



IACUC Guidance:	<b>TAMU-G-015</b>	Title:	<b>Guidelines for Reporting Animal Concerns, Unanticipated or Adverse Events, and Potential Noncompliance</b>
-----------------	-------------------	--------	---

Location	Effective Date	Review By
<b>College Station/Dallas/Galveston/Kingsville</b>	03/01/2023	02/28/2026
<b>Houston</b>	04/01/2023	02/28/2026

**1. PURPOSE**

- 1.1. To standardize reporting procedures by participants in the animal program to the IACUC for incidents that impact the health or safety of animals to identify ongoing trends, ensure adequate veterinary care, and minimize the effect on animal welfare, such as:
  - 1.1.1. Concerns involving the care and use of animals including misuse or mistreatment;
  - 1.1.2. Unanticipated or adverse events connected to clinical care, animal husbandry, animal well-being, or the performance of IACUC approved activities for a specific research, teaching or testing animal use protocol;
  - 1.1.3. Potential noncompliance related to the performance of IACUC approved activities for a specific research, teaching or testing animal use protocol, or violation of existing animal care and use regulations.
- 1.2. This reporting process is not intended to be punitive, but rather an effort to facilitate research effectiveness and improve animal care and welfare.

**2. SCOPE**

- 2.1. This Guidance applies to the conduct of research, teaching or testing activities, or related purposes, involving animal use as defined in TAMU Rule 15.99.07.M1.
- 2.2. This Guidance does **not** apply to expected clinical signs, negative phenotypes, adverse consequences, or failure rates as described in the IACUC approved animal use protocol.

**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** is responsible for:
  - 3.2.1. Reviewing reported animal concerns, unanticipated or adverse events, and noncompliance; and
  - 3.2.2. Assigning corrective actions such as protocol modification, additional training, oversight, or post-approval monitoring; or
  - 3.2.3. Suspending animal activities or protocols if warranted; and
  - 3.2.4. Reporting incidents as applicable to the Institutional Official.
- 3.3. The **IO** is responsible for reviewing reports of animal concerns and serious or continuing noncompliance from the IACUC and taking appropriate action, which may include temporarily halting on-going animal activities and reporting of incidents to the USDA, OLAW, and the funding agency, as applicable.
- 3.4. **PIs** are responsible for:
  - 3.4.1. Notifying the AV or designee when animals need **immediate attention** so that the health and well-being of the animal is addressed in an expedient manner; with a follow up report to the IACUC or AWO.
  - 3.4.2. Notifying the IACUC and/or AWO as soon as possible after the discovery of any incident that **impacts the health or safety of animals**, including animal concerns, unanticipated or adverse events, and potential noncompliance as directed in TAMU Rule 15.99.07.M1.
  - 3.4.3. Ensuring protocol personnel are aware of the need and procedure for the timely reporting of misuse or mistreatment of animals, as well as potential violation(s) of existing animal care and use regulations.



- 3.5. **Animal Program Participants** are responsible for timely reporting of misuse or mistreatment of animals, as well as potential violation(s) of existing animal care and use regulations to their supervisor, IACUC, AV (or designee) and/or AWO.

#### **4. DEFINITIONS AND/OR ACRONYMS**

- 4.1. **Animal Concern:** Concern related to the care and use of animals at Texas A&M University. May be expressed verbally or in writing by a participant in the animal program, member of the institution, or general member of the public; and may be submitted anonymously or through a third-party hotline. May require reporting to federal regulators and accrediting bodies.
- 4.2. **AUP:** Animal Use Protocol. Document submitted by the PI indicating the housing and procedures involving animals.
- 4.3. **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.
- 4.4. **AWO:** Animal Welfare Office. Supports the IACUC administratively.
- 4.5. **Complainant:** A person who submits an animal concern or makes an allegation of noncompliance.
- 4.6. **Core Support:** Individuals performing professional activities such as husbandry or technical services as a function of a dedicated service organization.
- 4.7. **EthicsPoint:** A third-party risk, fraud and misconduct hotline contracted through the Texas A&M University System.
- 4.8. **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.
- 4.9. **IACUC Chair:** Chair of the IACUC appointed by the Institutional Official.
- 4.10. **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.
- 4.11. **Morbidity:** State of disease or ill health
- 4.12. **Moribundity:** State of dying/approaching death
- 4.13. **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.
- 4.14. **OLAW:** Office of Laboratory Animal Welfare. Provides guidance and interpretation of the Public Health Service (PHS) Policy on the Humane Care and Use of Laboratory Animals (Policy) for PHS-funded research and monitors compliance with the Policy by Assured Institutions.
- 4.15. **PAM:** Post-Approval Monitoring. Mechanism used for continuing IACUC oversight of animal activities within the animal care and use program.
- 4.16. **PI:** Principal Investigator. The individual who has ultimate administrative and programmatic responsibility for the design, execution, and management of a project utilizing vertebrate animals.
- 4.17. **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.

4.18. **USDA:** United States Department of Agriculture. USDA Animal Care, a unit under the Animal and Plant Health Inspection Service, administers the Animal Welfare Act (AWA) and associated Animal Welfare Act Regulations (AWAR).

4.19. **USDA Regulated:** Species or activities which fall under the AWA/AWAR.

## 5. GUIDELINES OR PROCEDURE

### 5.1. General Comments

5.1.1. Texas A&M University is strongly committed to the humane and ethical care and use of animals in research, testing, and teaching, and complies with all applicable federal, state and local laws, regulations, policies and guidelines to ensure appropriate standards are upheld. Ensuring animal welfare and maintaining programmatic compliance is a shared responsibility between all members of the animal care and use program.

5.1.2. All allegations of animal abuse, misuse, mistreatment and noncompliance are taken seriously and investigated by the IACUC, even if the complainant chooses to remain anonymous.

5.1.3. Reports should be made in a timely manner to identify ongoing trends, to ensure adequate veterinary care, and to minimize the effect on animal welfare. Events that impact the health or safety of animals should be reported as soon as possible after discovery of the event.

5.1.4. In all cases where an animal's immediate health or welfare is threatened, the AV or veterinary designee has the authority to act on behalf of the animal's welfare, up to and including immediate euthanasia.

### 5.2. Animal Concerns and Potential Noncompliance

#### 5.2.1. Examples of reportable events

5.2.1.1. Conditions that jeopardize the ongoing health or well-being of animals, or that have caused injury, harm, or death of animals, including those caused by negligence and/or accidents

5.2.1.2. Performance of animal-related activities without current IACUC approval (e.g.: lack of AUP, expired AUP, activities not described in AUP, or activities not performed as described in AUP) with or without perceived harm to animals

5.2.1.3. Failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures)

5.2.1.4. Failure to ensure death of animals after euthanasia procedure (e.g., animal recovers from euthanasia)

#### 5.2.2. Mechanisms for reporting Animal Concerns or Potential Noncompliance

5.2.2.1. Animal Concerns and reports of Potential Noncompliance may be relayed in-person, on the phone, or in writing via email, memo or letter to the IACUC Chair or any member of the IACUC, the Attending Veterinarian or designee, and/or AWO Director or any member of the AWO staff; however, animals in immediate danger should be reported directly to the Attending Veterinarian or on-call veterinarian whenever possible.

5.2.2.2. Animal Concerns and reports of Potential Noncompliance may be submitted remotely through the Research Compliance & Biosafety webpage and may be anonymous.

5.2.2.3. Events that do not present an immediate threat to life of property may also be anonymously reported through EthicsPoint.

5.2.2.4. Reports of Potential Noncompliance may be submitted using the iRIS IACUC Reportable Event Form (PI or protocol personnel) or TAMU-F-022 (AV or designee, core support or vivarium staff).

5.2.2.5. See Section 6 for reporting contact information. *Animal Concerns* posters are available for review throughout the animal housing areas and contain reporting contact information.

#### 5.2.3. Additional Comments

5.2.3.1. Individuals who observe misuse or mistreatment of animals and/or potential noncompliance are strongly encouraged to report concerns to the IACUC, the AV (or designee) or the AWO staff as described below. It is helpful for the IACUC to have as much information as possible about the Animal Concern or Potential Noncompliance in order to conduct a thorough investigation.

- 5.2.3.2. Reports of Animal Concerns and/or Potential Noncompliance are confidential, to the extent permitted by law. Treatment of complaints will comply with state and federal whistleblower policies, nondiscrimination against the concerned/reporting party, and protection from reprisals, as applicable.
- 5.2.3.3. Individuals or groups whose animals or activities are the subject of the Animal Concern and/or Potential Noncompliance are expected to cooperate with the IACUC's designated investigators fully and respond promptly to any inquiries, correspondence or requests for interview(s).
- 5.2.3.4. The IACUC is apprised of the outcome of all investigations taken on its behalf and may require additional corrective actions. Based on the outcome of the IACUC's review, modifications to the protocol's activities, or other corrective actions such as additional training, post-approval monitoring, or suspension of the activities or protocol, may occur.
- 5.2.3.5. The Complainant, when not anonymous, may be apprised when the Animal Concern and/or Potential Noncompliance has been addressed and closed by the IACUC, though details will be withheld as necessary to maintain confidentiality.
- 5.2.3.6. Substantiated Animal Concerns and incidents of Serious or Continuing Noncompliance are reported by the IACUC to the IO, and may require additional reporting to federal regulators, funding agencies and accrediting bodies.
- 5.2.3.7. The Department Chair or Dean may be informed of Animal Concerns and/or Noncompliance where immediate action is required to protect animal welfare or address serious or continuing noncompliance.

**5.3. Unanticipated or Adverse Events**

- 5.3.1. Include increased or unanticipated morbidity, moribundity or mortality related to IACUC-approved procedures, as well as other conditions that jeopardize the health or well-being of animals such as natural disasters, accidents, and mechanical failures resulting in actual harm or death to animals or personnel.

**5.3.2. Examples of reportable events**

- 5.3.2.1. Unexpected clinical signs (including negative phenotype), morbidity, or moribundity not described within the AUP that are the result of research or teaching procedures or activities.
- 5.3.2.2. Performance of euthanasia when not described within the AUP (no planned or emergency euthanasia selected or described) and/or that is unsuccessful (e.g.: failure to ensure death during the initial procedure).
- 5.3.2.3. Unexpected or increased rate of mortality due to research or teaching procedures or activities:
  - 5.3.2.3.1. **Unexpected mortality** (e.g.: no expected death loss described in the AUP):
    - 5.3.2.3.1.1. **USDA regulated animals:** Any unexpected death
    - 5.3.2.3.1.2. **Non-USDA regulated animals:** Loss greater than 20% (fish) or 10% (all other species) of the animal subjects involved in research or teaching activities within a defined group (e.g.: study, population, class, etc.)
  - 5.3.2.3.2. **Increased rate of mortality:**
    - 5.3.2.3.2.1. **USDA regulated animals:** Any additional mortality beyond what is described in the protocol
    - 5.3.2.3.2.2. **Non-USDA regulated animals:** Mortality greater than 10% of that described in the IACUC protocol (e.g.: 20% expected death loss described in protocol + 10% additional death loss results in reporting when death loss exceeds 30%)
- 5.3.2.4. Facility issues that jeopardize or negatively impact the health or well-being of animals such as disruption of service, mechanical or life-support equipment failure, natural disasters, or weather-associated events. AV (or designee) must also be notified. Examples include, but are not limited to:
  - 5.3.2.4.1. HVAC or power failure

- 5.3.2.4.2. Destruction or damage to integrity of facility structure through flooding, fire, wind, etc. that renders the facility unsafe or uninhabitable.
- 5.3.2.4.3. Inability to provide daily husbandry or veterinary care
- 5.3.2.4.4. Extremes in heat or cold exposure in animals housed out of doors leading to euthanasia or death of impacted animals
- 5.3.2.4.5. Disruption of automatic watering system leading to lack of water or flooding of cages
- 5.3.2.5. Any other unanticipated or adverse event where the IACUC requests the submission of a report from the PI or facility

**5.3.3. Examples of events that are not required to be reported**

- 5.3.3.1. Expected clinical signs, negative phenotype, application of early removal criteria, morbidity, moribundity or death of animals, when as described in the IACUC approved protocol. (See TAMU-G-001 for more information regarding choosing appropriate endpoints.)
- 5.3.3.2. Animal injury, illness, or death unrelated to research or teaching procedures or activities when appropriate quarantine, preventive medical, surveillance, diagnostic, and therapeutic procedures were in place and followed do not need to be reported to the IACUC but must be reported to the AV (or designee).
- 5.3.3.3. Death of animals that have reached the end of their natural life spans.

**5.3.4. Mechanisms for reporting an Unanticipated or Adverse Event**

- 5.3.4.1. Report Unanticipated or Adverse Events using the iRIS IACUC Reportable Event Form (protocol personnel) or TAMU-F-022 (AV or designee, core support or vivarium staff).
- 5.3.4.2. If there is a question as to the need for reporting, the AV or designee, or Animal Welfare Office staff will be able to provide guidance.
- 5.3.4.3. It is appropriate to seek assistance from the AV (or designee) when Unanticipated Adverse Events occur. The AV or designee can assist in assessing the situation, identifying a resolution, and providing guidance on completion of the iRIS report or TAMU-F-022 (as applicable).
  - 5.3.4.3.1. For immediate veterinary assistance, call ARU/CMP/PAR/PRF veterinary staff (see contact info in Section 6).
  - 5.3.4.3.2. Consultation with the Attending Veterinarian or designee **MUST** occur when pain or distress is beyond the level anticipated in the protocol description or when interventional control (such as analgesics) is not possible.

**5.3.5. Additional comments**

- 5.3.5.1. Based on the outcome of the IACUC's review, modifications to the protocol's activities, or other corrective actions such as additional training, post-approval monitoring, or suspension of the activities or protocol, may occur. Activities leading to the Unanticipated Adverse Event may be determined by the IACUC to be noncompliant with the approved AUP or animal regulations.
- 5.3.5.2. Unanticipated or Adverse Events may be reported by the IACUC to the IO; and require reporting to federal regulators, funding agencies and accrediting bodies.

**6. REFERENCES, MATERIALS, AND/OR ADDITIONAL INFORMATION**

6.1. References/Resources:

6.1.1. OLAW:

- 6.1.1.1. [PHS Policy on Humane Care and Use of Laboratory Animals](#)
- 6.1.1.2. [Guide for the Care and Use of Laboratory Animals](#)
- 6.1.1.3. [Reporting Noncompliance](#)
- 6.1.1.4. Notice [NOT-OD-05-034](#) Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals

6.1.2. USDA:



6.1.2.1. [Animal Welfare Regulations 9 CFR Ch.1 Subpart C § 2.31](#)

- 6.2. TAMUS: [EthicsPoint](#)
- 6.3. TAMU:
  - 6.3.1. TAMU Rule [15.99.07.M1](#) Use of Vertebrate Animals
  - 6.3.2. Research Compliance & Biosafety – Animals: [Report a Concern](#)
- 6.4. Contacts:
  - 6.4.1. Animal Welfare Office - 979.845.1828 or [animalcompliance@tamu.edu](mailto:animalcompliance@tamu.edu)
  - 6.4.2. Contacts for AV/Designee by campus:
    - 6.4.2.1. College Station/Galveston (CMP): (979) 845-7433
    - 6.4.2.2. Dallas (ARU): (214) 828-8149
    - 6.4.2.3. Houston (PAR): (713) 677-7471
    - 6.4.2.4. Kingsville (PRF): (361) 221-0770
- 6.5. Additional Materials:
  - 6.5.1. TAMU-C-008c Protocol Review Checklist - USDA or Not Addendum
  - 6.5.2. TAMU-F-002 Reportable Event Form – Facility (available from AWO staff)
- 6.6. Acknowledgements
  - 6.6.1. This document was partially adapted using materials obtained from Washington State University and the Ohio State University.

**7. HISTORY**

Effective Date	Version #	Description
10/01/2020	000	College Station/Galveston: New document. Reviewed and approved via email.
11/2/2020	001	Houston/Kingsville: New format and content; replaces IBT-112 & 211. Reviewed and approved via email.
12/15/2020	002	Dallas: New format and content; replaces CD-112 & 211
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.
03/01/2023	005	College Station/Dallas/Galveston/Kingsville: Renewal; updated definitions, clarification of reportable and not reportable event examples, addition of TAMU-F-022 throughout. Reviewed and approved via email.
04/01/2023	006	Houston: Renewal; updated definitions, clarification of reportable and not reportable event examples, addition of TAMU-F-022 throughout. Reviewed and approved via email.