Supersedes:	Previous SOPs
Prepared by:	SOP Team 2019
Reviewed by:	Dr. Manuel Emerson Donaldo
Reviewed Date:	December 14, 2018
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1. **Policy Statement**
   The CIM CVGH IRB shall form a "site visit" committee to conduct visits to selected sites of submitted or approved protocols.
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2. **Objective of the Activity**
   Site visits shall be used as a mechanism to enable the CIM CVGH IRB to monitor compliance of the study to approved protocols. It will also be an opportunity to assess reasons for increases in reported risks.

3. **Scope**
   This SOP includes the processes followed in conducting site visits for reasons set by the IRB. This SOP begins with the selection of site to visit and ends with the draft of the site visit report and presentation of the report during a meeting and discussions for recommendation.

4. **Responsibility**
   The CIM CVGH IRB will select from among its members a team to compose the Site Visit Committee. The committee will have a designated Chair, Secretary and staff to facilitate the processes of the activity.

5. **Process Flow/Steps**

ACTIVITY	***RESPONSIBILITY***
Step 1: *Selection of site to visit*	*IRB Members*
Step 2: *Notification of Primary Researcher*	*IRB Secretariat*
Step 3: *Creation of Site Visit Team*	*IRB Chair*
Step 4: *Preparation of Documents for Site Visit*	*IRB Secretary*
Step 5: *Conduct of Site Visit*	*IRB Members and Chair*
Step 6: *Draft and presentation of report*	*IRB Chair / Secretary*
Step 7: *Discussion and Formulation of Recommendation*	*IRB Chair and Members*
Step 8: *Filing of Documents*	*IRB Staff*

6. Detailed Instructions

Step 1: *Selection of site to visit*

Selection of which sites to visit will be based on review of protocols falling within the following criteria:

- new study sites /new researcher
- reports of remarkable serious adverse events
- major protocol non compliance
- reports of complaints from study participants
- failure to submit continuing review requirements
- high risk studies
- studies requiring a large study population

Step 2: *Notification of Primary Researcher*

- A letter of notification will be sent to the primary researcher 2 weeks prior to a site visit. The letter will contain the reason for the site visit, and request for any additional documents, if any. It will also contain the members involved in the site visit and their travel arrangements.

Step 3: *Creation of Site Visit Team*

- The Committee that will become the site visit team will be created by the IRB members from among its roster. The IRB Chair may appoint a Committee Chair who will in turn choose a secretary. Review of the protocol in line for a site visit will be done with the rest of the IRB members. Familiarization with documents necessary for the site visit will be done the Committee members.

Step 4: *Preparation of Documents for Site Visit*

- The IRB Secretary shall prepare the documents needed for the site visit including documents requested from the primary researcher.

Step 5: *Conduct of Site Visit*

- During the site visit, the committee will review with the researcher the following points:
  - validity of study protocol
  - informed consent in its most recently approved version
  - random check that the same consent is signed by subjects of the study
  - post –approval documents and verification of its approval
  - facilities in the study site

- determination of the protection of the rights, safety and welfare of human participants in the study

Step 6: *Draft and presentation of report*

- A site visit checklist and report form will be used by the Committee members. A consensus of all the report forms will be collated by the Committee secretary and submitted to the Chair.
- A draft of the overall report will be prepared by the Chair within one week of the site visit for presentation to the IRB in the next scheduled meeting.

Step 7: *Discussion and Formulation of Recommendation*

- The report from the Committee Chair will be up for discussion on a scheduled IRB meeting. The course of action on the points reviewed during the site visit will be discussed and a consensus of the recommended changes will be determined in compliance to the IRB –approved protocol.
- The final report and recommendations will be relayed to the primary researcher in a formal letter.

Step 8: *Filing of Documents*

- All documents and forms will be filed by the IRB member in charge for documentation. A logbook of the site visits done, reports given and actions taken will be kept.

7. Form: Checklist for Site Monitoring**(See Annex 3)**

8. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
01	*November 22, 2016*	*CIM-CVGH-IRB MEMBERS*	*First Draft*
02	*April 13, 2019*	*CIM-CVGH-IRB MEMBERS*	*Formatting; Forms added*

9. References

A Workbook for Developing Standard Operating Procedures. (2015). Philippine Health Research Ethics Board; Department of Science and Technology Philippine Council for Health Research and Development

Standard Operating Procedure , Corazon Locsin Montelibano Memorial Regional Hospital (CLMMRH), Research Ethics Review Committee

ANNEX 1

CIM-CVGH

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

STUDY SITE VISIT REPORT FORM

Form 8

IRB Ref. No.		Date of the Visit:	
Study Title:			
Principal Investigator:		Phone:	
Sponsor		Site	
Reason for site visit		Persons interviewed	
Total number of expected subjects:		Total subjects enrolled:	

	YES	NO	COMMENTS
Are site facilities appropriate?			
Is confidentiality of documents maintained (e.g. cabinets with lock and keys)?			
Are the test articles properly kept and maintained?			
Are informed Consent Forms complete?			
Are approved ICF versions used?			
Are copies of the approved versions of the protocol documents kept in the site?			
Are files of all communication with the IRB found in the site?			
Does the site keep copies of all communication with the IRB in the site?			
Are copies of adverse event reports kept?			
Are investigator functions properly delegated to qualified research personnel?			
Is there appropriate documentation of qualifications of personnel?			
Are all Case Record Forms up to date?			
Are copies of protocol deviation/ violation reports kept in the site?			
Is there evidence of appropriate corrective action taken as recommended by the IRB?			

Summary of findings:

Recommendations:

Duration of visit: (hours)		Starting form:		Finish:
Name of IRB Member Visitors:				
Reported by:		Date:		
Signature				