Adverse Event Reporting	CR-304
Clinical Research Standard Practices	**Effective Date:** August 2022

SCOPE AND PURPOSE The document is applicable to the people and processes of the following Penn State College of Medicine and Penn State Health entities specified below engaged in clinical research:

Entities:

[ ]	Penn State Health Shared Services
[X]	Milton S. Hershey Medical Center
[X]	St. Joseph Medical Center
[X]	Holy Spirit Medical Center
[X]	Hampden Medical Center
[X]	Penn State College of Medicine
[X]	Medical Group – Academic Practice Division
[X]	Medical Group - Community Practice Division
[X]	Penn State Health Life Lion, LLC

Roles:

[X]	Principal Investigator
[X]	Sub-Investigators
[X]	Study Coordinators/Associates
[X]	Data Specialist
[ ]	Financial Analyst
[ ]	Key Study Ancillary Personnel

Participant safety is of the greatest importance for both the individual participant and the goals of the clinical study. Investigators are required to report to the sponsor all adverse events occurring during a study. If the event is serious and unexpected, prompt reporting to the sponsor is mandatory. Unexpected and related events must be reported to the IRB. This standard operating procedure (SOP) describes the steps this clinical research team follows to fulfill the regulatory and clinical requirements for adverse event reporting.

This standard operating procedure (SOP) describes the responsibilities of the research team for managing, reporting and documenting adverse events involving human subjects in research during all investigational phases of development from the time an adverse event is identified until all follow-up activities associated with its resolution have been completed. Finally, the procedures for processing and transmitting IND safety reports received from the sponsor to the IRB are defined.

POLICY AND PROCEDURE STATEMENTS

1. Policies, procedures, protocols, and other documents (collectively "Standard Practices") that pertain to direct research participant care must be reviewed on an annual basis. Otherwise, documents will be reviewed every other year.
    a. A direct research participant care document is one that involves any aspect of the health care of a patient, including treatments, counseling, self-care, patient

education, and administration of medication provided personally by a staff member

2. Managing adverse events
    a. Refer to Penn State University Human Research Protection Program (HRPP) website for management of adverse events
    b. Follow up appropriately when a research participant experiences any adverse change from baseline or pretreatment condition, ensuring that all appropriate resources are directed toward participant safety and well-being. Follow the participant until the event is resolved or as directed by the sponsor.
    c. If necessary for the immediate medical care of the participant only, break the drug blind after consultation (if possible) with the sponsor.
    d. If the adverse event is serious and/or unexpected, inform the sponsor as soon as possible after the participant is stabilized. If the event is unexpected and related, notify the IRB. Provide as much information as is available.
    e. Record the details of the adverse event in the source documentation and complete the appropriate CRFs according to sponsor requirements including:
        i. description of event;
        ii. onset, duration, date of resolution;
        iii. intensity of event (mild, moderate, severe);
        iv. assessment of relationship;
        v. treatment or action(s) taken;
        vi. if blind or randomization code broken;
        vii. outcome of event.
    f. Keep originals or photocopies of all relevant documentation, including facsimile confirmations, telephone logs, airbills, and file in the study binder with appropriate documents.

3. Reporting to the IRB
    a. Refer to Penn State University Institutional Review Board website and *Investigator Manual* (HRP-103) for management of adverse events.

4. Handling IND safety reports from sponsors
    a. Promptly review and assess IND safety reports received from sponsors.
    b. File IND safety reports in the study regulatory file.
    c. Ensure that IND safety reports received from sponsors are promptly submitted to the IRB as per the *Investigator Manual* (HRP-103). Retain a copy of correspondence.

RELATED POLICIES AND REFERENCES

Code of Federal Regulations: Investigational New Drug Application (21 CFR 312.32,33,44,812)

Code of Federal Regulations: Elements of Informed Consent (21 CFR 50.25)

Code of Federal Regulations: Institutional Review Board (21 CFR 56.108, 109, 115)

Code of Federal Regulations: General requirements for Informed Consent (45 CFR 46.103, 109,

115, 116)

IRB Continuing Review After Clinical Investigation Approval; U. S. Food and Drug Administration; February 2012

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APPROVALS

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