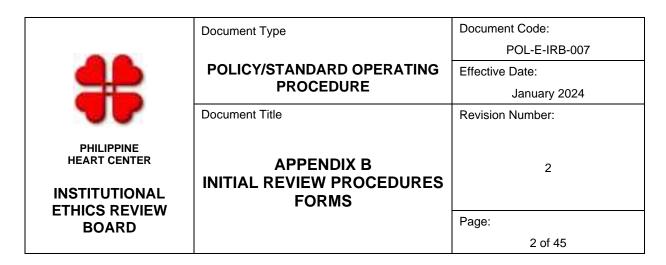


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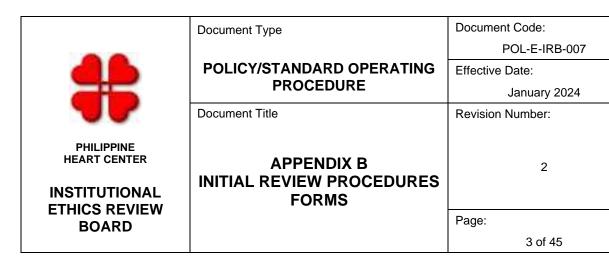
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	F	REVISION HISTORY	
Rev No.	Review Date	Description of Change	Date of Next Review
0		Original	July 2020
1	December 2020	Change of Format	December 2021
2	January 2024	Change of Format	January 2025

Reviewed by:	MARIA TERESA B. ABOLA, MD Deputy Executive Director for Education Training and Research Services	Approved by:	JOEL M. ABANILLA, MD Executive Director
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Appendix B Initial Review Procedures Forms

FM-E-IRB-2019-021 Rev. 07	Initial Review Application form
FM-E-IRB-2019-014 Rev. 04	Document Receipt Form
FM-E-IRB-2019-043 Rev. 08	IERB Reviewer's Evaluation Form
FM-E-IRB-2019-044 Rev. 07	Participants Information and Informed Consent Form
FM-E-IRB-2019-041 Rev. 04	Request for Waiver of Informed Consent Form
FM-E-IRB-2019-042 Rev. 05	Participant Information and Assent Form (For ages 12 to below 15)
FM-E-IRB-2019-076 Rev. 03	Parent Information and Informed Consent Form
FM-E-IRB-2019-017 Rev. 06	IERB Decision Form
FM-E-IRB-2019-056 Rev. 05	Modification Letter Template
FM-E-IRB-2019-022 Rev. 05	Resubmission Report Form
FM-E-IRB-2019-045 Rev. 08	Decision Letter for Protocol Approval Template
FM-E-IRB-2019-087 Rev. 00	Certificate of Exemption from Ethics Review
FM-E-IRB-2019-096 Rev. 00	Checklist for Exemption from Protocol Review
	FDA Clinical Trial Assessment Form Version 1.2/16 July 2012



FM-E-IRB-2019-021-Rev. 07 Initial Review Application Form



Initial IERB Application Form

For Initial IERB Review Only

IERB no.	
CTRD 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				
All personnel listed a Please attach current or	□ 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):



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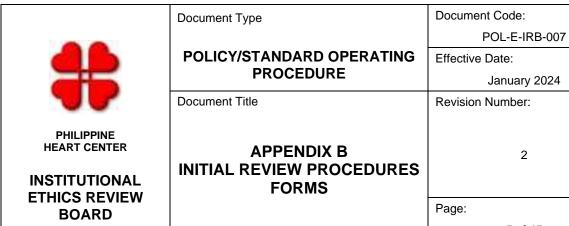
12. Study Summary

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

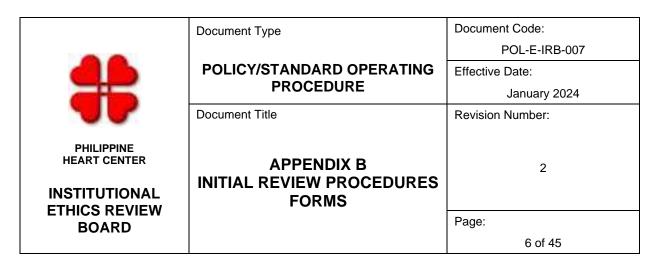
_	description		
	Summary		
	Proposed length (time period) of the study State number of years, months, or weeks		
	Purpose of the Study		
	Research Procedures Describe the source of the data and the data collection procedures		
	Risks	0 0	Minimal; justify why this category is appropriate Greater than 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	0	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	0	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

	Participant Ages (Please check)
Target Population :	0-7 (parental consent)
	 7-11(parental consent and verbal assent)
Estimated Project Duration	 12-14 (Parental consent and Child's assent)
Start Date:	 15-18 (parental permission and co-signature of the
End Date:	child in the ICP)
Life Delic.	□ 19-65
	□ 65÷



				5 of 45		
Will this Study Involve	Long-Term Follow-Up with participar	nts: 🗆 Yes	□ No.			
If Yes, please describ	2:					
Study Type						
Type of Study	□ Double-blind			Pilot		
	□ Single-blind			Observational		
	□ Open-label			Descriptive		
Phase of Study	N/A (not a clinical trial)		□ Pha	1		
	☐ Phase 1 ☐ Phase 2		□ Pha □ Pha			
Name of Drug	U Friase 2		□ Fria	36 7		
Sponsor						
	or of this study, I assure the IRB tha	_				
	I in this form is correct. I have evaluated					
	quate funding, appropriately trained sta- or any substantive modifications in the p					
	any unexpected or otherwise significant					
course of this study. I wil	I report in writing any significant new find	dings which develop during	g the course of th	nis study which may affect the risks		
	ion. I will not begin my research until I I					
	on the status of the study. I will maintain agency which is submitted with this II					
	itions are not met, I understand that app					
Signature ove	r PRINT Name of PI	Title of PI		Date		
Attachments to Includ	e in bue (1) hard and one (1) digits	al conv				
Always Submit These	Application for Initial IERS Applica		GCP Certification	on of PI and all Co-Investigator		
	Protocol Summery		Information for:			
Documents	Full Protocol			ent Form (English and Filipino versions)		
	☐ Declaration of No Conflict of Intere		and/or Assent	Form (English & Local Dialect) - (for		
	CV/Resume for Principal Investiga	tor and all Co-	pediatric patien	ts)		
Additional Documents to	Investigators					
Submit	Questionnaire (English and Tagalo	·	Information for:	-		
(For Clinical Trials)	Philippine Food and Drug Ar Approval	F 1	Investigator's B			
Sub-2 Only When						
Applicable	Ads for Advertisement, if applicab	»e		ubjects include vulnerable populations; sched the following appendices to this		
		d Tanalas Massians	form:			
	Pharmacogenetics ICF (English and Subject Worksheets/ Patient Diary		☐ Appendix :	Children		
	and Tagalog Versions)	areas caraa pangian	☐ Appendix : □	eception		
	☐ Data Collection Form(s)		☐ Appendix: Pr	regnant Women, Fetuses and Neonates		
	☐ Weiver of Authorization/Consent		☐ Appendix: Pr	risoners		
	☐ Appendix: Cognitively Impaire	:d	GANTT Chart			
I						
	☐ Appendix : Data Stored for Fu					



FM-E-IRB-2019-014 Rev. 05 **Document Receipt Form**



Document Receipt Form

1. IERB no.:			Submit		ted date:	
2. Source of Fund:		PHC Funded		□ N	on-PHC Funded	
3. DETR no.:			Protocol no).		
4. Sponsor / CRO			•			
5. Principal Investig	gator:					
6. Protocol Title: 7. Type of Submissi	loni	Initial Review			ontinuing Review	
7. Type of Submissi	ion: -				_	
		_Resubmission for a		I — ·	proved Protocols	
	_	_Protocol Amendmer	nts	Pr	otocol Termination	
8. Delivery Route:	<u>'</u>	□ Post	st		☐ In Person	
Submitted	□ Full Protocol □ Declaration of No Conflict of Interest □ Data Collection Form(s) □ Informed Consent Form (English & Local Dialed Assent Form (English & Local Dialect) □ Subject Worksheets/ Patient Diary /Alert Cards (English and Tagalog Versions) □ Pharmacokinetics ICF (English and Tagalog Versions) □ Questionnaire (English and Tagalog Versions) □ Philippine Food and Drug Administration (PFD Approval) □ Complete		& Local Dialect alect) y /Alert Cards nd Tagalog og Versions)		GANTT Chart Ads for Advertisement, if applicable Information for subjects Case Report Forms (CRF) Investigator's Brochure Certificate of Insurance (if applicable) CV of Proponent; GCP Certification Others Incomplete, will submit on	
11. Documents to be submitted later	Information for subjectsInformed consent/assent formOthers		 	Study budget Investigator's brochure Case report forms (CRF)		
12. Submitted by:		13. Sign	ature:	14.	Date submitted:	
15. Received by:		16. Sign	ature:	17.	Date received:	

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



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FM-E-IRB-2019-043 Rev. 08 IERB Reviewer's Evaluation Form



IERB Reviewer's Evaluation Form

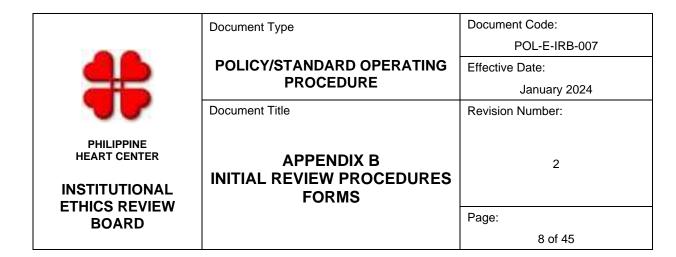
IERB No.		PROTOCOL No.	CTRD No.	
PROTOCOLTITLE				
PRINCIPALINVESTI	GATOR			

Please respond to the following questions (Lay Reviewers: Answer - Part II - Human Subjects Issues)

I. SCIENTIFIC ISSUES

Source - Management - Management	Secretary and the secretary and an analysis of the secretary and analysis of the secretary and analysis of the secretary and an anal	COMMENTS
1. Clear Unclear	Objectives of the Study	Sic a se carouse erroran. I
2. Clear Unclear	Methodology	
3. Sufficient Insufficient	Background Information and Data	
4. Appropriate Inappropriate	Inclusion Criteria	
5. Appropriate Inappropriate	Exclusion Criteria	
6. Appropriate Inappropriate	Withdrawal Criteria	
7. Yes No	Sufficient number of participants 2	
8. Yes No NA	Control Arms (placebo, if any) Justified	
9. Yes No	Are Qualification and experience of the Participating Investigators appropriate?	
10. Yes No	Disclosure or Declaration of Potential Conflicts of Interest, If applicable	
11. Yes No NA	Are the follow-up procedures sufficient?	

FM-E-IRB-2019-046 Rev. 08



II. HUMAN SUBJECTS ISSUES

A. Consent Form			
1. Yes No	Has the investigator requested WAIVER of the consent requirement? If <u>yes</u> , indicate whether acceptable and why.		
If <u>no</u> , who will consent:	subject or 🔲 parent/legally authorized representative?		
2. Yes No	Is the age of subjects detailed? If so, what is the age range of the subjects?		
3. Yes No	Does subject selection appear appropriate for the study? (Optional for Lay)		
	☐ Men ☐ Women ☐ Children ☐ He Ilnerable populations (pregnant women, fetuses, children		
4. Yes No	Does the recruitment plan allowfor equitable selection of subjects?		
5. Yes No	Are there appropriate protection for the subject's social welfare and legal concerns?		
6. ☐ Yes ☐ No	Is the consent form comprehensive and written in English and Tagalog? If changes to the consent form are recommended,		
7. Yes No NA	Are there clear distinctions between research and standard care?		
8. Yes No NA	Are the exams, history taking, lab tests, etc. adequate to monitor subject safety?		
9. Yes No NA	If there is a period when treatment will be withheld, are there adequate safeguards for subjects?		
10. Yes No NA	If monetary compensation will be provided to subjects, is the amount detailed and appropriate (not coercive)?		
11. Yes No NA	Is it clear what costs the subject is or is not responsible for?		
12. Yes No NA	Is the process of obtaining consent clearly stated?		
Does the consent form contain all of the required elements of informed consent, if <u>applicable</u>			
1. Yes No	A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;		
2. Yes No	A description of any reasonably foreseeable risks or discomforts to the subject;		

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3. Yes No	A description of any benefits to the subject or to		
	others which may reasonably be expected from the		
	research;		
4. Yes No	A disclosure of appropriate alternative procedures		
	or courses of treatment, if any, that might be		
E DVaa DNa	advantageous to the subject; A statement describing the extent, if any, to which		
5. Yes No	confidentiality of records identifying the subject will		
	be maintained:		
	be mantamed,		
6. Yes No No	A For research involving morethan minimal risk, an		
5. 6. 33 6.13 6.11	explanation as to whether any compensation and,		
	an explanation as to whether any medical		
	treatments, are available if injury occurs and, if so,		
	what they consist of, or where further information		
	may be obtained;		
7. Yes No	An explanation of whom to contact for answers to		
	pertinent questions about the research and research		
	subjects' rights, and whom to contact in the event of		
0 Elv Elv-	a research-related injury to the subject; and		
8. Yes No	A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits		
	to which the subject is otherwise entitled, and the		
	subject may discontinue participation at any time		
	without penalty or loss of benefits to which the		
	subject is otherwise entitled.		
	Subjectio Galerwise chaled.	I.	
The regulations further re	equire that the following additional information be pro	vided to subjects, if applicable	
1. Yes No NA	A statement that the particular treatment or procedure		
	may involve risks to the subject (or to the embryo or		
	fetus, if the subject is or may become pregnant) which		
	are currently unforeseeable;		
2. Yes No NA	Anticipated circumstances under which the subject's		
	participation may be terminated by the investigator		
	without regard to the subject's consent;		
3. Yes No NA	Any additional costs to the subject that may result from		
	participation in the research;		
4. Yes No NA	The consequences of a subject's decision to withdraw		
	from the research and procedures for orderly termination of participation by the subject:		
5. Yes No NA	A statement that significant new findings developed		
J. LI IS LINO LINA	during the course of the research which may relate to		
	the subject's willingness to continue participation will be		
	provided to the subject; and		
6. Yes No NA	The approximate number of subjects involved in the		
	study.		
	-		
B. ETHICAL ISSUES			
Vulnerable Populations,			
1. Yes No NA	Are there protections for vulnerable subjects (fetuses,		
	children, decisionally-impaired, prisoners, economically or socially disadvantaged populations, including		
	children who are wards of the state)?		
2. Yes No NA	Is it necessary for provisions to be made to determine		
	competency		
Risk/Benefit Assessmen		T	
1. Yes No	Is this a greater than minimal risk study? (See		
	definitions.)		

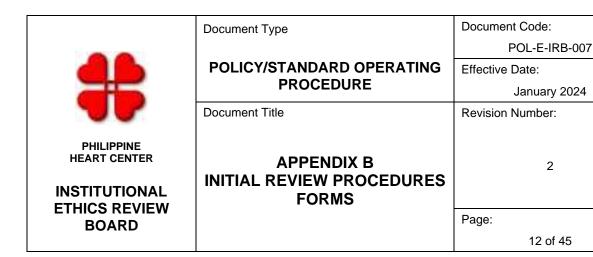
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Bielo There is a seebability	A home or injury (abustical accordance of a second accordance of a s	
	of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both e of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk."	
themselves, than those ordi	mal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of narily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of	
2. Yes No 1	VA Is there a prospect of direct benefit to the subjects?	
3. Yes No 1	NA Are the risks/benefits justifiable and adequately defined?	
4. Yes No 1		
5. Yes No	Based on the degree of risk to subjects, is the standard one year and subsequent annual review appropriate? If no, what would you recommend?	
6. Yes No NA If the study involves interventions that could have adverse effects on a fetus, are pre-enrollment and follow-up pregnancy tests included?		
7. Yes No 1	NA Are women (and men) of child-bearing potential advised to practice medically accepted methods of birth control?	
Pediatric Studies, if a	applicable	
1. Yes No	Should subject assent be REQUIRED? □Verbal assent (7-<12y/o) □Simplified Assent (12-<15y/o) □ Co-sign with parents/LAR the ICF ≥15y/o	
2. Yes No Can assent be WAIVED for all or some subjects?		
3. The category of ris	sk must be determined for research involving children (check the appropriate category):	
a) Yes No	Research not involving greater than minimal risk.	
b) Yes No	Research involving greater than minimal risk but presenting the	
c) Yes No	prospect of direct benefit to the individual subjects Research involving greater than minimal risk and no prospect of	
	direct benefit to the subject but likely to yield generalizable knowledge about the subject's disorder or condition (46.406)*.	
d) Yes No	Research not otherwise approvable which presents an opportunity to understand, prevent or alleviate a serious problem affecting	
	children (46.407)*.	
Confidentiality		
1. Yes No	Is there an appropriate procedure for protecting the subject's privacy and confidentiality?	
2. Yes No	Are there any special privacy/confidentiality issues, i.e., sensitive societal or legal information, genetic information, etc.?	
3. Yes No		
4. Yes No	•	

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A. Investigational Drugs

Yes No	1. Is this an investigational drug study? If yes, has a formal filing been made with PFDA for an Investigational New Drug (IND)? Yes No 2. Is this a marketed drug being studied for a new purpose (off-label use)? If yes, has an IND been filed or is there appropriate justification indicating that it is not necessary to file one?	
D. <u>Devices</u>		
1. Yes No	Is this an investigational device study? If <u>yes</u> , has an Investigational Device Exemption (IDE) been filed with PFDA? ☐ Yes ☐ No If <u>yes</u> , what is the appropriate classification? ☐ Significant Risk or ☐ Non-Significant Risk.	
2. Yes No No	A Is the device classification appropriate?	
COMMENTS: Kindly re additional sheet if neces	■ Minor Modifications ■ Major Modification ference any items listed above of which you have concern(s sary):	
ETHICAL: Approved COMMENTS: Kindly re	☐ Minor Modifications ☐ Major Modification ference any items. listed above of which you have concern(s	
additional sheet if neces	sary):	
Reviewer's Name:		



FM-E-IRB-2019-044 Rev. 07 **Participants Information and Informed Consent Form**

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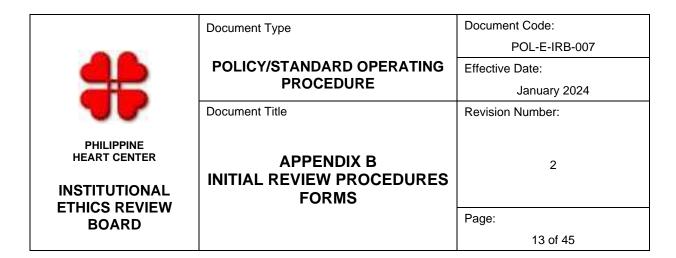
Participant Information and Informed Consent Form

IMPORTANT: PLEASE READ THE ENTIRE DOCUMENT. DELETE ALL TEXTS IN RED BEFORE SUBMITTING TO THE PHC IERB FOR REVIEW.

This template serves as a guide and may be edited according to your research requirements. This document is for a prospective participant who may not be familiar with scientific/medical terms therefore it is suggested not to use them, if possible, in this document. Use a language that is understandable to a grade 6 student. Use at least a 12pt font for the entire document. Write in second person.

IERB NUMBER	
PROTOCOL NUMBER	
SITE OF STUDY	
Lugar ng Pag-aaral	
TITLE OF STUDY	
Pamagat ng Pag-aaral:	
LANGUAGE	Frelish Tagalag
Wika:	English/Tagalog
NAME OF PARTICIPANT	
Pangalan ng Kalahok	
NAME OF STUDY DOCTOR	
Pangalan ng Doktor ng Pag-aaral	
ADDRESS OF STUDY DOCTOR	
Address ng Doktor ng Pag-aaral	Do not write down home address
CONTACT NUMBER	
Telepono at iba pang detalye sa pagkontak	

You are being considered to join a study about (Describe what the study is about) because you are(Explain why they are being considered to be part of the study)



Before you can take part in this study, it is important that you understand what the study involves. Please read theinformation carefully and ask any questions that you might have. The

Philippine Heart Center Institutional Ethics Review Board (PHC IERB) has reviewed the the study and has given a favorable opinion of it.
1) Pakikilahok Ikaw ay ibinibilang na sumali sa pag-aaral tungkol sa dahil ikaw ay
Bago ka makilahok sa pag-aaral na ito, mahalagang maintindhan mo kung ano ang nakapaloob sa pag-aaral na ito. Mangyaring basahin nang mabuti ang impormasyon at magtanong ka ng anumang gusto mong itanong. Ang Philippine Heart Center Institutional Ethics Review Board (PHC IERB) ang nakapagrepaso sa pag-aaral at nakapagbigay ng mabuti o paborableng valagay tungkol dito.
2) Purpose of the Study Explain why you are doing the research in lay terms. The language used must clarify rather than confuse. Do not copy paste objectives of the protocol. Do not use technical terms. If you must, then provide an explanation of the technical term in a language that a grade 6 student can comprehend.
2) Layunin ng Pag-aaral
3) Approximate Number of Participants and the Expected Duration of Your Participation

in the Study

The study will take place at Philippine Heart Center. About (write in numbers not in words) or more participants will be enrolled to participate in the study. Participants must meet all the qualifications to be included. If you are enrolled, the duration of your participation is (Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.).

3) Humigit-Kumulang na Bilang ng mga Kalahok at Inaasahang Tagal ng Iyong Pakikilahok sa Pag-aaral

Ang pag-aaral ay isasagawa sa Philippine Heart Center. Humigi't kumulang ililista sa pag-aaral. Para makasali, dapat matugunan ng kalahok ang lahat ng kwalipikasyon. Kapag ikaw ay napabilang sa mga kalahok, ang iyong pagsali ay inaasahang tatagal ng

4) Study Treatments and Procedures

Describe research procedures step by step in the simplest way understandable to a lay person. Avoid using scientific/medical terms. If not possible, define or describe such terms so that the participant may understand. It may be helpful to the participant if you use drawings or props to better illustrate the procedures. Do not copy paste study maneuver of the protocol.

4) Mga Pamamaraan ng Pag-aaral

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5) Benefits

Describe the benefits the PARTICIPANT may gain by joining the study and not those to which they are entitled regardless of participation. You may include benefits to the individual, benefits to the community in which the individual lives, and benefits to society as a whole as a result of finding an answer to the research question. If there is no direct benefit, you may say so, but there should at least be a benefit to the society.

5) Mga Benepisyo

6) Risk

Describe the risk/s or discomfort the study may bring to the participant, what will be done to minimize it. Provide enough information about the risks so that the participant can make an informed decision.

6) Mga Panganib

Compensation If there is no compensation, the standard line is You will not be paid for joining this study.

7) Kabayaran

Ikaw ay hindi babayaran sa pagsali sa pag-aaral na ito.

8) Voluntary Participation / Withdrawal from the Study

(May be modified according to the needs of the study.)

Your participation in this study is voluntary. It is up to you to decide whether to take part or not. If you choose not to participate in this study, you are free to refuse and it will not interfere with your future care. If you join the study and change your mind later, you may withdraw from the study anytime by informing the study doctor, and this will not affect your health care.

8) Kusang-Ioob na Pakikilahok / Pag-alis mula sa Pag-aaral

Kusang-loob ang pakikilahok mo sa pag-aaral na ito. Nasa iyo ang desisyon kung sasali ka o hindi. Kung ayaw mong sumali sa pag-aaral, ikaw ay maaring tumanggi at hindi nito maaapektuhan ang pangangalaga sa iyo. Kung sumali ka sa pag-aaral at nagbago ang isip mo, maari kang umalis sa pag-aaral sa pamamagitan ng pagsasabi sa doktor ng pag-aaral at hindi nito maapektuhan ang pangangalaga sa kalusugan mo.

Permission for Review of Records, Confidentiality and Access to Records (May be modified according to the needs of the study.)

Your study doctor will collect information. These information, called data, will be entered on a data collection form. In all of these data collection forms, a code will replace your name or any information that will identify you All the data collected will be kept confidential and will be used only as permitted by this consent form. The study doctor and the institution abides by the Data Privacy Act of 2012. You may request the Data Protection Officer for copy of information about yourself collected during the study, and may correct errors, if there are any.

9) Permiso sa Pagrepaso ng mga Talaan, Paglilihim at Pagkuha sa mga Talaan

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Kukuha ang inyong doktor ng pag-aaral ng mga impormasyon. Ang mga impormasyong ito na tinatawag na datos ay ipapasok sa isang data collection form. Papalitan ng code ang iyong pangalan at iba pang impormasyon na magpapakilala sa iyo sa lahat ng mga data collection forms. Lahat ng mga datos na nakolekta ay pananatilihing lihim at gagamitin lamang hanggang sa ipinahihintulot ng kasulatang ito. Ang doktor ng pag-aaral at ang institusyon ay sumusunod sa Data Privacy Act of 2012. Maari kang humingi mula Data Protection Officer ng kopya ng impormasyon tungkol sa iyo na nakolekta sa panahon ng pag-aaral, at iwasto ang mga pagkakamali, kung mayroon.

10) Questions/Information

- If you or your representative(s) have any questions regarding the study (or in case of study related injuries, if study involves any form of intervention or procedures), you should contact your study doctor: Study Doctor's name in BOLD letters, Phone number:
- If you or your representative(s) have any questions regarding your rights as participant
 to the study, you should contact Dr. Rafael R. Tenorio, Chair of the Institutional Ethics Review
 Board of the Philippine Heart Center, East Ave., Quezon City, Philippines, Tel: 892524011oc.
 3899.
 - Data Protection Officer: Tel: 8925-2401 loc. 3240.

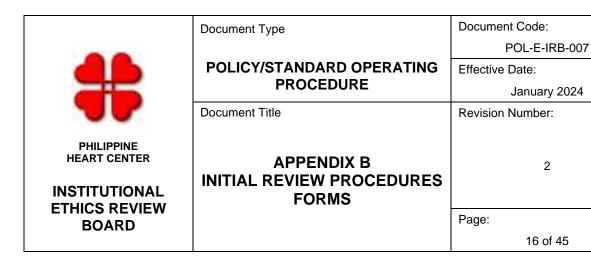
10) Mga Katanungan/Impormasyon

- Kung ikaw o ang iyong kinatawan/mga kinatawan ay mayroong anumang katanungan tungkol sa pag-aaral (o kung sakaling may mga kapinsalaan kaugnay sa pag-aaral, kung ang pag-aaral ay may eksaminasyon o ibibigay na interbensyon o gamot), ang iyong kakausapin ay si Study Doctor's name in BOLD letters, Mobile phone number:
- Kung ikaw o ang iyong kinatawan/mga kinatawan ay may katamungan tungkol sa iyong mga karapatan bilang kalahok sa pag-aaral, ang iyong kakausapin ay si Dr. Rafael R. Tenorio, Chair of the Institutional Review Board of the Philippine Heart Center, East Ave., Quezon City, Philippines, Tel:89252401 loc. 3899.
 - · Data Protection Officer: Tel: 8925-2401 loc. 3240.

11) Consent Signatures

Please read this section carefully and if in agreement please sign and date at the bottom of the page.

- I have been provided the details of the study, including the benefits and the risks of joining.
- I understand that I am free to accept or refuse my participation at any time without giving
 a reason. My decision to accept or refuse my participation will have no effect on my
 continuing treatment. I understand that I am free to discontinue my participation at any
 time without giving a reason. My decision to discontinue my participation will have no
 effect on my continuing treatment. I will keep all my rights to treatment and alternative
 therapy.
- I agree that the data collected for the study will be used for the purpose described above.
- I will not lose any rights that I have under local law by signing and dating this form.



- I have read and understood the information presented in this Informed Consent Form. I
 have been given the opportunity to ask questions and all my questions have been
 answered.
- · I will receive a signed and dated copy of this Informed Consent Form.

11) Mga Pirma ng Pagsang-ayon

Basahin nang mabuti ang bahaging ito at kung sumasang-ayon ka ay mangyaring pirmahan at isulat ang petsa sa huling bahagi ng kasulatang ito.

- Ibinigay sa akin ang mga detalye ng pag-aaral na ito, kasama na ang mga pakinabang at mga panganib ng pagsali rito.
- Naiintindihan ko na malaya akong sumali o tumangging sumali anumang oras kahit walang ibinibigay na dahilan. Ang desisyon ko na sumali o tumangging sumali ay walang epekto sa patuluyang paggagamot sa akin. Naiintindihan ko na may karapatan akong ihinto ang aking pakikilahok anumang oras nang walang ibinibigay na dahilan. Ang desisyon kong huminto sa aking pakikilahok ay walang magiging epekto sa patuluyang na paggagamot sa akin. Hindi ko maiwawala ang karapatan ko sa paggagamot at sa alternatibong gamutan.
- Sumasang-ayon ako na ang mga impormasyon na makukuha para sa pag-aaral na ito ay gagamitin para sa layunin na inilarawan sa itaas.
- Hindi mawawala ang anumang karapatan na mayroon ako sa ilalim ng batas sa pagpirma ko sa form na ito.
- Nabasa ko at naintindihan ang impormasyong iniharap sa Informed Consent Form na ito. Binigyan ako ng pagkakataon na makapagtanong tungkol dito at nasagot lahat ang aking mga katanungan.
- Ako ay makakatanggap ng kopya ng pirmado at may petsa na Informed Consent Form.

12) I FREELY ACCEPT TO PARTICIPATE IN THIS STUDY / KUSANG-LOOB NA TINATANGGAP KO ANG PAKIKILAHOK SA PAG-AARAL NA ITO

(May be modified according to the needs of the study.)

Sign and date at the same time, all party: Pirmahan ng sabay-sabay, (hal. parehong petsa), nang lahat ng kasali:

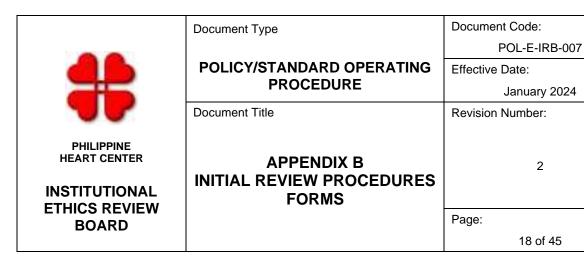
Printed Name of Participant Isinatitik na Pangalan ng Kalahok		
Date (to be entered by the participant)		
Petsa (isusulat ng Kalahok)		
Signature		
Lagda		
Printed Name of Study Personnel Obtaining Consent Isinatitik na Pangalan ng Kawani ng Pag-aaral		
na humihingi ng Pahintulot		



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		_
Date		
Petsa		
Signature Lagda		
Distribution: original for study doctor, copy to	(name of pa	artcipant)
Pamamahagi: ang orihinal para sa doktor ng kalahok)	pag-aaral, kopya para kay(pan	galan ng
For emergency situations where consent of the signature line must be signed:	participant cannot be obtained the f	ollowing
Para sa mga sitwasyong 'emergency,' kapag di ay nararapat idagdag ang sumusunod na linya ng		pasyente
Printed Name of Partcipant's Legally Authorized Representative Isinatitik na Pangalan ng Legal na Kinatawan ng Kalahok		
Date (to be entered by participant's Legally Authorized Representative) Petsa (isusulat ng Legal na Kinatawan ng Kalahok)		
Signature Lagda		
Relationship to Participant		

If the participant's legally authorized representative cannot read, the following signature line should be signed:



2

Kapag ang legal na kinatawan ng kalahok/pasyente ay hindi nakakabasa, nararapat idagdag ang sumusunod na linya ng pirma: Printed Name of Witness Isinatitik na Pangalan ng Saksi Date (to be entered by the witness) Petsa (isusulat ng Saksi) Signature Lagda At any given time, an incapacitated adult (e.g., intubated patients, unconscious patients, or patients in emergency situations, or patients with impairment in decision making) who regains capacity may explicitly refuse to participate in or request to be withdrawn from the study. The study doctor must respect the request. Wherever possible, the participant will be informed as soon as possible and his/her consent will be requested for the continuation of participation to the study. Sa anumang oras, ang isang kalahok na may limitasyon sa paggawa ng desisyon sa pagsali (e.g. mga pasyenteng nilagyan ng tubo, walang malay na pasyente, pasyenteng nasa emergency room, pasyenteng may limitasyon sa pagdedesisyon)na nanumbalik ang kakayahan sa pagdedesisyon ay maaring tahasang tumangging lumahok o makiusap na umurong sa pagsali sa pag-aaral na ito. Kailangang igalang ng doktor ng pag-aaral ang pakiusap nito. Kung kailangan, sasabihan sa lalong madaling panahon ang kalahok at hihingin ang kanyang pahintulot para makapagpatuloy sa paglahok sa pag-aaral na ito. CONFORME:

Date

ATTENDING PHYSICIAN



BOARD

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FM-E-IRB-2019-041 Rev. 04 **Request for Waiver of Informed Consent Form**

PHILIPPINE HEART CENTER Institutional Ethics Review Board 8/F Medical Arts Building East Avenue, Quezon City, 1100 Philippines Tel./Fax no. 89252401 loc.3899; email add: irbphc@gmail.co
Telurax no. 0323240 Floc.3033, elliali aud. Irupno@gillali.co

Request to Waive Written and Verbal Informed Consent Form

+‡+	•				
	IERB NO.		PROTOCOL NO.	CTRD NO.	
	PRINCIPAL INVESTIGATOR				
	PROTOCOL TITLE				

I am requesting a waiver of written and verbal informed consent. I believe that this protocol is eligible for waiver or alteration of all required elements of informed consent because the protocol meets all of the following criteria:

1. The risk to the subject's privacy is minimal.

The investigator of this study will use the minimum amount of protected health information necessary to conduct the research. This study will only need charts of eligible subjects. There will be no sensitive information (e.g. illegal drug use, sexual practices) to be collected. There is an assurance written below that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Rule.

- 2. This research cannot practicably be conducted without the use of the protected information.
- 3. This research cannot practicably be conducted without the waiver.
 - The number of research subjects proposed.
 - b. Difficulty of obtaining individual authorization and time since last contact with the research subjects.

RESEARCH ASSURANCES:

As a principal investigator of the research described above, I make the following assurance to the Institutional Ethics Review Board regarding the use and disclosure of protected health information.

"The investigators and research staff who used the disclosed protected health information in connection with this research will not reuse the protected health information or disclose to any other person or entity other than those authorized to receive it, except:

- As required by law,
 For authorized oversight of the research study, or
- 3. For other research which the use or disclosure of protected health information would be permitted by the Privacy Rule*

Pricipal Investigator	Date



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FM-E-IRB-2019-042 Rev. 05 Participant Information and Assent Form (For ages 12 to below 15)



Participant Information and Assent Form (For ages 12 to below 15)

IMPORTANT: PLEASE READ THE ENTIRE DOCUMENT. DELETE ALL TEXTS IN RED BEFORE SUBMITTING TO THE PHC IERB FOR REVIEW.

This template serves as a guide and may be edited according to your research requirements. This document is for a prospective participant who is a child and may not be familiar with scientific/medical terms therefore it is suggested not to use them, if possible, in this document. You may use pictures, drawings, and the like. Use a language that is simple and easy to understand for children under this age group. Use at least a 12pt font for the entire document. Write in second person. Do not copy and paste from protocol.

IERB NUMBER	
IERD NUMBER	
PROTOCOL NUMBER	
SITE OF STUDY	
Lugar ng Pag-aaral	
TITLE OF STUDY	
Pamagat ng Pag-aaral:	
LANGUAGE	Facility Taxabas
Wika:	English/Tagalog
NAME OF PARTICIPANT	
Pangalan ng Kalahok	
NAME OF STUDY DOCTOR (or RESEARCHER,	
whichever is applicable; use in the entire document)	
Pangalan ng Doktor ng Pag-aaral (Tagasaliksik)	
ADDRESS OF STUDY DOCTOR	
Address ng Doktor ng Pag-aaral	Do not write down home address
CONTACT NUMBER	
Telepono at iba pang detalye sa pagkontak	

Hello! I am (write your name). Doctors (researchers) like me sometimes do research or study to find out new ways or ideas on how to take care of children who are healthy and sick. To do this we ask children like you to be in this kind of studies. I will explain what the study is about and you



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can decide if	f you want t	o join or no	t. Your par	ent(s) know	that we ar	re going to	talk to y	ou about
the study.								

_. Ang mga doctor (tagasaliksik) katulad ko kung minsan ay gumagawa ng research o pag-agral para makahanap ng mga bagong paraan o ideya para alagaan ang mga bata na malusog at maysakit. Para magawa ito, isinasali namin ang mga batang katulad mo sa. ganitong mga pag-aaral. Ipapaliwanag ko sa iyo ang tungkol sa pag-aaral na ito at pwede kang mag desisyon kung gusto mong sumali o hindi. Alam ng mga magulang mo na kakausapin kita. tungkol sa pag-aaral na ito.

1. What is the study about and why do it?

This study is about (Describe what the study is about and its purpose in a language understandable to a child)

1. Tungkol saan ang pag-aaral at bakit ito ginagawa?

Ang pag-agral na ito ay tungkol sa

2. Why am I being asked to join this study?

You are being asked to join this study because you (Explain the reason why they are being targeted as participant to the study)

2. Bakit ako isinasali sa pag-agral na ito?

Isinasali ka sa pag-aaral na ito kasi

3. Do I have to join the study?

No, you don't have to if you do not want to. If you decide not to join, it's okay nobody will get mad at you. If you decide to join the study and later on you change your mind, it's still okay.

3. Kailangan ba akong sumali?

Hindi mo kailangan na sumali kung ayaw mo. Kung nag pasya ka na hindi sumali, okay lang walang magagalit sa iyo. Kung magpasya ka naman na sumali pagkatapos ay nagbago ang isip. mo at gygw mo ng sumali, okay lang din.

4. What will happen during the study?

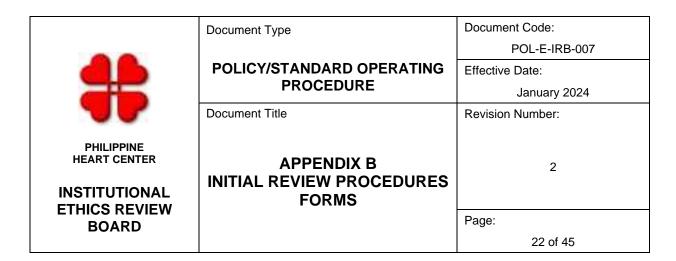
If you decide to join the study (Describe research procedures step by step)

4. Ano ang mangyayari sa pag-aaral?

Kung nag pasya ka na sumali

5. Will bad things happen to me? Explain any risks like pain or discomfort or inconvenience simply and clearly. State that they should tell you or their parent(s) in case they don't feel good. State what will be done to alleviate any pain or discomfort/inconvenience

Rev. 05



- Masasaktan ba ako?
- 6. Will this study help me in anyway? Describe any benefits to the child may gain from participating in the study.
- 6. May maitutulong ba ang pag-agral sa akin?
- 7. Who should I ask if I have questions?

You can ask me now or later. My telephone number is written on this form and you can call me anytime when you have questions to ask. You can also talk to anyone who is close to you about this and that's okay too.

7. Sino ang pwede kong tanungin?

Pwede ma akong tanungin ngayon na o sa ibang time. Ang telephone number ko ay nakasulat sa form na ito at pwede mo akong tawagan kung meron kang tanong. Pwede mo rin kausapin ang malalapit sa iyo tungkol dito at okay lang iyon.

8. What happens if I do not join this study?

Nothing will happen. It's your choice if you want to join this study or not. You can think about it and tell us later if you want to. You can say "yes" now and change your mind later and that is still okay.

8. Ano ang mangyayari kung hindi ako sumali?

Walang naman mangyayari. Ikaw ang pipili kung gusto mong sumali o hindi. Pwede mong pagisipan muna ito at sabihin na lang sa amin ang pasya mo. Okay lang din na magsabi ka na gusto mo ng sumali ngayon tapos magbago ang isip mo at ayaw mo ng sumali.

CERTIFICATE OF ASSENT

I have been invited to participate in this study. I have understood what the study doctor explained to me about the study and the good and bad things that may happen. I have asked my questions and I can ask questions any time. I have been informed that I can leave the study anytime I want to. I will be given a copy of this document.

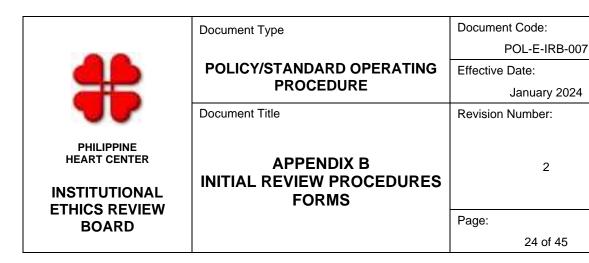
Ako ay inimbitahan na sumali sa pagzaaral na ito. Naintindihan ko ang paliwanag ng doktor ng pag-aaral tungkol dito at ang mabuti at masamang mga bagay na pwedeng mangyari. Nakapagtanong ako at pwedeng magtanong ulit sa ibang panahon. Nalaman ko na pwede akong umalis sa paz-aaral kahit kailan na gustuhin ko. Bibigyan ako ng kapya ng dakumentang ito.

- Okay, I'll be in the study/ Okay, sasali ako
- No, I don't want to be in the study/Hindi ako sasali

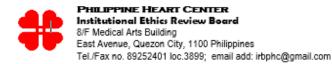


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Your Name:	Date:
Your Signature:	
If the participant is unable to read and write/Kung hindi nak	akabasa at nakakasulat ang kalahok
Thumb print of participant/ marka ng hinlalaki	
SIGNATURE OF WITNESS/PIRMA NG SAKSI (If write/kung hindi marunong bumasa at sumulat ang kalahok)	
I have witnessed the careful explaining of the study by the had the chance to ask questions. I confirm that the participal voluntarily. Nasaksikan ko ang maingat na pagpapaliwanag at nakapagtanong ang kalahok. Kinukumpirma ko na ang kapag-aaral nang hindi napipilitan.	nt has given his/her assent freely and g ng doktor ng pag-aaral tungko dito
Name:	Date:
Name:	Date:
Signature: SIGNATURE OF THE INDIVIDUAL OBTAINING ASS	SENT/PIRMA NG INDIBIDWAL have answered all the participant's
Signature: SIGNATURE OF THE INDIVIDUAL OBTAINING ASS NA KUMUKUHA NG PAHINTULOT I have carefully explained the study to the participant and questions. I believe that the participant understood all of	SENT/PIRMA NG INDIBIDWAL have answered all the participant's of the information described in this hok at nasagot ang lahat ng kanyang
SIGNATURE OF THE INDIVIDUAL OBTAINING ASS NA KUMUKUHA NG PAHINTULOT I have carefully explained the study to the participant and questions. I believe that the participant understood all of document and freely gave assent to participate. Naipaliwanag kong mabuti ang tungkol sa pag-aaral sa kala mga tanong. Naniniwala ako na naintindihan ng kalahok	SENT/PIRMA NG INDIBIDWAL have answered all the participant's of the information described in this hok at nasagot ang lahat ng kanyang
SIGNATURE OF THE INDIVIDUAL OBTAINING ASS NA KUMUKUHA NG PAHINTULOT I have carefully explained the study to the participant and questions. I believe that the participant understood all odocument and freely gave assent to participate. Naipaliwanag kong mabuti ang tungkol sa pag-aaral sa kala mga tanong. Naniniwala ako na naintindihan ng kalahok dokumentong ito at kusang-loob na sumang-ayon sa sumali.	SENT/PIRMA NG INDIBIDWAL have answered all the participant's of the information described in this hok at nasagot ang lahat ng kanyang ang lahat ng impormasyo na nasa



FM-E-IRB-2019-076 Rev. 03 Parent Information and Informed Consent Form



Parent Information and Informed Consent Form

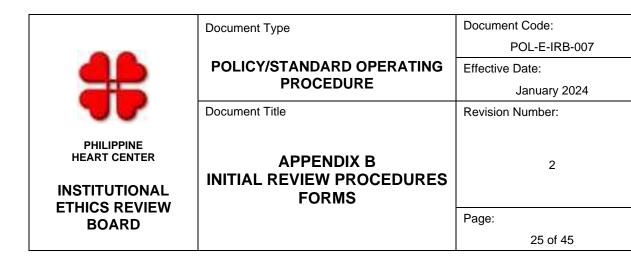
Impormasyon para sa Magulang at Form ng May-Kaalamang Pahintulot

IMPORTANT: PLEASE READ THE ENTIRE DOCUMENT. <u>DELETE ALL TEXTS IN RED BEFORE SUBMITTING TO THE PHC IERB FOR REVIEW.</u>

This template serves as a guide and may be edited according to your research requirements. This document is for a

This template serves as a guide and may be edited according to your research requirements. This document is for a parent AND child (15 to below 19 years old) who may not be familiar with scientific/medical terms therefore it is suggested not to use them, if possible, in this document. Use a language that is understandable to a grade 6 student. Use at least a 12pt font for the entire document. Write in second person. Do not copy and paste from protocol.

IERB NUMBER	
PROTOCOL NUMBER	
SITE OF STUDY	
Lugar ng Pag-aaral	
TITLE OF STUDY	
Pamagat ng Pag-aaral:	
LANGUAGE	T. 11.5
Wika:	English/Tagalog
NAME OF PARTICIPANT	
Pangalan ng Kalahok	
NAME OF STUDY DOCTOR (or RESEARCHER,	
whichever is applicable, use in the entire document)	
Pangalan ng Doktor ng Pag-aaral(Tagasaliksik)	
ADDRESS OF STUDY DOCTOR	
Address ng Doktor ng Pag-aaral	Do not write down home address
CONTACT NUMBER	
Telepono at iba pang detalye sa pagkontak	



1)Participation

1) Pagkikilahok

Your child is being considered to join a study about (Describe what the study is about) because your child (Explain why their child is being considered to be part of the study).

Before your child can take part in this study, it is important that you understand what the study involves. Please read this information carefully and ask any questions that you might have. The Philippine Heart Center Institutional Ethics Review Board (PHC IERB) has reviewed the purposes of the study and has given a favorable opinion of it.

Ang iyong anak ay ibinibilang na sumali sa pag-aaral tungkol sa	dahil siya
ay Bago sumali ang iyong anak sa pag-aaral na ito, mahalagang maintindhan mo ki nakapaloob sa pag-aaral na ito. Mangyaring basahin nang mabuti ang impormas magtanong ka ng anumang nais mong itanong. Ang Philippine Heart Center Insti Review Board (PHC IERB) ang nakapagrepaso sa mga layunin ng pag-aaral at n mabuti o paborableng palagay tungkol dito.	yon at itutional Ethics
2) Purpose of the Study Explain why you are doing the research in layman's terms. The lar clarify rather than confuse. Do not copy paste objectives of the protocol. Do not use technical term it, then provide an explanation of the technical term in a language that a grade 6 student can compress.	ns. If you must use
2) Layunin ng Pag-aaral	
3) Approximate Number of Participants and the Expected Duration of Your In the Study The study will take place at Philippine Heart Center. About (write in numbers not participants will be enrolled to participate in the study. Participants must meet all to be included. If your child is enrolled, the duration of your child's participant statement about the time commitments of the research for the participant including both the duration follow-up, if relevant.).	in words) or more the qualifications ation is (Include a
3) Humigit-Kumulang na Bilang ng mga Kalahok at Inaasahang Tagal ng Paga Ang pag-aaral ay isasagawa sa Philippine Heart Center. Humigi't kumulang _ ililista sa pag-aaral. Para makasali, dapat matugunan ng kalahok ang lahat n Kapag ang iyong anak ay napabilang sa mga kalahok, ang kanyang pagsali ay in ng	ang g kwalipikasyon.

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4) Study Treatments and Procedures

Describe research procedures step by step in the simplest way understandable to a lay person. Avoid using scientific/medical terms. If not possible, define or describe such terms so that the parent may understand. It may be helpful to the parent if you use drawings or props to better illustrate the procedures. Do not copy paste study maneuver of the protocol.

4) Mga Pamamaraan ng Pag-aaral

5) Benefits

Describe the benefits the PARTICIPANT, in this case the CHILD, may gain by joining the study and not those to which they are entitled regardless of participation. You may include benefits to the individual, benefits to the community in which the individual lives, and benefits to society as a whole as a result of finding an answer to the research question. If there is no direct benefit, you may say so, but there should at least be a benefit to the society.

Mga Benepisyo

6) Risk

Describe the risk/s or discomfort the study may bring to the participant, in this case the child, what will be done to minimize it. Provide enough information about the risks so that the parent and child can make an informed decision.

6) Mga Panganib

7) Compensation If there is no compensation, the standard line is

You or your child will not be paid for joining the study.

7) Kabayaran

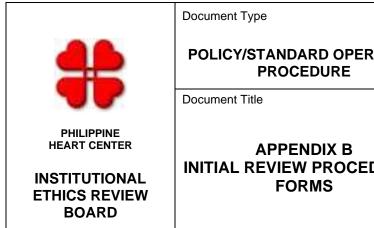
Ikaw o ang iyong anak ay hindi babayaran sa pag-aaral na ito.

8) Voluntary Participation / Withdrawal from the Study

(May be modified according to the needs of the study.)

Your child's participation in this study is voluntary. It is up to you to decide whether your child will take part or not. If you choose not to let your child participate in this study, you are free to refuse and it will not interfere with your child's future care. If you let your child join the study and change your mind later, you may withdraw your child's participation from the study anytime by informing the study doctor, and this will not affect your child's health care.

8) Kusang-Ioob na Pagsali / Pag-alis mula sa Pag-aaral



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Kusang-loob ang pagsali ng iyong anak sa pag-aaral na ito. Nasa iyo ang desisyon kung sasali ang iyong anak o hindi. Kung ayaw mong sumali ang iyong anak sa pag-aaral, ikaw ay pwedeng tumanggi at hindi nito maaapektuhan ang pangangalaga sa iyong anak. Kung pumayag kang sumali ang iyong anak sa pag-aaral at nagbago ang isip mo, maaring umalis sa pag-aaral ang iyong anak sa pamamagitan ng pagsasabi sa doktor ng pag-aaral at hindi nito maapektuhan ang pangangalaga sa kalusugan ng iyong anak.

9) Permission for Review of Records, Confidentiality and Access to Records

(May be modified according to the needs of the study.)

The study doctor will collect information. These information, called data, will be entered in a data collection form. In all of these data collection forms, a code will replace your child's name or any information that will identify your child. All the data collected will be kept confidential and will be used only as permitted by this consent form. The study doctor and the institution abides by the Data Privacy Act of 2012. You may request the Data Protection Officer for copy of information about yourself collected during the study, and may correct errors, if there are any.

9) Permiso sa Pagrepaso ng mga Talaan, Paglilihim at Pagkuha sa mga Talaan

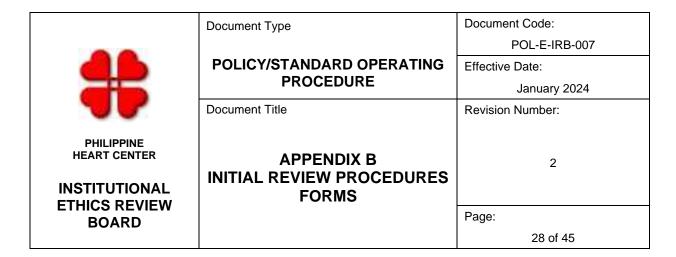
Kukuha ang inyong doktor ng pag-aaral ng mga impormasyon. Ang impormasyong ito na tinatawag na datos ay ipapasok sa isang data collection form.. Papalitan ng code ang pangalan ng iyong anak at iba pang impormasyon na magpapakilala sa kaniya sa lahat ng mga data collection forms. Lahat ng mga datos na nakolekta ay papanatilihing lihim at gagamitin lamang hanggang sa ipinahihintulot ng kasulatang ito. Ang doktor ng pag-aaral at ang institusyon ay sumusunod sa Data Privacy Act of 2012. Maari kang humingi mula Data Protection Officer ng kopya ng impormasyon tungkol sa iyo na nakolekta sa panahon ng pag-aaral, at iwasto ang mga pagkakamali, kung mayroon.

10) Questions/Information

- · If you or your child have any questions regarding the study (or in case of study related injuries, if study involves any form of intervention or procedures), you should contact your study doctor: Study Doctor's name in BOLD letters , Phone number:
- If you or your child have any questions regarding your child's rights as participant to the study, you should contact Dr. Rafael R. Tenorio, Chair of the Institutional Ethics Review Board of the Philippine Heart Center, East Ave., Quezon City, Philippines, Tel: 892524011oc. 3899.
 - Data Protection Officer: Tel: 8925-2401 loc. 3240.

10) Mga Katanungan/Impormasyon

 Kung ikaw o ang iyong anak ay mayroong anumang katanungan tungkol sa pag-aaral (o kung sakaling may mga kapinsalaan kaugnay sa pag-aaral, kung ang pag-aaral ay may eksaminasyon o ibibigay na interbensyon o gamot), ang iyong kakausapin ay si Study Doctor's name in BOLD letters, Mobile phone number:



- Kung ikaw o ang iyong anak ay may katanungan tungkol sa mga karapatan bilang kalahok sa pag-aaral, ang iyong kakausapin ay si Dr. Rafael R. Tenorio, Chair of the Institutional Review Board of the Philippine Heart Center, East Ave., Quezon City, Philippines, Tel: 89252401 loc. 3899.
 - Data Protection Officer: Tel: 8925-2401 loc. 3240.

11) Consent Signatures

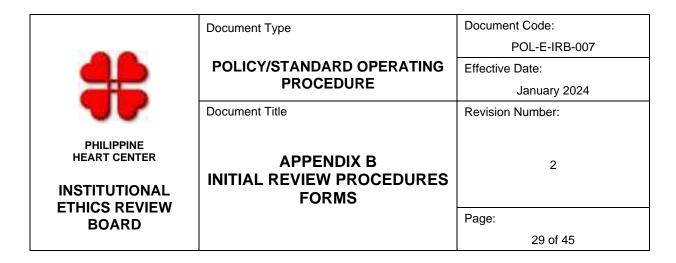
Please read this section carefully and if in agreement please sign and date at the bottom of the page.

- · I have been provided the details of the study, including the benefits and the risks of joining.
- I understand that I am free to accept or refuse my child's participation at any time without
 giving a reason. My decision to accept or refuse my child's participation will have no effect
 on my child's continuing treatment. I understand that I am free to discontinue my child's
 participation at any time without giving a reason. My decision to discontinue my child's
 participation will have no effect on my child's continuing treatment. My child will keep all
 rights to treatment and alternative therapy.
- I agree that the data collected for the study will be used only for the purpose described above.
- I and my child will not lose any rights that we have under local law by signing and dating this form.
- I have read and understood the information presented in this Informed Consent Form. I
 have been given the opportunity to ask questions and all my questions have been answered.
- · I will receive a signed and dated copy of this Informed Consent Form.

11) Mga Pirma ng Pagsang-ayon

Basahin nang mabuti ang bahaging ito at kung sumasang-ayon ka ay mangyaring pirmahan at isulat ang petsa sa huling bahagi ng kasulatang ito.

- Ibinigay sa akin ang mga detalye ng pag-aaral na ito, kasama na ang mga pakinabang at mga panganib ng pagsali rito
- Naiintindihan ko na malaya akong pumayag o tumanggi sa pagsali ng aking anak sa anumang oras nang walang ibinibigay na kadahilanan. Ang desisyon ko na pumayag o tumanggi sa pagsali ng aking anak ay walang epekto sa patuloy na paggagamot sa kaniya. Naiintindihan ko na may karapatan akong ihinto ang pagsali ng aking anak anumang oras nang walang ibinibigay na dahilan. Ang desisyon kong ihinto ang pagsali ng aking anak ay walang magiging epekto sa patuloy na paggagamot sa kaniya. Mananatili ang mga karapatan ng aking anak sa paggagamot at alternatibong gamutan.
- Sumasang-ayon ako na ang mga impormasyon na makukuha para sa pag-aaral na ito ay gagamitin para lamang sa layunin na inilarawan sa itaas.
- Hindi mawawala ang anumang karapatan na mayroon ako at aking anak sa ilalim ng batas sa pagpirma ko sa form na ito.
- Nabasa ko at nauunawaan ang impormasyong iniharap sa Form ng May-Kaalamang Pahintulot na ito. Binigyan ako ng pagkakataon na makapagtanong tungkol dito at pawang nasagot lahat ang aking mga katanungan.



 Ako ay makakatanggap ng kopya ng pirmado at may petsa na Form ng May-Kaalamang Pahintulot.

Sign and date at the same time, all party:

Pirmahan at ilagay ang petsa ng magkasabay, nang lahat ng kasali:

12) SIGNATURE OF PARTICIPANT/PIRMA NG KALAHOK

(For children ages 15 to under 19 years old who are capable pf providing assent/ Para sa mga batang edad 15 hanggang bago mag edad 19 na may kakayahang sumang-ayon sa pagsali)

Printed Name of Participant Isinatitik na Pangalan ng Kalahok	
isinullik na i angalan ng Kalanok	
Date (to be entered by Participant)	
Petsa (isusulat ng Kalahok)	
Signature	
Pirma	
13) SIGNATURE OF PARENT(S)/LEG PIRMA NG MAGULANG/LEGAL NA	ALLY AUTHORIZED REPRESENTATIVE(LAR) KINATAWAN NG KALAHOK
Printed Name of Parent/LAR Isinatitik na Pangalan ng Magulang/LAR	
Date (to be entered by the parent/LAR) Petsa (isusulat ng magulang)	
Signature	
Pirma	

14) SIGNATURE OF INDIVIDUAL OBTAINING CONSENT/PIRMA NG INDIBIDWAL NA KUMUKUHA NG PAHINTULOT

I have explained the study to the participant and to the participant's parent(s)/legally authorized representative and have answered all their questions. I believe that they understand all of the information described in this document and freely gave their consent/assent to participate.

Ipinaliwanag kong mabuti ang tungkol sa pag-aaral sa kalahok at sa kanyang magulang/legal na kinatawan ng kalahok at nasagot ang lahat ng kanilang mga tanong. Naniniwala ako na



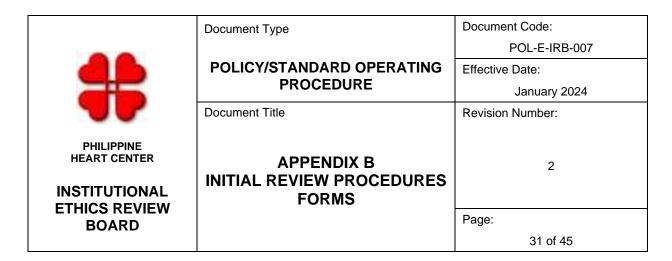
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naintindihan nila ang lahat ng impormasyon sa dokumentong ito at kusang loob na ibinibigay ang kanilang pagsang-ayon na sumali.

Driverd Name of Individual Obstaining	
Printed Name of Individual Obtaining Consent	
Isinatitik na Pangalan ng Kumukuha ng	
Pahintulot	
Date	
Petsa	
Signature	
Lagda	
_	
Distribution: original for study doctor, copy t	to(name of partcipant)
Pamamahagi: ang orihinal para sa dokto kalahok)	r ng pag-aaral, kopya para kay(pangalan ng
If the child's parent/legally authorized representations are should be signed:	resentative cannot read, the following signature line
Kapag ang legal na kinatawan ng batang k sumusunod na linya ng pirma:	alahok ay hindi nakakabasa, nararapat idagdag ang
Printed Name of Witness	
Isinatitik na Pangalan ng Saksi	
Date (to be entered by the witness)	
Petsa (isusulat ng Saksi)	
-	
Signature	
Lagda _	

Whenever a child participant does not have the capacity to assent (such in case of unconciousness, intubation, emergency situation, etc.) at the time of participation and regains the capacity, if the child refuses to participate or wants to be withdrawn from the study, the Study Doctor must respect the child's decision



Kapag ang batang kalahok ay walang kakayahang magbigay ng pahintulot (katulad sa mga kaso ng kawalang-malaya, may nakakabit na tubo, sa panahon ng emergency, at iba pa) sa panahon ng pagsali at nanumbalik ang kakayahan na magbigay pahintulot, kung ayaw ng bata na sumali o gusto niyang umalis sa pag-aaral, dapat igalang ng Doktor ng Pag-aaral and pasya ng bata.

CONFORME:	
ATTENDING PHYSICIAN	



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FM-E-IRB-2019-017 Rev. 06 IERB Decision Form



IERB's Decision Form

Mee	ting <u>No:</u>		Da	te (D/N	I/Y):_				_				
IERR N	<u>Vo</u>	tocol No.		CTRD No.									
Protoc				•			•						
Princi	pal Investi	gator	1										
Spons	Sponsor												
Eleme	Elements Reviewed												
Review of Accomplished Revision Yes No							Date	of Pre	vious	review	r:		
									Deci	sion			
	~						Prote				IC		
No.	Consensu	is of IE	RB membe	ers	Initial	AP	MMR	MJ	DA	AP	MMR	MJ	DA
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3				\dashv						1			
4				\dashv						1			
5				\neg									
6													
7													
8													
9													
Signa	Signature:												
	IERB				MMR-		modific modific	cations re ation	quired	ı			



POLICY/STANDARD OPERATING **PROCEDURE**

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Document Title

Document Type

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FM-E-IRB-2019-056 Rev. 05 **Modification Letter Template**



ETHICS REVIEW

BOARD

PHILIPPINE HEART CENTER Institutional Ethics Review Board

8/F Medical Arts Building East Avenue, Quezon City, 1100 Philippines Tel/Fax no. 89252401 loc.<u>3899; email</u> add: irbphc@gmail.com

Modification and Disapproval Letter

INSTITUTIONAL (Date) ETHICS REVIEW BOARD (Principal Investigator) (Position) (Address) Chair Members IERB no : CTRD no.: Title of Protocol: Dear_(PI), , the Institutional Ethics Review Board (IERB) reviewed the research protocol entitled : "_____(Title of Protocol) During the discussion, the IERB defers a final decision at this time. However, the IERB requests clarifications, additional information, and modifications on the following issues of concern: 1. 2. Philippine Heart Center 8/F Medical Arts Building East Avenue, Quezon City Tel. no. 9252401 loc.3899 Email Add: irbphc@gmail.com 3. 4. 5. Please submit the requested information or documents for a re-review on or before <u>(Date)</u>. You may not begin your study until your revised application is approved. at 9252401 loc.3899 if you have any questions or Kindly contact Ms. __ further information. Sincerely yours,

Chair, IERB



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FM-E-IRB-2019-022 Rev. 06 Resubmission Report Form



PHILIPPINE HEART CENTER Institutional Ethics Review Board 8/F Medical Arts Building East Avenue, Quezon City, 1100 Philippines

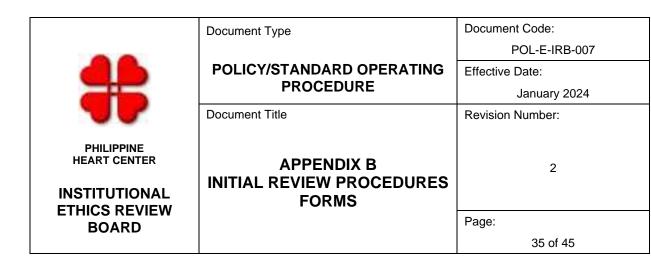
Tel./Fax no. 89252401 loc.3899; email add: irbphc@gmail.com

Resubmission Report Form

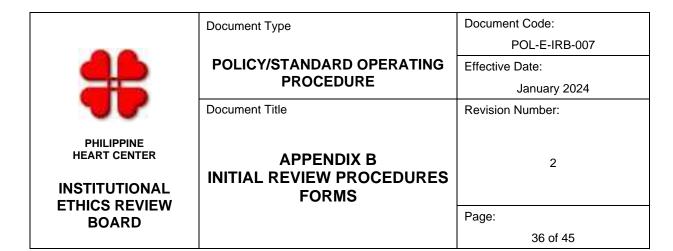
IERB No.		Protocol N	lo.			CTRD No.:			
Title of Protocol:									
Principal Investiga	ter_:					Contact No	D.		
Initial Review						Type of	Т	Full Board	
Date:						Review		Expedited	
Documents	Danis			col (latest				latest version	
Revised				per and dat rs (specify)	e)		num	ber and date)	
			Other	is (specify)					
Date of Review	1st Re	view	2nd l	d Review 3rd Re		view	4"	4 th Review	
of Resubmission:									
Required Modifica	ation	Indicate the page/s revi to be found	ision	Reviewe Comme	_	Reviewer's	s Recor	nmendations:	
Protocol:									
1.									
2.									
ICF:									
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Others:									
1.									
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Summary of									
Recommendations	s.								
Recommended Ac	tion:	App	rove			Maj	or Mod	lification	
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		N.45-	or Mor	dification			pprove		

FM-E-IRB-2019-022

Rev. 06



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	
SIGNATURES: Dat	te
Reviewer	
Dat	e:
Chair, PHC-IERB	



FM-E-IRB-2019-045 Rev. 09 Decision Letter for Protocol Approval Template



	Decision Letter for Protocol Approval
INSTITUTIONAL ETHICS REVIEW BOARD	DATE
Chair	Principal Investigator Philippine Heart Center IERB no.: CTRD no. Protocol no. SJREB no. <u>Title_of</u> Protocol:
Members	Dear Dr
	The following documents have been approved for use in the study. 1. 2. While the study is in progress, we request you to submit to us the following documents:
Contact Person: Philippine Heart Center 8/F Medical Arts Building East Avenue, Quezon City Tel. no. 9252401 loc. 3899 Email Add: irbphc@gmail.com	 Progress report annually from date of approval which include the following: (Note: In view of active ethical clearance, this report is mandatory even if the study has not started or is still awaiting release of funds. However for protocols that will terminate in six (6) months, they have to submit continuing review report or Interim Report two (2) months before termination of study) Date covered by the report Protocol summary and status report on the progress of the research Number of participants accrued Complaints on the research since the last IERB review

IERB no. PAGE 1/2

5. Notice of time of completion of the study

amendments since the last IERB review

2. Notice of termination of the study and reasons for such

3. Any event which may have ethical significance

ongoing review

final report.

e) Summary of relevant recent research literature, interim findings and

4. Any information which is needed by the institutional Ethics Review Board to do

6. After completion of the study, please submit an end study report and a copy of

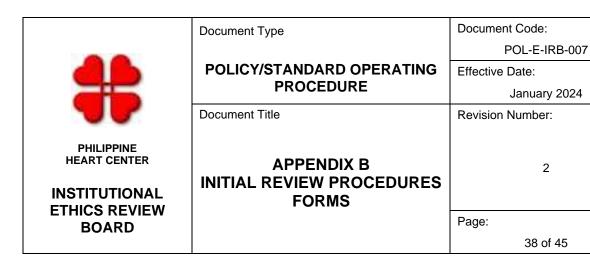


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Please be advised that you can continue the Good Clinical Practice.	e trial according to the approved protocol and
	on or <u>before</u> unless closed review form 6 weeks before the expiration of
,	that the Philippine Heart <u>Center Institutional</u> ilding, East Avenue, Quezon City is organized actice and applicable laws and regulations.
, , ,	as approved must be promptly reported and require further information, please contact
Sincerely yours, Chairman, IERB	
Note:	
Duration of Approval	Frequency of Continuing Review
<u>From :</u> To <u>:</u>	Due Date:
Received by:	
Print Name :	
Signature :	Date :

IERB no. PAGE 2/2



FM-E-IRB-2019-087 Rev. 00 Certificate of Exemption from Ethics Review



PHILIPPINE HEART CENTER Institutional Ethics Review Board 8/F Medical Arts Building

East Avenue, Quezon City, 1100 Philippines Tel./Fax no. 89252401 loc.3899; email add: irbphc@gmail.com

Certificate of Exemption from Ethics Review Template

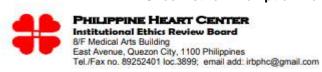
This is to certify that the following protocol and related documents have been reviewed and granted exemption from review by the Philippine Heart Center-Institutional Ethics Review Board for implementation

Date:		
Principal Investigator/s:		
IERB Number:	CTRD Number:	
Title:		
Sponsor:		
Protocol Version No.:	Version Date:	
ICF Version No.:	Version Date:	
Other documents:		
(Signature)		
Name of Chair Chairman		
Chairman		
Received by:		
Name:		
Signature		
Date:		



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FM-E-IRB-2019-096 Rev. 00 Checklist for Exemption from Protocol Review



IERB No.			Protocol No.	CTRD No./SJREB no:					
Title	of Prof	tocol:	4.	W					
Princi	pal Inv	estigator :							
Spons	sor:								
lease	check	the approp	riate:						
Yes	No		or Exemption						
				articipants nor identifiable human tissue,					
			samples, and data (e.g., r						
- 2	18	Protocol ti	nat involves minimal risks						
			Protocol is for research type like institutional quality assurance purposes,						
		100000		programs, public health surveillance,					
		100000		ities, and consumer acceptability tests.					
	 Protocol only includes human interactions involving survey pro 								
interview procedures, or observation of public behavior (including									
		THESE	erview procedures, or ob	[1] [[[[[[[[[[[[[[[[[[[[
		au	erview procedures, or ob ditory recording).	servation of public behavior (including visual					
-	,	au	erview procedures, or ob ditory recording).	[1] [[[[[[[[[[[[[[[[[[[[
Reco	mmen	c. Pro	erview procedures, or ob ditory recording).	servation of public behavior (including visual					
Reco	mmen	au	erview procedures, or ob ditory recording). otocol involves the use of	servation of public behavior (including visual operation)					
Reco	mmen	c. Pro	erview procedures, or obditory recording). otocol involves the use of	servation of public behavior (including visual of publicly available data or information.					
Reco		c. Pro	erview procedures, or obditory recording). otocol involves the use of Qualified fo Unqualified	servation of public behavior (including visual of publicly available data or information. TEXEMPTION For Exemption					
Reco		c. Pro	erview procedures, or obditory recording). otocol involves the use of	servation of public behavior (including visual of publicly available data or information. TEXEMPTION For Exemption					
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FDA Clinical Trial Assessment Form Version 1.2/16 July 2012

FDV	Form	No-		

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	FDA CLINICAL TRIAL ASSESSMENT FORM Version 1.2/16 July 2012						
I.	I. ADMINISTRATIVE INFORMATION						
1.	Clin	ical trial number	<fda-issued code="" unique=""></fda-issued>				
2.	Clin	ical trial protocol title	<full protocol="" title=""></full>				
3.	Clin	ical trial version number	<as in="" indicated="" protocol="" the=""></as>				
4.	Clin	ical trial version date	< As indicated in the protocol> <dd mm="" yyyy=""></dd>				
5.	FDA-	ical trial phase (Note: Review by recognized institutions is limited to indicated in this form)	Phase 1 Phase 2 Phase 3 Phase 4 Type:				
6.	Spor	nsor-applicant:	<name of="" sponsor=""></name>				
7.	CRC)-applicant:	<name cro="" of=""></name>				
8.	Date	received by institution:	<dd mm="" yyyy=""></dd>				
9.	Revi	ewing institution:	<name institution="" of="" reviewing=""></name>				
		9.1. Address					
		9.2. Signatory official:	<title, name,="" surname=""></title,>				
		9.3. Position & Designation:	<institutional &="" designation="" position="" review=""></institutional>				
		9.4. Signature:					
		9.5. Review date:	<dd mm="" yyyy=""></dd>				
	9.6. Telephone:						
9.7. Fax:		9.7. Fax:					
		9.8. Email:					
Th	10. Declaration of conflict of interest (COI) The <name institution="" of=""> declares that the institution and the experts involved in this review have no COI in any form related to the abovementioned clinical trial/that the <institution both="" experts="" in="" involved="" review="" this=""> have <financial, professional="" proprietary,=""> conflict of interest related to</financial,></institution></name>						

the abovementioned clinical trial due to <describe COI> and managed such COI by <describe COI management>.

11. Confidentiality Agreement

The <NAME OF INSTITUTION> as well as the experts involved in this review agreed to take reasonable measures to protect the confidential information pertinent to this review, subject to applicable legislation, not to disclose confidential information to any person; not to use confidential information for any purpose outside this review, and in a manner which would result in a benefit to itself or any third party; and to return all confidential information and documents (including any

minutes of notes) upon demand of the LDA.
12. Recommendations to the FDA:
Approval
Deferment of action pending resolution of conditions detailed under Section 8 (see assessment information)
Disapproval of the conduct of clinical trial in the Philippines due to:
 Objections as indicated in: <indicate relevant="" sections=""></indicate>
 Deficiencies as indicated in: sindicate relevant sections:>



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FDA CLINICAL TRIAL ASSESSMENT FORM

Version 1.2/16 July 2012

II. ASSESSMENT INFORMATION

Information under this section should be compiled through full board deliberation of the documents submitted to the relevant committee in the institution that performed this review. Recommendations issued through this review are based on the assessment of components outlined in this section. This template is accomplished electronically, but must be printed, then verified and signed by the designated institutional signatory official. A fully

accomplished form should be signed and submitted to the FDA within 30 days of receipt of									
protocol package.									
COMPONENT	Do the documents submitted have		Documents assessed &	ASSESSMENT					
ASSESSED	adequate information for assessment?		relevant sections						
SCIENTIFIC AND	Yes	No							
SOCIAL VALUE									
1.1. Philippine									
community <u>health</u>									
priority addressed									
1.2. Disease priority									
addressed									
1.3. Potential Impact on									
deeply-held values of									
the Filipino									
1.4. Conclusions on the pot	ential SC	IENTIF	IC AND S	OCIAL VALUE of this clinical trial:					
	Do the for		Documents						
COMPONENT	Do the documents submitted have		assessed &	ASSESSMENT					
ASSESSED	adequate information for assessment?		relevant sections						
2. PRE-CLINICAL	Yes	No	SECULATS						
DATA	103	140							
DAIN									

submitted have adequate information for assessment?		assessed & relevant sections	ASSESSMENT
Yes	No		
	adequate in for assessn	adequate information for assessment?	adequate information relevant for assessment? sections

2.3. Conclusions on the PRE-CLINICAL DATA supporting this clinical trial application:

COMPONENT ASSESSED	Do the documents submitted have adequate information for assessment?		Documents assessed & relevant sections	ASSESSMENT (Dose-response studies, clinical studies in special populations such as pediatric populations, pooled and meta-analysis, and other supporting studies)
3. PRIOR CLINICAL DATA	Yes	No		
3.1. Pharmacodynamics and pharmacokinetics				



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			city to your total	
3.2. Phase 1 (completed)				Years conducted
				Sites
				Enrolment: <number of="" patients=""></number>
				Findings
3.3. Phase 2 (completed)				Years conducted
				Sites
				Enrolment: <number of="" patients=""></number>
				Findings
3.4. Phase 3 (completed)				Years conducted
				Sites
				Enrolment: <number of="" patients=""></number>
				Findings
3.5. Conclusions on the PR	IOR CL	NICAL	DATA sup	porting this clinical trial application:
COMPONENT ASSESSED	Do the dos submitted adequate for assess	have information	Documents assessed & relevant sections	ASSESSMENT
4. STUDY DESIGN	Yes	No	accounts	
4.1. Duration	103	110		
4.1.1. Main phase				<time><n a=""></n></time>
4.1.2. Run-in phase				<time><n a=""></n></time>
4.1.3. Extension phase			1	<time><n a=""></n></time>
4.2. Hypothesis				<superiority> < Equivalence> <non-< td=""></non-<></superiority>
1				inferiority> <exploratory: specify=""></exploratory:>
				<others: specify=""></others:>
4.3. Treatment groups				
4.3.1. Group 1				<treatment≥_<duration>, <number< td=""></number<></treatment≥_<duration>
				randomized>
4.3.2. Group 2				<treatment>_<duration>, <number< td=""></number<></duration></treatment>
433 C 3				randomized>
4.3.3. Group 3				<treatment>_<duration>, <number randomized=""></number></duration></treatment>
4.3.4. <if group<="" placebo="" td=""><td>1</td><td></td><td></td><td><scientific and="" methodological<="" td=""></scientific></td></if>	1			<scientific and="" methodological<="" td=""></scientific>
included>				justification for the use of placebo>
4.4. Endpoints and				junior and the va passessor
definitions				
4.4.1. Primary				<appropriateness and<="" endpoint="" of="" td=""></appropriateness>
				method of measurement>
4.4.2. Secondary/Other				<appropriateness and<="" endpoint="" of="" td=""></appropriateness>
(specify)				method of measurement>
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(specify)				method of measurement>
4.4.4. <add as<="" rows="" td=""><td></td><td></td><td></td><td><appropriateness and<="" endpoint="" of="" td=""></appropriateness></td></add>				<appropriateness and<="" endpoint="" of="" td=""></appropriateness>
needed> 4.5. Statistical analysis for				method of measurement>
	1	I	I	<intent to="" treat=""> <per protocol=""></per></intent>



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primary endpoint				<other: specify=""><time point=""></time></other:>				
4.6. Statistical analysis for				<intent to="" treat=""> <per protocol=""></per></intent>				
secondary endpoint				<other: specify=""><time point=""></time></other:>				
4.7. Conclusions on the S	TUDY D	ESIGN	proposed fo	or this clinical trial:				
COMPONENT	Do the doc submitted		Documents assessed &	ASSESSMENT				
ASSESSED		nformation	relevant sections					
5. CLINICAL SAFETY	Yes	No	SELENNIS					
5.1. Expected adverse								
events								
5.2. Expected serious								
adverse events and								
deaths								
5.3. Expected adverse								
laboratory events								
5.4. Safety in special				<adequate identification="" of<="" td=""></adequate>				
populations				populations wherein precaution/				
				safety measures/exclusion is				
5.5. Adverse				exercised>				
	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \							
immunological events (if applicable)								
5.6. Drug-drug								
interactions and other								
interactions								
5.7. Pharmacovigilance				<adequacy compliance="" of="" td="" with<=""></adequacy>				
system and plan				regulatory reporting systems for				
				AEs>				
5.8. Risk management				<appropriateness of="" risk<="" td=""></appropriateness>				
system and plan				management method vis à vis				
				expected risks>				
5.9. Conclusions on the C	LINICA	L SAFET	Γ Y plan pro	posed for this clinical trial:				
	Do the doc	umente	Documents	I				
COMPONENT	submitted	have	assessed &	ASSESSMENT				
ASSESSED	adequate i for assessn	nformation nent?	relevant sections					
6. BENEFIT-RISK ASSESSMENT	Yes	No	Jenny M					
6.1. Beneficial effects of				<uncertainty certainty="" in="" p="" the<=""></uncertainty>				
the intervention to				knowledge about the beneficial				
the target population				effects>				



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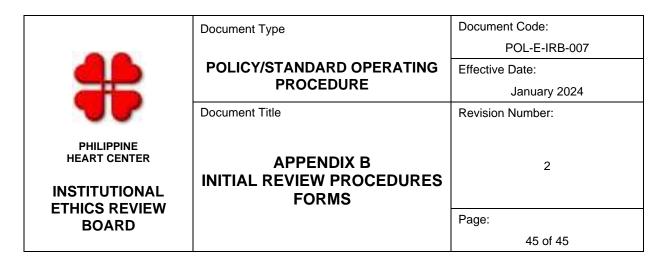
6.2. Unfavorable effects of	<uncertainty certainty="" in="" p="" the<=""></uncertainty>					
the intervention to	knowledge about the unfavorable					
the target population	effects>					
6.3. Vulnerable	<justification of="" p="" risks="" to="" vulnerable<=""></justification>					
populations involved	populations>					
6.4. Use of placebo	Compliance with international					
	and national ethical guidelines in					
	the use of placebo>					
6.5. Benefit-risk balance	Significance of favorable and					
	unfavorable effects as detailed					
	above>					

6.6. Conclusions on the BENEFIT-RISK ratio of this clinical trial: <favorable or unfavorable>

COMPONENT	Do the documents submitted have			Documents assessed &				
ASSESSED	adequate information for assessment?		nai	relevant sections				
7. STUDY SITES	Yes No							
7.1. List of sites			N.					
STUDY SITES	TYPE		I	PROFILE	ERC	If none		
7.1.1. <name of="" site=""></name>	<pre><tertiary secondary=""> <teaching hospital=""> <others: specify=""></others:></teaching></tertiary></pre>		ac go	acilities, creditation, overnment assification, c	<pre><phreb number="" registration=""></phreb></pre>	<pre><justification erc="" if="" institutional="" local="" no="" or=""></justification></pre>		
7.1.2. <add as<br="" rows="">needed></add>								

7.2. Conclusions on the appropriateness of the proposed STUDY SITES for this clinical trial:

- 8. SUMMARY OF RECOMMENDED CONDITIONS FOR APPROVAL OF IMPLEMENTATION OF CLINICAL TRIAL IN THE PHILIPPINES (with reference to the above discussions)
- 8.1. Social and Scientific Value
- 8.2. Assessment of Pre-Clinical Data
- 8.3. Assessment of Prior Clinical Data
- 8.4. Study design assessment
- 8.5. Safety assessment



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8.6. Benefits and risks assessment
8.7. Study Sites Assessment
9. SUMMARY OF REGULATIONA APPLICABLE TO THIS CLINICAL TRIAL
APPLICATION (and used in this assessment)
9.1. Regulation 1
9.2. Regulation 2
9.3. Regulation 3
9.4. Regulation 4
10. SUMMARY OF INTERNATIONAL AND NATIONAL GUIDELINES APPLICABLE
TO THIS CLINICAL TRIAL APPLICATION (and used in this assessment)
10.1. Guideline 1
10.2. Guideline 2
10.3. Guideline 3
10.4. Guideline 4
11. SUMMARY OF OTHER REFERENCES USED IN THIS ASSESSMENT
11.1. Reference 1
11.2. Reference 2
11.3. Reference 3
11 / Reference /