IRB RESEARCH RELATED INCIDENT REPORT

For Reporting Adverse Consequences to Humans Participating in Research

All forms must be completed, signed, and submitted via email to enamt@uapb.edu.

If there are multiple participants with adverse events, then complete multiple forms.

DEFINITIONS

Unanticipated Problem Involving Risks to Participants or Others (Unanticipated Problem): Any event or problem that (1) was **unforeseen** in terms of nature, severity, or frequency given the approved research protocol and participant population; (2) **related or probably related** to participation in the research or if the incident probably or definitely affects participants even if the event does not appear to be associated with the research protocol and (3) suggests that the research places participants or others at a **greater risk of harm** than was previously known or recognized.

Examples include: Adverse events, a breach of confidentiality or privacy that involves real or potential risk, data and safety monitoring reports that indicate the frequency or magnitude of harms or benefits may be different than initially presented to the IRB, incarceration of a participant in a protocol not approved to enroll prisoners, complaints from participants or others involved in the research that indicate unexpected risks or that cannot be resolved by the research team. This is not an exhaustive list.

Adverse event: Any physical, psychological or social harm to participants during the course of research. Unexpected: An event is "unexpected" when its specificity and severity are not accurately reflected in the informed consent document.

Related to the research: An event is "related to the research procedures" if in the opinion of the principal investigator, it was more likely than not to be caused by the research procedures or if it is more likely than not that the event affects the rights and welfare of current participants.

The problems or events above may be unanticipated risks to participants or others. The IRB needs this information to determine that risks to participants are minimized and are reasonable in relation to the anticipated benefits.

When to Use this Form: The Principal Investigator (PI) should complete and sign this form and submit it with related attachments for any event that falls into either Category A or Category B, below. If the PI is a student, the advisor must also sign. Please visit the following link for more information about AE/SAE: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html#Q2
Category A: Any *Serious Adverse Event* (SAE) that Occurs within 48 Hours of Participation in the Research

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Serious adverse events are those resulting in death, a life-threatening experience, hospitalization or prolongation of existing hospitalization, a persistent or significant disability or incapacity. Every serious adverse event must be reported on this form, even if the event does not appear to be associated with the research protocol. In addition, the IRB Chair at enamt@uapb.edu should be notified within 24 hours of discovery of any serious adverse event.

Category B: Any Adverse Event (AE) for which *All Three* of the Following are True:

1. **Risks to Participants or others have increased.** An event or outcome has occurred that has *resulted in harm* to the participant, has *affected the participant detrimentally*, has *worsened* a condition of the participant as a result of participation in the research, or that has resulted in *increased risk to the participant or to others*, whether or not the risk has actually resulted in harm (for example, misplacing a Participant's research records would constitute an increased risk event that should be reported).
2. **Unexpected Event**: An event or outcome that *was not described as a risk* of participation in the research, or, though described as a risk, has occurred with *unexpected severity or frequency*.
3. **Possibly, Probably, or Definitely Related Event:** An event or outcome that was *definitely related* to participation in the research or that it is *reasonable to conclude* was related to participation, or *that it is possible* to conclude was related to the research, but for which there is not enough information available at this time to assess the likelihood of this possibility.

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A. Study and PI Information			
IRB Number			
Date			
Principal Investigator (PI)		Email	
Department/School			
Protocol Title			
Faculty Advisor (If PI is a student)			

B. Sponsor/Funding Agency

Please fill out this section, if applicable.

Sponsor/Funding Agency:

Have you communicated with SPA regarding this incident? ☐ Yes ☐ No

Have the Sponsor/Funding Agency been notified of this event? ☐ Yes ☐ No

C. Incident Information

1. Type of Incident Please check all that apply.

The incident(s) must be reported to the IRB within 5 business days unless it is a Serious Adverse Event which must be reported within 24 hours after the incident.

- ☐ Breach of Privacy
- ☐ Breach of Data or Research Security
- ☐ Complaint Registered by Participant or Study Site
- ☐ Economic/ Social Harm
- ☐ Medical (Emergency, Hospitalization, Disability, Incapacitated, etc.)
- ☐ Possible FERPA Violation
- ☐ Possible HIPAA Violation
- ☐ Protocol Deviation
- ☐ Psychological Harm or Injury
- ☐ Other (Explain below):

2. Any Adverse Event/ or Serious Adverse Event?

☐ Adverse Event (AE) ☐ Serious Adverse Event (SAE) ☐ Not Applicable

Please visit the following link for more information about AE/SAE:
https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html#Q2

3. Start date		End date	

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4. Report Type	☐ initial ☐ follow-up (from previous reported event)

5. Was(were) any research team member(s) listed in the key personnel involved in this incident?

☐ Yes ☐ No

If yes, please list the name(s).

(name, affiliation, and role)

6. Was(were) any participant(s) involved in the incident?

☐ Yes, directly involved
☐ Yes, indirectly involved
☐ No

a. If participant(s) was(were) directly involved in the incident, please provide their information, if available.

(name, age, and contact information, if available)

b. Please check all that apply.

☐ The participant(s) completed the study
☐ The participant(s) continued to participate in the study.
☐ The PI withdrew the participant(s) from further participation.
☐ The participant(s) withdraw from the study.
☐ Other (explain):

7. Please provide a brief description of the event.

8. Please explain what corrective actions and preventative measures have been taken as a result of the incident (including revisions to the protocol, informed consent, and any other study documents).

D. Status of Research

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1. What is the status of the project?
   - ☐ Continue as planned without any modifications
   - ☐ Continue with changes
   - ☐ Suspend new participant enrollment until further assessment is complete
   - ☐ Terminate the study (all participants have been removed from the study and no data collection will occur

2. Is there any addition information IRB should know?

Submission for this IRB Research Related Incident Report Form must be signed by the Principal Investigator (and Faculty Advisor, if student is PI). Your electronic signature indicates your certification that the information provided in this document is accurate and current.

Name of the PI

Signature of the PI

Under the guidelines of HHS.gov
Adapted from University of Arkansas at Little Rock UALR (n.d.). Retrieved from https://ualr.edu/irb/irb-forms/
Adapted from Ball State University (n.d.). Retrieved from https://www.bsu.edu/about/administrativeoffices/research-integrity/research-proposals/irb-forms