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

# Appointment Letter	**PSH-IERB Form 1A**

DATE

Dear _____

Greetings of Peace!

You are hereby appointed as (Chair/co-chair/secretary/board member/administrative support staff/independent consultant/alternate member) of the PERPETUAL SUCCOUR HOSPITAL INSTITUTIONAL ETHICS AND REVIEW BOARD (PSH-IERB) for a term of 3 years starting _____ until _____.

As (Chair/co-chair/secretary/board member/administrative support staff/independent consultant/alternate member), you have the following responsibilities:

_____
_____
_____
_____
_____

PSH is confident that you will faithfully, dynamically, and zealously work for the good and continuous development of the Board.

We look forward to a mutually beneficial and meaningful relationship with you. Please indicate your acceptance of this appointment by signing at the space provided below.
May God bless you and your endeavors!

Very truly yours,

_____
SR. ZETA CARIDAD R. RIVERO, SPC
Chief Executive Officer

Accepted:

_____ Date: _____
Signature over printed name

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# Curriculum Vitae	**PSH-IERB Form 1B**

BASIC INFORMATION

Name:	Age:	Contact No:
Email Address:		
IERB Position:		
Date of First Appointment:		

EDUCATIONAL BACKGROUND

Bachelor's Degree:
Advance Education:
Research and Ethics Trainings:
Other Qualifications/Specialization:

WORK EXPERIENCE

Present Work Experience	
Previous Work Experience	
Research Related Experience:	
Publications: if applicable	

Name and Signature	Date:

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# Confidentiality Agreement and Conflict of Interest Disclosure	**PSH-IERB Form 1C**

In the course of my activities as a **member** of the Perpetual Succour Hospital – Institutional Ethics and Review Board (PSH-IERB), I will be provided with confidential information and documentation. I agree to take reasonable measures to protect the confidential information, not to disclose the confidential information to any person; not to use the confidential information for any purpose outside the board's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all confidential information (including any minutes or notes I have made as part of my Board duties) to the Chairperson upon termination of my functions as a member.

Whenever I have a conflict of interest, I shall immediately inform the Chair not to count me toward a quorum for voting. A conflict of interest is a situation in which personal and/or financial considerations have the potential to influence or compromise professional judgment in clinical service, research, consultation, instruction, administration, or any other professional activity.

I have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____
Signature over printed name
Date:_____

Noted:

_____
Dr. Ellie May Villegas
CHAIRPERSON, PSH - IERB
Date: _____

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# EC Review Fee	**PSH-IERB Form 1E**

Date

Name
Principal Investigator
Perpetual Succour Hospital
Cebu City

PSH-IERB CODE:
PROTOCOL NUMBER:
PROTOCOL TITLE:

RE: EC REVIEW FEE

Dear,

Peace be with you!

As required by the Perpetual Succour Hospital-Institutional Ethics and Review Board, please remit the amount of One Hundred Thousand Pesos (Php 100,000.00) **net of tax** as onetime payment for the review fee of the abovementioned clinical trial.

Please make your payment in cheque payable to **PERPETUAL SUCCOUR HOSPITAL – INSTITUTIONAL ETHICS AND REVIEW BOARD.**

Thank you very much for your kind attention in this regard.

Sincerely,

_____
PSH-IERB Chairperson

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Application for Protocol Review

PSH-IERB Form 2A

PSH-IERB Code:	Date Submitted
Protocol No: Protocol Title:	

Principal Investigator:	Sub Investigator:	Study Coordinator:

Email Address:	Contact No:
Name of Sponsor/CRO:	
Sponsor's Local Address	
Insurance Policy:	Previous Review and Approvals:

PROTOCOL INFORMATION

Target Number of Participants (All Sites):	Target Number of Participants (PSH Site):
Duration of Study:	

STUDY TYPE: (Mark "✓ " whichever apply to the study)

☐ Survey ☐ Social ☐ Medical ☐ Community based ☐ Individual based
☐ Screening ☐ Observational ☐ Epidemiology ☐ Intervention study
☐ Clinical Trial: ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV
☐ Genetic Study ☐ Retrospective ☐ Prospective
☐ Others_____

STUDY POPULATION:
☐ Healthy ☐ Patient ☐ Vulnerable groups, pls specify _____

CHARACTERISTICS of PARTICIPANTS PARTICIPATED :

Age Range:	☐ 0 -17 yrs	☐ 18 - 44 yrs	☐ 45 - 65 yrs	☐ ≥ 66 yrs
Pediatric	☐ None	☐ < 1 yr	☐ 1-3 yrs	☐ 4 -14 yrs
Impaired	☐ None	☐ Physically	☐ Cognitively	☐ Mentally

BENEFITS FROM PARTICIPATING IN THE STUDY: Pls. specify

REQUESTED EXCLUSION OF PARTICIPANTS:
☐ None ☐ Male ☐ Female ☐ Children ☐ Other (specify)

Submitted by: SIGNATURE OVER PRINTED NAME	DATE:

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Initial Submission Checklist

PSH-IERB Form 2B

PSH-IERB Code:		Date Submitted:
Protocol Number: Protocol Title:		
Sponsor:		Sponsor's Local Address:
Principal Investigator:	Sub-Investigator:	Study Coordinator:
Email address:		Contact No.:

No. of Copies required	Document to be Submitted:	No. of Copies submitted
2	a. Letter of Intent addressed to the Chairperson with itemized list of documents submitted in protocol package	
1	b. Proof of payment of review fee	
2	c. Application for Protocol Review Form ***(Form 2A)***	
2	d. Initial Submission Checklist ***(Form 2B)***	
***For expedited review*:** **2 copies** ***For full board review*:** **12 copies** **or** **3 hard copies provided soft copy is available**	e. Protocol Package including the ff: i. Clinical Study Protocol	
	ii. Informed Consent Form in at least 2 languages (English and Cebuano)	
	iii. Investigator's Brochure	
	f. Curriculum Vitae of the Principal Investigator	
	g. GCP Training Certificate of PI	
	h. Conflict of Interest Statement Form of the PI ***(Form 2C)***	
	i. Contracts and approval of relevant offices (Memorandum of Agreement if study is collaborative in nature; Materials Transfer Agreement, Intellectual Property Approval, Investigational Device Exemption, when relevant)	
	j. Description of the arrangements for indemnity (WHO 5.3.13), and the arrangements for insurance; if applicable.	
2	k. Previous decisions by other regulatory authorities on the proposed study, if applicable, such as: i. Results of technical/ethical review from other Ethics committees	
	ii. Approval Letter from Department Research Committee for Residents'/Fellows' studies	
2	l. Authorization from Chief Executive Officer if accessing medical records	

Submitted by:_____ Date: _____

Signature over Printed Name

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Financial Disclosure and Conflict of Interest Statement Form

PSH-IERB Form 2C

Principal Investigator Name:		
This financial Disclosure form is submitted for : at IERB request	☐ Principal Investigator ☐ Sub-investigator (please print)_____ ☐ Other ** (please print and include role)_____	
Information collected at study time-point:	☐ Initial disclosure ☐ Updated Disclosure [Enter date change begins(dd/mm/yy] _____	**Update** if legal name or financial interests and arrangements changes from the information provided during the clinical study or within 1 year post clinical study close/end of study participation. (*4)

Please indicate by marking YES or NO below if any of the financial interests or arrangements applies to you, your spouse, dependent children, or any combination	
1. Are you, your spouse or any of your dependent children an employee of the study sponsor(s)/Co-Development Partner(s)	☐ Yes ☐ No
2. Have you, your spouse or any of your dependent children entered into a financial arrangment with the study sponsor(s)/ Co-Development Partner(s) whereby the value of the compensation could be influenced by the outcome of the trial, such as a bonus, royalty or other financial incentive (i.e ., compensation that could be higher for a favourable outcome than for and unfavourable outcome)? This could be compensation that is explicitly greater for a favourable result, compensation in the form of an equity interest in Study Sponsor(s) or compensation tied to sales of the product , such as a royalty interest.	☐ Yes ☐ No
3. Do you, your spouse or any of your dependent children have a proprietary interest in the tested product, including, but not limited to , a patient, trademark , copyright or licensing agreement? Proprietary interest would include, but not limited to, a patient, trademark, copyright or licensing agreement.	☐ Yes ☐ No
4. Do you, your spouse , any of your dependent children , or any combination hold any significant equity interest in Study Sponsor(s) / Co-Development Partner(s) (Stock, Stock options, or other financial	

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interest that exceeds $50, 000.00 U.S dollars? Equity interest includes any options, puts, calls, straddles and other priviliges in addition to an equity ownership position in Study sponsor(s) . This does not include ownership interest, stock options, or other financial interest over which you have no direct control or input as to the quantities or amounts, e.g., a 401k , IRA, Mutual Fund .	☐ Yes ☐ No
5. Have you, your spouse, any of your dependent children or any combination received significant payment of other sorts(SPOOS) having total value in excess of $25,000.00 from study sponsor(s) / co-Development partner(s) other than payments for conducting on this clinical study or other clinical studies . Example of such significant payment, include, but are not limited to , grants or funding for ongoing research , compensation in the form of equipment, retains for ongoing consultation or honoraria that are (A) paid directly to me or the institution with which I am affiliated . and (B) paid in support of my activities (i. e., payment paid directly or indirectly to me by study sponsor(s)?	☐ Yes ☐ No
For each YES response above , please provide detailed information disclosing the nature of the financial arrangement , including total value amounts. (If additional space is needed. Please attach to this document. Indicate the number of attached pages ____)	

By signing this form:

1. I confirm/declare that the information provided on this form is, to the best of my knowledge and belief , true , complete and correct.
2. I also confirm that to the extent I have provided any information about other individuals, I have appropriate permission to provide financial information their behalf to the sponsor(s) listed above.
3. I consent to this disclosure , collection and further use of the relevant information outside of my country /region to employees, agents and contractors of study sponsor(s), Its representatives , and business partners, for the submission to the regulatory authorities. I further understand and agree that such recipients may be based in countries whose laws do not provide equivalent protection for personal data to those in the country in which I reside .
4. I agree to promptly update the above information if my legal name or financial interests and arrangements, or those of my spouse and dependent children, changes from the information provided above during the clinical study or within 1 year post clinical study close/end of study participation.

Signature:		Date: (dd/mm/yyyy)	

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Assessment Of Scientific Soundness

PSH-IERB Form 3A

PSH-IERB CODE	
PROTOCOL NUMBER	
DATE OF PROTOCOL SUBMITTED	
PROTOCOL TITLE	
PRINCIPAL INVESTIGATOR	
LEAD PROTOCOL REVIEWER	
LEAD ICF REVIEWER	
SPONSOR/ CRO	
CONFLICT OF INTEREST	

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**

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Assessment Of Ethical Issues and Informed Consent Form

PSH-IERB Form 3B

PSH-IERB CODE	
PROTOCOL NUMBER	
DATE OF PROTOCOL SUBMITTED	
PROTOCOL TITLE	
PRINCIPAL INVESTIGATOR	
LEAD PROTOCOL REVIEWER	
LEAD ICF REVIEWER	
SPONSOR/ CRO	
CONFLICT OF INTEREST	

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**

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# Checklist for the Assessment of Protocol Submission	**PSH-IERB Form 3C**

DATE OF REVIEW**:**	
PSH-IERB CODE:	
PROTOCOL NO.: PROTOCOL TITLE:	
PRINCIPAL INVESTIGATOR:	
ADDRESS:	SPONSOR / PROPONENT:
REVIEWER: **SIGNATURE:** **DATE:**	

What are the probable risks entailed in the proposal?

_____

- Are they minimal?

  _____
- More than minimal?

  _____
- High Risk

  _____

	YES	**NO**	**COMMENTS**
1. Does the protocol adequately address the risk/ benefits balance?			
2. Does the protocol present adequate informational background as to results of previous studies prior to human experience ability?			
3. Are the inclusion, exclusion and withdrawal criteria well defined?			
4. If placebo is used, is the use appropriate?			

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5. Does the protocol safeguard that consent is voluntary?			
6. Does the protocol involve vulnerable subjects? If yes, LAR must be present			
7. Does the consent include the following elements: **a. Purpose of the research?**			
b. Expected duration of participation?			
c. Description of procedure to be followed?			
d. Random management to the trial treatment?			
e. Benefits to the participants?			
f. Alternative procedure or summary of treatment?			
g. Extent of Confidentiality of records?			
h. Explanation of compensation and/or medical treatment in case of injury?			
i. Whom to contact for questions and/or for assistance in research related injury?			
j. Explanation that refusal to participate or discontinuance of participation at any time will involve no penalty or loss of benefits to which the subject is entitled.			

RECOMMENDATIONS:

- ❑ Approved
- ❑ Minor modifications
- ❑ Major Modifications
- ❑ Disapproved

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Progress Report Form

PSH-IERB Form 4A

PSH-IERB Code:		Date Submitted:
Protocol Number/Study Title:		
Sponsor:		Sponsor's Local Address:
Principal Investigator:	Sub-Investigator:	Study Coordinator:
Email address:		Contact No.:
Date of Initial Approval:		Date of Last Approval:

Please fill out the needed information below:

Number of Study Arms:
Target PSH Sample Size:
Total # of screened patients: Total # of screen failures: Total # of patients successfully enrolled:
# of patients who have withdrawn from the study: (state reason for withdrawal)
# of patients currently enrolled in the study:
Summary of Amendments*
Summary of SAE's reported*
Summary of reported SUSARs*
Summary of Protocol Deviations*
Submitted by:

For IERB Members: **Please indicate decision and state the reason and action required to continue the study.**	❑ Approved for 1 year ❑ Modification required: _____ _____ _____ Reviewer's signature over printed name Date reviewed:_____	❑ Approved for 1 year ❑ Modification required: _____ _____ _____ Reviewer's signature over printed name Date reviewed: _____

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Review of Amendments

PSH-IERB Form 4B

PSH-IERB Code:		Date Submitted:
Protocol Number/Study Title:		
Sponsor:		Sponsor's Local Address:
Principal Investigator:	Sub-Investigator:	Study Coordinator:
Email address:		Contact No.:

Date of Initial Approval:
Documents to be Amended: please specify _____ *(Highlight the changes made)*
Note: (Attach two copies of the amended documents together with the Letter of Intent. Include summary of the revisions made on the protocol and the list of documents submitted)

Submitted by: *SIGNATURE OVER PRINTED NAME*	DATE:

For IERB Members: **Please indicate decision and state the reason and action required to continue the study.**	❑ Approved ❑ Modification required: _____ _____ _____ Reviewer's signature over printed name Date reviewed:_____	❑ Approved ❑ Modification required: _____ _____ _____ Reviewer's signature over printed name Date reviewed: _____

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Certificate of Approval

PSH-IERB Form 4C

Date

Principal Investigator's Name
Site Address

PSH-IERB CODE:
CLINICAL PROTOCOL NUMBER:
SPONSOR:
PROTOCOL TITLE:

Type of Review: ☐ **Full Board** ☐ **Expedited**

This is to inform you that your study has been reviewed and APPROVED by PSH-IERB for 1 year from (date approved) until (date of expiry).

LIST OF DOCUMENTS:

Investigator's Responsibility after Approval:

A. Two copies of the following documents should be submitted to Ethics committee within the study period with attached corresponding IERB forms.
   1. Amendments for IERB Approval (Form 4B).
   2. SAEs within 7days after the knowledge of the event (Form 4D).
   3. Bi-annual off site Safety Reports.
   4. Study Protocol Deviations (Form 4H).
   5. Yearly Status Update Report to be submitted 1 month prior to study approval expiration date (Form 4A). Due Date _____.
   6. Final Report (Form4L).

B. Comply with all relevant international and national guidelines and regulations.

C. Abide by the principles of good clinical practice and ethical research.

(Note: All subsequent communications will have to include the **PSH-IERB code** aside from the sponsor assigned protocol no.)

INSTITUTIONAL REVIEW BOARD MEMBERS WHO REVIEWED THE PROTOCOL:

Member	**Position on EC**	**Qualification**	**Attendance**

The Perpetual Succour Hospital – Institutional Ethics and Review Board is organized and operates according to ICH-GCP and applicable laws and regulations.

_____
PSH-IERB Chairperson

INSTITUTIONAL ETHICS AND REVIEW BOARD
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Serious Adverse Event and SUSAR Report Form

PSH-IERB Form 4D

PSH-IERB Code:		Date Submitted:
Protocol Number/Study Title:		
Sponsor:	Sponsor's Local Address:	
Principal Investigator:	Sub-Investigator:	Study Coordinator:
Email address:		Contact No.:

☐ SAE ☐ SUSAR	☐ On-site ☐ Off-site	☐ Initial ☐ Follow- up #_____ ☐ Final	
Date of SAE		Date of Site Awareness	
SAE Term		☐ Related ☐ Not Related	☐ Expected ☐ Unexpected
Subject's History:			
Treatment:			
Action Done by PI		Outcome	

Submitted by: SIGNATURE OVER PRINTED NAME	DATE

FOR IERB MEMBERS: PLEASE INDICATE DECISION:

❑ May continue study ❑ Request an amendment to the protocol or informed consent form (pls specify) _____ _____ ❑ Request further information (pls specify) _____ _____ ❑ Suspended (state reason)_____ _____ _____ **Reviewer's signature over printed name** **Date reviewed:** _____	❑ May continue study ❑ Request an amendment to the protocol or informed consent form (pls specify) _____ _____ ❑ Request further information (pls specify) _____ _____ ❑ Suspended (state reason)_____ _____ _____ **Reviewer's signature over printed name** **Date reviewed:** _____

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# Review of Serious Adverse Events (SAEs)	**PSH-IERB Form 4E**

PSH-IERB CODE:
CLINICAL PROTOCOL NUMBER:
PROTOCOL TITLE:
PRINCIAL INVESTIGATOR:

We have received and reviewed the Serious Adverse Events (SAEs) for the above named protocol.

Date of SAE			
Date of Site Awareness			
SAE Term		☐ Related ☐ Not Related	☐ Expected ☐ Not Expected
Action Done by Principal Investigator			
Treatment			
Outcome			

After thorough review of the document (study continuation is granted/amendment is needed to the protocol or the consent form/ further information is needed/study is suspended for further investigation) state reason.

_____
PSH-IERB Chairperson
Date:

_____
PSH-IERB Member assigned as
SAE/SUSAR Reviewer for the protocol
Date:

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# Review of Suspected Unexpected Serious Adverse Reports (SUSARs)	**PSH-IERB Form 4F**

PSH-IERB CODE:
CLINICAL PROTOCOL NUMBER:
PROTOCOL TITLE:
PRINCIAL INVESTIGATOR:

We have received and reviewed the Suspected Unexpected Serious Adverse Reports (SUSARs) dated _____ for the above named protocol.

SUSAR:

After thorough review of the document (study continuation is granted/amendment is needed to the protocol or the consent form/ further information is needed/study is suspended for further investigation) state reason.

_____
PSH-IERB Chairperson
Date:

_____
PSH-IERB Member assigned as
SAE/SUSAR Reviewer for the protocol
Date:

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Protocol Deviation Report Form

PSH-IERB Form 4H

PSH-IERB Code:		Date Submitted:
Protocol Number/Study Title:		
Sponsor:	Sponsor's Local Address:	
Principal Investigator:	Sub-Investigator:	Study Coordinator:
Email address:		Contact No.:

Date of Deviation	☐ Major ☐ Minor	☐ Deviation by PI ☐ Deviation by Subject
Description of Deviation:		
Corrective Action by Principal Investigator:		
Sponsors Assessment of Severity:		

Submitted by: SIGNATURE OVER PRINTED NAME	DATE

FOR IERB MEMBERS: PLEASE INDICATE DECISION:

❑ No Further action, may continue study ❑ Action needed: ❑ Suspend enrolment ❑ Recommend training; specify training needed_____ _____ ❑ Site visit ❑ Ask for more information_____ _____ _____ **Reviewer's signature over printed name** **Date reviewed:** _____	❑ No Further action, may continue study ❑ Action needed: ❑ Suspend enrolment ❑ Recommend training; specify training needed_____ _____ ❑ Site visit ❑ Ask for more information_____ _____ _____ **Reviewer's signature over printed name** **Date reviewed:** _____

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Protocol Deviation Response Letter to PI

PSH-IERB Form 4I

PSH-IERB CODE:
CLINICAL PROTOCOL NUMBER:
PROTOCOL TITLE:
PRINCIAL INVESTIGATOR:

We have received and reviewed the Protocol Deviation dated _____

for the above named protocol.

Date of Deviation	☐ Major ☐ Minor	☐ Deviation by PI ☐ Deviation by Subject
Description of Deviation:		
Corrective Action by Principal Investigator:		
Sponsors Assessment of Severity:		

After thorough review of the document (study continuation is granted/enrolment for study is suspended/training on ___ is recommended/study is scheduled for site visit on ___/ further action/information is needed: specify).

_____
PSH-IERB Chairperson
Date:

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# Action Letter to PI	**PSH-IERB Form 4J**

Date

Principal Investigator's Name
Site Address

PSH-IERB CODE:
CLINICAL PROTOCOL NUMBER:
SPONSOR:
PROTOCOL TITLE:

This is to inform you that the following documents have been reviewed (with MINOR MODIFICATION REQUIRED (pls specify)/with MAJOR MODIFICATIONS required (pls specify)/ and DISAPPROVED (state reason)) by PSH-IERB.

LIST OF DOCUMENTS:

INSTITUTIONAL REVIEW BOARD MEMBERS WHO REVIEWED THE PROTOCOL:

Name of Member	**Position on EC**	**Qualification**	**Attendance**

The Perpetual Succour Hospital – Institutional Ethics and Review Board is organized and operates according to ICH-GCP and applicable laws and regulations.

_____
PSH-IERB Chairperson

INSTITUTIONAL ETHICS AND REVIEW BOARD
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Early Study Termination Form

PSH-IERB Form 4K

PSH-IERB Code:		Date Submitted:
Protocol Number/Study Title:		
Sponsor:		Sponsor's Local Address:
Principal Investigator:	Sub-Investigator:	Study Coordinator:

Initial Protocol Approval Date:	Termination Date:
Number of Study Arms:	
Target PSH Sample Size:	
Start of Recruitment:	Date of Last Recruitment:
Actual # of patients successfully enrolled:	
Date of Last Progress report:	
Summary of Results:	
Reason for Termination:	
Submitted by:	

For IERB Members: **Please indicate decision and state the reason and action required to continue the study.**	❑ Approved ❑ With pending stipulations: _____ _____ Reviewer's signature over printed name Date reviewed:_____	❑ Approved ❑ With pending stipulations: _____ _____ Reviewer's signature over printed name Date reviewed: _____

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Final Report Form

PSH-IERB Form 4L

PSH-IERB Code:		Date Submitted:
Protocol Number/Study Title:		
Sponsor:	Sponsor's Local Address:	
Principal Investigator:	Sub-Investigator:	Study Coordinator:
Email address:		Contact No.:

Please fill out the needed information below:

Date of Initial Approval: Date of Last Approval:
Number of Study Arms:
Target PSH Sample Size:
Total # of screened patients: Total # of screen failures: Total # of patients successfully enrolled:
# of patients who have withdrawn from the study: (state reason for withdrawal)
# of patients at end of the study:
Summary of Amendments
Summary of SAE's reported
Summary of reported SUSARs
Summary of Protocol Deviations
Summary of Findings:
Submitted by:

For IERB Members: **Please indicate decision and state the reason and action required to continue the study.**	❑ Approved ❑ Modification required: _____ _____ _____ Reviewer's signature over printed name Date reviewed:_____	❑ Approved ❑ Modification required: _____ _____ _____ Reviewer's signature over printed name Date reviewed: _____

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

Resubmission Form

PSH-IERB
Form 4M

PSH-IERB CODE:	PROTOCOL NO.:
PRINCIPAL INVESTIGATOR:	CONFLICT OF INTEREST:
LEAD REVIEWER:	LEAD ICF REVIEWER:
SPONSOR:	
PROTOCOL TITLE:	
DOCUMENT SUBMITTED:	
RECOMMENDATIONS:	**ACTION DONE BY PI**

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# 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 • 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	
❑ Related ❑ Not Related	❑ Expected ❑ 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 ❑ Minor ❑ Major	 ❑ Deviation by PI ❑ Deviation by Subject
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:	Corrected By:	Approved By:
Administrative Support Staff	Member-Secretary	Chairperson

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# 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 • 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: • Summary of Findings:	
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	
❑ Related ❑ Not Related	❑ Expected ❑ 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 ❑ Minor ❑ Major	 ❑ Deviation by PI ❑ 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:	Corrected By:	Approved By:
Administrative Support Staff	Member-Secretary	Chairperson

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Site Visit Checklist Form

PSH-IERB Form 7A

PSH-IERB Code:	Date of the Visit:
Protocol Number/Study Title:	
Principal Investigator:	Phone:
Institute:	Address:
Sponsor:	Address:
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:
Completed by: Name and Signature of IERB Member	Date:

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Queries or Complaints Form

PSH-IERB Form 8A

Date Received:	
Received by:	
Request from:	❑ Telephone No…….. ❑ Fax No……. ❑ Mailed letter / Date…… ……. ❑ E-mail / Date…… ❑ Walk-in / Date / Time……. ❑ Other, specify …….
Participant's Name:	
Contact Address: Phone:	
Title of the Study	
Starting date of participation:	
Nature of queries or complaints:	

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# Request for Review/ Revision of SOP	**PSH-IERB Form 9A**

TO :

FROM : _____ Signature:_____

SUBJECT: Request for review / revision of SOP

DATE : _____

Please consider for review and possible revision the following provision/s of our Standard Operating Procedure (SOP):

Enumerate the provision/s recommended for review and/or revision:

1)

Ground / Reason for review:

2)

Ground / Reason for review:

Received copy:_____
(Signature over printed name)

Date & Time of Receipt: _____