

	<p style="text-align: center;">Far Eastern University NICANOR REYES MEDICAL FOUNDATION Institutional Ethics Review Committee</p>	<p style="text-align: center;">EFFECTIVE DATE: August 1, 2022</p>
	<p style="text-align: center;">STANDARD OPERATING PROCEDURES</p>	<p style="text-align: center;">REV. NO.: 4.2</p>

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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

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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.