

University of Texas at Austin

Institutional Animal Care and Use Committee

IACUC Policy # 6.3

Title	Reporting Adverse Events		
Date of Approval	05-11-2020		
Date of Last Revision	N/A	Version	1.0

An adverse event is an instance of unanticipated (not in the approved protocol) signs or outcomes where there is direct harm to animals or personnel. Adverse events include debilitation, animal death, illness, distress, or trauma that exceeds normal expectations as described in the approved protocol. Examples include increased or unexpected morbidity or mortality or facility or weather-associated events (e.g., HVAC or power failure, flooding, fire) that negatively impact the welfare of an animal. **IACUC or veterinary staff may assist investigators in determining if an adverse event is reportable on an individual basis.**

6.3.1 Reporting of Adverse Events

The Principal Investigator and/or protocol personnel must report adverse events that affect animal welfare by using the criteria described above. The report should be submitted in eProtocol IACUC by completing and submitting the Adverse Event Form. The self-report should include the following information:

- full explanation of the situation, including what happened, when and where, the species of animal(s) involved, and the category of individuals involved (e.g., principal or co-principal investigator, technician, animal caretaker, student, veterinarian, etc.);
- description of actions taken by PI to address the situation; and description of short- or long-term corrective plans and implementation schedule(s).

The IACUC and veterinary staff will work with the investigator to modify the protocol or refine procedures in order to prevent future adverse events. If protocol noncompliance is discovered as a result of reporting an adverse event, it will be addressed as described in Policy 6.0.

Approval Date	Major Change(s) Approved
05-11-2020	<ul style="list-style-type: none"> • Title changed from “Non-Compliance with IACUC Protocol, Policies, Procedures, or Decisions” to “Reporting Adverse Events” • Original information relocated to IACUC Policy 6.0