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	Document Title **APPENDIX B INITIAL REVIEW PROCEDURES FORMS**	Revision Number: 2
		Page: 1 of 45

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

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

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

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				
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 one (1) hard and one (1) digital copy

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

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

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

Document Receipt Form

1. IERB no.:		**Submitted date:**	
2. Source of Fund:	☐ PHC Funded	☐ Non-PHC Funded	
3. DETR no.:		**Protocol no.**	
4. Sponsor / CRO			
5. Principal Investigator:			
6. Protocol Title:			
7. Type of Submission:	___Initial Review ___Resubmission for a re-review ___Protocol Amendments	___Continuing Review ___Approved Protocols ___Protocol Termination	
8. Delivery Route:	☐ Post	☐ In Person	
9. Documents Submitted	☐ Full Protocol ☐ Declaration of No Conflict of Interest ☐ Data Collection Form(s) ☐ Informed Consent Form (English & Local Dialect) ☐ 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 (PFDA) Approval	☐ 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 ……	
10. Remarks	☐ Complete	☐ Incomplete, will submit on_____	
11. Documents to be submitted later	___Information for subjects ___Informed consent/assent form ___Others……	___Study budget ___Investigator's brochure ___Case report forms (CRF)	
12. Submitted by:		**13. Signature:**	**14. Date submitted:**
15. Received by:		**16. Signature:**	**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

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

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

IERB Reviewer's Evaluation Form

IERB No.		PROTOCOL No.		CTRD No.	
PROTOCOL TITLE					
PRINCIPAL INVESTIGATOR					

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

I. SCIENTIFIC ISSUES

		COMMENTS
1. ☐ Clear ☐ Unclear	Objectives of the Study	
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 ?	
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?	

II. HUMAN SUBJECTS ISSUES

A. Consent Form

1. ☐ Yes ☐ No	Has the investigator requested WAIVER of the consent requirement? If yes, indicate whether acceptable and why. If no, 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)	
Who will be enrolled? ☐ Men ☐ Women ☐ Children ☐ Healthy Volunteers ☐ Minorities ☐ Vulnerable populations (pregnant women, fetuses, children, decisionally-impaired)		
4. ☐ Yes ☐ No	Does the recruitment plan allow for 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 applicable

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;	

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 advantageous to the subject;	
5. ☐ Yes ☐ No	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;	
6. ☐ Yes ☐ No ☐ NA	For research involving more than minimal risk, an 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 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.	

The regulations further require that the following additional information be provided 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 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, if applicable

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 Assessment

1. ☐ Yes ☐ No	Is this a greater than minimal risk study? (See definitions.)	

Risk: There is a probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk."

Minimal Risk: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.

2. ☐ Yes ☐ No ☐ NA	Is there a prospect of direct benefit to the subjects?	
3. ☐ Yes ☐ No ☐ NA	Are the risks/benefits justifiable and adequately defined?	
4. ☐ Yes ☐ No ☐ NA	Are the risks minimized?	
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 ☐ NA	Are women (and men) of child-bearing potential advised to practice medically accepted methods of birth control?	

Pediatric Studies, if 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 risk 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 prospect of direct benefit to the individual subjects	
c) ☐ Yes ☐ No	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 ☐ NA	If there will be any third-party access to subjects or subject records, are subjects appropriately advised of this potential breach of confidentiality?	
4. ☐ Yes ☐ No ☐ NA	If so, are safeguards appropriate for such access?	

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	
☐ 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? ☐ Yes ☐ No	

D. Devices

1. ☐ Yes ☐ No	Is this an investigational device study? If yes, has an Investigational Device Exemption (IDE) been filed with PFDA? ☐ Yes ☐ No If yes, what is the appropriate classification? ☐ Significant Risk or ☐ Non-Significant Risk.	
2. ☐ Yes ☐ No ☐ N/A	Is the device classification appropriate?	

RECOMMENDATION:

SCIENTIFIC:

☐ **Approved** ☐ **Minor Modifications** ☐ **Major Modifications** ☐ **Disapproved**

COMMENTS: Kindly reference any items listed above of which you have concern(s) and comment (attach an additional sheet if necessary):

_____

_____

_____

_____

_____

ETHICAL:

☐ **Approved** ☐ **Minor Modifications** ☐ **Major Modifications** ☐ **Disapproved**

COMMENTS: Kindly reference any items listed above of which you have concern(s) and comment (attach an additional sheet if necessary):

_____

_____

_____

_____

_____

Reviewer's Name: _____

Reviewer's Signature: _____ **Date:** _____

FM-E-IRB-2019-044 Rev. 07
Participants Information and 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.com

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 *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*	

1) Participation
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 palagay 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 _____ang 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

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

7) 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-loob 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.

9) 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

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 katanungan 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 _____

_____

Date
Petsa _____

Signature
Lagda _____

Distribution: original for study doctor, copy to _____(name of partcipant)

Pamamahagi: ang orihinal para sa doktor ng pag-aaral, kopya para kay ___(pangalan ng kalahok)

For emergency situations where consent of the participant cannot be obtained the following signature line must be signed:

Para sa mga sitwasyong 'emergency,' kapag di makuha ang pahintulot ng kalahok na pasyente ay nararapat idagdag ang sumusunod na linya ng pirma

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
Kaugnayan sa Pasyente _____

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

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:

_____ _____
ATTENDING PHYSICIAN *Date*

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.com

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.**

   a. 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:

1. As required by law,
2. 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**

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

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

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	
PROTOCOL NUMBER	
SITE OF STUDY *Lugar ng Pag-aaral*	
TITLE OF STUDY *Pamagat ng Pag-aaral:*	
LANGUAGE *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

can decide if you want to join or not. Your parent(s) know that we are going to talk to you about the study.

Hello! Ako si _____. Ang mga doctor (tagagaliksik) katulad ko kung minsan ay gumagawa ng research o pag-aaral 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. Inapaliwanag 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-aaral 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-aaral 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 ayaw 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

5. 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-aaral 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 mo 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 pag-isipan 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 pag-aaral 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 pag-aaral kahit kailan na gustuhin ko. Bibigyan ako ng kopya ng dokumentong ito.

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

Your Name: _____ Date: _____

Your Signature: _____

If the participant is unable to read and write/*Kung hindi nakakabasa at nakakasulat ang kalahok*:

Thumb print of participant/ *marka ng hinlalaki*

SIGNATURE OF WITNESS/PIRMA NG SAKSI (If participant is unable to read and write/*kung hindi marunong bumasa at sumulat ang kalahok*)

I have witnessed the careful explaining of the study by the study doctor and that the participant had the chance to ask questions. I confirm that the participant has given his/her assent freely and voluntarily./ *Nasaksikan ko ang maingat na pagpapaliwanag ng doktor ng pag-aaral tungko dito at nakapagtanong ang kalahok. Kinukumpirma ko na ang kalahok ay sumang-ayon na sumali sa pag-aaral nang hindi napipilitan.*

Name: _____ Date: _____

Signature: _____

SIGNATURE OF THE INDIVIDUAL OBTAINING ASSENT/*PIRMA NG INDIBIDWAL NA KUMUKUHA NG PAHINTULOT*

I have carefully explained the study to the participant and have answered all the participant's questions. I believe that the participant understood all of the information described in this document and freely gave assent to participate.

Naipaliwanag kong mabuti ang tungkol sa pag-aaral sa kalahok at nasagot ang lahat ng kanyang mga tanong. Naniniwala ako na naintindihan ng kalahok ang lahat ng impormasyo na nasa dokumentong ito at kusang-loob na sumang-ayon sa sumali.

Name: _____ Date: _____

Signature: _____

FM-E-IRB-2019-076 Rev. 03
Parent Information and 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.com

Parent Information and Informed Consent Form

Impormasyon para sa Magulang at Form ng May-Kaalamang Pahintulot

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 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 *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

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.

1) Pagkikilahok

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 kung ano ang nakapaloob sa pag-aaral na ito. Mangyaring basahin nang mabuti ang impormasyon at magtanong ka ng anumang nais mong itanong. Ang Philippine Heart Center Institutional Ethics Review Board (PHC IERB) ang nakapagrepaso sa mga layunin ng pag-aaral at nakapagbigay ng mabuti o paborableng palagay tungkol dito.

2) Purpose of the Study Explain why you are doing the research in layman's 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 use it, 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 your child is enrolled, the duration of your child's 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 Pagsali sa Pag-aaral

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

5) 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-loob na Pagsali / Pag-alis mula sa Pag-aaral

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 _____

Date (to be entered by Participant)
Petsa (isusulat ng Kalahok) _____

Signature
Pirma _____

13) SIGNATURE OF PARENT(S)/LEGALLY AUTHORIZED REPRESENTATIVE(LAR)/ PIRMA NG MAGULANG/LEGAL NA 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

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

Printed Name of Individual Obtaining Consent
Isinatitik na Pangalan ng Kumukuha ng Pahintulot

_____

Date
Petsa

_____

Signature
Lagda

_____

_____

Distribution: original for study doctor, copy to _____(name of partcipant)

Pamamahagi: ang orihinal para sa doktor ng pag-aaral, kopya para kay ___(pangalan ng kalahok)

If the child's parent/legally authorized representative cannot read, the following signature line should be signed:
Kapag ang legal na kinatawan ng batang kalahok 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

_____

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

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

IERB's Decision Form

Meeting No: _____ Date (D/M/Y):_____

IERB No.		Protocol No.			CTRD No.	
Protocol Title :						
Principal Investigator						
Sponsor						
Elements Reviewed						
Review of Accomplished Revision ☐ Yes ☐ No			Date of Previous review:			

			Decision							
			Protocol				ICF			
No.	Consensus of IERB members	Initial	AP	MMR	MJ	DA	AP	MMR	MJ	DA
1										
2										
3										
4										
5										
6										
7										
8										
9										

Signature:

Chair, IERB

Date: _____

Note:
AP - Approved
MMR–Minor modifications required
MJ – Major modification
DA – Disapproved

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

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

Modification and Disapproval Letter

INSTITUTIONAL ETHICS REVIEW BOARD

Chair

Members

Philippine Heart Center
8/F Medical Arts Building
East Avenue, Quezon City
Tel. no. 9252401 loc.3899
Email Add: irbphc@gmail.com

(Date)

(Principal Investigator)
(Position)
(Address)

IERB no.:_____ CTRD no.:_____

Title of Protocol:

_____

Dear (PI),

On (Date)_____, 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.
3.
4.
5.

Please submit the requested information or documents for a re-review on or before (Date)_____. You may not begin your study until your revised application is approved.

Kindly contact Ms. _____ at 9252401 loc.3899 if you have any questions or further information.

Sincerely yours,

Chair, IERB

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 No.		CTRD No.:			
Title of Protocol:							
Principal Investigator :				Contact No.			
Initial Review Date:				Type of Review		Full Board	
						Expedited	
Documents Revised		Protocol (latest version number and date)			ICF (latest version number and date)		
		Others (specify)					
Date of Review of Resubmission:	1st Review	2nd Review	3rd Review	4th Review			

Required Modification	**Indicate the page/s revision to be found**	**Reviewer's Comments**	**Reviewer's Recommendations:**
Protocol: 1. 2. ICF: 1. 2. Others: 1. 2.			
Summary of Recommendations:			

Recommended Action:		Approve		Major Modification
				Major Modification (Expedited at the level of the Chair/Reviewer)
		Minor Modification		Disapprove

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:

_____ Date_____
Reviewer

_____Date: _____
Chair, PHC-IERB

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

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

Decision Letter for Protocol Approval

INSTITUTIONAL ETHICS REVIEW BOARD

Chair

Members

Contact Person:

Philippine Heart Center
8/F Medical Arts Building
East Avenue, Quezon City
Tel. no. 9252401 loc.3899
Email Add: irbphc@gmail.com

DATE

Principal Investigator
Philippine Heart Center

IERB no.: **CTRD no.** **Protocol no.** **SJREB no.**

Title of Protocol:

Dear Dr. _____,

We wish to inform you that your research study has been reviewed and is hereby granted approval for implementation by the PHC – Institutional Ethics Review Board after all required modifications have been addressed.

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:

1. 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)*
   a) Date covered by the report
   b) Protocol summary and status report on the progress of the research
   c) Number of participants accrued
   d) Complaints on the research since the last IERB review
   e) Summary of relevant recent research literature, interim findings and 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
4. Any information which is needed by the institutional Ethics Review Board to do ongoing review
5. Notice of time of completion of the study
6. After completion of the study, please submit an end study report and a copy of final report.

Please be advised that you can continue the trial according to the approved protocol and Good Clinical Practice.

The study is subject to continuing review on or before _____ unless closed before that date. Please submit continuing review form 6 weeks before the expiration of the approval.

Furthermore, we would like to inform you that the Philippine Heart Center Institutional Ethics Review Board at 8/F Medical Arts Building, East Avenue, Quezon City is organized and it operates according to Good Clinical Practice and applicable laws and regulations.

Please note that any changes to the study as approved must be promptly reported and approved. If you have any questions or require further information, please contact Ms._____ at tel. no.9252401 loc.3899.

Sincerely yours,
Chairman, IERB

Note:

Duration of Approval	***Frequency of Continuing Review***
From : To :	**Due Date:**

Received by:

Print Name : _____

Signature : _____ Date : _____

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

Received by:

Name:

Signature

Date:

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

Checklist for Exemption from Protocol Review

IERB No.	Protocol No.	CTRD No./SJREB no:
Title of Protocol:		
Principal Investigator :		
Sponsor :		

Please check the appropriate:

Yes	No	Criteria for Exemption
		Protocol does not involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols)
		Protocol that involves minimal risks. a. Protocol is for research type like institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests. b. Protocol only includes human interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording). c. Protocol involves the use of publicly available data or information.

Recommendation:

Decision		Qualified for Exemption
		Unqualified for Exemption (re-classify to) ☐ Expedited Review ☐ Full board Review
Summary of Comments		

Reviewer's Name:		Date:	
Signature:			

FM-E-IRB-2024-096
Rev. 00

FDA Clinical Trial Assessment Form
Version 1.2/16 July 2012

FDA Form No: _____

FDA CLINICAL TRIAL ASSESSMENT FORM

Version 1.2/16 July 2012

I. ADMINISTRATIVE INFORMATION		
1. Clinical trial number		<FDA-issued unique code>
2. Clinical trial protocol title		<Full protocol title>
3. Clinical trial version number		<As indicated in the protocol>
4. Clinical trial version date		< As indicated in the protocol> <dd/mm/yyyy>
5. Clinical trial phase *(Note: Review by FDA-recognized institutions is limited to phases indicated in this form)*		___ Phase 1 ___ Phase 2 ___ Phase 3 ___ Phase 4 *Type*: _____
6. Sponsor-applicant:		<Name of sponsor>
7. CRO-applicant:		<Name of CRO>
8. Date received by institution:		<dd/mm/yyyy>
9. Reviewing institution:		<Name of reviewing institution>
	9.1. Address	
	9.2. Signatory official:	<Title, Name, Surname>
	9.3. Position & Designation:	<Institutional position & review designation>
	9.4. Signature:	
	9.5. Review date:	<dd/mm/yyyy>
	9.6. Telephone:	
	9.7. Fax:	
	9.8. Email:	

10. Declaration of conflict of interest (COI)

The <NAME OF INSTITUTION> 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/experts involved in this review/both> have <financial, proprietary, professional> conflict of interest related to 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 or notes) upon demand of the FDA.

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>
- Deficiencies as indicated in: <indicate relevant sections>

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 ASSESSED	*Do the documents submitted have adequate information for assessment?*		*Documents assessed & relevant sections*	ASSESSMENT
1. SCIENTIFIC AND SOCIAL VALUE	**Yes**	**No**		
1.1. Philippine community health priority addressed				
1.2. Disease priority addressed				
1.3. Potential Impact on deeply-held values of the Filipino				
1.4. Conclusions on the potential **SCIENTIFIC AND SOCIAL VALUE** of this clinical trial:				

COMPONENT ASSESSED	*Do the documents submitted have adequate information for assessment?*		*Documents assessed & relevant sections*	ASSESSMENT
2. PRE-CLINICAL DATA	**Yes**	**No**		
2.1. Toxicology				
2.2. Environmental risk				
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				

FDA CLINICAL TRIAL ASSESSMENT FORM

Version 1.2/16 July 2012

3.2. Phase 1 (completed)				Years conducted
				Sites
				Enrolment: <number of patients>
				Findings
3.3. Phase 2 (completed)				Years conducted
				Sites
				Enrolment: <number of patients>
				Findings
3.4. Phase 3 (completed)				Years conducted
				Sites
				Enrolment: <number of patients>
				Findings
3.5. Conclusions on the **PRIOR CLINICAL DATA** supporting this clinical trial application:				
COMPONENT ASSESSED	*Do the documents submitted have adequate information for assessment?*		*Documents assessed & relevant sections*	**ASSESSMENT**
4. STUDY DESIGN	**Yes**	**No**		
4.1. Duration				
4.1.1. Main phase				<time><N/A>
4.1.2. Run-in phase				<time><N/A>
4.1.3. Extension phase				<time><N/A>
4.2. Hypothesis				<Superiority> < Equivalence> <Non-inferiority> <Exploratory: specify> <Others: specify>
4.3. Treatment groups				
4.3.1. Group 1				<treatment>,<duration>, <number randomized>
4.3.2. Group 2				<treatment>,<duration>, <number randomized>
4.3.3. Group 3				<treatment>,<duration>, <number randomized>
4.3.4. <if placebo group included>				<scientific and methodological justification for the use of placebo>
4.4. Endpoints and definitions				
4.4.1. Primary				<appropriateness of endpoint and method of measurement>
4.4.2. Secondary/Other (specify)				<appropriateness of endpoint and method of measurement>
4.4.3. Secondary/Other (specify)				<appropriateness of endpoint and method of measurement>
4.4.4. <add rows as needed>				<appropriateness of endpoint and method of measurement>
4.5. Statistical analysis for				<Intent to treat> <Per protocol>

FDA CLINICAL TRIAL ASSESSMENT FORM

Version 1.2/16 July 2012

primary endpoint				<other: specify><time point>
4.6. Statistical analysis for secondary endpoint				<Intent to treat> <Per protocol> <other: specify><time point>
4.7. Conclusions on the **STUDY DESIGN** proposed for this clinical trial:				
COMPONENT ASSESSED	*Do the documents submitted have adequate information for assessment?*		*Documents assessed & relevant sections*	**ASSESSMENT**
5. CLINICAL SAFETY	**Yes**	**No**		
5.1. Expected adverse events				
5.2. Expected serious adverse events and deaths				
5.3. Expected adverse laboratory events				
5.4. Safety in special populations				<adequate identification of populations wherein precaution/ safety measures/exclusion is exercised>
5.5. Adverse immunological events (if applicable)				
5.6. Drug-drug interactions and other interactions				
5.7. Pharmacovigilance system and plan				<adequacy of compliance with regulatory reporting systems for AEs>
5.8. Risk management system and plan				<appropriateness of risk management method *vis à vis* expected risks>
5.9. Conclusions on the **CLINICAL SAFETY** plan proposed for this clinical trial:				
COMPONENT ASSESSED	*Do the documents submitted have adequate information for assessment?*		*Documents assessed & relevant sections*	**ASSESSMENT**
6. BENEFIT-RISK ASSESSMENT	**Yes**	**No**		
6.1. Beneficial effects of the intervention to the target population				<Uncertainty/certainty in the knowledge about the beneficial effects>

FDA CLINICAL TRIAL ASSESSMENT FORM

Version 1.2/16 July 2012

6.2. Unfavorable effects of the intervention to the target population				<Uncertainty/certainty in the knowledge about the unfavorable effects>
6.3. Vulnerable populations involved				<Justification of risks to vulnerable 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 ASSESSED	*Do the documents submitted have adequate information for assessment?*		*Documents assessed & relevant sections*	
7. STUDY SITES	**Yes**	**No**		
7.1. List of sites				

STUDY SITES	**TYPE**	**PROFILE**	**ERC**	**If none**
7.1.1.<Name of site>	<tertiary/ secondary> <teaching hospital> <others: specify>	Facilities, accreditation, government classification, etc	<PHREB registration number>	<justification if no institutional or local ERC>
7.1.2.<add rows as needed>				

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

FDA CLINICAL TRIAL ASSESSMENT FORM

Version 1.2/16 July 2012

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
11.4. Reference 4