

University of California, Merced
Institutional Animal Care and Use Committee Guidelines

Reporting Adverse Events or Unanticipated Outcomes

- I. **Purpose:** To standardize the procedures for reporting adverse events or unanticipated outcomes to the IACUC and Attending Veterinarian.
- II. **Regulations:** Both the PHS Policy (IV.C.5) and USDA Animal Welfare Regulations [9 CFR 2.31(d)(5)] require continued review of previously approved protocols. The IACUC, as a part of post-approval monitoring, requires investigators and animal care staff to notify the IACUC and Attending Veterinarian of any adverse events or unanticipated outcomes to animals during the course of the project.
- III. **Definition:**
Adverse event/unanticipated outcomes: Any happening that is not consistent with routine expected outcomes that results in any unexpected animal welfare issues (death, disease, or distress) or human health risks (zoonotic disease or injuries).
- IV. **Guidelines:** The IACUC expects that everyone involved in the care and use of animals is aware of the need to report and procedure to report adverse events and/or unanticipated outcomes. Reporting must be in a timely manner (as soon as possible) to identify ongoing trends, to ensure adequate veterinary care and to minimize the effect on animal welfare. Examples of adverse events and/or unanticipated outcomes include:
- Unexpected clinical signs, either related or unrelated to a protocol procedure
 - Unexpected euthanasia that is not part of the approved animal activities
 - Increased or unexpected morbidity or mortality
 - Surgical complications such as anesthetic deaths, infection or wound dehiscence
 - Phenotypes associated with transgenic animals (e.g., tumor development, early death) that negatively impact the welfare of an animal
 - Facility or weather-associated events (e.g., HVAC or power failure, flooding, fire) that negatively impact the welfare of an animal

Adverse events and/or unanticipated outcomes do not include those described in a protocol or amendment, as they are potentially expected from the animal activities. In addition, animals removed from study or euthanized under early removal criteria are not considered adverse events and/or unanticipated outcomes, as they are potentially expected from the animal activities.

If there is a question as to the need for reporting, the Attending Veterinarian or IACUC staff will be able to provide guidance.

- V. **Reporting:** To report an adverse event or unanticipated outcome:
- If immediate veterinary assistance is required, call the Attending Veterinarian at 1-530-304-5954
 - In all other cases, report adverse events or unanticipated outcomes directly to IACUC staff 1-209-228-4613 or Attending Veterinarian 1-530-304-5954.

When an Adverse Event/Unanticipated Outcome is received, the following steps occur:

- The IACUC is notified of the event. A member may request discussion by the full committee, in which case the report will be discussed at a fully convened IACUC

meeting. The Principal Investigator and Attending Veterinarian will be notified, if this has not already occurred.

- Based on veterinary and IACUC review, modifications to the protocol activities or other corrective actions such as additional training or post-approval monitoring may be required. Reporting to external agencies may be necessary depending on the type of event.