REGISTRATION AND APPLICATION FORM

For Initial Review

SECTION I: APPLICATION INFORMATION	
1. RIHS ERC CODE: *(assigned by the RIHS ERC upon initial submission)*	
2. Date of Submission	
3. Study Title	
4. List of documents for approval *(include the version number and date)*	☐ Study protocol version number and date ☐ Informed consent form version number and date ☐ Case report form ☐ Others *(please specify)*:
5. Study Category	☐ 5.1 Research involving human participants ☐ 5.2 Research involving non-human living vertebrates ☐ 5.3 Others (indicate):
6. Study Duration	(in months)

7. Type of study	☐ 7.1 **Non-clinical trial**, specifically (**choose one**): ☐ Biomedical Studies include Retrospective, Prospective and Diagnostic Studies, and use of human material and data ☐ Health Operations Research includes studies on Health Programs and Policies ☐ Social Research includes KAPs of communities, behavioral research, impact of Public Health interventions ☐ Public Health Research includes epidemiologic researches (prevalence, surveys, incidence) ☐ 7.2 **Clinical Trials (sponsor-initiated)** ☐ Phase 1 ☐ Phase 2 ☐ Phase 3 ☐ Phase 4 ☐ 7.3 **Clinical Trials (researcher-initiated)** ☐ 7.4 Others, please specify: _____
8. Study site	☐ 8.1 UERMMMCI unit ☐ 8.2 Non-UERMMMCI with local IRB/ERB/ERC ☐ 8.3Non-UERMMMCI without local IRB/ERB/ERC
9. Funding agency	**NAME**:
	TYPE OF FUNDING AGENCY *(pls. check below)*:
	☐ 9.1 UERMMMCI or UERMMMCI unit ☐ 9.2 Investigator ☐ 9.3 PHL Government agency/office/entity ☐ 9.4 Multilateral Agency (UN agencies and other intergovernmental agencies) ☐ 9.5 Private company or Non-governmental organization (NGO) ☐ 9.6 Others (indicate):
10. Previous ethics approval or clearance issued by other sites	☐ 10.1 Name of Institutional Review Board or Ethics Review Committee: ☐ 10.2 Date of ethics approval: ☐ 10.3 Date of expiration of ethics approval: ☐ 10.4 Not applicable

11. Principal Investigator			
12. PI Address	<Institutional Address>		
13. PI Contact Number	**Fax**	**Tel**	**Mobile**
14. PI Email			
15. Other ongoing studies	☐ 15.1 Title: ☐ 15.1.1 RIHS ERC Code (if applicable):	☐ 15.3 Title: ☐ 15.3.1 RIHS ERC Code (if applicable):	
	☐ 15.2 Title: ☐ 15.2.1 RIHS ERC Code (if applicable):	☐ 15.4 Title: ☐ 15.4.1 RIHS ERC Code (if applicable):	
16. Declaration of Conflict of Interest of PI	☐ 16.1 I have no conflict of interest in any form (financial, proprietary, professional) with sponsor, the study, Co-Investigators, or the site ☐ 16.2 I have personal/family financial interest in the results of the study NATURE: ☐ 16.3 I have proprietary interest in the research (patent, trademark, copyright, licensing) NATURE:		
17. Other investigators with corresponding task description *(add additional rows as applicable)*	Co-Investigator: Task description:		
	Co-Investigator: Task description:		
18. Submitted by	<Title, Name, Surname>		
19. PI signature			

SECTION II: 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 UERMMMCI and the PI is non UERMMMCI 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:		
This is to certify that the **<NAME OF RESEARCH SITE>:** 1) Has no local Institutional Review Board/ Ethics Review Committee; and 2) Authorizes and acknowledges the University of the East Ramon Magsaysay Memorial Medical Center Inc. Research Institute For Health Sciences Ethics Review Committee, located at the 2nd Floor JMC Bldg., Aurora Blvd. 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.		
Name of Research Site		
Address of Research Site		
Signatory Official		
Position of Official		
Signature		Date:

THIS PORTION FOR ETHICS REVIEW COMMITTEE USE

Type of review
☐ **Full board** • Clinical trial about investigational new drugs, biologics or devices in various phases (Phase 1, 2, 3) • Phase 4 intervention research involving drugs, biologics or devices • Protocol including questionnaires and social interventions that are confidential in nature (about private behavior, e.g., related to sexual preferences etc.; or about sensitive issues that may cause social stigma, psychological, legal, economic and other forms of social harm • Intervention protocols involving vulnerable participants • Protocols that involve collection of identifiable biological specimens from vulnerable groups, etc.
☐ **Expedited** • Non-confidential nature, not likely to harm the status or interests of the study participants and not likely to offend the sensibilities or cause psychological stress to the people involve • Not involving vulnerable subjects • Anonymous survey or retrospective chart review • Analysis of discarded pathological specimens / stored paraffin blocks without personal

identifiers
- Proposal involving previously banked materials and/or tissues as per policies of respective authorities like – tumor tissue repository
- Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes

☐ **Exempted**

- Does not involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols)
- Institutional quality assurance studies, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests
- Involve the use of publicly available data or information

Primary Reviewers:

1.
2.