

POLICY/STANDARD OPERATING PROCEDURE

Document Title

Document Type

APPENDIX D DOCUMENTATION AND ARCHIVING

Document	Code:

POL-E-IRB-009

Effective Date:

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

	Reviewed by:	MARIA TERESA B. ABOLA, MD Deputy Executive Director for Education	Approved by:	JOEL M. ABANILLA, MD Executive Director
_		Training and Research Services		



BOARD

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Appendix D Documentation and Archiving

FM-E-IRB-2019-050 Rev. 07	Meeting Agenda Template
FM-E-IRB-2019-032 Rev. 05	Notice of Meeting
FM-E-IRB-2019-033 Rev. 07	Minutes of the Meeting Template
FM-E-IRB-2019-047 Rev. 02	Research Concern Notice
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
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FM-E-IRB-2019-050 Rev. 07

Meeting Agenda Template



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

Agenda Template

DATE TIME VENUE:

Attendance:	

- 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

FULL REVIEW

7.1.1. Protocols for Initial Review

,,	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

/.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
	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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Name of PI	
Sponsor	
Designated Reviewer	
Report	
Action taken	

7.1.8 SAE Reports: 7.1.8.1

	7.1.8.1		
Accession No.		CTRD No	
Protocol No.		Date of Report	
Title			
Name of PI			
Sponsor			
Designated Reviewer			
Location			
Document Submitted	On Site SAE Report:		
	Date Site was Informed:		
	Subject's Number:	Age: Sex:	
	Nature of Problem:		
	Title of the Report:		
	Event associated with :		
	Related to the Protocol?:		
	Action to be taken :		
Action Taken			

- 7.1.9. Notification/Queries/Compliants None
- 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	
Deviation Reported	
Comments	
Action Taken	



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7.1.12 Early Study Termination/Suspension Applications:

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

Noted by:

- 7.4.8 Early Study Termination None
- 8 Other Matters
- Next Meeting-
- 10 Adjournment-

Prepared by:

(Signature Above and Full Name)

Secretariat

Reviewed:

(Signature Above and Full Name)

(Signature Above and Full Name)

Board Secretary

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)

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Notice of Meeting

то PHC Institutional Ethics Review Board Members:

DATE :

TIMEVENUE:

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

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
 - Continuing Review 7.2.4.
 - 7.2.5. End of Study Reports
 - 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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INSTITUTIONAL ETHICS REVIEW BOARD

7.4.1 Protocols for Initial Review - None

Document Type

Document Title

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



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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 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 St	tarted	:			
Time E	nded	:			
Attenda	ance:		Absent:		
Attend	ancei		Absenti		
1.	Call to	order			
	1.1.	, IERB Chair, called	the meeting to order at		
	Datam	nination of quorum and presence of	non institutional mambars		
2.					
	2.1.		d quorum with the presence of _ members (_ medical		
			ative); _ non-medical/scientist, _ non-medical/non-		
		scientist, who are also non-instituti	onal.		
	2.2.				
3.	Approv	al of the Agenda			
	3.1.	The proposed agenda was approve	d without any corrections as moved byand		
		seconded by			
,					
4.	Conflic	t of interest disclosure			
5.	Readin	g and approval of the Minutes of th	e 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		

IERB MINUTES OF THE MEETING _____



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Name of PI	
Sponsor	
Type of Review	
Required Expertise	
Designated Reviewer	
Quorum status	Quorum present with
Dr summarized the tech the Board	nical and ethical issues in the protocol and presented recommendations to
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	•
Assessment of ethical	
issues	
Vulnerability Issues	•
Risk/Benefit ratio	•
Involvement of Minors	•
Confidentiality and privacy	•
	ments for the ICF and presented recommendations to the Board
Informed Consent process,	•
form and consent	
Conclusion and	The board, on consensus, recommended the following modification/s as
recommendations	summarized by the PI and Dr:
	•
Action taken	

7.1.2. Protocols for Modification (or Resubmission):

7.1.2.1

7111211			
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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Action Taken					
	nd of Study Reports:				
IERB No.	 	CTRD No	,		
Protocol No		Date of	Submission		
Title					
Name of PI					
Sponsor					
Designated Reviewer					
Quorum status	Quorum present with				
Report	Quality present man				
Action taken					
7	AE Reports: .1.8.1				
IERB No.			CTRD No.	↓	
Protocol No.			Date of Report		
Title					
Name of PI					
Sponsor					
Designated Reviewer					
Quorum status	Quorum present with				
Location					
Document Submitted	On Site SAE Report:				
	Date Site was Informed:				
	Subject's Number:		Age: Se	2X:	
	Nature of Problem:				
	Title of the Report:				
	Event associated with :				
	Related to the Protocol?:				
Action Taken	Action to be taken :				
Action Taken					
	Notification/Queries/Com	plaints:			
Accession No.			CTRD No.		
Protocol No.			Date of Submission	n	
Title					
Name of PI					



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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:

	.1.11.1		
IERB No.	ст	RD No.	
Protocol No.	Da	te 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:

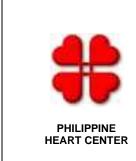
7.1.12.1

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

ERB MINUTES OF THE MEETING		



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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



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

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



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

FM-E-IRB-2019-047 Rev. 02



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Protocols For Archive Form

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

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Log of Requested IERB's Document Form

#	Document/s requested	# of Copies	Name of Recipient	Signature of Recipient	Secretary Initials	Date
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+		+				
-						
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+		+ +				
4		1				

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Log of Request for Copies of Original Documents Form

Title of Name of # of Date Reason for Signature of Secretariat Date Documents Recipient copies Request Recipient Initials Out In

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