UNIVERSITY OF PERPETUAL HELP SYSTEM –DALTA
UNIVERSITY OF PERPETUAL HELP SYSTEM- JONELTA
INSTITUTIONAL ETHICS REVIEW BOARD
Biomedical Research Institute,
Upper Basement, Tamayo Tower, UPHDMC
Alabang Zapote Road, Las Piñas City, Tel. No. (632) 874-8515 local 631; 873-3772

Form 2.1 (A) 2018
Application Form

Application Form
For Initial and Resubmission

SECTION I: APPLICATION INFORMATION		
1. Reference Code	1.1 PROTOCOL CODE:	
	1.2 IERB CODE:	
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 Title		
5. Purpose of study	☐ 5.1 Academic requirement (Thesis, Dissertation, Training Requirement) ☐ 5.2 Independent research work ☐ 5.3 Multi-institutional or multi-country collaboration ☐ 5.4 Others (indicate):	
6. Study Category	☐ 6.1 Research involving human participants ☐ 6.2 Research involving non-human living vertebrates ☐ 6.3 Others (indicate):	
7. Study Duration	(in months)	

8. Type of study:	☐ 8.1 Pre-clinical Research ☐ 8.2 **Non-clinical trial**, specifically (choose one): ☐8.2.1 Diagnostics ☐8.2.2 In vitro study ☐8.2.3 Genetic or genomic research ☐8.2.4 Stem Cell Research ☐8.2.5 Herbal Research ☐8.2.6 Complementary and Alternative Medicine Research ☐8.2.7 Research on Assisted Reproductive Technology ☐8.2.8 Research on Indigenous Materials ☐8.2.9 Review of medical records ☐8.2.10 Epidemiological study ☐8.2.11 Socio behavioral Research ☐8.2.13 Health informatics ☐8.2.14 Operations/process research ☐ 8.3 **Clinical Trial Type 1**(*drug or pharmaceutical trials, diagnostic trials, trials on devices, and other therapy trials)* intended for marketing registration ☐ 8.4 **Clinical Trial Type 2** (*drug or pharmaceutical trials, diagnostic trials, trials on devices, and other therapy trials)* **NOT** intended for marketing registration ☐ 8.5 **Post Marketing Surveillance** ☐ 8.6 Others, please indicate: _____
9. Category of Investigator	☐ 9.1 UPHS Faculty ☐ 9.2 UPHS Undergraduate Student ☐ 9.3 UPHS Graduate Student (MS, Medical Student) ☐ 9.4 UPHDMC Fellows, Residents, Nursing staff, Researcher ☐ 9.5 Non-UPHS (NOTE: This category requires completion of PART *II: AUTHORIZATION AND ACKNOWLEDGEMENT OF REVIEW* below) ☐ 9.6 Others, please specify: _____

10. Study Protocol Synopsis	*Please write a synopsis (maximum 500 words) of the study in a SEPARATE 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** 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
11. Study site	☐ 11.1 UPHDMC unit ☐ 11.2 UPHSD unit ☐ 11.3 Non-UPHS with local IRB/ERB/ERC ☐ 11.4 Non-UPHS without local IRB/ERB/ERC

12. Endorsing/College/ Unit/ Institution	☐ 12.1 College of Medicine ☐ 12.2 College of Nursing ☐ 12.3 College of Allied Rehabilitation Services ☐ 12.4 Graduate School ☐ 12.5 UPHDMC Hospital (Put department and section): <name of department & section> ☐ 12.6 Non-UPHS (local): <name of institution> ☐ 12.7 Non-UPHS (foreign institution): <name of institution>
13. Use of special populations or vulnerable groups	☐ 13.1 Children (under 18) ☐ 13.2 Indigenous People ☐ 13.3 Elderly ☐ 13.4 People on welfare/social assistance ☐ 13.5 Poor and unemployed ☐ 13.6 Patients in emergency care ☐ 13.7 Homeless persons ☐ 13.8 Refugees or displaced persons ☐ 13.9 Patients with incurable diseases ☐ 13.10 Others (indicate): ☐ 13.11 Not applicable
14. Funding agency	**NAME**:
	TYPE OF FUNDING AGENCY *(pls. check below)*:
	☐ 14.1 UPHS 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, just indicate total amount and attach budget sheet
16. Previous ethics approval	☐ 16.1 Name of Institutional Review Board or Ethics Review Committee:

or clearance issued by other sites	☐ 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. PI Address	<Institutional Address>		
19. PI Contact Number	**Fax**	**Tel**	**Mobile**
20. PI Email			
21. Other Ongoing studies	☐ 21.1 Title: ☐ 21.1.1 UPHS-IERB Code (if applicable):	☐ 21.3 Title: ☐ 21.3.1 UPHS IERB Code (if applicable):	
	☐ 21.2 Title: ☐ 21.2.1 UPHS IERB Code (if applicable):	☐ 21.4 Title: ☐ 21.4.1 UPHS-IERB Code (if applicable):	
22. Declaration of Conflict of Interest of PI	☐ 22.1 I have no conflict of interest in any form (financial, proprietary, professional) with sponsor, the study, Co-Investigators, or the site ☐ 22.2 I have personal/family financial interest in the results of the study NATURE: ☐ 22.3 I Have proprietary interest in the research (patent, trademark, copyright, licensing) NATURE:		
23. Other investigators with corresponding task description *(add additional rows as applicable)*	Co-Investigator: Task description:		
	Co-Investigator: Task description:		
24. Submitted by:	<Title, Name, Surname>		
	Study designation		
25. PI signature			
26. Received by:		**27. Signature:**	**28. Date received:**

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 UPHS and the PI is non UPHS 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>:** 1) Has no local Institutional Review Board/ Ethics Review Committee; and 2) Authorizes and acknowledges the University of Perpetual Help System, Institutional Ethics Review Board, Biomedical Research Institute, Upper Basement, Tamayo Tower, UPHDMC, Las Pinas 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	<Title, Name, Surname>	
Position of Official		
Signature		Date: <mm/dd/yyyy>

NOTE TO APPLICANTS: Please make sure that you have a copy of this form duly signed by the person who received the application