

Institutional Review Board

Adverse Event Form

Use this form to report any serious adverse events or protocol deviations to IRB via email at irb@tamusa.edu. **Event forms must be submitted within 24 hours of the incident.** In the event of an injury or an exposure involving biological agents and materials, submit the incident report online at [TAMU System, Office of Risk Management](#).

IRB, an adverse event is defined as any event that results in potential harm/ increases risk to the subjects.

PI Name: Enter Here **IRB Protocol #:** Enter Here

Event Report

- A. **Type of report.** Indicate the type of report that you are filing (adverse event or protocol deviation).
Choose type of report
- B. **Date of event.** Select date
- C. **Personnel involved.** Please do not identify individuals by name. Provide only number of people involved and position titles (e.g. graduate student, post doc, facility maintenance worker.)
Enter personnel involved
- D. **Location of event.** Enter location (Building and room)
- E. **Description of incident.** Provide detailed description of adverse event or non-compliance event.
Enter description of event
- F. **Actions taken.** Describe actions taken immediately following the incident/violation and by whom.
Describe actions taken
- G. **Materials involved.** Describe any materials or equipment involved.
Enter materials involved
- H. **Equipment failure.** Indicate if equipment failure occurred.
Describe equipment failure
- I. **Risk.** Provide an explanation of the risk to people, animals, and environment.
Describe exposure risk
- J. **Protocol/ Procedure Specific Training.** Provide training received by the individual(s) including CITI and lab-based training.
Enter training and dates
- K. **Corrective Actions.** Describe the corrective actions implemented or planned to prevent future incidents.
Describe corrective actions
- L. **Parental/Guardian Notification.** If the event involved a minor, were the parents/legal guardians notified?
 Yes No

Assurances:

I assure the above information about the incident is accurate and complete. I agree to cooperate with any investigation of the incident and provide information to the IRB, or other federal, state, or local agencies having jurisdiction.

Signature of PI

Select date

Date

Form	Version: V.1
Title: Adverse Event Form/Protocol Deviation Form	
Authorized: Dr. Vijay Golla, Vice Provost for Research and Graduate Studies	
Date Approved by IO: March 29, 2023	