Registration and Application Form

For Initial Review and Resubmission

SECTION I: APPLICATION INFORMATION	
1. MDH IRB CODE	
2. Type of Submission	☐ Initial Review ☐ 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:	<dd/mm/yyyy>
4. Type of study:	☐ 5.2 **Non-clinical trial**, specifically (choose one): ☐ 5.2.1 Diagnostics ☐ 5.2.2 In vitro study ☐ 5.2.3 Genetic or genomic research ☐ 5.2.4 Stem Cell Research ☐ 5.2.5 Herbal Research ☐ 5.2.6 Complementary and Alternative Medicine Research ☐ 5.2.7 Research on Assisted Reproductive Technology ☐ 5.2.8 Research on Indigenous Materials ☐ 5.2.9 Review of medical records ☐ 5.2.10 Epidemiological study ☐ 5.2.11 Socio-behavioral Research ☐ 5.2.13 Health informatics ☐ 5.2.14 Operations/process research ☐ 5.3 **Clinical Trial Type 1** (*drug or pharmaceutical trials, diagnostic trials, trials on devices, and other therapy trials)* intended for marketing registration ☐ 5.4 **Clinical Trial Type 2** (*drug or pharmaceutical trials, diagnostic trials, trials on devices, and other therapy trials)* **NOT** intended for marketing registration ☐ 5.5 **Post Marketing Surveillance** ☐ 5.6 Others, please indicate:

5. Category of Investigator	☐ 6.1 MDH Consultant ☐ 6.2 MDH Undergraduate Student ☐ 6.3 MDH Graduate Student (MS, PhD, Medical Student) ☐ 6.4 MDH Institute/Study Group Researcher, Faculty ☐ 6.5 MDH Fellows, Residents, Nursing staff, Researcher ☐ 6.7 Others, please specify:
6. Purpose of study	☐ 7.1 Academic requirement (Thesis, Dissertation, Training Requirement) ☐ 7.2 Independent research work ☐ 7.3 Multi-institutional or multi-country collaboration ☐ 7.4 Others (indicate):
7. Study Title	
8. Study Protocol Synopsis	*Please submit a synopsis of the study in a separate sheet based on the specified components below, 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
9. Study Duration	(in months)

10. Total no. of Study Participants for the Site	
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. Study site	☐ 12.1 MDH ☐ 12.2 MDH Unit/ Department:
13. Funding agency:	**13.1 (NAME):**
	TYPE OF FUNDING AGENCY
	☐ 13.1 MDH or MDH 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. Principal Investigator	<Title, Name, Surname>
16. Birthday	<dd/mm/yyyy>
17. PI Address	<Institutional Address>
18. PI Telephone:	
19. PI Facsimile:	
20. PI Mobile:	

21. PI Email:		
22. Other Ongoing studies	☐ 22.1 Title: ☐ 22.1.1 MDH Code (if applicable):	☐ 22.3 Title: ☐ 22.3.1 MDH Code (if applicable):
	☐ 22.2 Title: ☐ 22.2.1 MDH Code (if applicable):	☐ 22.4 Title: ☐ 22.4.1 MDH Code (if applicable):
23. 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 (patent, trademark, copyright, licensing) NATURE:	
24. Other investigators with corresponding task description *(add additional rows as applicable)*	Co-Investigator: Task description:	
	Co-Investigator: Task description:	
25. Submitted by:	<Title, Name, Surname>	
	Study designation	
26. PI signature		

FOR MDH RESIDENTS, INTERNS, MEDICAL STAFF RESEARCHES AND INVESTIGATOR-INITIATED STUDIES

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 **MANILA DOCTORS HOSPITAL INSTITUTIONAL REVIEW BOARD (MDH-IRB)** 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: <dd/mm/yyyy>
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:	<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 Manila Doctors Hospital Institutional Review Board. I also confirm that the Principal Investigator has a regular appointment in this institution.		
Issuing unit:		
Head of unit:	<Title, Name, Surname>	
Signature:		Date of Signature: <dd/mm/yyyy>