



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

Agenda of the Meeting

PSH-IERB
Form 5A

Date

NOTICE OF MEETING

To: IERB Members

Date of Meeting:

Time of Meeting:

Venue of Meeting:

AGENDA:

1. Call to order
2. Determination of quorum and presence of non-institutional members
3. Reading and Approval of the Agenda for the Meeting
4. Disclosure of Conflict of Interest (**PSH-IERB Code, Protocol Number, IERB Member**)
5. Reading and approval of the Minutes of the last meeting
6. Business arising from the Minutes of the last meeting
7. Protocol review

7.1. FULL REVIEW

7.1.1. Protocols for Initial Review

PSH-IERB CODE	PROTOCOL NO
PRINCIPAL INVESTIGATOR	CONFLICT OF INTEREST
LEAD REVIEWER	LEAD ICF REVIEWER
DATE OF SUBMISSION	SPONSOR/CRO
PROTOCOL TITLE	
ASSESSMENT OF SCIENTIFIC SOUNDNESS	
ASSESSMENT OF ETHICAL ISSUES	

7.1.2 Continuing Review Applications:

7.1.2.1 Progress Reports

PSH-IERB CODE	PROTOCOL NUMBER
PRINCIPAL INVESTIGATOR	CONFLICT OF INTEREST
LEAD 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"> • Number of Study Arms: • Target PSH sample size: • Total # of screened patients: 	

- Total # of screen failures:
- Total # of patients successfully enrolled:
- # of Participants currently enrolled in the study:
- # of Participants withdrawn from study:
- Summary of Amendments:
- Summary of Reported SAE(On-site):
- Summary of Reported SUSARs:
- Summary of Deviations:

7.1.3 SAE Reports:

PSH-IERB CODE	PROTOCOL NUMBER
PRINCIPAL INVESTIGATOR	CONFLICT OF INTEREST
LEAD 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"/> Expected
<input type="checkbox"/> Not Related	<input type="checkbox"/> Unexpected
Action Done by Principal Investigator	Outcome

7.1.4 Protocol Deviation/Non-compliance/Violation Reports

PSH-IERB CODE	PROTOCOL NUMBER
PRINCIPAL INVESTIGATOR	CONFLICT OF INTEREST
LEAD REVIEWER	LEAD ICF REVIEWER
SPONSOR/CRO	
PROTOCOL TITLE	
DATE OF DEVIATION	
Type of Deviation	<input type="checkbox"/> Deviation by PI
<input type="checkbox"/> Minor	<input type="checkbox"/> Deviation by Subject
<input type="checkbox"/> Major	
Description of Deviation	
Corrective Action By Principal Investigator	
Sponsor's Assessment of Severity	

7.1.5 Site Visit Reports

PSH-IERB CODE	PROTOCOL NUMBER
PRINCIPAL INVESTIGATOR	CONFLICT OF INTEREST
LEAD 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	

7.2 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 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 Protocol 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 Protocol 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:	

7.2.6 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