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1. Overview

This document establishes procedures for identifying, documenting, and assessing Adverse Events (AEs) and Serious Adverse Events (SAEs), related to human subjects research, in compliance with applicable regulatory standards and good clinical practice (GCP). Please note, sponsors may provide alternate definitions, severity ratings, and documentation procedures; use these procedures when the sponsor does not define these parameters.

This procedure applies to all investigators, study coordinators, and research team members conducting research under the auspices of Drexel University.

2. Definitions

Adverse Event (AE) - Any untoward medical occurrence in a study participant undergoing intervention which does not necessarily have a causal relationship with the intervention. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the study intervention, whether or not related to the study intervention. Adverse events encompass both physical and psychological harms.

Adverse Event Severity – The severity of an AE is based on the participant's reporting of the impact the AE has had on their routine activities or in the investigator's assessment of the impact to the participant, and are recorded as:

- **Asymptomatic** – No limitation to routine activities, no discomfort
- **Mild** – No limitation to routine activities, slight discomfort
- **Moderate** – Some limitation of activities, moderate discomfort
- **Severe** – Inability to perform routine activities, intolerable discomfort/pain

Relationship – The probability that an AE is related to the study intervention or participation in the study. The relationship probability is recorded as:

- **Not Related** – the AE is clearly not related
- **Not Likely** – the AE is doubtfully related
- **Possibly** – the AE may be or is likely related
- **Related** – the AE is clearly related

Serious Adverse Event – Any adverse event that results in:

- Death
- Life-threatening circumstances
- Inpatient hospitalization/prolonged current hospitalization
- Disability/incapacity (persistent or permanent)
- Congenital anomalies/birth defects

Unexpected – The incident, experience or outcome is not expected (in terms of nature, severity, or frequency) given the research procedures that are described in the study-related documents, such as the IRB-approved research protocol/research plan and informed consent documents; and the characteristics of the subject population being studied.

3. Adverse Event Assessment

Adverse event information may be obtained through observation by study personnel, spontaneous report from the participant, report from the participant in response to an open-ended question, through self-report surveys and questionnaires, or from clinical test results, e.g., abnormal lab results.

Unless otherwise specified in the protocol, adverse events should be assessed at each study visit by asking the participant an open-ended question, such as "How do you feel?" and "How have you felt since your last visit?". Any AEs reported since the previous visit and changes to previously reported events, e.g., event severity changed from moderate to mild, must be documented. As applicable, participant charts or medical records should be reviewed to identify any additional AEs.

4. Adverse Event Documentation

Reported or observed adverse events must be documented in the study records; AEs are often recorded in an adverse event log. See template options linked in Section 9 or use template logs available in Florence eBinders or other file management systems, as applicable. If a diagnosis is known, this should be recorded in place of a description of the symptoms, e.g., record pneumonia in place of cough and shortness of breath. If a diagnosis is unknown, the symptoms are recorded in as much detail as possible. AE documentation should include the start date of the event or symptoms, the event severity and expectedness, any actions taken (e.g., treatments administered, participant withdrawn from the study, etc.), the outcome and end date, if known. Study records should indicate the start date of the AE and when the study team became aware of the event to demonstrate timely documentation. The principal investigator (PI) or a qualified investigator, as designated on the delegation of authority log, should document the event relationship/causality assessment.

5. Serious Adverse Events and Events of Special Interest

Serious adverse events are reported as defined by the protocol. Some protocols may specify events of special interest which are often treated the same as SAEs in regard to expedited reporting but do not meet the definition of an SAE. Follow the sponsor and protocol reporting requirements for SAE reporting; sponsors frequently require SAE reporting with 24 hours of becoming aware of the event.

At a minimum, documentation of SAEs should be the same as with AEs unless otherwise specified by the protocol. The PI must be notified immediately of any reported SAE and the investigator's assessment/causality must be documented. All SAEs should be followed to resolution or stability of the condition.

6. Reportable Events

Refer to HRP-071 – Prompt Reporting Requirements for a full list of examples and reportable events to the IRB. AEs and SAEs are reportable to the IRB if they are determined to be unexpected (in

nature, severity, or frequency) and related to participation in the research study. Sponsors/funding agencies and/or data safety monitoring plans (DSMP) may specify additional reporting requirements.

7. Internal Review/Data and Safety Monitoring

All events must be evaluated to determine if changes to the study protocol, consent forms, or procedures are needed. If applicable, the PI should convene a Data Safety Monitoring Board (DSMB) or have safety officer review, in accordance with the Data Safety Monitoring Plan (DSMP). When designing the DSMP, the PI must follow the funder and IRB reporting requirements and consider the risk level of the study. All potential study risks must be described in the informed consent form and protocol. Additionally, the PI must review and understand any differences between funding source requirements and IRB requirements (e.g., reporting windows may vary). For studies with differing reporting requirements, the PI should follow the more stringent reporting requirement and consider making revisions to align or standardize reporting requirements when possible.

8. Responsibilities

8.1 Office for Research & Innovation Responsibilities

The Office for Research & Innovation is responsible for maintaining this guidance document, applicable tools, training, and monitoring. For inquiries regarding these procedures, please contact the Associate Vice Provost for Research Compliance and Regulatory Affairs, as part of the Office for Research & Innovation (ORI).

8.2 Principal Investigator

The PI retains overall responsibility for the study and adverse event documentation in accordance with this guidance and sponsor requirements. The Principal Investigator is responsible for overall safety monitoring, assessment of relationship/causality and severity, timely documentation, and reporting of all relevant events. The PI is accountable for understanding and complying with any additional reporting requirements from sponsors.

8.3 Study Personnel Responsibilities, as delegated by the PI

Study personnel, as delegated by the PI, are responsible for notifying the PI and sponsor, as applicable, of reported adverse events, assisting the PI in maintaining up to date documentation of adverse events, communicating with the PI/IRB/sponsor as appropriate.

9. Resources

- ORI-623 TEMPLATE – Adverse Event Log Version 001
- ORI-623 TEMPLATE – Adverse Event Log Version 002
- NIMH Adverse Event Log Template
- HRP-071 Prompt Reporting Requirements
- HRP-214 Form – Reportable New Information
- ICH E6 R2 Guidance for Industry Good Clinical Practice
- ICH E6 R3 Guidance for Industry Good Clinical Practice

10. Revision and Workgroup Members

10.1 Revision

Version 001/Effective Date 05/22/2026 - Original Document – Adverse Events Reporting

10.2 Workgroup Member

The Office for Research and Innovation appreciates the following individuals who served as Workgroup Members:

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