PHILIPPINE HEART CENTER
Institutional Ethics Review Board
8/F Medical Arts Building
East Avenue, Quezon City, 1100 Philippines
Tel./Fax no. 9252401 loc.3899; email add: irbphc@gmail.com

Initial IERB Application Form

For Initial IERB Review Only

IERB no.	
DETR no.	

Administrative Information

1. Protocol no.		**2. Date of this Request**	
3. Study Title			
4. Department		**5. Division**	

Role	Name	Email	Mobile/Phone /Fax	PRC License #
6. Principal Investigator				
7. Contact Person				
8. Co-Investigator				
9. All personnel listed above have completed GCP training Please attach current certificate			☐ Yes	☐ No

10. Declaration of Conflict of Interest of PI	☐ I have no conflict of interest in any form (financial, proprietary, professional) with sponsor, the study, Co-Investigators, or the site ☐ I have personal/family financial interest in the results of the study NATURE: ☐ I Have proprietary interest in the research (patent, trademark, copyright, licensing) NATURE:

11. Study Category	☐ Research involving human participants ☐ Research involving non-human living vertebrates ☐ Others (indicate):

12. Study Summary

Summarize your study. The summary should be written in language intelligible to a moderately educated, non-scientific layperson. It should contain a clear statement of the rationale and hypothesis of your study, a concise description

Summary	
Proposed length (time period) of the study *State number of years, months, or weeks*	
Purpose of the Study	
Research Procedures *Describe the source of the data and the data collection procedures*	
Risks	☐ Minimal; justify why this category is appropriate ☐ Greater than minimal What precautions have been taken to minimize these risks and what is their likely effectiveness? Describe other alternative and accepted procedures, if any, that were considered and why they will not be used: ☐ Unknown, describe
Vulnerable subjects *If this study involves vulnerable subjects describe additional safeguards included in the protocol to protect the rights and welfare of these subjects*	☐ No ☐ Yes, describe:
More than Minimal Risk of Harm *If the research involves more than minimal risk of harm to subjects, describe the provisions for monitoring the data to ensure the safety of subjects*	☐ No ☐ Yes, describe:
Benefits *Assess the potential benefits to science and/or society which may occur as a result of this research. If the risk in this study is more than minimal, explain how the risks are reasonable in relation to the benefits*	

General Study Information

Target Population : _____ **Estimated Project Duration** Start Date: _____ End Date:_____	Participant Ages (Please check) ☐ 0-7 (parental consent) ☐ 7-11(parental consent and verbal assent) ☐ 12-14 (Parental consent and Child's assent) ☐ 15-18 (parental permission and co-signature of the child in the ICP) ☐ 19-65 ☐ 65+
Will this Study Involve Long-Term Follow-Up with participants: ☐ Yes ☐ No. If Yes, please describe:	

Study Type

Type of Study	☐ Double-blind ☐ Single-blind ☐ Open-label	☐ Pilot ☐ Observational ☐ Descriptive
Phase of Study	☐ N/A (not a clinical trial) ☐ Phase 1 ☐ Phase 2	☐ Phase 3 ☐ Phase 4
Name of Drug		
Sponsor		

As Principal Investigator of this study, I assure the IRB that the following statements are true:

The information provided in this form is correct. I have evaluated this protocol and determined that I have the resources necessary to protect participants, such as adequate funding, appropriately trained staff, and necessary facilities and equipment. I will seek and obtain prior written approval from the IERB for any substantive modifications in the proposal, including changes in procedures, co-investigators, funding agencies, etc. I will promptly report any unexpected or otherwise significant adverse events or unanticipated problems or incidents that may occur in the course of this study. I will report in writing any significant new findings which develop during the course of this study which may affect the risks and benefits to participation. I will not begin my research until I have received written notification of final IERB approval. I will comply with all IERB requests to report on the status of the study. I will maintain records of this research according to IERB guidelines. The grant that I have submitted to my funding agency which is submitted with this IRB submission accurately and completely reflects what is contained in this application. If these conditions are not met, I understand that approval of this research could be suspended or terminated.

Signature over PRINT Name of PI	Title of PI	Date

Attachments to Include in ten (10) copies

Always Submit These Documents	☐ Application for Initial IERB Application Form ☐ Protocol Summary ☐ Full Protocol ☐ Declaration of No Conflict of Interest ☐ CV/Resume for Principal Investigator and all Co-Investigators	☐ GCP Certification of PI and all Co-Investigator ☐ Information for subjects ☐ Informed Consent Form (English and Filipino versions) and/or Assent Form (English & Local Dialect) – *(for pediatric patients)*
Additional Documents to Submit (For Clinical Trials)	☐ Questionnaire (English and Tagalog Versions) ☐ Philippine Food and Drug Administration (PFDA) Approval	☐ Information for subjects ☐ Investigator's Brochure ☐ Certificate of Insurance (if applicable)
Submit Only When Applicable	☐ Ads for Advertisement, if applicable ☐ Case Report Forms (CRF) ☐ Pharmacogenetics ICF (English and Tagalog Versions) ☐ Subject Worksheets/ Patient Diary /Alert Cards (English and Tagalog Versions) ☐ Data Collection Form(s) ☐ Waiver of Authorization/Consent ☐ Appendix: Cognitively Impaired ☐ Appendix : Data Stored for Future Use	☐ Your research subjects include vulnerable populations; you have to attached the following appendices to this form: ☐ Appendix : Children ☐ Appendix : Deception ☐ Appendix: Pregnant Women, Fetuses and Neonates ☐ Appendix: Prisoners ☐ GANTT Chart