



IACUC SOP:	TAMU-S-015	Title:	Review of Unanticipated or Adverse Event Reports		
		Location	Effective Date	Review By	
		College Station/Dallas/Galveston/Kingsville	07/01/2023	06/30/2026	
		Houston	08/01/2023	06/30/2026	

1. PURPOSE

- 1.1. To standardize procedures for the review of unanticipated or adverse events reported in animals overseen by the IACUC.

2. SCOPE

- 2.1. While noncompliance may be discovered through the Unanticipated or Adverse Event Reporting process, procedures related to noncompliance investigation and remediation are addressed in TAMU-S-012 and are outside of the scope of this document.

3. RESPONSIBILITY

- 3.1. The **AV** (or designee) is responsible for ensuring adequate veterinary care, including emergency euthanasia when appropriate, and may temporarily halt on-going animal activities to protect animals from immediate or on-going jeopardy to health or well-being.
- 3.2. The **IACUC Chair** (DMR) and **Attending Veterinarian** (VR) are responsible for reviewing initial Unanticipated or Adverse Event Reports submitted to the IACUC. This responsibility may be delegated to an appropriate designee as described in TAMU-S-002 and TAMU-S-006.
- 3.3. The **IACUC** is responsible for:
 - 3.3.1. Reviewing reported unanticipated or adverse events; and
 - 3.3.2. Assigning corrective actions as appropriate through the DMR or FCR process, such as protocol modification, additional training, oversight, or post-approval monitoring; or
 - 3.3.3. Suspending animal activities or protocols by majority vote at a convened meeting of a quorum of the IACUC (FCR); and
 - 3.3.4. Reporting incidents as applicable to the Institutional Official; and through the IO to federal regulatory agencies and AAALAC, as applicable.
- 3.4. The **AWO Staff** is responsible for coordination of the IACUC review of Unanticipated or Adverse Event Reports, communicating with personnel associated with the unanticipated/adverse event on behalf of the IACUC, and maintaining records or documents generated by the IACUC external to the online submission system used to manage Unanticipated or Adverse Event Reports. AWO staff may also assist the IACUC in drafting subcommittee reports, as well as reports to the IO, TAMUS, regulatory or accrediting bodies. Documents may be transmitted to the IO by AWO staff on behalf of the IACUC.
- 3.5. The **IO** is responsible for reviewing reports of unanticipated or adverse events when submitted by the IACUC and taking appropriate action, which may include temporarily halting on-going animal activities and reporting of incidents to ACURO, AAALAC and TAMUS, as applicable.

4. DEFINITIONS AND/OR ACRONYMS

- 4.1. **ACUP:** Animal Care and Use Program. Comprises all activities related to research, teaching and testing conducted by and at an institution that have a direct impact on the well-being of animals, including animal and veterinary care, policies and procedures, personnel and program management and oversight, occupational health and safety, IACUC functions, and animal facility design and management.
- 4.2. **ACURO:** Animal Care and Use Review Office of the United States Army Medical Research and Development Command.
- 4.3. **Ad-hoc Consultant:** Individual who is not an IACUC member, but who has sufficient training and experience to conduct an inspection or participate in a review or evaluation on behalf of the IACUC. Most often an experienced faculty member, veterinarian or AWO staff member, depending on the activity to be performed.



When ad hoc consultants are utilized, the IACUC remains responsible for the evaluation, determination of corrective action, and reporting of all findings.

- 4.4. **AUP:** Animal Use Protocol. Document submitted by the PI indicating the housing and research procedures involving animals.
- 4.5. **AV:** Attending Veterinarian. Individual designated by Texas A&M University to fulfil the regulatory role of AV. May also describe veterinary staff who report directly to, and have delegated authority from, the AV.
- 4.6. **AVP/RCO:** (TAMU) Associate Vice President for Research/Research Compliance Officer.
- 4.7. **AWO:** Animal Welfare Office. Supports the IACUC administratively.
- 4.8. **Core Support:** Individuals performing professional activities such as husbandry or technical services as a function of a dedicated service organization.
- 4.9. **DMR:** Designated member review. Review performed by qualified IACUC member(s) appointed by the IACUC Chair to serve as the designated reviewer(s) as described in TAMU-S-002.
- 4.10. **FCR:** Full committee review. Review and formal vote performed by a convened quorum of the members of the IACUC as described in TAMU-S-002.
- 4.11. **IACUC:** Institutional Animal Care and Use Committee. Institutional body responsible for ensuring adherence to federal regulation and institutional policy relating to the care and use of animals in teaching, testing and research. Appointed by the Institutional Official.
- 4.12. **Investigative Subcommittee:** Subcommittee authorized by the IACUC Chair (or designee) to collect information associated with a report or allegation. The subcommittee must include at least **one** IACUC member. Ad-hoc consultants may participate in the subcommittee at the IACUC Chair's request. Subcommittee member(s) must have no actual or perceived conflicts of interest. The Institutional Official also has the authority to convene an investigative subcommittee, if needed.
- 4.13. **IO:** Institutional Official. Individual within the University with the administrative and operational authority to commit institutional resources to ensure that the animal care and use program will comply with the requirements of federal regulation.
- 4.14. **Noncompliance:** Accidental or intentional failure to comply with state and federal regulations, System policies or regulations, University rules or procedures, IACUC guidance, or the requirements to conduct research, teaching or testing using animals; including adherence to the approved animal use protocol. **Serious noncompliance** has a negative impact on the welfare of an animal and/or is in direct violation of a federal standard regulating animal activities, including provisions of the Occupational Health and Safety Program, and may require reporting to federal regulators, funding agencies and accrediting bodies. (Also see Federal Notice NOT-OD-05-034 for examples of situations that constitute reportable noncompliance under the PHS Policy)
- 4.15. **PI:** Principal Investigator. The individual who has ultimate administrative and programmatic responsibility for the design, execution, and management of a project utilizing vertebrate animals.
- 4.16. **PR:** Primary Review. Pre-review performed by a qualified IACUC member(s) prior to review by FCR. Reviewer may be appointed by the IACUC Chair.
- 4.17. **SRS:** Sponsored Research Services. Consortium of research administrators supporting Texas A&M University System Members throughout the grant/award process.
- 4.18. **TAMUS:** Texas A&M University System
- 4.19. **Unanticipated or Adverse Event:** Any happening that is not consistent with routine expected outcomes that results in any unforeseen animal welfare issue that impacts the health or safety of animals (unintended injury or illness, unrelieved pain or distress, death). May require reporting to federal regulators and accrediting bodies.
- 4.20. **VR:** Veterinary review. Review performed by Attending Veterinarian or their designee, also a qualified veterinarian associated with the animal program.

5. PROCEDURE

- 5.1. Unanticipated or Adverse Event Reports ("Reports") are submitted to the IACUC as described in TAMU-G-015.

- 5.1.1. The AV is notified by the AWO staff in the event that a report indicates that the health or well-being of animals is in immediate or on-going jeopardy. The AV (or designee) will take immediate action to investigate the animal(s)/environment and has the authority to halt animal procedures, and if necessary to protect the animals from further harm, confiscate or remove animals from the control of the PI. The AV also has the authority to treat the animal, institute appropriate measures to relieve severe pain or distress, or perform emergency euthanasia.
- 5.2. Reports are reviewed by the IACUC as described in TAMU-S-002 with the following clarifications described herein.
- 5.3. Upon receipt of a Report, the AWO staff will review the incident to determine:
 - 5.3.1. Relevance to the ACUP:
 - 5.3.1.1. If not related or relevant to the ACUP, no action is taken by the IACUC, though the Report may be forwarded by the AWO staff to another department or unit, as appropriate. The Report, if submitted in iRIS or Huron, is withdrawn prior to IACUC review.
 - 5.3.1.1.1. The Report is routed for IACUC review when relevance to the ACUP is in question.
 - 5.3.2. If the incident is not a reportable event as described in TAMU-G-015:
 - 5.3.2.1. No action is taken by the IACUC when the incident is excluded from reporting requirements; for example, if the adverse event reported is already described in the approved AUP.
 - 5.3.2.2. The Report, if submitted in iRIS or Huron, is withdrawn prior to IACUC review.
 - 5.3.2.2.1. The Report is routed for IACUC review when exclusion from reporting as described in TAMU-G-015 is in question.
 - 5.4. If related/relevant to the ACUP and a reportable event as described in TAMU-G-015:
 - 5.4.1. Reports are automatically assigned to the IACUC Chair (or designee) for DMR (PR if called to FCR) and AV (or designee) for VR, though the IACUC Chair may assign additional IACUC members to perform DMR/PR as described in TAMU-S-002.
 - 5.4.2. When corrective actions (such as additional training, oversight, or post-approval monitoring) or needed modifications to the approved AUP are identified during the review of the Report, the Report review may be finalized as described in TAMU-S-002 prior to completion of the corrective actions and/or approval of the amendment at the discretion of the DMR or IACUC (if undergoing FCR).
 - 5.4.2.1. Examples of AUP modifications related to unanticipated or adverse events may include:
 - 5.4.2.1.1. Change in procedure(s) to avoid reoccurrence of the event; and/or
 - 5.4.2.1.2. Clarification of AUP adverse consequences when potential to recur; and/or
 - 5.4.2.1.3. Other modifications as determined by DMR/FCR review of the Report.
 - 5.4.3. Initiation of the IACUC noncompliance procedure described in TAMU-S-012 will occur (as a separate process) if the incident reported meets the threshold for potential serious or continuing noncompliance. The Report review may be finalized as described in TAMU-S-002 prior to completion of the IACUC's noncompliance review at the discretion of the Report DMR or IACUC (if undergoing FCR).
 - 5.4.3.1. Note: Minor or administrative noncompliance that is not serious or continuing will be addressed by the IACUC or AWO as a function of the Report process.
 - 5.4.4. In absence of a call for FCR, the IACUC Chair determines if the IACUC is to be informed of the outcome of Report review, with the following exception:
 - 5.4.4.1. The IACUC must be informed of the outcome of review for all Reports related to natural disasters, accidents, fire, mechanical or life-support equipment failure (HVAC, power, water) where no actual animal harm or death occurred. (Reports of this nature which include actual harm or death of animals are reviewed through the noncompliance process as described in TAMU-S-012 in alignment with NOT-OD-05-034.).
 - 5.4.4.2. Notification of the IACUC may occur at a convened meeting of a quorum of the IACUC or through another mechanism (electronic distribution, tele- or web-conference, etc.) as determined by the IACUC Chair.
 - 5.5. Notification and reporting of related/relevant reportable events:
 - 5.5.1. PI: The PI is notified of the outcome of Report review when the Report is finalized in iRIS/Huron.

- 5.5.2. Department Head/Dean: The applicable Department Head/Dean is notified by the IACUC Chair or AWO Director (or designees) of the nature of the Report and provided with a description of the IACUC review process at the discretion of the IACUC Chair (or designee).
- 5.5.3. IO and TAMUS:
 - 5.5.3.1. Notification concerning the receipt of a Report is made by the IACUC Chair, AV or AWO Director (or designees) to the IO and TAMUS through the AVP/RCO following the guidelines, timing and format established by the IO and/or TAMUS.
 - 5.5.3.2. A copy of the Report from iRIS/Huron along with an Outcome Report (AWO-F-004) outlining the results of DMR is submitted to the IO through the AVP/RCO by the IACUC Chair or AWO Director (or designees) where an initial notification was made to the IO/TAMUS. Alternatively, an Incident Report (AWO-F-003) is provided for Reports reviewed by FCR.
- 5.5.4. OLAW/USDA: No reporting anticipated through this process; IACUC review and reporting to be performed as described in TAMU-S-012 consistent with published reporting requirements.
- 5.5.5. ACURO: The IACUC Chair, AV or AWO Director (or designees) will promptly report applicable events to ACURO consistent with published reporting requirements and in consultation with the AVP/RCO on behalf of the IO. TAMU SRS is also notified about the outcome and notification to ACURO.
- 5.5.6. AAALAC: The designated Unit Contact (AWO Director), in consultation with the IACUC Chair, AV (or designees) and AVP/RCO on behalf of the IO, will include a description of the Report in the AAALAC annual report for the reporting period consistent with published reporting requirements.
- 5.5.7. Collaboration: The IACUC Chair, AV or AWO Director (or designees) will notify the applicable institution for inbound collaborations as outlined in the executed intrasystem agreement, interagency agreement, or MOU of the nature of the Report and review outcome (also see TAMU-S-017).
 - 5.5.7.1. A preliminary notification may be made by the AWO Director (or designee) to the collaborator as a courtesy or when outlined in the intrasystem agreement, interagency agreement, or MOU.

6. REFERENCES, MATERIALS, AND/OR ADDITIONAL INFORMATION

- 6.1. References/Resources:
 - 6.1.1. [USDA Animal Welfare Regulations 9 CFR Ch.1 Subpart C § 2.31](#)
 - 6.1.2. [PHS Policy on Humane Care and Use of Laboratory Animals](#)
 - 6.1.3. [Guide for the Care and Use of Laboratory Animals](#)
 - 6.1.4. [Guide for the Care and Use of Agricultural Animals in Research and Teaching](#)
 - 6.1.5. Notice [NOT-OD-05-034](#) Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals
 - 6.1.6. US Army Medical Research and Development Command Animal Care and Use Review Office (ACURO): [ACURO Reporting Guidance](#)
 - 6.1.7. [IACUC Guidebook, p. 154](#)
 - 6.1.8. TAMU Rule [15.99.07.M1](#) Use of Vertebrate Animals in Research, Teaching and Testing
- 6.2. Additional Materials:
 - 6.2.1. [AWO](#): (requires TAMU NetID authentication)
 - 6.2.1.1. AWO-F-003 IACUC Incident Report – FCR
 - 6.2.1.2. AWO-F-004 IACUC Outcome Report - DMR
 - 6.2.1.3. TAMU-G-015 Guidelines for Reporting Animal Concerns, Unanticipated or Adverse Events, and Potential Non-compliance
 - 6.2.1.4. TAMU-F-022 Reportable Event Form – Facility (not on web, available from AWO staff)
 - 6.2.1.5. TAMU-S-002 Mechanisms of IACUC Review, Veterinary Consultation and Confirmation
 - 6.2.1.6. TAMU-S-006 Composition, Appointment, Responsibilities, and Training of the IACUC
 - 6.2.1.7. TAMU-S-012 Investigation of Animal Welfare Concerns and Potential Noncompliance
 - 6.2.1.8. TAMU-S-017 Review and Approval of Collaborative and Contracted Animal Activities



7. HISTORY

Effective Date	Version #	Description
10/1/2020	000	College Station/Galveston: New document. Reviewed and approved via email.
11/2/2020	001	Houston/Kingsville: New document. Reviewed and approved via email.
03/16/2021	002	Dallas: New document
03/24/2022	003	College Station/Dallas/Galveston: Merging of Dallas animal care and use program with College Station/Galveston
10/20/2022	004	College Station/Dallas/Galveston/Kingsville: Merging of Kingsville animal care and use program with College Station/Dallas/Galveston.
07/01/2023	005	College Station/Dallas/Galveston/Kingsville: Renewal; updated definitions, clarification of when reports are provided to the IACUC, IO, Department Head, and outside entities. Reviewed and approved via TEAMS.
08/01/2023	006	Houston: Renewal; updated definitions, clarification of when reports are provided to the IACUC, IO, Department Head, and outside entities.