PHILIPPINE HEART CENTER **INSTITUTIONAL ETHICS REVIEW BOARD**	Document Type **POLICY/STANDARD OPERATING PROCEDURE**	Document Code: POL-E-IRB-008
		Effective Date: January 2024
	Document Title **APPENDIX C MONITORING PROCEDURES FORMS**	Revision Number: 2
		Page: 1 of 24

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 C
Monitoring Procedures Forms

FM-E-IRB-2019-072 Rev. 04	Amendment Application Form
FM-E-IRB-2019-024 Rev. 06	Continuing Review Form
FM-E-IRB-2019-012 Rev. 05	Continuing Review Notice
FM-E-IRB-2019-070 Rev. 05	Continuing Review Approval Template
FM-E-IRB-2019-029 Rev. 08	Serious Adverse Event Report Form
FM-E-IRB-2019-026 Rev. 07	Deviation/Violation/Non-Compliance Report Form
FM-E-IRB-2019-028 Rev. 07	Study Termination Form
FM-E-IRB-2019-025 Rev. 07	Final Study Report Form
FM-E-IRB-2019-031 Rev. 05	Site Visit Report Form
FM-E-IRB-2019-069 Rev. 03	Research Participant Complaint Form

FM-E-IRB-2019-072 Rev. 04
Amendment 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

Amendment Application Form

IERB no.		Protocol no.		CTRD no.	
Study Title:					
Principal Investigator					

AMENDMENT TO RESEARCH STUDY (Choose all that apply)

- ☐ Change(s) to research protocol *(attach tracked versions of protocol)*
- ☐ Change(s) to consent form scripts *(attach clean and tracked version of document(s)*
- ☐ Change to study population
- ☐ Addition of Study Site
- ☐ Change to sample size
- ☐ Initiation of new study phase
- ☐ Changes of recruitment materials, data collection forms, instruments, questionnaires/surveys *(attach tracked version of revised documents with new version number)*
- ☐ Change to drug or device information for FDA regulated study
- ☐ Change in conflict of Interest
- ☐ Other change *(describe below)*

Describe changes to the approved protocol/IERB application form. Explain in detail in the space below the reasons for requesting these changes and which part(s) of the approved document will be amended. Please highlight changes in the revised document.

Describe changes to the ICF/assent form/recruitment advertisement, etc. Explain which sections of these items are being changed. Please highlight changes in the revised document.

SIGNATURE

_____ _____
Signature of Principal Investigator Date
(signature of co-investigator or study staff is not acceptable)

To be filled up by IERB

Date received:		Received by:
		Signature over Printed Name:

To be filled out by Reviewer:

_____This amendment *does not* increase risks to participants enrolled in the study.

_____This amendment *may or will* increase risks to participants enrolled in the study.

please describe the requested revision.

_____

Recommendations	Type of review:
☐ Approved: no increase in risk	☐ Expedited review
☐ Major changes required to the Protocol/Informed Consent Form	☐ Full board review
☐ Minor changes required to the Protocol/Informed Consent Form	Date of meeting: _____
☐ Disapproval	
Comments: _____	

IERB Final Decision:	

Primary Reviewer :	Approved by : IERB Chair
Signature over Printed Name / Date	*Signature over Printed Name / Date*

FM-E-IRB-2019-024 Rev. 06
Continuing Review 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

CONTINUING REVIEW FORM

DIRECTIONS FOR SUBMITTING A CONTINUING REVIEW FORM

- This form must be submitted four weeks before the expiration date
- Request for continuation of a current approved research protocol will be reviewed at a regularly convened meeting of the IRB committee that issued the original approval unless the criteria for expedited review are met.
- Continuation forms will not be accepted for studies 60 days past the expiration date of a study; a new submission is required. Studies that are expired are lapsed in IRB approval and this is non-compliance
- Please ensure that the PI and all key personnel have completed the GCP within the last 3 years.
- Once you receive approval to conduct research, it is the PI's responsibility to gain approval to continue the research at the interval set by the IRB for your study as well as to close the study by submitting a closure form at the end of the study
- Please call us if you have any questions along the way: 9252401 loc.3899

WHAT TO SUBMIT

All required documents must be submitted four weeks prior to the expiration date

- Submit one copy single-sided of the Continuation Form with original signature
- Two clean unstamped copies, single sided, of the informed consent/assent/information sheet currently in use (if applicable)
- 1 copy of the completed and signed original **Investigator's Progress Report**.
- 1 copy of the most recently approved **Consent/Assent Form.** If the study is closed to enrollment, do not send a consent form. If using an addendum consent form for currently enrolled participants, send 1 copy for review.
- 1 copy of the revised consent/assent form, if applicable, with changes highlighted. Please use underlining or shading to highlight changes.
- 1 copy of all **approved amendments/revisions** since their last renewal. copy of each previously submitted **Investigator's Progress Report**
- 1 copy of any progress report/s submitted to the sponsoring/funding agency since last renewal, if applicable.

ACTION REQUESTED:

- ☐ Renew - New participant accrual to continue
- ☐ Renew - Enrolled participant follow up only
- ☐ Terminate - Protocol discontinued

PRINCIPAL INVESTIGATOR (PI)

Name of PI			
PI's Signature		Specialization	
Mobile no.		Email add.	

Has any potential and/or financial conflict of interest arisen since the last IERB review ? If yes, a "Financial Conflict of Interest Detailed Disclosure Form" must be submitted to the IERB annually or when a change occurs.	☐ Yes ☐ No

STUDY INFORMATION

IERB No.		Protocol No.		CTRD No.	
Sponsor/CRO					
Protocol Title					
a) Original Approval Date		Expiration Date			
b) Date of Submission					
c) Is the submission date after or on the expiration date?	☐ Yes If yes, please answer below ☐ No				
If yes, your study has a lapse in IERB approval. Please indicate whether or not any research activities have taken place during the lapse in IERB approval.	☐ Yes, I did conduct research activities during the lapse in approval ☐ No research activities occurred during the lapse				
Note: If your protocol does not receive approval prior to the expiration date, non participants can be enrolled, no data can be collected or used for research if collected during the period of lapse approval. Repeat lapses of IERB approval is deemed non-compliance.					

C. STATUS OF PROJECT

Any amendment since the last review? (Describe briefly.)	☐ No ☐ Yes
Any change in participant population, recruitment or selection criteria since the last review? (Explain the changes.)	☐ No ☐ Yes
Any change in the Informed Consent process or documentation since the last review? (Please explain.)	☐ No ☐ Yes

Is there any new information in recent literature or similar research that may change the risk/ benefit ratio for participants in this study? (Discuss and attach a narrative.)	☐ No	☐ Yes
Any complaints about the research from subjects enrolled at the local site since the last IERB review	☐ No	☐ Yes
Any unexpected complication or side effect noted since the last review? (Discuss and attach a narrative.)	☐ No	☐ Yes
Were these protocol deviation/ violation reports? Summarize, to include the nature and frequency of deviation/violation. What corrective actions were taken?	☐ No	☐ Yes
Did any participant withdraw from this study since the last approval? (Reasons for withdrawal)	☐ No	☐ Yes
Any new investigator that has been added to or removed from the research team since the last review? (Please identify them and submit the CVs of new investigators.)	☐ No	☐ Yes

Summary of protocol participants:

☐ Accrual ceiling set by IERB

☐ New participants accrued since last review

☐ Total participants accrued since protocol began

Accrual Exclusions:

☐ None

☐ Male

☐ Female

☐ Others (Specify) _____

Are there any new collaborating sites that have been added or deleted since the last review? Please identify the sites and note the addition or deletion. ☐ No ☐ Yes

Impaired Participants:

☐ None

☐ Physically

☐ Cognitively

☐ Both

Action Requested:

☐ Renew - New participant accrual to continue

☐ Renew - Enrolled participant follow up only

☐ Terminate - Protocol discontinued

To be filled up by IERB

Date received:		Received by: *Signature over Printed Name*

Is the risk-benefits ratio still favorable? Yes or No. Explain.

Recommended Action:

- ☐ Approve
- ☐ Request an amendment to the protocol or the consent form. (State the required amendment below)
- ☐ Request further information.
- ☐ Suspend or terminate the study
- ☐ Others: _____

Type of review:

- ☐ Expedited review
- ☐ Full board review

Date of meeting: _____

Recommendation:

Changes to the protocol :

Changes to the informed consent form :

IERB Final Decision:	

Primary Reviewer :	Approved by : IERB Chairman
Signature over Printed Name / Date	*Signature over Printed Name / Date*

Date IERB Approval Expires (One year from approval date):	

FM-E-IRB-2019-012 Rev. 05
Continuing Review Notice

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

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

Continuing Review Notice Template

Date:

To:

From:

RE: IERB no. _____ Protocol No: _____ Sponsor No. _____

Protocol Title:

We wish to inform you that your study is due for continuing review on (insert date of schedule). In this regard, you are reminded to submit a continuing report one month before the said date which will fall on (insert date of expiration).

Attached herewith is a copy of the continuing review form to be accomplished and submitted.

Failure to receive approval for continuing review before the expiration date will result to automatic suspension of the approval of the study protocol on the expiration date.

If you have any question, please contact us at telephone no.9252401 loc.3899 or via email: irbphc@gmail.com. Please include your study title and IERB accession no. in all correspondence with this office.

For your compliance.

Chair, IERB

FM-E-IRB-2019-070 Rev. 05
Continuing Review Approval Template

Republic of the Philippines
PHILIPPINE HEART CENTER
East Avenue, Quezon City 1100, Philippines
Telephone No.9252401 to 50 www.phc.gov.ph

APPROVAL NOTICE

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:

To:

From:

RE: IERB no. DETR No: Protocol No.

Protocol Title:

Approval date :
Schedule of Continuing Review:
Expiration Date :

Thank you for your submission of documents for continuing review for the above mentioned study. The PHC-IERB has approved your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All researches/studies must be conducted in accordance with this approval submission.

It is the Principal Investigator's responsibility to obtain review and continued approval before the expiration date. You may not continue any research activity beyond the expiration date without IERB approval.

Failure to receive approval for continuing review before the expiration date will result in the automatic suspension of the approval of this protocol on the expiration date.

All changes or amendments to your protocol or consent form require review and approval by the IERB before implementation

If the research, including data analysis, has been completed or, if you wish to terminate the study, please notify the IERB.

If you have any question, please contact us at telephone no.9252401 loc.3899 or via email: irbphc@gmail.com. Please include your study title and IERB no. in all correspondence with this office.

MARCELITO L. DURANTE, MD
Chair, IERB

FM-E-IRB-2019-029 Rev. 07
Serious Adverse Event Report 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

SERIOUS ADVERSE EVENT REPORT FORM

Whenever there is any SAE event in any research approved by the PHC-IERB, it has to be reported by the principal investigator (PI) to the IERB. Section 1 of this form should be filled up by the PI.

SECTION 1

Principal Investigator:

Study Title: Protocol No.:

Name of the study medicine/device:

Report Date:
☐ Initial ☐ Follow-up :
Onset Date:

Date Site was Informed:

Sponsor:

Date of first use:

Title of the Report

Date of the report

Subject's initial/number: _____ Age: _____ ☐ Male ☐ Female

Subject's history:

Laboratory findings:

SAE:

Treatment:
Outcome: ☐ Resolved ☐ On-going

Seriousness:
☐ Death ☐ Life Threatening
☐ Hospitalization:
☐ Initial ☐ Prolonged
☐ Disability/Incapacity
☐ Congenital Anomaly
☐ Others

Relation to
☐ Drug ☐ Device ☐ Study
☐ Not related
☐ Possibly
☐ Probably
☐ Definitely related
☐ Unknown

Action Taken as the result of the report

Signature over Printed Name of PI / Date

Note: PI should attach standard SAE report form to this IERB form.

(to be filled up by the designated IERB representative)

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Institutional Ethics Review Board
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SECTION 2 **(to be filled out by the designated IERB representative)**

Document receipt by the IERB

Name (IERB Secretariat)	Signature	Date

Reviewer/s Recommendations

Reviewer's Name:	Signature	Date

Changes to the protocol recommended ☐ No ☐ Yes
Comments:

Changes to the informed consent form recommended? ☐ No ☐ Yes
Comments:

IERB Final Action:

- ☐ Request an amendment to the protocol or the consent form.
- ☐ Request further information.
- ☐ Suspend or terminate the study
- ☐ Take note and no further action is needed.
- ☐ Others: _____

Type of review:

- ☐ Full board review

Date of meeting _____

IERB Final Decision:	

Primary Reviewer :	Approved by : IERB Chair
Signature over Printed Name / Date	*Signature over Printed Name / Date*

FM-E-IRB-2019-026 Rev. 07
Deviation/Violation/Non-Compliance 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

Deviation/Violation/Non-compliance Report Form

I. **General Information:**

IERB no.	CTRD no.	Protocol no.
Project Title:		
Protocol Version no. and Date		Phone Number:
Person Completing Form:		
Name of Principal Investigator (PI):		Research Site:
Patient ID#	Age:	Gender: ☐ Male ☐ Female
Protocol violation identified by: ☐ PI ☐ Coordinator ☐ Monitor ☐ Other: _____		

II. **Reporting Criteria:**

This deviation/violation adversely affects: *(check all that apply)*

YES	NO	
[ ]	[ ]	rights/welfare of subject(s)
[ ]	[ ]	safety of subject(s)
[ ]	[ ]	integrity of research data
[ ]	[ ]	subject's willingness to continue study participation

(Note: if you have checked "NO" to all of the above, please do not proceed with this report. This is not a reportable deviation/violation. However, if the IRB has specifically requested that you submit this report because of a lapse in approval or late submission, all sections of this form must be completed.)

III. Characterization:

The deviation/violation involves:

- [ ] Enrollment process *(inclusion/exclusion criteria, ascertainment/recruitment, etc.)*
- [ ] Consent process *(oral or written)*
- [ ] Drug/Device Administration *(dosage, schedule, route of administration, formulation, etc.)*
- [ ] Other Protocol Activities (*research activities, data analysis, reporting, etc.)*
- [ ] Complaint from research subject
- [ ] Audit finding that requires corrective action
- [ ] Other:

III. **Description:**

1. Date(s) of the deviation/violation: _____

Note: If more than 14 business days prior to the date of submission to the IRB (or more than 7 days for an unanticipated study-related death), please explain the delay in reporting.

2. Please describe in detail the specific deviation/violation: _____

3. If the purpose of this deviation report is a lapse in IRB approval, please describe all study activities, including enrollment, interventions, data analysis, that have occurred during the lapse: _____

4. Please explain how/why the deviation/violation occurred: _____

5. Please describe how the deviation/violation affected the:
   (i) risk/benefit ratio for the subject(s): _____
   (ii) integrity of the research data: _____
   (iii) subject's willingness to continue study participation: _____

6. Does this protocol deviation/violation require revision of the protocol and/or consent form?
   [ ] Yes *(if yes, please submit a completed Amendment form and revised documents with changes marked)*
   [ ] No

7. Please describe: (i) corrective actions, if applicable, for the deviation/violation; and (ii) a plan for preventing the recurrence of the deviation/violation:

By signing below, I declare that the above is an accurate and complete description of the protocol deviation/violation and that, upon receipt of the IRB's review, I will fully and immediately implement any corrective actions required by the IRB.

Signature of PI

Date

To be filled up by IERB

Date received:		Received by: *Signature over Printed Name*

Type of Review:		Expedited Review		Full Board Review
Date of Meeting				

IERB Chairman/Designee Review of Problem Report:

I have reviewed this reported protocol deviation/violation and determined that: *(check all that apply)*

[ ] No further action is required.
[ ] PI must complete the Prompt Reporting
[ ] The corrective action described in this form below is acceptable. PI must issue a statement to the IERB that he/she has implemented the corrective action plan as described.
[ ] PI must submit an interim report to the IERB on _____ describing his/her progress in implementing the corrective action described below.
[ ] The attached corrective actions must be implemented.
[ ] The deviation/violation reported appears to represent serious or continuing non-compliance. Review according to that policy is required.
[ ] Other: _____

IERB Final Decision:	

Primary Reviewer :	IERB Chairman
Signature over Printed Name / Date	*Signature over Printed Name / Date*

FM-E-IRB-2019-028 Rev. 07
Early Termination/Suspension of Study 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

EARLY TERMINATION/SUSPENSION OF STUDY FORM

IERB No:		Protocol No.	
Protocol Title:			
Principal Investigator:			
Phone :		E-Mail:.	
Department:			
Sponsor:		CRO	
IERB Approval Date:		Date Of Last Report:	
Starting Date:		Termination Date:	
No. of Participants:		No. Enrolled:	
Plan for enrolled subjects after study termination:			
Summary of Results			
Reason for termination			
Accrual Data:			
P.I. Signature:		Date:	

FM-E-IRB-2019-028
Rev. 07

To be filled up by IERB

Date received:		Received by:
		Signature over Printed Name:

Recommendations

- ☐ For Archiving
- ☐ Request further information.

Type of review:

- ☐ Expedited review
- ☐ Full board review

Date of meeting: _____

IERB Final Decision:	

Primary Reviewer :	Approved by : IERB Chair
Signature over Printed Name / Date	*Signature over Printed Name / Date*

FM-E-IRB-2019-025 Rev. 07
Final Study Report Form

PHILIPPINE HEART CENTER
Institutional Ethics Review Board
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East Avenue, Quezon City, 1100 Philippines
Tel./Fax no. 89252401 loc.3899; email add: irbphc@gmail.com

Final Study Report Form

IERB No.		Protocol No.		Approval Date	
Protocol Title					
Principal Investigator					
Phone number		E-mail address :			
Sponsor / CRO					
Study site(s):					
				Compliant with the approved protocol? *(To be filled by the Primary Reviewer)* **YES / NO**	
Total Number participants who completed the study:					
No. of Study Arms					
Summary of Recruitment: Accrual ceiling set by IERB					
• New participants accrued since last review					
• Total number of participants accrued since protocol began					
• No. of participants who are lost to follow-up					
• No. of participants withdraw from the study					
• No. of participants who experienced SAEs/SUSARs					
Amendment to the original protocol (including dates of approval)					
Summary of onsite SAEs					

reported			
Summary of participant's complain or grievances documented regarding conduct of study			
Summary of benefits to participants			
Summary of indemnification of study related injury			
Progress report submitted (with dates of approval)			
Duration of the study (months)			
		Compliant with the approved protocol? *(To be filled by the Primary Reviewer)* **YES / NO**	
Objectives:			
Methodology			
Dissemination Plan			
Results: *(Use extra blank paper, if more space is required.)*			
Signature of P.I.			

To be filled up by IERB

Date received:		Received by:
		Signature over Printed Name

Recommendations	Type of review:
☐ For Archiving ☐ Request further information. Comments:	☐ Expedited review ☐ Full board review Date of meeting: ----------

IERB Final Decision:	

Primary Reviewer:	Approved by : IERB Chair
Signature over Printed Name / Date	Signature over Printed Name / Date

FM-E-IRB-2019-031 Rev. 05
Site Visit Report Form

PHILIPPINE HEART CENTER
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Tel./Fax no. 9252401 loc.3899; email add: irbphc@gmail.com

SITE VISIT REPORT

IERB No.		Date of the Visit:	
Study Title:			
Principal Investigator/s:		Phone:	
Department:		Room No.	
Sponsor		CRO	
Total number of expected subjects:		Total subjects enrolled:	

Are site facilities appropriate? ☐ Yes ☐ No Comment:

Are Informed Consents Recent? ☐ Yes ☐ No Comment:

Any adverse events found? ☐ Yes ☐ No Comment:

Any protocol non-compliance/violation? ☐ Yes ☐ No Comment:

Are all Case Record Forms up to date? ☐ Yes ☐ No Comment:

Are storage of data and investigating products locked? ☐ Yes ☐ No Comment:

How well are participants protected? ☐ Good ☐ Fair ☐ Not good Comment:

Any outstanding tasks or results of visit? ☐ Yes ☐ No Give details:

Duration of visit: (hours)		Starting from:		Finish:	
Name of IERB member/representatives and companion:					
Completed by:		Date:			

FM-E-IRB-2019-069 Rev. 03
Research Participant Complaint 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

Research Participant Complaint Form

As a participant in research conducted at Philippine Heart Center (PHC) or by a researcher affiliated with PHC, you have the right to report any concerns you have about the way the research was conducted or possible misconduct by the researcher. The Institutional Ethics Review Board (IERB) will keep this report confidential and conduct an investigation if necessary. Please be as specific as possible in completing this form.

Study Title: _____

Principal Investigator: _____

Department: _____ **Phone**: _____

Date(s) you participated in the research: _____

What did your participation require? _____

_____

_____

_____

_____

_____

Describe what specifically concerned you about the research.

_____

_____

_____

_____

_____

_____

☐ I prefer to submit this report anonymously.
☐ I prefer to provide the following contact information.

Your name: _____

Phone number: _____ **Email**: _____

FM-E-IRB-2019-069
Rev. 03