



**INSTITUTIONAL ETHICS AND REVIEW BOARD**  
**12<sup>th</sup> Floor, Our Mother of Perpetual Succour Medical Specialty Center**  
**Perpetual Succour Hospital**  
**Gorordo Avenue, Cebu City**  
**Tel No/Fax No: +63-32-342-0853**

# Minutes of the Meeting

**PSH-IERB**  
**Form 5B**

**Minutes of the PSH-Institutional Ethics and Review Board**  
**Nth REGULAR/SPECIAL MEETING**

**Date and Time of Meeting**

**Venue of Meeting**

**Members Present:**

**Members Absent:**

**Minutes:**

**1. CALL TO ORDER**

Panel Chair, called this regular meeting to order at \_\_\_\_

**2. DETERMINATION OF QUORUM**

A quorum was declared with the presence of \_\_ members, inclusive of the presence of \_\_ non-institutional and \_\_ lay members and as and as confirmed by the member secretary.

**3. READING AND APPROVAL OF THE AGENDA OF THE PRESENT MEETING**

**4. DISCLOSURE OF CONFLICT OF INTEREST**

**The Chairman**, called for disclosure of Conflict of Interest (COI) in the Study Protocol scheduled for deliberation in the meeting. Some members inhibited from participating in the panel reviews during the meeting (**PSH-IERB Code, Protocol Number, IERB Member**)

**5. READING AND APPROVAL OF THE MINUTES OF THE LAST MEETING**

The Chairman presided over the discussion of the minutes of the meeting held last \_\_\_\_\_. The minutes were corrected during the discussion and approved as amended upon the motion of \_\_\_\_\_ and duly seconded by \_\_\_\_\_.

**6. BUSINESS ARISING FROM THE MINUTES OF THE LAST MEETING.**

**7. PROTOCOL REVIEW**

**7.1 FULL BOARD REVIEW**

**7.1.1 Protocols for Initial Review**

PSH-IERB CODE	Protocol Number
Principal investigator	Conflict of interest
Lead protocol Reviewer	Lead ICF Reviewer
Date of Submission	Sponsor/ CRO
Protocol Title	
Assessment of Scientific Soundness:	
1. Objectives/Expected output	
2. Literature review	
3. Research design	
4. Use of placebo	
5. Sampling design, sample size	
6. Inclusion criteria, exclusion criteria, withdrawal criteria	
7. Specimen collection and processing	
8. Statistical and data analysis plan	

9. PI qualifications	
10. Suitability and choice of site	
11. Validation of research instruments among Filipino participants	
Assessment of Ethical Issues:	
1. Conflict of Interest:	
2. Privacy and confidentiality including data protection plan	
3. Vulnerability and protection	
4. Risks	
5. Benefits	
6. Informed consent process and recruitment:	
7. Informed Consent Form (ICF) (including translation)	
8. Insurance and Material Transfer Agreement (MTA)	
9. Documentation of collaborative study TOR	
Comments	
DECISION	
VOTING: YES	NO: ABSTAINED:

### 7.1.2 Continuing Review Applications:

#### 7.1.2.1 Progress Reports

PSH-IERB CODE	Protocol Number
Principal investigator	Conflict of interest
Lead protocol Reviewer	Lead ICF Reviewer
Date of Submission	Sponsor/ CRO
Date of Initial Approval	Date of Last Approval
Protocol Title	
Type of Report: Progress Report	
<ul style="list-style-type: none"> <li>• Number of Study Arms:</li> <li>• Target PSH sample size:</li> <li>• Total # of screened patients:</li> <li>• Total # of screen failures:</li> <li>• Total # of patients successfully enrolled:</li> <li>• # of Participants currently enrolled in the study:</li> <li>• # of Participants withdrawn from study:</li> <li>• Summary of Amendments:</li> <li>• Summary of Reported SAE(On-site):</li> <li>• Summary of Reported SUSARs:</li> <li>• Summary of Deviations:</li> <li>• Summary of Findings:</li> </ul>	
DECISION	
VOTING: YES	NO: ABSTAINED:

#### 7.1.3 SAE Reports:

PSH-IERB CODE	Protocol Number
Principal investigator	Conflict of interest
Lead protocol Reviewer	Lead ICF Reviewer
Sponsor/ CRO	
Protocol Title	
Date of Submission	SAE Type: Initial /Follow-up #
Date of SAE	Date of Site Awareness
SAE Term	
<input type="checkbox"/> Related <input type="checkbox"/> Not Related	<input type="checkbox"/> Expected <input type="checkbox"/> Unexpected
Action Done by Principal Investigator	Outcome
DECISION	

VOTING: YES	NO:	ABSTAINED:
-------------	-----	------------

**7.1.4 Protocol Deviation/Non-compliance/Violation Reports**

PSH-IERB CODE	Protocol Number
Principal investigator	Conflict of interest
Lead protocol Reviewer	Lead ICF Reviewer
Sponsor/ CRO	
Protocol Title	
Date of Deviation	
Type of Deviation	
<input type="checkbox"/> Minor	<input type="checkbox"/> Deviation by PI
<input type="checkbox"/> Major	<input type="checkbox"/> Deviation by Subject
Description of Deviation	
Corrective Action By Principal Investigator	
Sponsor's Assessment of Severity	
DECISION	
VOTING: YES	NO: ABSTAINED:

**7.1.5 Site Visit Reports**

PSH-IERB CODE	Protocol Number
Principal investigator	Conflict of interest
Lead protocol Reviewer	Lead ICF Reviewer
Sponsor/ CRO	
Protocol Title	
Date of Site Visit	IERB Member who Performed the Site Visit
Notes During Site Visit	
Recommendation by IERB Member who Performed the Site Visit	
DECISION	
VOTING: YES	NO: ABSTAINED:

**7.1 REPORT OF PROTOCOL SUBMISSIONS FOR EXPEDITED REVIEW AND FULL BOARD PROTOCOLS WITH MODIFICATIONS EXPEDITED AT THE LEVEL OF THE CHAIR/LEAD REVIEWER**

**7.2.1 Protocol for Initial Review**

PSH-IERB CODE	Protocol Number
Principal investigator	Sponsor
Lead protocol Reviewer	Lead ICF Reviewer
Date of Submission	
Protocol Title	
Decision	

**7.2.2 Resubmissions**

PSH-IERB CODE:	Protocol Number
Principal Investigator	Conflict of Interest
Lead Reviewer	Lead ICF Reviewer
Sponsor	
Protocol Title	
Document submitted	
RECOMMENDATIONS	ACTION DONE BY PI
DECISION:	

### 7.2.3 Final Reports

PSH-IERB CODE	Protocol Number
Principal Investigator	Conflict of Interest
Lead Reviewer	Lead ICF Reviewer
Date of Submission	Sponsor /CRO
Protocol Title	
DECISION:	

### 7.2.4 Protocol Amendments:

PSH-IERB CODE	Protocol Number
Principal investigator	Sponsor
Lead Reviewer	Lead ICF Reviewer
Protocol Title	
Date of Initial Approval	
Documents to be Amended:	
DECISION	

### 7.2.5 SUSAR Reports:

PSH-IERB CODE	Protocol Number
Principal investigator	Sponsor
Protocol Title	
SUSAR Report Date	
DECISION	

### 7.26 Notifications:

PSH-IERB CODE	Protocol Number
Principal investigator	Sponsor
Protocol Title	
Document Submitted	
DECISION	

## 8. Other Matters

## 9. Adjournment

Prepared By:  
Administrative Support Staff

Corrected By:  
Member-Secretary

Approved By:  
Chairperson