Application Form

For Initial Review and Resubmission

Please print in LETTER size paper

SECTION I: APPLICATION INFORMATION		
1. Study Protocol Code:	1.1 FEU-NRMF IERC CODE:[1]	
2. Type of Submission	☐ 2.1 Initial Review ☐ 2.2 Resubmission (responses to initial review recommendations or submission of studies with investigator-initiated changes prior to ethics approval). NOTE: version and date of version must be inserted as a document footer for all resubmissions	
3. Date of Submission:	<mm/dd/yyyy> (to be filled by FEU-NRMF IERC staff)	
4. Study Category	☐ 4.1 Research involving human participants ☐ 4.2 Research involving non-human living vertebrates ☐ 4.3 Others (indicate):	

[1]To be issued upon initial processing by FEU-NRMF IERC

5. Type of study:	☐ 5.1 Biomedical studies (includes Retrospective, Prospective, and Diagnostic Studies, and use of human material and data) ☐ 5.2 Health operations Research (includes studies on Health Programs and Policies ☐ 5.3 Social Research (includes KAPs [knowledge, attitudes, practices] of communities, behavioral research, impact of public health interventions) ☐ 5.4 Public Health Research (includes epidemiologic researches – prevalence, surveys, incidence) ☐ 5.5 Clinical Trials (researcher-initiated; drug or pharmaceutical trials, diagnostic trials, trials on devices, and other therapy trials NOT intended for marketing registration) ☐ 5.6 Clinical Trials (sponsor-initiated; drug or pharmaceutical trials, diagnostic trials, trials on devices, and other therapy trials intended for marketing registration) ☐ 5.6.1 Phase 1 ☐ 5.6.2 Phase 2 ☐ 5.6.3 Phase 3 ☐ 5.6.4 Phase 4 ☐ 5.7 Others, please indicate:
6. Category of Investigator	☐ 6.1 FEU-NRMF Employees, Faculty and Consultants ☐ 6.2 FEU-NRMF Undergraduate Student ☐ 6.3 FEU-NRMF Fellows, Residents ☐ 6.4 Non-FEU-NRMF (NOTE: This category requires completion of *PART III: AUTHORIZATION AND ACKNOWLEDGEMENT OF REVIEW* below) ☐ 6.5 Others, please specify:
7. Purpose of study	☐ 7.1 Academic requirement (Thesis, Dissertation, Training Requirement) ☐ 7.2 Independent research work ☐ 7.3 Multi-institutional or multi-country collaboration ☐ 7.4Others (indicate):
8. Study Title	

9. Study Protocol Synopsis	*Please write a synopsis (maximum 500 words) of the study in the space provided below based on the specified components, and indicate page where such components may be found in the full study protocol or in annexes/appendices. If items are not applicable, indicate by N/A. Attach the full study protocol to this application. Make a diagrammatic workflow and attach it to the study protocol* 1. **Technical Synopsis** a. Objectives/Expected output _____ b. Literature review rationalizing the design _____ c. Research design _____ d. Sampling design, sample size _____ e. Inclusion criteria, exclusion criteria, withdrawal criteria _____ f. Data collection plan _____ g. Specimen collection and processing plan (including plans for specimen storage and duration of storage) _____ h. Data analysis plan (including statistical basis for design, as applicable) _____ i. Rationalization for choice of study site (including capacity of site to address known risks of study protocol, such as availability of equipment and facilities, as applicable) (Cross reference information with statements provided in the informed consent) _____

	2. **Ethical Considerations Section** a. Protection of privacy and confidentiality of research information including data protection plan _____ b. Vulnerability of research participants _____ c. Risks of the study (including social risks) _____ d. Benefits of the study _____ e. Patient-related compensations/reimbursements/entitlements _____ f. Informed consent process and recruitment procedures _____ g. Terms of reference of collaborative study (as applicable, such as intellectual property agreements and similar concerns) _____ h. Terms of available study-related insurance _____
10. Study Duration	(in months)
11. Use of special populations or vulnerable groups	☐ 11.1 Children (under 18) ☐ 11.2 Indigenous People ☐ 11.3 Elderly ☐ 11.4 People on welfare/social assistance ☐ 11.5 Poor and unemployed ☐ 11.6 Patients in emergency care ☐ 11.7 Homeless persons ☐ 11.8 Refugees or displaced persons ☐ 11.9 Patients with incurable diseases ☐ 11.10 Others (indicate): ☐ 11.11 Not applicable

12. Endorsing/College/ Unit/ Institution	☐ 12.1 School of Medicine ☐ 12.2 School of Medical Laboratory Science ☐ 12.3 School of Nursing ☐ 12.4 School of Physical Therapy ☐ 12.5 School of Respiratory Therapy ☐ 12.6 School of Radiologic Technology ☐ 12.7 School of Pharmacy ☐ 12.8 School of Nutrition and Dietetics ☐ 12.10 FEU-NRMF Medical Center (specify department or office): <name of institute or office> ☐ 12.12 Non-FEU-NRMF (local): <name of institution> ☐ 12.13 Non-FEU-NRMF (foreign institution): <name of institution>
13. Study site	☐ 13.1 FEU-NRMF unit ☐ 13.2 Non-FEU-NRMF with local IRB/ERB/ERC (please specify) ☐ 13.3 Non-FEU-NRMF without local IRB/ERB/ERC (please specify)
14. Funding agency:	**14.1 (NAME):**
	TYPE OF FUNDING AGENCY
	☐ 14.1 FEU-NRMF or FEU-NRMF unit ☐ 14.2 Investigator ☐ 14.3 PHL Government agency/office/entity ☐ 14.4 Multilateral Agency (UN agencies and other intergovernmental agencies) ☐ 14.5 Private company or Non-governmental organization (NGO) ☐ 14.6 Others (indicate):
15. Study Budget	NOTE: This refers to line item amounts. However, if a separate budget sheet is available, indicate total amount and attach budget sheet
16. Previous ethics approval or clearance issued by other sites	☐ 16.1 Name of Institutional Review Board or Ethics Review Committee: ☐ 16.2 Date of ethics approval: ☐ 16.3 Date of expiration of ethics approval: ☐ 16.4 Not applicable

17. Principal Investigator	<Title, Name, Surname>	
18. Birthday	<mm/dd/yyyy>	
19. PI Address	<Institutional Address>	
20. PI Telephone:		
21. PI Facsimile:		
22. PI Mobile:		
23. PI Email:		
24. Other Ongoing studies	☐ 24.1 Title: ☐ 24.1.1 FEU-NRMF IERC Code (if applicable):	☐ 24.3 Title: ☐ 24.3.1 FEU-NRMF IERC Code (if applicable):
	☐ 24.2 Title: ☐ 24.2.1 FEU-NRMF IERC Code (if applicable):	☐ 24.4 Title: ☐ 24.4.1 FEU-NRMF IERC Code (if applicable):
25. Declaration of Conflict of Interest of PI	☐ 25.1 I have no conflict of interest in any form (financial, proprietary, professional) with sponsor, the study, Co-Investigators, or the site	
	☐ 25.2 I have personal/family financial interest in the results of the study	
	NATURE:	
	☐ 25.3 I Have proprietary interest in the research (patent, trademark, copyright, licensing)	
	NATURE:	
26. Other investigators with corresponding task description *(add additional rows as applicable)*	Co-Investigator: Task description:	
	Co-Investigator: Task description:	
27. Single Joint Research Ethics Board (SJREB) Review	☐ 27.1 This study will undergo SJREB review. (specify SJREB Protocol No:_____) ☐ 27.2 This study will not undergo SJREB review.	
28. Submitted by:	<Title, Name, Surname>	

	Study designation	
29. PI signature		

SECTION II: SCIENTIFIC/TECHNICAL REVIEW APPROVAL ENDORSEMENT *This section should be signed by the Chair/Head of the Scientific/Technical Review committee/office that reviewed the scientific soundness of the study and issued the appropriate approval. Alternatively, results of Scientific/Technical Review disposition may be appended to this application, instead of completing this section, provided that the information required below had been appropriately addressed.*		
STUDY PROTOCOL TITLE:	<with Version Number and Date>	
Principal Investigator:	<Title, Name, Surname>	
I confirm that the (NAME OF SCIENTIFIC/TECHNICAL REVIEW COMMITTEE/OFFICE) has reviewed and approved the following study protocol-related information: Objectives/Expected output supported by literature review; overall research design; sampling design, sample size, Inclusion/exclusion/ withdrawal criteria; data collection plan and specimen collection, processing, and storage as applicable; data analysis plan including statistical design/framework, as applicable.		
Issuing committee/office:		
Head of committee/office:	<Title, Name, Surname>	
Signature:		Date of Signature: <mm/dd/yyyy>
SECTION III: INSTITUTIONAL ENDORSEMENT *This section should be signed by the head of unit of the Principal Investigator. This section is required only for initial submission,* ***provided there are no changes in study protocol information below.***		
STUDY PROTOCOL TITLE:		
Principal Investigator:	<Title, Name, Surname>	
I confirm that I have read this Application and that the research will be implemented under the oversight of this Department/Institution in accordance with the conditions of approval by the FEU-NRMF IERC.		
Issuing unit:		
Head of unit:	<Title, Name, Surname>	
Signature:		Date of Signature: <mm/dd/yyyy>
SECTION IV: AUTHORIZATION AND ACKNOWLEDGEMENT OF REVIEW *This section should be completed by the signatory official who can sign on behalf of the institution that has oversight on the research site,* ***IF the research site is OUTSIDE the scope of authority of FEU-NRMF and the PI is non FEU-NRMF personnel****. If not applicable, put N/A in all fields. This section is required only for initial submission,* ***provided there are no changes in study protocol information below.*** *In case regional IRB will opt not to review, attach letter of endorsement.*		
STUDY PROTOCOL TITLE:		
Principal Investigator:	<Title, Name, Surname>	
This is to certify that the **<NAME OF RESEARCH SITE>**authorizes and acknowledges the Far Eastern		

University – Nicanor Reyes Medical Foundation Institutional Ethics Review Committee (FEU-NRMF IERC), located at the Room 218 2nd Floor, Institute of Medicine, Regalado Avenue, West Fairview, Quezon City, to perform the ethical review of the abovementioned study protocol in accordance with international ethical standards and national regulatory requirements, and oversee the conduct of the research study which includes progress monitoring, adverse event monitoring, and site visits because of the following conditions:

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

Name of Research Site		
Address of Research Site		
Signatory Official	<Title, Name, Surname>	
Position of Official		
Signature		Date of Signature: <mm/dd/yyyy>