Supersedes:	Previous SOPs
Prepared by:	SOP Team 2019
Reviewed by:	Dr. Manuel Emerson Donaldo
Reviewed Date:	December 14, 2018
Approved by:	Ma. Nona A. Velez, RN, MN
Date Approved	December 20, 2018
Date Effective:	January 2, 2019

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1. Policy Statement

The IRB shall require the submission of an application for an amendment to an approved protocol and/or other related documents (e.g. Informed Consent Form) prior to the implementation of these changes.

2. Objective of the Activity

This activity provides instructions for the application for an amendment required by the CIM-CVGH IRB to be submitted by the PI to monitor the safety of participants enrolled in a study.

3. Scope

This SOP begins with the reminder to the PI to submit progress or final report, and ends with the communication of IRB decision to the PI.

4. Responsibility

It is the responsibility of the CIM-CVGH IRB Secretariat to manage protocol amendment package submitted by the PI. It is the responsibility of preferably the original primary reviewers to review the amendments and recommend appropriate action. It is the responsibility of the CIM-CVGH IRB Chair to determine whether the amendment goes for expedited or full board review. The CIM-CVGH IRB approves the final decision for amendments submitted by the PI to the IRB.

5. Process Flow/Steps

ACTIVITY	***RESPONSIBILITY***
Step 1:*Submit Application for Amendment (Form 4.2)*	*Investigator*
Step 2:*Receive and manage Amendment Package*	*Secretariat*
Step 3:*Refer Amendment Documents to original primary reviewers*	*Primary Reviewers*
Step 4:*Review amendments and make a recommendation*	*Primary Reviewers*
Step 5:*Review recommendations and determine if amendment should be referred to full board*	*Chair*
Step 6:*Discuss at full board, if necessary and make a decision*	*Members, Secretariat*
Step 7: *Communicate CIM-CVGH IRB decision to PI*	*Secretariat*
Step 8:*Keep a copy of all amendment related documents in the protocol file*	*Secretariat*

6. Description of Procedures

Step 1: *Submit Application for Amendment (Form 4.2)*

- The investigators shall submit an amendment application whenever there is any change regarding the composition of the study team, the study site and the protocol related documents for approvals previously granted by the IRB.

Step 2: *Receive and manage Amendment Package*

- The IRB Secretariat checks the completeness of the amendment package submitted by the Investigator.

Step 3: *Refer Amendment Documents to original primary reviewers*

- The CIM-CVGH Secretariat refers the amendment packagepreferablyto the original primary reviewers within 7 days from submission.

Step 4:*Review amendments and make a recommendation*

- The original primary reviewers shall check the amended documents and compare them with the previously IRB approved documents in the protocol files. . They decide if the amendments would alter the risk/benefit ratio of the study, and make appropriate recommendations
- For amendments that will potentially affect the risk/benefit ratio, a full board for discussion shall be conducted using the amendment review form.

Step 5: *Review recommendations and determine if amendment should be referred to full board*

- The Chair shall review the recommendations by the Primary Reviewer and decide if the study needs a full board review.

Step 6: *Discuss at full board, if necessary and make a decision*

- Amendments that may potentially alter the risk/benefit ratio of a study are referred to full board for discussion. Members shall make a decision.
- Amendments are then classified into major amendments and minor amendments. Major protocol amendment which increase risk to study participants may include, but is not limited to the following:
  - a change in study design
  - additional treatments or the deletion of treatments
  - any change in the inclusion/exclusion criteria
  - change in method of drug intake or route of drug intake (e.g. oral changed to intravenous)
  - significant change in the number of subjects (increase or decrease in sample size that alters the fundamental characteristics of the study)
  - significant decrease or increase in dosage amount

- Otherwise amendments are considered minor especially if they do not compromise the integrity of the research data or change the risk benefit ratio

Step 7: *Communicate CIM-CVGH IRB decision to PI*

- CIM-CVGH Secretariat shall communicate the decision to the PI (Communicating IRB Decisions – SOP 6.2)

Step 8: *Communicate CIM-CVGH IRB decision to PI*

- The Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required. (SOP on Communicating IRB Decisions SOP #6.2)

7. Forms

Annex 1: Form 4.2A PROTOCOL AMENDMENT SUBMISSION FORM
Annex 2: Form 4.2B PROTOCOL AMENDMENT STANDARD TEMPLATE

8. History

Version No.	***Date***	***Authors***	***Main Change***
1	*Nov. 8, 2017*	*SOP Team*	*First draft*

9. References

- International Ethical Guidelines for Health-related Research Involving Humans Council for International Organizations of Medical Sciences (CIOMS) 2016
- Philippine Health Research Ethics Board (PHREB) Workbook 2015
- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- Chong Hua Hospital Institutional Review Board SOPs http://chonghua.com.ph/irb/SOP.html

ANNEX 1

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
79 F. RAMOS ST., CEBU CITY
Tel. 253-7413 Fax. (63-32) 253-9127

PROTOCOL AMENDMENT SUBMISSION FORM

FORM 4.2A

Any amendment to an approved protocol must be reviewed and approved by the IRB before the amendment is implemented. Such amendments could include changes to the study design, procedures, enrollment, methods of recruitment, personnel, funding source or the consent form/information sheet. This includes changes that appear to reduce risks to subjects. There are NO EXCEPTIONS to this rule.

Principal Investigator:	Date of submission:
Sub-Investigators:	Sponsor:

Protocol No._____

Study Title:

1. Using the standard template attached describe each proposed amendment and provide the reason for such.

2. For each amendment listed above, explain whether the proposed amendment increases or decreases the level risk to participants (thereby changing the risk/benefit ratio) and, if so, describe.

☐ Does not change the risk/benefit ratio

☐ Increase the risk to participants

_____

☐ Decrease the risk to participants

3. Has the funding source or the status of funding changed since initial or last re-approval review?

☐ YES ☐ NO

ANNEX 2

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PROTOCOL AMENDMENT STANDARD TEMPLATE FORM

FORM 4.2B

Sponsor:	Title:	Protocol No.:
Version No.:		Superseded:
Effective Date:		

Clinical Study Protocol Title:	

Section	Before Amendment	After Amendment	Rationale