Republic of the Philippines
Department of Health
Center for Health Development 2
REGION II TRAUMA AND MEDICAL CENTER

Protocol Application Form
For Initial Review and Resubmission

SECTION I: APPLICATION INFORMATION	
1. RIITMC-IRB 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:	
4. Study Category	☐ 4.1 Research involving human participants ☐ 4.2 Others (indicate):
5. Category of Investigator	☐ 5.1 University/College Faculty/REPS ☐ 5.2 University/College Undergraduate Student ☐ 5.3 Graduate Student (MS, PhD, Medical Student) ☐ 5.4 University/ Institute/Study Group Researcher, or other agency involve in research ☐ 5.5 Veterans Regional Hospital ☐ 5.5.1 Residents-in-training ☐ 5.5.2 Fellows-in-training ☐ 5.5.3 Residents/Fellows graduated completing research requirements ☐ 5.5.4 Nursing ☐ 5.5.5 Other Researchers ☐ 5.6 Others, please specify: _____.
6. Purpose of study	☐ 6.1 Academic requirement (Thesis, Dissertation, Training Requirement) ☐ 6.2 Independent research work ☐ 6.3 Multi-institutional or multi-country collaboration ☐ 6.4 Others (indicate):

7. Study Title	
8. Study Protocol Synopsis	*Please write a synopsis (maximum 500 words) of the study in the space provided below or another sheet 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** *This should be stated in the study protocol, as applicable.* 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
9. Study Duration	(in months)

10. Use of special populations or vulnerable groups	☐ 10.1 Children (under 18) ☐ 10.2 Indigenous People ☐ 10.3 Elderly ☐ 10.4 People on welfare/social assistance ☐ 10.5 Poor and unemployed ☐ 10.6 Patients in emergency care ☐ 10.7 Homeless persons ☐ 10.8 Refugees or displaced persons ☐ 10.9 Patients with incurable diseases ☐ 10.10 Others (indicate): ☐ 10.11 Not applicable
11. Endorsing/College/ Unit/ Institution	☐ 11.1 RIITMC Department of Anesthesiology Department of Cardiology Department of Endocrinology Department of Internal Medicine Department of Obstetrics and Gynecology Department of Pathology Department of Pediatrics Department of Surgery ☐ 11.2 Other Institutions ☐ 11.3 Foreign institution:
12. Study site	☐ 13.1 RIITMC unit ☐ 13.2 Outside RIITMC with local IRB/ERB/ERC ☐ 13.3 Outside RIITMC without local IRB/ERB/ERC
13. Funding agency:	**14.1 (NAME):**
	TYPE OF FUNDING AGENCY

	☐ 13.1 RIITMC unit ☐ 13.2 Investigator ☐ 13.3 PHL Government agency/office/entity ☐ 13.4 Multilateral Agency (UN agencies and other intergovernmental agencies) ☐ 13.5 Private company or Non-governmental organization (NGO) ☐ 13.6 Others (indicate):	
14. Study Budget	NOTE: This refers to line item amounts. However, if a separate budget sheet is available, just indicate total amount and attach budget sheet	
15. 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	
16. Principal Investigator		
17. Birthday		
18. PI Address	(Institutional Address)	
19. PI Telephone:		
20. PI Facsimile:		
21. PI Mobile:		
22. PI Email:		
23. Other Ongoing studies	☐ 23.1 Title:	☐ 23.3 Title:
	☐ 23.2 Title:	☐ 23.4 Title:
24. Declaration of Conflict of Interest of PI	☐ 24.1 I have no conflict of interest in any form (financial, proprietary, professional) with sponsor, the study, Co-Investigators, or the site	
	☐ 24.2 I have personal/family financial interest in the results of the study NATURE:	

	☐ 24.3 I Have proprietary interest in the research for which this application is being made (patent, trademark, copyright, licensing)	
	NATURE:	
25. Other investigators with corresponding task description *(add additional rows as applicable)*	Co-Investigator: Task description:	
	Co-Investigator: Task description:	
26. Submitted by:		
	Study designation	
27. 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:		
Principal Investigator:		
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:		
Signature:		Date of Signature:
SECTION III: INSTITUTIONAL ENDORSEMENT *This section should be signed by the head of unit (administrative authority legally empowered to sign on behalf the unit such as Dean, Director, and the like) 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:		
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 R2TMC Research Ethics Board. I also confirm that the Principal Investigator has a regular appointment in this institution.		
Issuing unit/college/:		
Head of unit:		
Signature:		Date of Signature:

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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 R2TMC and the PI is non R2TMC 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 Veterans Regional Hospital –Institutional Review Board (**R2TMC-IRB**), located at Maharlika Highway, Magsaysay, Bayombong, Neva Vizcaya 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 of Signature: