
 <p><b>PHILIPPINE HEART CENTER</b></p> <p><b>INSTITUTIONAL ETHICS REVIEW BOARD</b></p>	Document Type	Document Code: POL-E-IRB-009
	<b>POLICY/STANDARD OPERATING PROCEDURE</b>	Effective Date: January 2024
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### **Appendix D Documentation and Archiving**

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FM-E-IRB-2019-062 Rev. 04	Protocol for Archive Form
FM-E-IRB-2019-036 Rev. 03	Log of Requests for Copies of IERB's Documents
FM-E-IRB-2019-037 Rev. 03	Log of Request for Copies of Original Documents

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**FM-E-IRB-2019-050 Rev. 07**  
Meeting Agenda 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

**Agenda Template**

DATE :  
TIME :  
VENUE :

<b>Attendance:</b>	
--------------------	--

1. Call to order
2. Determination of quorum and presence of non-institutional members
3. Approval of the Agenda
4. Conflict of interest disclosure
5. Review and approval of the Minutes of the last meeting
6. Business arising from the Minutes
7. Protocol review

**7.1. FULL REVIEW**

**7.1.1. Protocols for Initial Review**


**7.1.1.1**

IERB No.		CTRD No.	
Protocol No.		Date of Protocol Submission	
Title			
Name of PI			
Sponsor			
Type of Review			
Designated Reviewer			
Summary			
Action Taken			

**7.1.2. Protocols for Modification (or Resubmission):**

**7.1.2.1**

IERB No.		CTRD No.	
Protocol No.		Date of Protocol Submission	
Title			
Name of PI			

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Sponsor	
Type of Review	
Designated Reviewer	
Conclusion and recommendations	The board, on consensus, recommended the approval of the protocol after the PI complied with the following modification/s:  •
Action taken	

7.1.3. Protocols for Clarificatory Interview – None

7.1.4. Application for Protocol Withdrawal – None

7.1.5. Protocol Amendment/s:

7.1.5.1

IERB No.		CTRD No.	
Protocol No.		Date of Submission	
Title			
Name of PI			
Sponsor			
Type of Review			
Designated Reviewer			
Document Submitted			
Action Taken			

7.1.6. Continuing Review Reports/Progress Report/ Annual Report:

7.1.6.1


IERB No.		CTRD No.	
Protocol No.		Date of Submission	
Title			
Name of PI			
Sponsor			
Type of Review			
Designated Reviewer			
Progress Report			
Action Taken			

7.1.7 End of Study Reports:

7.1.7.1

IERB No.		CTRD No.	
Protocol No..		Date of Submission	
Title			



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**7.1.12 Early Study Termination/Suspension Applications:**

**7.1.12.1**

IERB No.		CTRD No.	
Protocol No..		Date of Report	
Title			
Name of PI			
Sponsor			
Designated Reviewer			
Report	•		
Action taken			

**7.2. REPORT OF PROTOCOL SUBMISSIONS FOR EXPEDITED REVIEW AND FULL BOARD  
PROTOCOLS WITH MODIFICATION EXPEDITED AT THE LEVEL OF THE CHAIR**

- 7.2.1 Protocols for Initial Review -None
- 7.2.2 Protocols for Modification-None
- 7.2.3 Protocol Amendments- None
- 7.2.4 Continuing Review/ Study Progress Report–None
- 7.2.5 End of Study Reports–None
- 7.2.6 Protocol Deviation/Violation/Non-Compliance Reports –None
- 7.2.7 Early Study Termination-None

**7.3 REPORT OF PROTOCOL SUBMISSIONS EXEMPTED FROM REVIEW – None**

**7.4 REPORT OF PROTOCOLS REVIEWED FOR SINGLE JOINT ETHICS REVIEW BOARD (SJREB)**

- 7.4.1 Protocols for Initial Review – None
- 7.4.2 Protocols for Modification (Resubmission) – None
- 7.4.3 Protocol Amendment/s - None
- 7.4.4 Continuing Review/ Study Progress Report - None
- 7.4.5 End of Study Reports - None
- 7.4.6 SAE Reports - None
- 7.4.7 Protocol Deviation/Non-Compliance/Violation Reports – None
- 7.4.8 Early Study Termination – None

**8 Other Matters**

**9 Next Meeting-**

**10 Adjournment-**




Prepared by:  
(Signature Above and Full Name)  
Secretariat

Reviewed:  
  
(Signature Above and Full Name)  
Board Secretary

Noted by:  
  
(Signature Above and Full Name)  
Chair, Institutional Ethics Review Board



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**FM-E-IRB-2019-032 Rev. 05**  
Notice of Meeting



**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

(Date)

**Notice of Meeting**

**TO :** PHC Institutional Ethics Review Board Members:

(NAME OF IERB CHAIR) (NAME OF IERB MEMBER 1) (NAME OF IERB MEMBER 2) (NAME OF IERB MEMBER 3)	(NAME OF IERB MEMBER 4) (NAME OF IERB MEMBER 5) (NAME OF IERB MEMBER 6) (NAME OF IERB MEMBER 7)
---	--

**DATE :**

**TIME :**  
**VENUE:**

**AGENDA:**

1. Call to order
2. Determination of quorum and presence of non-institutional members
3. Approval of the Agenda
4. Conflict of interest disclosure
5. Review and approval of the Minutes of the last meeting
6. Business arising from the Minutes
7. Protocol review

**7.1. FULL REVIEW**


- 7.1.1. Protocol for Initial Review
- 7.1.2. Protocol for Modification (or Resubmission)
- 7.1.3. Protocol for Clarificatory Interview
- 7.1.4. Application for Protocol Withdrawal
- 7.1.5. Protocol Amendments
- 7.1.6. Continuing Review
- 7.1.7. End of Study Reports
- 7.1.8. SAE/AE Reports
- 7.1.9. Notification/Queries/Complaints
- 7.1.10. Site Visit Reports
- 7.1.11. Protocol Deviation/Violation/Non-Compliance Reports
- 7.1.12. Early Study Termination/Suspension Application

**7.2. REPORT OF SUBMISSIONS FOR EXPEDITED REVIEW**

- 7.2.1. Protocol for Initial Review
- 7.2.2. Protocol for Modification (or Resubmission)
- 7.2.3. Protocol Amendments
- 7.2.4. Continuing Review
- 7.2.5. End of Study Reports
- 7.2.6. SAE/AE Reports

**7.3 REPORT OF PROTOCOL SUBMISSIONS EXEMPTED FROM REVIEW – None**

**7.4 REPORT OF PROTOCOLS REVIEWED FOR SINGLE JOINT ETHICS REVIEW BOARD (SJREB)**


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- 7.4.1 Protocols for Initial Review – None
- 7.4.2 Protocols for Modification (**Resubmission**) – None
- 7.4.3 Protocol Amendment/s - None
- 7.4.4 Continuing Review/ Study Progress Report - None
- 7.4.5 End of Study Reports - None
- 7.4.6 SAE Reports - None
- 7.4.7 Protocol Deviation/Violation/Non-Compliance Reports – None
- 7.4.8 Early Study Termination/Suspension Application – None

- 8. OTHER MATTERS
- 9. ADJOURNMENT

**(Name of IERB Chair)**  
 Chair, Institutional Ethics Review Board



 <p><b>PHILIPPINE HEART CENTER</b></p> <p><b>INSTITUTIONAL ETHICS REVIEW BOARD</b></p>	Document Type	Document Code: POL-E-IRB-009
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**FM-E-IRB-2019-033 Rev. 07**  
Minutes of the Meeting 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

**Minutes of the Meeting Template**


Reference Number: MOM-E-IRB-2019-000

Venue :  
Date :  
Time Started :  
Time Ended :

<b>Attendance:</b>	<b>Absent:</b>

1. **Call to order**
  - 1.1. \_\_\_\_\_, IERB Chair, called the meeting to order at \_\_\_\_\_.
2. **Determination of quorum and presence of non-institutional members**
  - 2.1. \_\_\_\_\_, Board Secretary, declared quorum with the presence of \_ members ( \_ medical (1 of whom is a TRC Representative); \_ non-medical/scientist, \_ non-medical/non-scientist, who are also non-institutional.
  - 2.2. \_\_\_\_\_
3. **Approval of the Agenda**
  - 3.1. The proposed agenda was approved without any corrections as moved by \_\_\_\_\_ and seconded by \_\_\_\_\_.
4. **Conflict of interest disclosure**
5. **Reading and approval of the Minutes of the last meeting**
  - 5.1. Minutes was approved without any correction as moved by \_\_\_\_\_ and seconded by \_\_\_\_\_
6. **Business arising from the Minutes**
7. **Protocol review**
  - 7.1. **FULL REVIEW**
    - 7.1.1. **Protocols for Initial Review**
      - 7.1.1.1

IERB No.		CTRD No.	
Protocol No.		Date of Protocol Submission	
Title			


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Name of PI	
Sponsor	
Type of Review	
Required Expertise	
Designated Reviewer	
Quorum status	Quorum present with
<b>Dr. ___ summarized the technical and ethical issues in the protocol and presented recommendations to the Board</b>	
Assessment of Social Value	•
Assessment of scientific soundness	•
Objectives of the study	
Study Design	•
Inclusion and Exclusion Criteria	•
Withdrawal Criteria	•
Sample size	•
Control Arms	•
Qualification and experience of the PI	•
Conflict of Interest	•
Other Comments	•
<b>Assessment of ethical issues</b>	
Vulnerability Issues	•
Risk/Benefit ratio	•
Involvement of Minors	•
Confidentiality and privacy	•
<b>Ms. ___ summarized the comments for the ICF and presented recommendations to the Board</b>	
Informed Consent process, form and consent	•
Conclusion and recommendations	The board, on consensus, recommended the following modification/s as summarized by the PI and Dr. _____: •
Action taken	

**7.1.2. Protocols for Modification (or Resubmission):**

**7.1.2.1**

IERB No.		CTRD No.	
Protocol No.		Date of Protocol Submission	
Title			
Name of PI			

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Sponsor	
Type of Review	
Designated Reviewer	
Quorum status	Quorum present with
Conclusion and recommendations	The board, on consensus, recommended the approval of the protocol after the PI complied with the following modification/s: •
Action taken	

7.1.3. Protocols for Clarificatory Interview – None

7.1.4. Application for Protocol Withdrawal – None

7.1.5. Protocol Amendment/s:

7.1.5.1


IERB No.		CTRD No.	
Protocol No.		Date of Submission	
Title			
Name of PI			
Sponsor			
Type of Review			
Designated Reviewer			
Quorum status	Quorum present with		
Document Submitted			
Reviewer's Assessment			
Action Taken			

7.1.6. Continuing Review Reports/Progress Report/ Annual Report:

7.1.6.1

IERB No.		CTRD No.	
Protocol No.		Date of Submission	
Title			
Name of PI			
Sponsor			
Type of Review			
Designated Reviewer			
Quorum status	Quorum present with		
Progress Report			
Reviewer's Assessment			



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Sponsor	
Document Submitted	
Reviewer's Assessment	
Action Taken	

**7.1.10 Site Monitoring Visit Reports - None**

**7.1.11 Protocol Deviation/Violation /Non-Compliance Reports:**

**7.1.11.1**

IERB No.		CTRD No.	
Protocol No.		Date of 1st Approval	
Date of Report			
Title			
Name of PI			
Sponsor			
Type of Review			
Primary Reviewer			
Quorum status	Quorum present with		
Deviation Reported			
Comments			
Action Taken			

**7.1.12 Early Study Termination/Suspension Applications:**

**7.1.12.1**

IERB No.		CTRD No	
Protocol No..		Date of Report	
Title			
Name of PI			
Sponsor			
Designated Reviewer			
Quorum status	Quorum present with		
Report	•		
Action taken			

**7.2. REPORT OF PROTOCOL SUBMISSIONS FOR EXPEDITED REVIEW AND FULL BOARD PROTOCOLS WITH MODIFICATION EXPEDITED AT THE LEVEL OF THE CHAIR**

**7.2.1 Protocols for Initial Review -None**


**7.2.2 Protocols for Modification-None**

**7.2.3 Protocol Amendments- None**

**7.2.4 Continuing Review/ Study Progress Report–None**

**7.2.5 End of Study Reports–None**

**7.2.6 Protocol Deviation/Violation/Non-Compliance Reports –None**

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- 7.2.7 Early Study Termination/Suspension Application-None
- 7.3 REPORT OF PROTOCOL SUBMISSIONS EXEMPTED FROM REVIEW – None
- 7.4 REPORT OF PROTOCOLS REVIEWED FOR SINGLE JOINT ETHICS REVIEW BOARD (SJREB)
  - 7.4.1 Protocols for Initial Review – None
  - 7.4.2 Protocols for Modification (Resubmission) – None
  - 7.4.3 Protocol Amendment/s - None
  - 7.4.4 Continuing Review/ Study Progress Report - None
  - 7.4.5 End of Study Reports - None
  - 7.4.6 SAE Reports - None
  - 7.4.7 Protocol Deviation/Violation/Non-Compliance Reports – None
  - 7.4.8 Early Study Termination/Suspension Application – None


**8 Other Matters**

**9 Next Meeting-**

**10 Adjournment-**

Prepared by:  
(Signature Above and Full Name)  
Board Secretary

Noted by:  
(Signature Above and Full Name)  
Chair, Institutional Ethics Review Board

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**FM-E-IRB-2019-047 Rev. 02  
Research Concern Notice Template**



**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 Concern Notice**

<b>INSTITUTIONAL ETHICS REVIEW BOARD</b>
 Chair
 Members
  Contact Person: <hr/> Philippine Heart Center 8/F Medical Arts Building East Avenue, Quezon City Tel. no. 9252401 loc.3899 Email Add: irbphc@gmail.com

Date:

INVESTIGATOR'S NAME AND ADDRESS:

IERB No:

Protocol No.:

TITLE:

Dear Dr. \_\_\_\_\_,

This is with regards to the submitted letter dated \_\_\_\_\_ regarding \_\_\_\_\_

If you have any questions or require further information, please contact Ms. \_\_\_\_\_ at tel. no.9252401 loc. 3899.

Sincerely yours,

**Chair, IERB**



**PHILIPPINE  
HEART CENTER**

**INSTITUTIONAL  
ETHICS REVIEW  
BOARD**

Document Type

**POLICY/STANDARD OPERATING  
PROCEDURE**

Document Code:

POL-E-IRB-009

Effective Date:

January 2024

Document Title

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**FM-E-IRB-2019-062 Rev. 04  
Protocol For Archive 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

**Protocols For Archive Form**

Date of Archive	IERB No.	Protocol No. / CTRD No.	Title	Retention Period





