

IACUC Policy

IACUC ANIMAL ADVERSE EVENT POLICY

IACUC Reviewed and Approved: May 14, 2018

Policy

As part of their work under their San Diego State University (SDSU) Institutional Animal Care and Use Committee (IACUC) approved animal protocol, principle investigators are obligated to report animal-related adverse events to the IACUC when those events occur. With the awareness of each such event, the IACUC will work with the investigator to understand the circumstances for the event and as much as possible, make changes to avoid similar future events.

Definition of Adverse Event

An adverse event includes any unusual occurrences, unexpected or unanticipated problems, and illnesses or deaths not described or expected in the IACUC-approved animal protocol. Such events are interpreted to negatively impact animal well-being. For the purposes of this policy, these events include any such outcome that was not described as an expected or likely adverse outcome in the approved protocol. These types of events also include adverse outcomes that were described as expected or likely outcomes in the approved protocol, but occur at higher rates than originally anticipated.

This policy applies to all research or teaching activities whether being conducted in field or laboratory settings, regardless of where the animals are handled or housed.

Reporting to the IACUC

It is the responsibility of the Principal Investigator (PI) to promptly alleviate any pain associated with the event, then to promptly (no more than 24 hours later) report *any* adverse event to the IACUC Chair, IACUC administrative office, OLAC personnel and veterinarian(s) using contact information posted in each SDSU animal housing facility. In the case of ongoing animal injury, suffering or deaths, the report should be immediate.

The PI will provide a summary report of each adverse event using the SDSU IACUC “Adverse Event Report” form. The report will include:

- Date of event,
- Description of event, Including;
 - Number of animals affected,
 - Indicate the steps taken after notification/discovery of the event
 - Treatment given to affected animals (include administration of agents if any)
 - Animals euthanized
 - Evaluation and follow-up of surviving animals

- Explanation of the cause or potential causes for the adverse event
- How the event will be avoided in the future
- Any other relevant information that would help the IACUC in understanding the event.

OLAC staff or other witness to an adverse event, that is not part of the PI's research group can provide the details of the event to the PI and facilitate a plan to alleviate pain and distress.

Once notified, the veterinarian(s), OLAC staff, IACUC administrative office and the IACUC Chair will work with the research/teaching personnel to find and clarify the circumstances and cause of the event, and to determine whether a formal Adverse Event Report form needs to be filed with the IACUC. As part of that formal report, the PI, research and veterinary personnel will develop a resolution plan to ensure the well-being of the animals involved in the adverse event circumstances, currently and/or in the future, by circumventing or alleviating the impact of the circumstances that led to or caused the adverse event.

The formal Adverse Event Report will be completed and submitted by the PI to the IACUC even if the issue was initially reported to OLAC personnel or a veterinarian. The report is sent as an attachment to iacuc@sdsu.edu and it will be placed on the agenda for discussion at the next convened meeting to determine if further action needs to be taken.

Examples of adverse event which must be reported include, but are not limited to:

- Any clinical, experimental or surgical procedure that results in unexpected complications;
- Morbidity or mortality rates more than 10% higher than described in the protocol, regardless of the reason;
- Adverse events that may happen to animals during transit or related to housing.
- Equipment failure resulting in animal injury, illness or death
- Physical restraint of an animal that results in lesions, illness, or behavioral changes;
- Genetically modified or mutant animals that manifest a phenotype that negatively affects animal well-being;

Examples of potential resolutions which might be requested include, but are not limited to:

- Procedural modifications;
- More frequent monitoring intervals and/or additional types of monitoring parameters;
- Additional or modified humane endpoints;
- Change in anesthetic regimen;
- Updated description of expected or likely adverse outcomes in the approved protocol.

Examples of adverse outcomes that are not required to be reported as an adverse event include:

- Injury/illness unrelated to approved procedures and being treated by the clinical veterinarian(s).
- Death or morbidity of animals described as expected in the approved IACUC protocol.

Natural Disaster or Catastrophic Event

For more information about adverse or unexpected events that may occur as an act of nature or other catastrophic events see the [SDSU Disaster Plan](#).