

**Adverse Event Form**

Use this form to report any serious adverse events or protocol deviations. Reports need to be submitted

as soon as possible after the PI learns of the event. Event forms need to be submitted within 24 hours.

**Adverse Event** - for the purposes of the Texas A&M University-San Antonio IBC, an adverse event is defined as any event that results in an exposure or release of a potentially harmful agent/organism. Such events may include, but are not limited to the following:

* Exposure to or release of recombinant DNA or a genetically modified organism,
* Release of a biohazard from containment within the lab e.g. a sealed container was broken, resulting in a bacterial spill or a power outage caused samples to thaw and leak out of a freezer.
* Release of a biohazard from the laboratory e.g. a lab coat contaminated with BSL-2 bacteria was worn outside the lab or an autoclave bag containing BSL-1 or BSL-2 organisms was split on the way to the autoclave.
* Potential for a laboratory acquired infection (LAI) e.g. a needle stick that occurred during the disposal of a needle used in a human blood draw or the exposure to an aerosol during the handling of a BSL-2 organism.

 **PI Name:** Enter PI **IBC Permit #:** Enter IBC permit #

 **Event Report**

1. **Type of report.** Indicate the type of report that you are filing (adverse event or protocol deviation).

Choose type of report

1. **Date of event.** Select date
2. **Personnel involved.** (Please do not identify individuals by name. Provide only gender and position titles (e.g. graduate student, post doc, facility maintenance worker.)

Enter personnel involved

A TAMUS Incident Report must be completed to report an injury or an exposure involving biological agents and materials. This form is completed online at [TAMU System, Office of Risk Management.](https://live.origamirisk.com/Origami/IncidentEntry/Direct?token=moTn1T4gmzSucpRjPWLlSBlYhna%2BEZfM8DJcYKUZjA2fxYtWZsSEGmSPadR8JS0FXS31Twf1BKpDooWOu6c7Dm9tu5hrx9uu7lW62wDsIfEIc5c7L1trKaB44vGNiWws)

Instructions for completing the form can be obtained from the [University Police web site](https://www.tamusa.edu/upd/documents/safety-injury-reporting-procedure.pdf).

1. **Location of event.** Enter location (Building and room)
2. **Description of incident.** Provide detailed description of adverse event or non-compliance event.

Enter description of event

1. **Actions taken.** Describe actions taken immediately following the incident/violation and by whom.

Describe actions taken

1. **Materials involved.** Describe the biohazardous agent or material involved in the incident, including vector type (e.g. adenovirus), vector subtype (e.g. type 5, relevant deletions), and any genomic alternations made (e.g. additions, deletions, inactivation without deletion).

Enter materials involved

1. **Equipment failure.** Indicate if equipment failure occurred and describe specifics.

Describe equipment failure

1. **Exposure risk.** Provide an explanation of the exposure risk to people, animals, and environment.

Describe exposure risk

1. **Medical attention.** Describe the medical attention provided to exposed/injured individuals. Include treatment received.

Describe medical attention/treatment

1. **Training.** Provide training (include Occupational Health) received by the individual(s) involved and the date(s) the training was conducted.

Enter training and dates

1. **PPE.** List the Personal Protective Equipment in use at the time of the incident event.

Describe PPE in use

1. **Corrective Actions.** Describe the corrective actions implemented or planned to prevent future incidents.

Describe corrective actions

1. **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 IBC, CDC, NIH, or other federal, state, or local agencies having jurisdiction.*

|  |  |  |
| --- | --- | --- |
|  |  | Select date |
| Signature of PI |  | Date |

Please return this form to the IBC at the Office of Research Compliance or by email at IBC@tamusa.edu