentiality Agreement prior to completion of Feasibility study • PI/SC coordinates with FEU-NRMF the required data in the completion of the Feasibility study • Completed Feasibility study is sent back to the CRO
2. Pre-study meeting/visit (PSV)	PI, SC	• CRA schedules PSV • PI/SC attends the PSV/meeting to show the CRU facility
3. Site Selection	PI, SC	• Sponsor selects the site thru the CRO • PI receives selection letter • PI notifies CRU-Chair/SC

3. Site Selection	PI, SC	• Sponsor selects the site thru the CRO • PI receives selection letter • PI notifies CRU-Chair/SC
4. Submission to the IERC	PI, SC	• PI/SC facilitates submission of the study protocol prepared by the Sponsor and CRO which have been approved by the regulatory bodies such as FDA, HTAC, and SJREB in parallel to the IERC for review and approval • PI/SC receives notification from the IERC upon completion of review
5. Clinical Trial Agreement (CTA) and Budget negotiation	PI/SC, COO, President	• PI, COO, and President review and sign CTA and Budget
6. Site Initiation Visit (SIV)	PI, SC	• CRO coordinates with the SC for SIV meeting on site or virtually • 2-3 weeks after SIV, first subject first visit
7. Study Monitor	CRO, IERC	• CRO conducts regular site/virtual monitoring • IERC monitors progress of the clinical study
8. Study Close-out	PI, SC	• Sponsor thru CRO/CRA sends notification for study close-out • SC facilitates PI meeting with the CRO/CRA and Sponsor of the study close-out. • Study Close-out letter submitted to the IERC, Chair-CRU, COO and President
9. Archiving	CRO, Third Party vendor	• All study-related documents are archived with a third-party vendor
10. Return and destruction of study related documents	FEU-NRMF Waste management, CRO, CRU-Staff	• Study-related documents for destruction follows Data Privacy Act and waste management disposal protocol of FEU-NRMF • Unused investigational product is returned or is included for destruction as directed by the Sponsor/CRO
11. Publication	Sponsor, PI	• PI reviews protocol write-up for publication • Sponsor facilitates publication

17.0 PROCESS OF APPLICATION FOR ANIMAL RESEARCH PERMIT

17.1 PURPOSE

17.1.1 The purpose of this policy is to guide the researchers on the process of applying animal research permit prior to conducting animal research.

17.1.2 To ensure the researchers comply with the Animal Welfare Act of the Philippines and Administrative Order 40, s. 1999 of the Department of Agriculture.

17.2 SCOPE

17.2.1 This policy covers the general guidelines for the application of animal research permit.

17.3 DEFINITION OF TERMS

17.3.1 Protocol Review Form (PRF) – refers to the animal care and use statement accomplished by the researchers for review of the Institutional Animal Care and Use Committee (IACUC) of the institution.

17.3.2 Principal Investigator (PI) - primary individual responsi ble for the preparation and conduct of research in com pliance with applicable laws and regulations and institu tional policy governing the conduct of research.

17.4 STEPS IN DETAILS

Steps	Responsible	Details
1. Download the Protocol Review Form and Application for Authorization at FEU NRFM website.	Researchers: Students/Faculty/Residents	Accomplish 01-RCD-ACU-F-01 and 01-RCD-ACU-F-02
2. Scan the Protocol Review Form	Researchers: Students/Faculty/Residents	ve it in pdf file using me following file name
Steps	Responsi	Details

	1. Download the Protocol Review Form and Application for Authorization at FEU NRFM website.	Researchers/Faculty/Residents		Accomplish 01-RCD-ACU-F-01 and01-RCD-ACU-F 2		*School abbreviation rname of the PI year* *ample:*
	2. Scan the Protocol Review Form	Researchers/Faculty/Residents		Save it in pdf file usi the following file na format:		*H_ACOSTA_2022*
	3. Send your protocol review form to iacuc@feu-nrmf.edu.ph		Researchers: Students/Faculty	*School abbreviatio* *Surname of the PI ye* *Example: SPH_ACOSTA_2022*		Content of Email:Subject: A_Protocol Review rm Body: Name of PI Contact Number *NA for New Application RF for Revised Form Application
	3. Send your protocol review form to iacuc@feu-nrmf.edu.ph	Researchers/Faculty/Residents		Content of Email: Subject: NA_Protocol Review Form Body: Name o PI Contact Number***NA for New Application RF for Revised Form Application		
	4. Wait for the status of your protocol via email.	Research	Researchers ents/Faculty/Resid /Faculty/Resident	Status may be approvedor with revisions.		tus may be provedor with visions.

***School of Abbreviation

	School/Department	Abbreviation		
	***School of Abbreviation School of Medical Laboratory Science	SMLS		
	School/Department School of Physical Therapy		SPT	breviation
	School of Nursing		SN	
	School of Medical Labo Science School of Respiratory		SRT	SMLS
	School of Physical Therapy School of Nutrition and Dietetics		SND	SPT

	School of Radiologic Technology		RdT	
	School of Nursing School of Pharmacy		SPH	SN
	Medicine		MED	
				SRT
	School of Respiratory Therapy FEU – NRMF Residents		RES	
School of Nutrition and Dietetics			60 SND	
School of Radiologic Technology			SRdT	
School of Pharmacy			SPH	

Medicine MED

18.0 PROCESS OF MAKING STUDENT RESEARCHES

18.1 PURPOSE

18.1.1. The purpose of this policy is to standardize the process for efficient and timely submission of Research Protocols
of Students.

18.1.2 To decrease the probability of errors and protect the FEU-NRMF from risks associated with Protocol making.

18.2 SCOPE

18.2.1 This policy covers Research Protocols of Students.

18.3 DEFINITION OF TERMS

18.3.1 Research Adviser – responsible party for assisting the student investigator with making ethical decisions throughout the life of the project

18.3.2 Research Protocol – a document that outlines the planning of your study.

18.3.3 Research Paper – an essay in which you explain what you have learned after exploring your topic in depth.

18.3.4 Turnitin – promote academic integrity, streamline grading and feedback, deter plagiarism, and improve student outcomes.

18.3.5 IERC – ethical clearance was obtained from Institutional Ethical Review Committee (IERC) to conduct the study.

18.4 STEPS IN DETAILS

Steps	Responsible	Details
1. Topic Approval	Students	• Approved by Research Professor
2. Research Adviser Assigned	Students' Research Coordinator	• Research Adviser signs Agreement form provided by RCD
3. Research Protocol undergoes Turnitin review	Students	• Turnitin review done at the FEU-NRMF Library

4. Research Protocol submitted to IERC

5. Research Paper finalized

Students • Protocol approved by IERC

Students • Submitted to Research Professor and RCD copy

rooco

undergoes Turnitin review

e - rary

4. Research Protocol submitted to IERC	Students	• Protocol approved by IERC
5. Research Paper finalized	Students	• Submitted to Research Professor and RCD copy also submitted to FEU NRMF Library

19.0 PROCESS FOR PUBLICATION OF RESEARCH PAPERS

19.1 PURPOSE

19.1.i To standardize the processes for efficient and timely dissemination of scientific articles submitted for publication.

19.1.ii To decrease the probability of errors and protect the FEU-NRMF from risks associated with publication.

19.2 SCOPE

19.2.i. This procedure covers the availability of scientific articles in medical and allied health sciences and its accessibility to internal and external clients of the Foundation.

19.3 DEFINITION OF TERMS

19.3.i Peer Reviewers - composed of subject experts who are not active consultants of FEU- Dr. Nicanor Reyes Medical Foundation.

19.3.ii Editorial Board - composed of the Editor-in-Chief and consultants from the different programs who see to it that the published articles are in conformity with the policies of FEU-NRMF.

19.4 STEPS IN DETAILS

Steps	Responsible	Details
1. Evaluation of submitted article	Editor-in Chief Editorial Consultants	• The Journal Editor-in-Chief and the Editorial Consultants evaluate the topic, structure, and format of the submitted article if it fits with the journal requirement. • If not, the Journal Editor-in-Chief sends the article back to the author with advice as rejection or for revision.

2. Peer-review Editor-in・If the article fits the journal

Consultants
, , of the submitted article if it fits with the journal requirement.
・If not, the Journal Editor-in-Chief sends the article back to the author with advice as rejection or for revision.

2. Peer-review	Editor-in Chief Peer-reviewer	・If the article fits the journal requirement, the Editor-in-Chief sends all articles submitted for publications for peer review. online data integrity and preservation.
3. Revision of peer reviewed article	Editor-in Chief Author	・The Editor-in-Chief sends back the peer-reviewed article to the author for revision.
4. Editing of articles	Editor-in Chief Publisher	・The Editor-in-Chief gets the revised article and arranges the edited articles into topics and themes of the journal and sends to the publisher for layout.
5. Proof copy of the Journal	Publisher	・The publisher sends the proof copy to the Editor-in-Chief
6. Final approval of proof copy	Editor-in Chief Authors	・The proof copy is circulated to authors for final approval prior to publication

7. Publication of Journal issue	Editor-in Chief Chief Librarian Chief Information Officer	・ Publication of the journal issue if there are no more comments and revisions ・ Mailing of hard copies to identified schools, agencies and organizations ・ Publication of journal articles at FEU-NRMF website

FEU-NRMF POLICIES AND GUIDELINES ON INTELLECTUAL PROPERTY RIGHTS (IPR)

The Intellectual Property Rights Policy of the Far Eastern University Nicanor Reyes Medical Foundation were approved by the Board of Trustee. The FEU-NRMF IPR Policy have been formulated by various stakeholders and are being implemented to promote and support the Research Center for Development function to provide an institutional mechanism for recognition of research output , foster innovation and protection of IPR resources to propel and sustain further research and to establish a process to protect the creative works and interests among the various stakeholders..

This policy is applicable to all faculty, employees, researchers, students and visitors from other universities or external linkages recognized by the institution or under grant from the institution.

This policy embodies all research and/or creative activities, discernible research outputs with or without patent or copyright protection, whether for commercial or non-commercial purpose.

Based on IP Code (RA 8293), the following will be covered in this policy: laws on patent, laws on trademarks, service marks and trade names and laws on copyright.

I. Laws on Patents

A. Claims for patents for inventions which offer solutions to specific technological problems must meet relevant patentability requirements such as novelty, usefulness and non-obviousness.

These inventions may be products or processes. The exclusive right granted to a patentee in the Philippines is the right to prevent others from commercially making, using, selling, importing, or distributing a patented invention without permission.

1. Commissioned Inventions

a. Inventions that received a financial grant from FEU-NRMF and had utilized the school resources;
b. Inventions produced under the main control of the University in pursuit of a specific project or purpose regardless of the source of funding;

c. Works whose inventorship could not be attributed to one or a discrete number of inventors despite the application of existing processes or rules;
d. Those that may be stipulated by contract as commissioned inventions.

2. Disclosure and Assignment

Appropriate disclosure and assignment of the patent to these works to the University in accordance with existing rules and implementing guidelines which may be promulgated by the Chairman of the Board of Trustees.

3. Inventions as a Result of Collaborative Efforts

Inventorship shall be determined by contractual stipulation, applications of the rules and standards of a publication primarily intended by the collaborative effort and by different modes of dispute processing thru mediation and arbitration.

4. Inventions Funded by External Grant

In the event that funding for the research is from external grant which is sourced thru FEU-NRMF, the school shall negotiate with the funding entity with respect to the ownership of the invention, patent rights and royalty sharing subject to confirmation of the institution. The agreement shall bind parties including the inventors.

Royalty Sharing

FEU-NRMF shall assign to the author(s), inventor(s) or creator(s) 100% of the first five hundred thousand pesos (or less) of the royalty received by the university from commercialization of the intellectual property. This amount may be adjusted on a yearly basis, taking into account factors such as inflation rate.

In excess of this amount, the author(s), inventor(s) or creator(s)shall receive at least 40% of the royalty received by the university. Collaborating authors or inventors shall share in accordance with the determination of their participation in the authorship or invention.

Twenty-five percent (25%) of the remainder of the royalty (i.e. 60%) shall go to FEU-NRMF, while seventy-five percent (75%) shall go to the constituent school, without prejudice to such policies or arrangement that the constituent university may have with respect to sharing its allocation of the net income with the department(s) or unit(s) from which the intellectual property originated.

Portability of Shares

Shares in royalty and other revenues such as upfront, milestones, and other payments shall be payable to the creator(s)/ inventor(s) of the intellectual property even after retirement, termination of their employment with the university or their contract of service or in the case of students after their graduation from the university; provided further, that said creator(s)/ inventor(s) have not been dismissed from the university because of violations (e.g. selling or compromising university trade secrets). The department/ institute from which the invention originated shall also continue to receive its shares in royalty or other payments.

Rules and Regulations Regarding Patents:

1. As a general rule, rights to patents shall belong to the inventors except in commissioned inventions where FEU-NRMF shall own all patents. All researches published in the FEU-NRMF Journal becomes the exclusive property of the FEU-NRMF Research Center for Development through the Committee on Publications

2. The FEU Journal shall be the first option for publication of all researches done at the FEU-NRMF through the different colleges as well as the FEU-NRMF Medical Center. However , on a case to case basis, the authors may opt to publish their researches in specialty journals both local and international. They however have to seek permission from the Research Center for Development through the Committee on Publication, and must always carry the name of the FEU-NRMF.
3. All researches done at FEU-NRMF through the various colleges as well as the FEU-NRMF Medical Center shall have the first option to be presented in the various research fora organized by the Research Center For Development. On a case to case basis, if the authors decide to have them presented in other research fora, whether local or international, they must seek permission from the Research Center for Development and must always carry the name of FEU-NRMF

4. If the researches completed involves innovations in terms of ideas, procedures, books, manuals, equipment, gadgets or other technologies, then the Research Center for Development may assist the authors in obtaining patents and copyrights to protect their rights of exclusive ownership, based on the Intellectual Property Code of the Philippines.

II. Laws on Copyright

As a general rule, the author/s of the work hold/s the copyright unless this is done in collaboration with the institution or with grant or support from it. In which case, the author must turnover the copyright to FEU-NRMF and disclose this. If the work done in collaboration or under grant of the institution is not printed within one year from its disclosure by FEU-NRMF for whatever reason, then the copyright is then automatically awarded to the author. Additionally, the author may request for the institution to forego with this time allotment if the work is to be approved for publishing in international journals provided that the FEU-NRMF is duly acknowledged.

Copyrights claims may be made for original literary and artistic works which may include books ,manuals , photos, or videos, etc made in our various colleges or even the FEU-NRMF Medical Center

In general, Copyright covers literary and artistic works, which is

understood to include every original work of authorship regardless of artistic or literary merit. It may also include but are not limited to literary works such as novels, poems, and plays; newspaper articles; films and television programs; letters; artistic works including paintings, sculptures, drawings, and photographs; architecture; computer programs; advertisements; maps and technical drawings.

The copyright law grants to the owner both economic and moral rights or rights of paternity.

Procedures for borrowing:

Section 1-List of FEU-NRMF Publications:

Section 2-Accessible Sections of the publications:

A. Free online or photocopy of the following

Cover page, year, volume number, editorial board, table of contents, references of:

- Abstract of journals (published from year ____to present to include contact details of authors
- Dissertations /Theses submitted to FEU-NRMF by authors
- Published books, manuals, or workbooks
- Full journal articles or books published later than above may be fully accessed (either online or photocopied)

B. With special permission: requires accomplishment of an official request form issued by the library and approved by the chief librarian ● Whole article of journals (of time period above) or book chapters (within 3 years from date of request) Theses/ Dissertations of any date

- Published, Unpublished works such as journal articles, workbook done within 3 years from time of request

Section 3 - The following are approved purpose of request for access : ● Shall be for research undertakings (done for FEU-NRMF or any other learning institution)

- Information source for any official teaching -learning activity in any

course of the FEU-NRMF learning community

Section 4 - Proper use of requested material:

- The materials obtained for purposes of research should be properly cited using APA format by the researcher. A copy of the portion of citation of the finished paper must be submitted to the FEU-NRMF library in pdf format within six months after completion of the work.
- No part of the work must be lifted verbatim and placed in the researcher's work unless properly referenced.
- No part of the borrowed work shall be reproduced and distributed by the borrower without permission from the chief librarian.

ABBREVIATION INDEX

*Abbreviations of terms utilized throughout the Standard Operating Procedures

ABBREVIATION	DEFINITION
ADR	Adverse Drug Reaction
CIOMS	Council for International Organizations of Medical Sciences
COI	Conflict of Interest
CRF	Case Report Form
CRO	Contract Research Organization or Clinical Research Organization
CTA	Clinical Trial Agreement

CV	Curriculum Vitae
DENR	Department of Environment and Natural Resources
FDA	Food And Drug Administration
FEU – NRMF	Far Eastern University – Nicanor Reyes Medical Foundation
IACUC	Institutional Animal Care and Use Committee
ICF	Informed Consent Form
ICH – GCP	International Conference on the Harmonization of Good Clinical Practice
ICU	Intensive Care Unit
IDE	Investigational Device Exemption
IERC	Institutional Ethics Review Committee
IND	Investigational New Drug
mm/dd/yyyy	month/day/year
MOA	Memorandum of Agreement
NCIP	National Commission on Indigenous Peoples
PHREB	Philippine Health Research Ethics Board
PI	Principal Investigator
RCD	Research Center for Development
SAE	Serious Adverse Event
SIDCER – FERCAP	Strategic Initiative for Developing Capacity in Ethical Review – Forum for Ethical Review Committees in Asia and the Western Pacific
SJREB	Single Joint Research Ethics Board
SOP	Standard Operating Procedures
SUSAR	Suspected, Unexpected Serious Adverse Reaction
TOR	Terms of Reference
UPMREB	University of the Philippines Manila Research Ethics Board
VPAA	Vice President for Academic Affairs
WHO – UMC	World Health Organization – Uppsala Monitoring Center

	Far Eastern University Far Eastern University NICANOR REYES MEDICAL FOUNDATION **NICANOR REYES MEDICAL FOUNDATION** Institutional Ethics Review Committee **Institutional Ethics Review Committee**	EFFECTIVE DATE: EFFECTIVE DATE: August 1, 2022 August 1, 2022
	STANDARD OPERATING PROCEDURES STANDARD OPERATING PROCEDURES	REV. NO.: 4.2 REV. NO.: 4.2

INTRODUCTION

The Far Eastern University – Nicanor Reyes Medical Foundation (FEU – NRMF) has for its vision, the pursuit of excellence in medical and paramedical education, quality health care services, and relevant research. Indeed, research has become a *sine qua non* in all aspects of sciences if they are to evolve and progress. Medical research is no exception to this rule. Research in medicine takes an extra special role because it utilizes human participants. Thus, while research is a necessary tool for the advancement of medical science, it too must ensure ample protection and safeguard the dignity, rights, safety, and well being of all human participants in research. Several national and international guidelines aimed specifically at protecting human participants have been developed so as they will not be placed in jeopardy

The FEU – NRMF Institutional Ethics Review Committee (IERC) addresses ethical issues in research involving human participants. The committee reviews all research protocols by principal investigators (PI), including PI-Initiated (FEU – NRMF faculty, consultant, resident/fellow-in-training, student) studies and Sponsor-Initiated studies done in this institution prior to implementation. For PI-initiated studies, a technical review approval from this institution is required prior to ethics review. The FEU-NRMF IERC may also review studies where the research site is outside the scope of authority of FEU-NRMF and the PI is a non FEU-NRMF personnel, provided that a technical review of the study has been accomplished in their institution and an official of the institution signifies capability to provide oversight in research site. For purposes of organization, the FEU – NRMF IERC is a subcommittee of the Research Center for Development, which coordinates researches from both the FEU – NRMF Medical Center and the FEU – NRMF Institute of Medicine. However, it must be emphasized that the committee's actions, including composition, procedures, and decision-making, are independent of political, institutional, professional, and market influences, as embodied in the World Health Organization – Operational Guidelines for Ethics Committees that Review Biomedical Research (2011). It utilizes the World Medical Association (WMA) Declaration of Helsinki as its guiding principle in reviewing research protocols.

The FEU-NRMF IERC had developed this Standard Operating Procedures (SOP), pursuant to Section 12 of the Philippine National Health Research System (PNHRS) Act of 2013, which states that the Philippine Health Research Ethics Board (PHREB), created under DOST Special Order No. 091 s. 2006, shall ensure adherence to the universal principles for the protection of human participants in research studies conducted in the Philippines.

The FEU – NRMF IERC has mainly adapted the University of the Philippines Manila Research Ethics Board SOP because of their close similarity in structure and organization as academic institutions which are closely associated with their respective medical centers that provide health care to patients, as well as being a training institution for specialty and subspecialty medical and paramedical practice. Other sources of information include the Philippine National Ethical Guidelines for Health and Health-Related
Research (2017), Makati Medical Center – Institutional Review Board SOP, "The SOP Workbook" (2020) of PHREB, and the technical expertise of the current FEU – NRMF IERC Members.

Appendix 1.1 **STRUCTURE AND COMPOSITION**

Institutional Ethics Review Committee
Far Eastern University
NICANOR REYES MEDICAL FOUNDATION

DOCUMENT CODE:
EFFECTIVE DATE:
SOP 01/04-02-2022
August 1, 2022

Institutional Ethics Review Committee
DOCUMENT TITLE:

EFFECTIVE DATE:
REV. NO.:
August 1, 2022
4.2

REV. NO.:
PAGE: 2 of 21
4.2

DOCUMENT TITLE: 1.1. STRUCTURE AND COMPOSITION

1. STRUCTURE AND COMPOSITION

PAGE: 2 of 21

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
Authored by:	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
Version Date:	08/01/2022
Approved by:	Atty. Antonio H. Abad President Far Eastern University - NICANOR REYES MEDICAL FOUNDATION
Approval Date:	

FAR EASTERN UNIVERSITY – NICANOR REYES MEDICAL FOUNDATION
INSTITUTIONAL ETHICS REVIEW COMMITTEE
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Document History

Author	Version	Date	Description of main change
Milagros F. Neri, MD, MA, MPH, MSAbraham 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, MSAbraham 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, MSAbraham 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

			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

Milagros F. Neri, MD, MA, MPH, MSAbraham Daniel C. Cruz, MD, MS – editor Trina C. Tan, RN, MAN Nimfa R. Baria, MD Joselito C. Matheus, MD Priscila Doctolero, EdD Lorelie Ann C. Rivera, MD Jures Mae Frias	04	03/15/2022	• Included Policy Statement at the Overview/Introduction or at the beginning of every SOP • 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) • Numbers placed in the workflow steps that correspond to the specific detailed procedures • Differentiated regular from alternate members in the appointment document – see From 1A2; Section 4 for definition of "alternate member"