Table of Contents

1. Purpose

The purpose of this SOP is to ensure that the safety and welfare of human participants in the study are safeguarded and that information on SAEs and SUSARs is properly documented.

2. Scope

This SOP applies to the review of SAE and SUSARS reports submitted by investigators, Data Safety Monitoring Board (DSMB), sponsor, local safety monitor, CHH IRB

3. Responsibility

The primary responsibility of the CHH IRB is to review and address SAE and unexpected events involving risks to subjects or others as well as ethics complaints. The Chair notes the submission and ensures that the report of the SAE primary reviewer is included in the agenda of the next IRB meeting.

CHH IRB should also make sure that researchers are made aware of the policies and procedures concerning reporting and continuing review requirements.

The CHH IRB Secretariat is responsible for first screening the assessment of the reports and seeing whether they need a review by full Board, by Chairperson only, or by other qualified CHH IRB members or experts.

4. Flowchart

No.	ACTIVITY	RESPONSIBLE PERSONNEL
I	Receipt & documentation of submitted reports in logbook/database	CHH IRB Secretariat
II	Retrieval of pertinent protocol file	CHH IRB Secretariat
III	Notification of Chair	CHH IRB Secretariat
IV	Submission of report to the SAE Subcommittee/Point Person	CHH IRB members and Chairperson
V	Inclusion of report of Subcommittee in the agenda of the next IRB meeting	CHH IRB members and Chairperson
VI	Communication of IRB recommendation/ action to Principal Investigator	CHH IRB Secretariat and Chairperson

5. Detailed Instructions

5.1 Receipt & documentation of submitted report of SAEs and SUSARs in the logbook/ database

- Report should use the specified IRB form (**HRP-IRB-024, HRP-IRB-025 and CIOMS, see ANNEX 1-3**) and to accomplish completely and properly.
- Date of submission should be within the required timeline as mentioned in CHH IRB Guidelines.
- Record the submission in the logbook/database.

5.2 Retrieval of pertinent protocol file

- Retrieve pertinent information about corresponding protocol (e.g. identity of primary reviewers and earlier reports on SAEs and SUSARs)

5.3 Notification of Chair

- Notify thru the agenda of the next regular IRB meeting.

5.4 Submission of the report to SAE subcommittee or point person

- The reports should be submitted 1 – 2 weeks before the next IRB regular meeting to the SAE subcommittee or to the point person
- The specified forms should be used in presenting the SAEs and SUSARs during the regular IRB meeting

5.5 Inclusion of report of Subcommittee in the agenda of the next IRB meeting

- After reading and reviewing the report, the designee entertains discussion on the study and similar adverse experiences or advisories.
- If appropriate to the discussions, the Chairperson or another Board member may call for a consensus on whether to:
  - *Request further information.*
  - *Suspend or terminate the study*
  - *Take note and no further action is needed*

5.6 Communication of IRB recommendation/ action to Principal Investigator

- The recommendations/actions derived after the SAEs and SUSARs discussion will be communicated to the Principal Investigator/researcher according to SOP on Communicating IRB decisions.

6. ANNEX 1:

ANNEX 1

CHONG HUA HOSPITAL
Healing with Passion. Caring with Compassion.

SERIOUS ADVERESE EVENT REPORT FORM

Form HRP-IRB-024

Principal Investigator:	Protocol No.:	Application 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 –O initial O prolong ☐Disability / Incapacity ☐Congenital Anomaly ☐Other	Relation to O Drug O Device O 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:

SERIOUS ADVERSE EVENT REPORT FORM

Page 1 of 1

ANNEX 2:

ANNEX 2

CHONG HUA HOSPITAL
Healing with Passion. Caring with Compassion.

UNEXPECTED ADVERESE EVENT REPORT FORM

Form HRP-IRB-025

Principal Investigator:	Protocol No.:	Application 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 –O initial O prolong ☐ Disability / Incapacity ☐ Congenital Anomaly ☐ Other	Relation to O Drug O Device O 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: Comment:	Date: Action:	

UNEXPECTED ADVERSE EVENT REPORT FORM Page 1 of 1

ANNEX 3:

CHONG HUA HOSPITAL
Healing with Passion. Caring with Compassion.

ANNEX 3

CIOMS FORM

I. REACTION INFORMATION

SUSPECT ADVERSE REACTION REPORT	

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

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 RE/INTRODUCITON? ☐ YES ☐ NO ☐ NA
17. INDICATION(S) FOR USE		
18. THERAPY DATE (from/to)	19. THERAPY DURATION	

III. CONCOMITNAT 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		
	24b. MFR CONTROL NO.	
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL	
DATE OF THIS REPORT	25a. REPORT TYPE ☐ INITIAL ☐ FOLLOW/UP	

ANNEX 4: Template for IRB reporting of SAE and SUSARs only

ANNEX 4

Protocol No.: **IRB Reference No.:**
Principal Investigator: **Sponsor:**

"Study Title"

Place of SAE occurred		Type of SAE		SAEs	Causality				Outcome
					Investigator		Sponsor		
On-Site	Off-Site	SUSAR	Non-SUSAR		R	UR	R	UR	

ANNEX 5: Guidelines for Reporting Adverse Events

Institutional Review Board
CHONG HUA HOSPITAL
Don Mariano Cui St., corner J. Llorente St., Cebu City, Philippines 6000
☎ 255-8000 (local 7434); Email: chh_irb@chonghua.com.ph

Guidelines for Reporting Adverse Events

Per requirements of the Food and Drug Administration (FDA) the following serves as a guide for the reporting of adverse events within or outside the Chong Hua Hospital System.

Definition of Terms

An **Adverse Event (AE)** is any undesirable experience or any adverse change in health or "side-effect" which is unintended, although not necessarily unexpected that occurs in a subject who participates in a clinical trial while the subject is receiving the treatment (study medication, application of the study device, etc.) or within a pre-specified period of time after their treatment has been completed.

A **Serious Adverse Event (SAE)** in human drug trials is defined as any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of ongoing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.

An Unexpected Adverse Experience (UAE) is any adverse experience associated with the use of the drug/device, the specificity or severity of which is not consistent with the current investigator brochure; or, if an investigator brochure is not required or available, the specificity or severity of which is not consistent with the risk information provided to subjects (in the Informed Consent Document) and the IRB.

A **Related adverse event** occurs when there is a reasonable possibility that the adverse event is caused by the research activity (drug/device/procedure).

The relationship of the Adverse Events to the Investigational Product, Study drug, device or procedure is left to the discretion of the Primary Investigator of the study. Likewise it is the responsibility of the Principal Investigator to decide if the event warrants a change to the protocol to minimize risks and/or the informed consent form to better inform subjects of the potential risks and procedures to minimize such risks.

On Site Adverse Events
On Site adverse event is any untoward medical occurrence in a patient or clinical investigation participant which happens under the study conducted inside CHH Research Facility Unit. An adverse event that meets any of the following criteria must be reported to the CHH IRB.

Reporting requirement

1. The event is Serious or Unexpected, and Related to the research activity.
2. If the event is Related, Expected or not Serious but in the opinion of the investigator the protocol and/or informed consent form requires modification. Examples: identification of a "new trend" (adverse event occurring with greater frequency than anticipated) or a change in the risk/benefit ratio.
3. All non serious adverse events regardless of the relationship to the study drug.

Timelines for reporting

1. Serious and related AEs must be reported within 24 hours after discovery.
2. Serious but unrelated AEs must be reported within 2 weeks after discovery.
3. If the event is Related, Expected or not Serious but in the opinion of the investigator the protocol and/or informed consent form requires modification. Examples: identification of a "new trend" (adverse event occurring with greater frequency than anticipated) or a change in the risk/benefit ratio the event must be reported within 2 weeks after discovery.
4. All other non serious AEs must be reported within 24 weeks after discovery.

Off Site Adverse Events

Reporting requirement

An Off Site adverse event is any untoward medical occurrence in a patient or clinical investigation participant which happens under the study conducted outside CHH Research Facility Unit. These may include sponsor provided adverse events reports. An Off Site event that meets any of the following criteria must be reported to the CHH IRB:

1. The event is Serious or Unexpected and Related to the submitted research.
2. For a study not conducted at CHH, submit only those event reports that require a change in the submitted protocol and/or informed consent form.

Timelines for reporting

1. Serious and related AEs must be reported within 2 weeks after discovery.
2. Serious but unrelated AEs may be reported within 4 weeks after discovery.
3. Events that require a protocol or informed consent form modification must be reported within 2 weeks upon receipt from the study sponsor.
4. All other non serious AEs may be reported within 48 weeks after discovery.

Institutional Review Board
CHONG HUA HOSPITAL
Don Mariano Cui St., corner J. Llorente St., Cebu City, Philippines 6000
255-8000 (local 7434); Email: chh_irb@chonghua.com.ph

How to Submit an Adverse Event Form

1. For reporting of the Adverse Events/Reactions the investigator may use the **CIOMS** or any other similar form deemed appropriate by the investigator.
2. On Report form should be accomplished per event.
3. Incomplete forms will be returned to the investigator for completion.
4. Provide a brief description/summary of the adverse event.
5. Attach pertinent supporting documents (e.g., hospitalization summary) as needed.
6. The **IRB** expects regular updates from the reported Adverse Events and the resolution of the **Serious Adverse Drug Reaction**/s reported.

N.B.: There are situations where a serious or unexpected adverse event requires an immediate change to a protocol in order to eliminate apparent immediate hazards to research subjects. In these situations, the principal investigator may immediately implement a protocol change necessary to protect the welfare of the research subjects without a CHH IRB approved amendment. Investigators are required to notify the IRB in writing of the change, within 7 working days, and include a written description of the change and events that necessitated immediate implementation. The investigator must indicate in the report whether a change to the protocol and/or informed consent is necessary.

7. References

- 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.
- National Ethical Guidelines for Health Research 2011 PNHRS
- Philippine Health Research Ethics Board, Workbook for Developing Standard Operating Procedures