



Policy: Management of External Safety Reports

- 1. Purpose:** This SOP pertains to outside safety reports distributed by Sponsors for adverse events that occur at other sites.
- 2. Scope:** UAHS Research Administration Regulatory staff and UAHS clinical research staff
- 3. Definitions**
 - AE: Adverse event
 - Banner University Medical Center
 - CFR: Code of Federal Regulations
 - FDA: US Food and Drug Administration
 - GCP: Good Clinical Practice
 - ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
 - IRB: Institutional Review Board
 - OHRP: Office of Human Research Protections
 - RA: Research Administration
 - SAE: Severe adverse event
 - SOP: Standard Operating Procedure
 - UAHS: University of Arizona Health Sciences
- 4. Procedure**
 1. UAHS seeks to follow FDA, OHRP, and ICH-GCP guidance for the review of outside SAEs, i.e. SAEs occurring at study locations other than UAHS/BUMC.
 2. It is the responsibility of the Sponsor to determine if an outside SAE meets the definition of reportable [ICH 5.16.1].
 3. UAHS will only perform a local review [21 CFR 312.32(c)(1)(i) and 45 CFR 46] for outside AEs that the Sponsor determines meet all three criteria of reportable:
 - i Unexpected, and
 - ii Related or possibly related to participation in the research (reasonable possibility), and
 - iii Suggests that the research places subjects or others at a greater risk of harm.In addition, the event must have clear implications for the conduct of the study, such as: a significant risk is identified for subject notification, a new monitoring requirement is established for the study, or a change to the study has been identified such as revising the protocol, investigator's brochure, and/or the informed consent form. Only outside AEs that met these criteria will be reported the IRB and maintained in the study binder.
 4. UAHS Investigators and their designees will not download, process, or maintain outside AE reports from outside web portals. The Sponsor will provide directly to the UAHS Investigator or designee, a written notification to accompany the outside AE report(s), clearly indicating how the AE(s) meets FDA definition as reportable [21 CFR 312.32 and ICH 5.16.2], and what the



implications are for the conduct of the study. UAHS and Investigators will not review, process, or retain outside SAE reports where the Sponsor does not provide this identification.

5. UAHS Investigators may delegate to a study coordinator the responsibility to manage and process reportable outside AE reports, which begins at the time UAHS opens the study to accrual and continues until the trial closes to enrollment with zero participants on active treatment (≤ 30 days from last dose) and in long-term or survival follow-up.
6. Reportable outside AE reports will be submitted to the IRB of record within the IRB's required timeframe. The IRB approval/acknowledgment, associated outside AE reports, and additional updated documents will be distributed to the PI and study team for review. Only reportable outside AE reports will be maintained in the study files.
7. If the sponsor submits a safety report directly to the IRB of record and does not provide the site with the information listed above, documents provided to the site by the IRB of record will be processed and filed according to usual site procedures for IRB documentation.

5. References, Materials, and/or Additional Information

Code of Federal Regulations (<https://www.ecfr.gov/>)

- 21 CFR Part 312: Investigational New Drug Application
- 45 CFR Part 46: Protection of Human Subjects

ICH E6 (R2) Good clinical practice (https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf)

- 5.16: Sponsor – Safety Information

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1.0	1/19/2023	Gustavo Cornejo	Drafted

