Eastern Visayas Health Research and Development Consortium- Ethics Review Committee (EVHRDC-ERC) STANDARD OPERATING PROCEDURE CHAPTER 3: POST APPROVAL PROCEDURES		
REVIEW OF SAE AND SUSAR REPORTS	SOP No.	16A
	Version No.	04
	Version Date	04-25-2023
	Effective Date	04-30-2023

1. STATEMENT OF POLICY

The ERC shall require the submission of reports of SAEs and SUSARs. For investigator-initiated clinical trials, onsite SAEs and SUSARs shall be reported within 24 to 48 hours after the event has come to the attention of the principal investigator while sponsor-initiated clinical trials onsite SAEs and SUSARs are reported within 7 calendar days after the event. The evaluation of the SAEs and SUSARs shall be conducted by the primary reviewers within 3 working days from receipt and recommendations and shall be submitted to the ERC for final action during the special meeting.

Offsite SAEs and SUSARs are reported to the ERC by the principal investigator 15 days to 90 days for inclusion in the next full board meeting.

All SAE and SUSARs of researcher-initiated studies are reviewed. However, for sponsored studies, only the on-site SAEs/SUSARS are reviewed formally. Only trends are noted for the off-site SAEs and SUSARs.

2. OBJECTIVE/S OF THE ACTIVITY

Review of SAE and SUSAR reports aims to ensure that the safety and welfare of human participants in the study site are safeguarded and that information on SAEs and SUSARs are properly documented and evaluated

3. SCOPE / APPLICABILITY

This SOP applies to the review of SAE and SUSAR reports submitted by investigators and sponsors to the ERC to comply with ICH GCP. The ERC 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. ROLES AND RESPONSIBILITIES

Compliance shall be the responsibility of the Principal Investigator, ERC Chair, ERC Members and the ERC Staff Secretary.

Principal Investigator - if PI initiated onsite SAEs and SUSARs shall be reported within 24-48 hours from occurrence. If offsite, it shall be reported 15 days to 90 days from occurrence.
For sponsor-initiated, the PI shall report the SAEs and SUSARs within 7 calendar days from occurrence.

ERC Chair - calls for a special meeting to discuss the onsite SAE and SUSAR

5. WORKFLOW

ONSITE SAE and SUSAR *(All SAE and SUSARs of researcher-initiated studies are reviewed. However, for sponsored studies, only the on-site SAEs/SUSARS are reviewed formally. Only trends are noted for the off-site SAEs and SUSARs)*

ACTIVITY	RESPONSIBILITY
Step 1: Submission and documentation of submission of report of SAEs and SUSARs	Principal Investigator
Step 2: Retrieval of pertinent protocol file	ERC Staff Secretary
Step 3: Notification of ERC chair	ERC Staff Secretary
Step 4: Submission of report to primary reviewers	ERC Chair, ERC Staff Secretary
Step 5: Inclusion of report of the SAE primary reviewer in ERC meeting agenda	ERC Chair, ERC Staff Secretary
Step 6: Conduct of Special Meeting	ERC Chair, Primary Reviewers
Step 7: Communicate ERC decision	ERC Staff Secretary
Step 8: Filing of protocol-related documents and updating of the Protocol Database	ERC Staff Secretary

OFFSITE SAE and SUSAR *(All SAE and SUSARs of researcher-initiated studies are reviewed. However, for sponsored studies, only the on-site SAEs/SUSARS are reviewed formally. Only trends are noted for the off-site SAEs and SUSARs)*

ACTIVITY	RESPONSIBILITY
Step 1: Submission and documentation of submission of report of SAEs and SUSARs	Principal Investigator
Step 2: Initial review of Primary Reviewers	Primary Reviewers
Step 3: Inclusion of report of the SAE primary reviewer in ERC meeting agenda	ERC Chair, ERC Staff Secretary
Step 4: Discussion during the Full Board Meeting	ERC Chair, Primary Reviewers
Step 5: Communicate ERC decision	ERC Staff Secretary
Step 6: Filing of protocol-related documents and updating of the Protocol Database	ERC Staff Secretary

6. DESCRIPTION OF PROCEDURES

6.1 ONSITE: Serious Adverse Event/s (SAE) and Suspected, Unexpected, Serious Adverse Reaction (SUSAR) Reports

6.1.1 Submission and documentation of submission of report of SAEs and SUSARs

The PI accomplishes **Form 16A.1 SAE and SUSAR Report** and submits to the ERC Staff Secretary within 24 to 48 hours from awareness of the event. The staff secretary receives the accomplished SAE/SUSARs report forms and enters the submission into the logbook. He/she notes whether the submission is within the required timeline. The staff secretary informs the ERC chair of the submission and forwards the SAE Report Package comprised of the following documents to the ERC Chair and to the primary reviewers within 48 hours of receipt:

- **Form 16A.1 SAE and SUSAR Report**
- **Form 16A.2 SAE and SUSAR Summary Report**
- Latest Investigator's Brochure
- Protocol Summary
- Other supporting documents, if any

6.1.2 Retrieval of pertinent protocol file

The staff secretary retrieves the identity of the primary reviewers and a tabulation of earlier SAE/SUSAR reports. If the primary reviewers assess that the report/s need/s

immediate action, he/she will forward the report/s and his/her recommendation to the ERC Chair for further assessment.

6.1.3 Notification of ERC chair

The ERC staff secretary notifies and sends the report and the retrieved documents to the ERC Chair. The staff secretary includes the SAE report/s on the agenda of the next special meeting,

6.1.4 Submission of report to primary reviewers

The ERC Chair forwards the report and pertinent documents to the primary reviewers for action which should not be later than 3 days prior to the next special meeting. Copies of the **Form 16A.1 SAE and SUSAR Report** are distributed to each primary reviewer together with the agenda.

6.1.5 Inclusion of report of the SAE primary reviewer in ERC meeting agenda

For Onsite SAE and SUSAR, a special meeting shall be called for by the ERC Chair ***(see SOP No. 25 Conduct of Special Meetings).***

6.1.6 Conduct of Special Meeting

During the meeting, the ERC Chair calls for a decision on the SAE report/s with respect to his/her recommendation/s or Primary Reviewers assigned to the concerned study.

The committee may require any of the following actions as Decision Points:

- No further action; documents for filing
- Modification of participant inclusion or exclusion criteria to mitigate the newly identified risks or informed consent documents to include a description of newly recognized risks;
- Recommend implementation of additional procedures for protecting/ safeguarding participants;
- Suspension of enrollment of new participants or research procedures among participants who are currently enrolled (check consistency)
- Request information.
- Recommend suspension of the entire study.

6.1.7 Communicate ERC decision

The decision of the committee is communicated to the researcher within seven (7) working days after the final deliberation ***(See SOP No. 27 Communicating the ERC Decision).***

6.1.8 Filing of protocol-related documents and updating of the Protocol Database

The ERC Staff Secretary then logs the date of decision and stores the signed forms in the study protocol file folder ***(See SOP No. 29 Management of Active Files (Administrative and Study Files)).***

6.2 OFFSITE: Serious Adverse Event/s (SAE) and Suspected, Unexpected, Serious Adverse Reaction (SUSAR) Reports

6.2.1 Submission and documentation of submission of report of SAEs and SUSARs

The PI must submit the offsite SAE and SUSAR report every 15 days to 90 days. The staff secretary forwards the SAE Report Package to the primary reviewers and the chair which comprises of the following documents at least seven (7) working days before the next full board meeting ***(See SOP No. 06 Full Review)***:

- **Form 16A.1 SAE and SUSAR Report**
- **Form 16A.2 SAE and SUSAR Summary Report**
- Latest Investigator's Brochure
- Protocol Summary
- Other supporting documents, if any

6.2.2 Initial review of Primary Reviewers

The primary reviewers assigned to the particular study review and return the signed and accomplished **Form 16A.1 SAE and SUSAR Report** to the staff secretary together with the SAE report package. The ERC chair and primary reviewers may recommend any of the following actions:

- notation with no further action required
- further information or action required or
- suspension of recruitment or suspension of the entire study

6.2.3 Inclusion of report of the SAE primary reviewer in ERC meeting agenda

The ERC Chair submits the recommendations to the staff secretary for inclusion in the agenda of the next full board meeting. The staff secretary includes the SAE reports on the agenda. Copies of the **Form 16A.2 SAE and SUSAR Summary Report** are distributed to each ERC member together with the agenda.

6.2.4 Discussion during the Full Board Meeting

During the meeting, the ERC Chair calls for a decision on the SAE report with respect to the recommendations of the Chair and the primary reviewers. The ERC can recommend any of the following actions:

- No action required, study to continue;
- Modification of participant inclusion or exclusion criteria to mitigate the newly identified risks or informed consent documents to include a description of newly recognized risks;
- Recommend implementation of additional procedures for protecting/safeguarding participants;
- Suspension of enrolment of new participants or research procedures among participants who are currently enrolled (check consistency)

Protocols with reported Off-Site SAE/SUSARs and decisions arrived at by expedited procedure are reported during the Full Board Review Meeting.

6.2.5 Communicate ERC decision

The decision of the committee is communicated to the researcher within seven (7) working days after the final deliberation ***(See SOP No. 27 Communicating the ERC Decision).***

6.2.6 Filing of protocol-related documents and updating of the Protocol Database

The ERC Staff Secretary then logs the date of decision and stores the signed forms in the study protocol file folder ***(See SOP No. 29 Management of Active Files (Administrative and Study Files)).***

7. FORMS AND TOOLS

Form 16A.1 SAE and SUSAR Report
Form 16A.2 SAE and SUSAR Summary Report

8. HISTORY

Version No.	Date (mm/dd/yyyy)	Authors	Main Change
1	10/23/2015	ERC	First Draft
2	11/21/2019	ERC	Updates on procedures and policy.
3	11/28/2022	Dr. Jane R. Borrinaga Ms. Sarah B. Delorino Engr. Florentino L. Quiñones Ms. Noreen S. Buhat Fr. Charles Gingco Dr. Jose Carlo K. Del Pilar Ms. Erleta S. Piñero Atty. Alma Sonia Q. Sanchez-Danday Mr. Ricky T. Serrano Mr. Raymond G. Campo	Updates on procedures and policy.
4	04/25/2023	Dr. Jane R. Borrinaga Ms. Sarah B. Delorino Engr. Florentino L. Quiñones Ms. Noreen S. Buhat Fr. Charles Gingco	Updated statement of policy

		Dr. Jose Carlo K. Del Pilar Ms. Erleta S. Piñero Atty. Alma Sonia Q. Sanchez-Danday Mr. Ricky T. Serrano Mr. Raymond G. Campo	

9. REFERENCES

- World Medical Association Declaration of Helsinki, 2013
- ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)
- WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
- International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016
- National Ethical Guidelines for Health and Health Related Research 2017
- Philippine Health Research Ethics Board Standard Operating Procedures 2020
- BatMC RERC SOP 2020

Prepared by:	Reviewed and Approved by:	Approved by:
ETHICS REVIEW COMMITTEE	**DR. JANE R. BORRINAGA, MD, FPCP** ERC Chair	**EXUPERIA B. SABALBERINO, MD, MPH, CESe** EVHRDC Executive Committee Chair
Date: 04-25-2023	Date: 04-25-2023	Date: 04-25-2023