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
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1. Policy Statement

The CIM-CVGH IRB shall require the submission of reports of onsite SAEs and SUSARs as soon as possible, and no later than 7 calendar days after first knowledge of the investigator. The evaluation of the SAEs and SUSARs shall be conducted by the Primary Reviewers whose recommendation shall be submitted to the IRB Chair for final action.

2. Objective of the Activity

This activity of reviewing aims to ensure that the safety and welfare of human participants in the study are safeguarded and that information on SAEs and SUSARs are properly documented.

3. Scope

This SOP applies to the review of SAE and SUSAR reports submitted by investigators and sponsors to the CIM-CVGH IRB. The IRB reviews such reports to determine appropriate action to protect the safety of participants in an approved study.

ICH-GCP E6 defines a serious adverse event (SAE) or a serious adverse drug reaction (ADR) as any untoward medical occurrence that at any dose

- Results in death,
- Is life threatening,
- Requires hospitalization or prolongation of existing hospitalization,
- Results in persistent or significant disability or incapacity, or
- Results in a congenital anomaly or birth defect.

A suspected unexpected serious adverse reaction (SUSAR) is a serious event the nature and severity of which is not consistent with the applicable product information. In the case of an unapproved investigational product, the event is not consistent with the Investigator's Brochure (IB). In the case of a licensed product, the event is not consistent with the approved package insert or summary of product characteristics

4. Responsibility

It is the primary responsibility of the CIM-CVGH IRB to receive and review SAE and SUSAR reports from its own site and to take the necessary action to ensure the safety of participants in the study. These are categorized as Onsite SAEs/SUSARs

In multicenter studies, the IRB also receives SAE and SUSAR reports from other sites within and outside the country. These are categorized as offsite SAEs/SUSARs. It is the responsibility of the CIM-CVGH IRB to be updated about safety issues related to studies that it has approved.

The CIM-CVGH IRB has the authority to suspend or terminate approval of research at its site when the safety of participants is no longer assured. When CIM-CVGH IRB takes such action, it is required to provide the reasons for its action and to promptly report such decision to the investigator, the sponsor, the institution and relevant regulatory authorities.

5. Process Flow/Steps

ACTIVITY	***RESPONSIBILITY***
Step 1:*Report SAE and SUSAR*	*Investigators / Sponsors*
Step 2:*Receipt and documentation of submission of report of SAEs and SUSARs in the logbook/database*	*Secretariat*
Step 3:*Retrieval of pertinent protocol file*	*Secretariat*
Step 4:*Notification of Chair and Primary Reviewers*	*Secretariat*
Step 5:*Review SAE and SUSAR reports and make a recommendation*	*Primary Reviewer, Chair*
Step 6:*Summarize and report to full board for appropriate action*	*Secretariat*
Step 7:*Communication of REC recommendation to the Principal Investigator/researcher (SOP on Communication of IRB Decisions SOP#6.2)*	*Secretariat*
Step 8:*Filing of all related documents (SOP on Management of Active Files - SOP# 7.2)*	

6. Description of Procedures

Step 1: *Report SAE and SUSAR*

- The investigators shall inform the CIM-CVGH IRB all cases of SAEs and SUSARs for all studies approved by the IRB**.** The submission of reports of onsite SAEs and SUSARs as soon as possible, and no later than 7 calendar days after first knowledge of the investigator. Offsite reports maybe submitted quarterly
- Report should use the specified IRB form (Form 3.1 SAE Forms, 3.2 USAE Form, Form 3.3 CIOMS) and to accomplish completely andproperly.
- Date of submission should be within the required timeline as mentionedin IRB Guidelines.

Step 2: *Receipt and documentation of submission of report of SAEs and SUSARs in the logbook/database*

- The IRB Secretariat shall accept and document the submission of documents in the manual log book. The following information should be recorded: Date of occurrence of the SAE / SUSAR, date reported, title of the study, and the nature of the SAE/SUSAR as indicated in the FORM.

Step 3: *Retrieval of pertinent protocol file*

- The IRB Secretariat shall retrieve the protocol from the Active Files to determine the identity of primary reviewers, and to check if there were earlier reports on SAEs and SUSARs

Step 4: *Notification of Chair and the Primary Reviewers*

- The IRB Secretariat shall notify the Chair who designates the Primary Reviewer. The secretariat staff will then notify the Primary Reviewer of the report through SMS and a phone call within48 hours from submission.

Step 5: *Review SAE and SUSAR reports and make a recommendation*

- The Primary Reviewer shall do a comprehensive review of the report using the SAE Assessment Form (Form 3.4) and make a recommendation to the IRB Chair who will decide if there is a need for a full board review. Only onsite SAEs/SUSARs are reviewed wile offsite reports are noted for significant trends.

Step 6: *Summarize and report to full board for appropriate action.*

- All SAEs/SUSARS are presented for FULL BOARD review the designated reviewer shall prepare the report to be presented in the IRB meeting

Step 7: *Communication of IRB recommendation to the Principal Investigator/researcher (SOP on Communication of IRB Decisions SOP#6.2)*

- 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)

Step 8: *Filing of all related documents (SOP on Management of Active Files - SOP# 7.2)*

- The IRB shall file all the documents, to include the submitted reports, and IRB decision in the Active File. (SOP on Managing Active Files SOP #7.2)

7. Form

Annex 1: Form 3.1 Serious Adverse Event Form
Annex 2: Form 3.2 Unexpected Serious Adverse Event Form
Annex 3: Form 3.3 CIOMS Form
Annex 4: Form 3.4 SAE Assessment Form

8. History

Version	*Date*	*Authors*	*Main Change*
1	*November 8, 2018*	*IRB Members*	*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.
- Chon Hua Hospital Institutional Review Board Standard Operating Procedures 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

SERIOUS ADVERSE EVENT REPORT FORM

FORM 3.1

Principal Investigator:	Protocol No.:	IRB Reference No: ☐☐☐☐ ☐☐☐ ☐☐
Study Title:		
Name of the study medicine/device:	Report Date: ☐ initial ☐ follow-up	Onset date:
	Sponsor:	Date of first use:

Subject's initial/number:	Age:	☐ Male ☐ Female
Subject's history:	Laboratory findings:	
SAE:	Treatment: Outcome: ☐ resolved ☐ on-going	
Seriousness: ☐ Death ☐ Life Threatening ☐ Hospitalization – ○ initial ○ prolong ☐ Disability / Incapacity ☐ Congenital Anomaly ☐ Other	Relation to ○ Drug ○ Device ○ study ☐ Not related ☐ Possibly ☐ Probably ☐ Definitely related ☐ Unknown	
Changes to the protocol recommended?		☐ No ☐ Yes , attach proposal
Changes to the informed consent form recommended?		☐ No ☐ Yes , attach proposal
Reviewed by:		Date:
Comment:		Action:

ANNEX 2

CIM-CVGH

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

UNEXPECTED ADVERSE EVENT REPORT FORM

FORM 3.2

Principal Investigator:	Protocol No.:	IRB Reference No: ☐☐☐ - ☐☐☐☐ - ☐☐
Study Title:		
Name of the study medicine/device:	Report Date: ☐ initial ☐ follow-up	Onset date:
	Sponsor:	Date of first use:

Subject's initial/number:	Age:	☐ Male ☐ Female
Subject's history:	Laboratory findings:	
SAE:	Treatment: Outcome: ☐ resolved ☐ on-going	
Seriousness: ☐ Death ☐ Life Threatening ☐ Hospitalization – ○ initial ○ prolong ☐ Disability / Incapacity ☐ Congenital Anomaly ☐ Other	Relation to ○ Drug ○ Device ○ study ☐ Not related ☐ Possibly ☐ Probably ☐ Definitely related ☐ Unknown	
Changes to the protocol recommended?		☐ No ☐ Yes , attach proposal
Changes to the informed consent form recommended?		☐ No ☐ Yes , attach proposal
Reviewed by:		Date:
Comment:		Action:

ANNEX 3

CIM-CVGH

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

CIOMS FORM

FORM 3.3

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2.a AGE Years	3. SEX	4-6 REACTION ONSET Day	Month	Year	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
7 + 13 DESCRIBE REACTIONS (including relevant tests/lab data)										PATIENT DIED INVOLVED OR PROLONGED INPATIENT HOSPITALISATION INVOLVED PERSISTENCE OF SIGNINFICANT DISABILITY OR INCAPACITY LIFE THREATENING

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG? YES ☐ NO ☐ NA
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID REACTION REAPPEAR AFTER REINTRODUCITON? YES ☐ NO ☐ NA
17. INDICATION(S) FOR USE		
18. THERAPY DATE (from/to)	19. THERAPY DURATION	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergics, pregnancy with last month of period, etc.)

IV. MANUFACTURER INFORMATION

24A. NAME AND ADDRESS OF MANUFACTURER		26. REMARKS
	24b. MFR CONTROL NO.	25b. NAME AND ADDRESS OF REPORTER
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE STUDY ☐ LITERATURE HEALTH PROFESSIONAL	
DATE OF THIS REPORT	25a. REPORT TYPE INITIAL ☐ FOLLOW UP	

ANNEX 4

IRB Reference No.	
Protocol No. & Title	

CIM-CVGH INSTITUTIONAL REVIEW BOARD

SAE ASSESSMENT FORM

FORM 3.4

Site of reported SAE		Type of SAE (Number)		On-site SAEs					
On-Site (Site in the country)	Off – Site (Site in foreign countries)	SUSAR	Non-SUSAR	Date of SAE	Date reported to REC	Date presented in REC meeting	Relation to Investigational New Drug	Action taken	Reviewed By
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☐	☐	☐	☐						
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