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

TABLE OF CONTENTS

1. Policy Statement

The IRB shall require the submission of progress reports at a frequency based on the level of risk of the study. At the very least progress reports/continuing review reports are submitted yearly. Submission of a final report shall be within a month after completion of the research. Early termination of the research should ensure adequate protection and welfare of subjects that had been recruited.

2. Objective of the Activity

This activity aims to ensure that the conduct of the study is in compliance with the approved protocol and that the safety and welfare of study participants are promoted.

3. Scope

This SOP provides instructions for the review of progress reports that are required by the CIM-CVGH IRB to be submitted by the PI to monitor the safety of participants enrolled in a study. The annual progress report becomes the basis for continuing review of protocols whose approval needs to be renewed every year. This SOP also aims to provide instructions for the review of final reports that are submitted by the PI after completion of subject enrollment and all follow up procedures.

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 remind investigators to submit the progress and final reports before due date, to forward the reports to the primary reviewers for review comments, to communicate with the investigators if there is need for further information or action and to submit to full board a list of progress and final reports for approval.

It is the responsibility of the primary reviewers to review the reports to check completeness of information and ensure that the data are in accordance with the protocols and other related documents approved by the IRB.

5. Work Flow

ACTIVITY	***RESPONSIBILITY***
Step 1: *Remind PIs to submit progress report 2 months before expiry date of approval*	*IRB Secretariat*
Step 2: *Submit progress or final report not later than one month before expiry date of approval*	*Investigators*
Step 3: *Check completeness of information in the report and forward to the primary reviewers for assessment/comments*	*IRB Secretariat*
Step 4: *Review the progress or final report if it is in accordance*	*Primary Reviewer*

with the approved protocol and related documents as well as changes in the benefit risk ratio.	
Step 5: *Recommend approval or require more information or other action from the PI*	*Primary Reviewer*
Step 6:*Report approval/ other recommendations to full board*	*Primary Reviewer*
Step 7:*Discuss at full board and make a decision*	*Members, Secretariat*
Step 8: *Communicate RERC decision to PI/Furnish a renewal of approval of the protocol with the new approval date and the date of subsequent expiry of approval stated*	*Secretariat*

6. Description of Procedures

Step 1: *Remind PI's to submit progress report two months before due date*

- The Secretariat checks the database and tracks due dates of progress reports of Study Protocols approved by the CIM-CVGH IRB.
- The Secretariat prepares and sends reminder letter/notice addressed to the PI *two months* before the *expiry date of approval*.

Step 2: *Submit progress or final report on or before due date*

- The Primary Investigators will submit progress / final report to CIM-CVGH IRB one month before *expiry date of approval*

. For Final reports the PI Should submit at least 1 month before expiry.

Step 3: *Check completeness of information in the report and forward to the primary reviewers for assessment/comments*

- The Secretariat reviews the completeness of submitted report based on the items in Progress Report (Form 4.1) and Final Report (Form 4.2) and forwards the report to the primary reviewers within three days from submission.

Step 4: *Review the progress or final report if it is in accordance with the approved protocol and related documents*

- The primary reviewers conduct continuing review of progress/ final report if they are in accordance with the protocol and related documents approved by the IRB.
- The primary reviewer will assess for but not limited to any change in the benefit ratio.
- The primary reviewers refer to the protocol file to check compliance with approval given by the IRB during initial review and upon submission of amendments.

Step 5: *Recommend approval or require more information or other action from the PI*

- The primary reviewers recommend approval of the progress/final report if there is no deviation or violation of IRB approvals.
- If there is any issue of approvals given by the IRB, the primary reviewers recommend that appropriate action be taken by the PI (e.g. amendment of the protocol or consent

form, etc. for progress reports; explanation of deviation or violation for final reports, etc.)

Step 6: *Report approval/ other recommendations to full board*

- Approval or other recommendations by the primary reviewers of progress report is reported to the board meeting by the Secretariat.

Step 7: *Discuss at full board and make a decision*

- Related issues or recommendations related to progress reports are included in the agenda for discussion during the board meeting in order to arrive at a renewed approval or disapproval.

Step 8: *Communicate RERC 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 4.1A Progress Report Form
Annex 2: Form 4.1B Final Report Form

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.

ANNEX 1

CIM-CVGH

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

PROGRESS REPORT FORM

FORM 4.1A

PROGRESS REPORT FORM

IRB REF. NO.		Primary Investigator :	
PROTOCOL TITLE:			
RESEARCH STATUS:	☐ Not commenced ☐ Terminated ☐ In progress with expected completion date of _____ ☐ Completed with completion date of: _____		
Please give a brief statement of progress since the previous report and results/outcomes if any			
Are there any changes to the researchers listed in your original application? *(If yes please provide an updated list of researchers including their role and qualifications.)*		☐ **Yes**	☐ **No**
Have there been any changes to the project for which an amendment request has not been provided since approval by the CIM-CVGH IRB?		☐ **Yes**	☐ **No**
Have you received any complaints about the project?		☐ **Yes**	☐ **No**
Have all the conditions of approval been met		☐ **Yes**	☐ **No**
Have the approved procedure for confidentiality and security of data been followed?		☐ **Yes**	☐ **No**
Please describe the current arrangements for the storage of data.			

DECLARATION

I agree that the above information is accurate and that the project will continue to abide by the conditions of the original approval of the CIM-CVGH IRB.

Name and Signature of Primary Investigator _____

Date _____

ANNEX 2

CIM-CVGH

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

CLOSURE/FINAL REPORT FORM

FORM 4.1B

FINAL REPORT FORM

IRB Reference No.:		
Protocol Title:		
Principal Investigator:		
Protocol (Initial)Approval Date:		
Email:	Telephone:	Mobile:
Study Site:		
Sponsor:		
Sponsor Contact Person:		
Email:	Telephone:	Mobile:
1. Study Arms:		
2. Summary of Recruitment ☐ Accrual ceiling set by IRB ☐ New participants accrued since last review ☐ Total number of participants accrued since protocol began ☐ No. of participants who are lost to follow up ☐ No. of participants withdrawn from the study ☐ No. of participants who experienced SAEs/ SUSARs Number of participants who completed the study: _____		
3. Amendments to the original protocol (including dates of approval):		
4. Summary of onsite SAEs reported:		
5. Summary of participants' complaints or grievances documented regarding conduct of study:		
6. Summary of benefits to participants:		
7. Summary of indemnifications of study related injury (If Applicable):		
8. If terminated early, specify reason for termination:		
9. Progress reports submitted (with dates of approval):		
10. Duration of the study (months):		
11. Informed consent form used (with version no./date) and attach most recent version:		
12. Study objectives and summary of results:		