TEXAS A&M UNIVERSITY
SAN ANTONIO

Institutional Review Board

# GUIDELINE # 11: REPORTING ADVERSE OR UNANTICPATED EVENTS

## I. PURPOSE

This guideline is to ensure that human subjects' research conducted complies with federal, state, and local laws, regulations, directives, and instructions. This guideline provides guidance for reporting an adverse or unanticipated event(s).

## II. STATEMENT

All human subjects research, irrespective of the source of funding, conducted by A&M- SA faculty, staff, and students must be submitted and reviewed in accordance with the Federal research regulations, Texas A&M System Guidelines, A&M-SA IRB policies and local consideration.

## III. SCOPE

This guideline applies to all research conducted where the A&M-SA IRB serves as the Reviewing IRB.

## IV. DEFINITIONS

**OHRP Adverse Events (AE)** term: Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

**Texas A&M System Adverse Events (AE) term:** Any unfavorable and unintended event, including an abnormal laboratory finding, symptom, or disease associated with the research or the use of a medical investigational test article. It does not necessarily have to have a causal relationship with the research.

**Unanticipated Problem (UAP):** An unanticipated problem involving risk to participants or others is defined by meeting ALL 3 of the following criteria:

1. Unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol-related documents and the characteristics of the subject population being studied;

2. Related or possibly related to participation in the research; and

3. Suggests that the research places participants or others at a greater risk of harm than was previously known or recognized.

## V. PROCEDURES

### What, When and How to Report AEs

Federal regulations from OHRP require the IRB to ensure that investigators promptly report "any unanticipated problems [UPs] involving risk to subjects or others." All reporting guidelines apply to research also conducted internationally. A&M- SA IRB is required by federal regulations to regularly and routinely report any unanticipated problems involving risks to subjects or others, or any serious or continuing noncompliance events that occur at A&M- SA as well as others in the institution as appropriate.

### Reporting Requirements

**Responsibility**: Investigators or key study personnel receiving reportable new information are required to report the event.

The Post-Approval Reporting Requirements chart below describes which adverse events (AEs), other events and safety information updates need to be reported to the IRB/HRPP and how/when to submit the report.

What is a Reportable Event? How do I determine if an event should be submitted as a Reportable Event? When do I submit it?

A reportable event is an adverse event or incident that has the potential to be classified by the IRB as an unanticipated problem posing risks to participants or others. An incident is determined to be reportable to the IRB when it is both:

1. Probably, possibly, or definitely related to participation in the research.
2. Unexpected in terms of nature, severity, or frequency.

Events that meet these criteria must be submitted to the IRB within 10 business days of discovery. **However, if the event involved a death, investigators should report within 3 calendar days.**

Please refer to the following table regarding whether the event is reportable to the IRB, and if so, when it should be reported.

| Relatedness | Expectedness | Reportable to IRB? | When to Report |
|---|---|---|---|
| Unrelated or Unlikely related | Expected and Unexpected | NO | N/A |
| Possibly, Probably, or Definitely related | Expected | NO | N/A |
| Possibly related | Unexpected | YES* ONLY IF: The event suggests that the research places **subjects or others** at greater risk than was previously known or recognized (i.e., changes to the study conduct are required to mitigate risk and/or participants' willingness to participate may be adversely impacted) | EXPEDITED REPORTING WITHIN 10 bus. days<br><br>Summarize at continuing review |
| Probably or Definitely related | Unexpected | YES* | EXPEDITED REPORTING WITHIN 10 bus. days<br><br>Summarize at continuing review |
| Probably or Definitely related death | Unexpected | YES* | EXPEDITED REPORTING WITHIN 3 calendar days<br>Summarize at continuing review |

*Includes serious and non-serious events.

If you do not have enough information to complete the Adverse Event form within the required timeframe, you still must submit an Adverse Event Form with the information available. You should indicate that a follow-up report will be provided once additional information has been obtained. You should also reach out to the IRB for additional guidance in these situations.

**Reporting Reminders**

- Submit follow-up reports for unresolved events.
- Remove subject identifiers from reports/attachments.
- Complete violation/incident info sections during Continuing Review.
- Remember outside reporting requirements to sponsors, FDA, NIH, etc.

## VI. APPLICABLE AGENCIES, GUIDELINES AND REGULATIONS

Reports are submitted to the following agencies as applicable:

| Agency | Regulatory Requirement | Applicability by Study Status |
|---|---|---|
| Department of Health and Human Services' Office of Human Research Protections (OHRP) | 45 CFR 46.103(a) and (b)(5) | Federally Funded or Federally Conducted Studies |
| The Food and Drug Administration (FDA) | 21 CFR 6.108(b)(1),<br>21 CFR 312.53(c)(1)(vii),<br>21 CFR 312.66 | Studies involving an Investigational Product (Drug, Device or Biologic) |
| Department of Defense Human Research Protection Office (DoD HRPO) | 32 CFR 216 DODI 3216.02 | Studies funded or conducted by the DoD |

- Texas A&M San Antonio Institutional Review Board Adverse Event Form
- Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events: OHRP Guidance (2007)
- Reporting Incidents to OHRP (2022)
- 45 CFR 46
- IRB Member: AAHRPP Site Visit Guide Human Research Protection Program

## VII. REVISIONS

June 2024

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| **Guideline: # 11** | **Version: V.1** |
| **Title: Reporting Adverse or Unanticipated Events** | |
| **Authorized: Dr. Vijay Golla, Vice Provost for Research and Health Sciences** | |
| **Date Approved by IO: June 27, 2024** | |