West Virginia Clinical and Translational Science Institute Center of Excellence

STANDARD OPERATING PROCEDURE

Title:	No.: COE-111.00	
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	Date of Issuance: 16 APR 2021	Date Effective: 17 MAY 2021
	Supersedes: NA	

Prepared by: 09APR2021	Reviewed by: 09 APR 2021	Approved by: 17APR2021
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Purpose:
This standard operating procedure (SOP) describes the operations followed by the Morgantown, West Virginia University (WVU) Health Science Center (HSC) campuses for the maintenance of sponsor provided external safety reports. Adherence to this SOP ensures that this clinical research site receives and reviews current safety information to enable the site investigators to make appropriate decisions regarding participant safety at West Virginia University.

Scope:
This SOP describes procedural pathways utilized at this site for the maintenance of sponsor provided safety report(s). It will describe the steps for the receipt, review, reporting and retaining an external safety report according to institutional policies, protocol and regulatory procedures.

Definition:
Safety Report: A report generated by the sponsor describing all adverse drug/device effects that are both serious and unexpected.

Materials:
NA

Responsibility:

This SOP applies to the HSC Institutions and associated clinical departments involved in ensuring the appropriate management of external safety reports.

Procedure:
The sponsor is responsible to inform the FDA and all participating investigators when a determination has been made that any event(s) meet the criteria for an unanticipated problem in the form of a safety report according to regulatory requirements. The Food and Drug Administration (FDA) and the Office of Human Research Protections advises that it is neither useful nor necessary for reports of individual adverse events occurring in subjects enrolled in multicenter studies to be distributed routinely to investigators or IRBs at all institutions conducting the research.

A. Receipt and review process

Communicate this SOP to the sponsor prior to study initiation at this site, for example during contract negotiations or at the site qualification and/or initiation visit.

Upon receipt, the provided safety report will be reviewed and processed as below.

Investigators will only review and retain individual safety reports (e.g. action letters, alerts, etc.) distributed by external sponsors that are determined by the sponsor to be *unanticipated problems* as described below:

- Unexpected,
- Related or possibly related to participation in the research, and
- Serious or otherwise one that suggests that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized.

AND

- There are implications for the conduct of the research study (e.g. requiring significant, and usually safety related, changes to the protocol such as revising inclusion and exclusion criteria, or including a new monitoring requirement, informed consent, or investigators brochure).

Safety reports that do not meet the criteria outlined above will not be reviewed nor retained by the PI. This includes any type of safety report notification (e.g., including online portals and databases).

B. Reporting

Individual reports that do meet the criteria above will be reviewed by the PI, reported to and reviewed by the IRB, and maintained in the study file(s). Summary reports distributed by external sponsors are accepted for review and routine reporting to the IRB.

C. Retaining
File outside safety reports meeting the above criteria (reportable UPIRTSO) in the study regulatory file along with corresponding IRB documentation.

References/Regulations/Guidelines
ICH E6 (R2) Good Clinical Practice: Integrated Addendum to ICH E6 Guidance for Industry, March 2018
21 CFR Part 312: Investigational New Drug Application
FDA Guidance for Industry and Investigators Safety Reporting Requirements for INDs and BA/BE Studies
21 CFR Part 812: Investigational Device Exemptions
FDA Guidance for Clinical Investigators, Sponsors, and IRBs Adverse Event Reporting to IRBs — Improving Human Subject Protection
45 CFR Part 46: Protection of Human Subjects
HHS Office for Human Research Protections Unanticipated Problems Involving Risks & Adverse Events Guidance (2007)

History of Revisions to SOP

Effective Date	Nature of Revision
17 MAY 2021	New SOP