



IACUC GUIDELINE:	Managing reported concerns related to the use of animals in research, teaching, and all other activities		
Guideline #	ACUP-120.00	IACUC Approval:	July 13 2016

Purpose:

The IACUC must review and address any reported concerns related to the use of animals in research, teaching and demonstration, to help ensure that animals are used appropriately and receive humane care and treatment in accordance with the highest ethical standards, laws, regulations and policies governing animal care and use. This policy outlines the process for managing such concerns.

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- E. The current version of the Guide for the Care and Use of Agricultural Animals in Research and Teaching

1) Guideline:

The following guidelines document the principles for addressing concerns related to the humane care and use of animals in research, teaching and demonstration at Texas A&M University-Commerce.

- A. IACUC Guideline ACUP 110: Reporting Animal Welfare Concerns
- B. IACUC Guideline ACUP 100: Texas A&M University-Commerce Whistleblower Policy

Concerns about animal care and use, or the reporting of instances of suspected non-compliance with laws, rules, regulations and policies can be reported to the IACUC office directly, in writing (iacuc@tamuc.edu), by phone (903-886-5766), online at <http://www.tamuc.edu/research/forms/animalCareForm.aspx> or anonymously via the Texas A&M University-Commerce Ethics Point Hotline. The Whistleblower Policy and contact information are posted in all animal facilities at Texas A&M University-Commerce. The University prohibits unlawful retaliation against employees as a consequence of good faith actions in the reporting of, or the participation in an investigation pertaining to, allegations of wrongdoing.

2) Procedures

A. Reporting Criteria, methods and procedures:

- 1. Examples of reportable situations and activities include:
 - Situations where animals may be in immediate, actual or perceived jeopardy.



- Situations involving alleged violations of the Animal Welfare Regulations (“AW Regulations”) or the Texas A&M University-Commerce 15.99.07.R1 Use of Vertebrate Animals

- Situations involving procedural violations or protocol non-compliance, including but not limited to, performing unauthorized surgery or other procedures not listed on a protocol, allowing persons not approved on protocols to participate in animal use, giving animals drugs that the IACUC has not approved, or conducting other activities involving animals that are not pre-approved for the involved personnel on an AUP or ACUP or conducted under the AV's supervision as part of the veterinary care program.

2. An actual or suspected concern related to animal welfare can be reported to the IACUC office directly, in writing (iacuc@tamuc.edu) by phone (903-886-5766), or anonymously via the Texas A&M University Hotline. If a concern is reported orally, the individual who receives the phone call should document the circumstances fully to ensure that the issues are clear and to prevent any potential misunderstandings. The report will be shared with the IACUC chair and IO (Institutional Official) and the AV for further action.

3. Information relating to an open inquiry or investigation will be shared only with others at the University (or at a University-affiliated organization whose animal program is covered by the IACUC) who have a need to know, those who are involved in or necessary to the investigative process, and with federal agencies, as required.

4. It should be understood by all University personnel and animal care and use program participants that participation in the animal care and use program is a privilege that is extended to PIs and other individuals by the IACUC under conditions of voluntary compliance and submission to IACUC authority, and an implied or explicit promise to cooperate with the IACUC and AV and abide by their instructions.

B. Initial evaluation and actions by the IACUC:

1. Upon review of the reported concern, the IO, IACUC Chair, or the Attending Veterinarian will determine if immediate action is required or if routine IACUC investigative procedures will be followed.

2. If the reported concern falls into any of the categories listed below, immediate action is required and must be initiated by the IO, AV, IACUC Chair or Designate to mitigate safety, security or health concerns:

- Conditions that may jeopardize the health or well-being of animals should be evaluated and acted upon immediately. In such cases, the IO, IACUC Chair, Attending Veterinarian (each individual) is authorized severally to halt procedures, including procedures listed on previously IACUC-approved AUPs, that, in his/her/their judgment, do not comply with institutional policies OR represent an unexpected or unpredicted level of risk to animal health or well-being, until the IACUC can be convened to review the matter.

- Conditions that reportedly jeopardize the health or well-being of animals should be evaluated and acted upon immediately. In such cases, the IO is authorized to temporarily suspend faculty, staff, students or community members from animal activities who, in his/her judgment, do not comply with institutional policies until the IACUC can be convened to review the matter. Animal activities in this context may also include the supervision of other personnel in any given animal care and use activity (including on approved AUPs). This suspension may carry the additional sanction of the individual being temporarily barred from entering any or all A&M Commerce animal facilities if the IO feels that this is critical to maintaining the safety of animals or personnel or the integrity of the animal care and use program.

- Situations that may involve potential criminal activity, human safety or security of Texas A&M University-Commerce property are evaluated immediately by the institution's compliance or occupational health and safety officials, or law enforcement authorities, as appropriate. In this case, the IACUC retains authority over animal care and use aspects of the potential violations, and will work in tandem and in cooperation with other University bodies or other appropriate authorities.

3. Allegations of other ongoing policy or procedural matters, or other situations that do not involve apparent immediate danger to animals may not require such immediate attention, but nonetheless must be investigated promptly.

4. In all cases, the IO will make a preliminary report to the Office of Laboratory Animal Welfare (OLAW) promptly, if required by PHS Policy (referenced below). The IO will also report to USDA APHIS officials, as indicated by regulation and USDA Regulatory interpretation.



5. After an initial action, a report must be submitted to the IACUC for review of issues related to animal care and use. Emergency meetings of the IACUC may be called as necessary.

- Upon receipt of the reported concern, the IACUC Chair or Designate will lead the investigation, working with the AV and the IACUC staff to gather as much information as possible to inform the IACUC of the relevant details. The IACUC Chair, will, at his or her discretion, involve a subcommittee of the IACUC in the collection and review of the information. The initial report will ideally contain a description of the incident, including the species and the number of animals, potential infractions, corrective actions that were implemented or are in progress, and any follow up actions that may be required. This process may include consultation with the PI and the research staff, members of the Veterinary staff, animal care staff and any other individuals who may have information pertinent to the incident. Information required by the IACUC will vary depending on the circumstances, but may involve:

- (a) Interviewing complainants (if known), any persons against whom allegations were directed, members of the research team, veterinary staff, the PI's department head, and any other pertinent program officials;
- (b) Observing the animals and their environment;
- (c) Reviewing any pertinent records, (e.g., animal health records, protocols, and other documents); and
- (d) Consulting with appropriate experts. Appropriate experts may include veterinary specialists, research subject matter experts, regulatory experts, law enforcement personnel, University-retained attorneys, or others.
- (e) It should be noted that the IACUC has the authority to request testimony from any member of the University community who may have information of concern to the animal care and use activity under investigation, even when the member may not be a direct participant in the animal care and use program; for example, administrative staff, administrative superiors of animal care and use program personnel, students, or other pertinent witnesses.
- (f) The University should make all reasonable attempts to assist the IACUC in requesting and receiving any and all physical, documentary, and testimonial evidence that is pertinent to cases being investigated by the IACUC.

- Generally, the investigation will result in a report detailing the investigators' findings and recommendations, which will be sent to the IACUC Chair, IO, AV and other institutional officials, as appropriate, and reviewed at the next convened IACUC meeting for further determination of actions. The report will typically include:

- (a) A description of the concern(s);
- (b) The results of any interviews that were conducted;
- (c) The condition of the animals and their environment;
- (d) The results of document reviews;
- (e) Copies of all supporting documentation including correspondences, reports, animal records, and any other pertinent materials; and
- (f) Conclusions regarding the substance of the concerns vis-à-vis requirements of the AWRs, the PHS Policy, the Guide, institutional policies and procedures, and recommended actions, if appropriate.

6. The Chair of the IACUC and the AV shall review, and then submit, the report to the IACUC during a convened meeting. After initial review of the report, the IACUC shall determine subsequent actions that are required, including notifications or reporting (either internal or external). The IACUC will report all investigative outcomes to the IO.

The following categories of actions are possible:

- No credible concern related to noncompliance or animal welfare: Close the report with No action:
 - (a) If the IACUC determines that no further action such as reporting or follow up is required, the discussion is documented in the minutes of the IACUC meeting and the IO is notified. No further action is taken.
- Confirmed case of non-compliance and/or animal welfare: No further investigation required:
 - (a) If the IACUC determines that the incident constitutes serious non-compliance or an unresolved animal welfare concern, and that no further investigation is needed to determine causes and corrective actions, it may make a decision based on the information provided in the report. Please refer to the section "Outcomes and final actions" for possible courses of action that the IACUC may take.
- Incomplete or insufficient information to make a determination: Further investigation required:
 - (a) If deemed necessary by the IACUC, then the Chair, a subcommittee or an individual appointed by the Chair will conduct a further investigation on the facts and circumstances related to the incident and report back to the



IACUC by an assigned completion date. Special care will be taken to avoid actual or perceived conflicts of interest in this process.

6. Notifications

- The PI responsible for the protocol ordinarily shall be provided with notice of the investigation, and an opportunity to provide relevant information to the investigators and to the IACUC.
- Other Animal Care and Use Program participants who are the subject of investigations may be notified at the time of their testimony to the IACUC that their activities are the subject of the complaint under investigation.

C. Outcomes and final actions

1. The IACUC shall review all reports from the investigation or initial report (in cases where further investigation was not required) and any information provided by the PI or other personnel under investigation before reaching a decision. After evaluating these materials, the IACUC may request additional information and/or take action with respect to the investigation, including but not limited to the following:

- Dismissal of the complaint/concern for lack of evidentiary support or lack of impact on animals or the program;
- Requirement of submission and approval of a protocol amendment, or placement of specific additional conditions or stipulations on the protocol;
- Imposition of specific remedial education and training for the PI and/or other personnel listed under the protocol;
- Increased Post Approval Monitoring of research, testing, or training that involves animals;
- Temporary revocation of an individual's privileges to provide animal care or to conduct research, testing, demonstration or training (or any other animal care or use activity) that involves animals, pending compliance with specific, IACUC-mandated conditions;
- Issuing letters of reprimand to the PI or to individual personnel listed on AUPs or who are otherwise part of the program;
- Restricting research practices, such as limiting the PI to conduct studies with certain procedures, eliminating the approval to conduct specific procedures, or conduct research under supervision;
- Suspension of approval for one or more of the PI's studies and establishment of conditions for reinstatement;
- Termination of approval for one or more of the PI's studies; meaning significant noncompliances in one study / AUP held by a given PI could result in the termination of other AUPs held by the same PI.
- Permanent revocation of privileges for a PI or any other individual to provide animal care or to conduct research, testing, demonstration or training that involves animals; and
- Recommending to the Institutional Official that institutional (e.g., reassignment to non-animal care and use positions, or temporary or permanent suspension from the animal care and use program, or termination of employment) sanctions be imposed.

- The above outcomes apply not only to personnel whose approvals to participate in the animal care and use program reside under approved AUP activities, but also apply to personnel whose participation is based in animal care or husbandry or other non-research/non-teaching or support activities of the animal care and use program. This includes personnel whose job description may explicitly involve animal care and use.

2. The IACUC will notify the PI in writing of any action taken by the IACUC and the reasons for that action. In addition, the IACUC will notify, as it deems appropriate:

- Other investigators involved in the animal care and use activities at issue;
- The PI's department head (and any additional department heads where the PI holds multiple professional appointments);
- Any additional departments involved in the research;
- The direct supervisor of personnel involved in animal care and use program disciplinary sanctions in cases where the individual's job directly involves husbandry or husbandry management;



- The Institutional Official (who will contact any additional institutional authorities) and other pertinent program officials as required (such as appropriate supervisory and management staff, the public affairs office, the compliance office, the office of the general counsel);
 - Any funding, regulatory or accreditation agencies, as required.
3. The PI or other suspended employee may elect to respond in writing to the final report to the Chair of the IACUC if he/she would like to appeal the IACUC decision or present further information related to the incident. The IACUC may reconsider the case one time. The IACUC's decision is final and can't be overruled by any other authority.
4. As participation in the animal care and use program involves voluntary compliance and cooperation with the IACUC, no PI or other personnel will be allowed to provide third party representation, legal or administrative or otherwise, during IACUC proceedings and / or investigations.
5. Refusal to cooperate with IACUC investigations, including refusal to testify upon request, refusal to provide documentary or other evidence, or refusal to cooperate without precondition, may be interpreted by the IACUC as a revocation of an individual's voluntary cooperation and compliance with the IACUC in the program, and may be cause for IACUC removal of some or all of that individual's animal care and use privileges as noted above in this section.

D. Suspension of Protocol

1. As indicated above, the IACUC is empowered to suspend a protocol if it finds violations of the PHS Policy, Guide, Assurance, or Animal Welfare Regulations. Suspension may occur only after review of the matter at a convened meeting of a quorum of the IACUC, and with a vote for suspension from a majority of the quorum present. In addition, the PI may (and in appropriate cases will be encouraged to) agree to voluntarily suspend his/her protocol pending review by the IACUC. If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW and any federal agency funding that activity. At the time of suspension of a protocol, the IACUC will vote on terms for reactivation of the protocol. The IACUC may vote for the IACUC Chair to be empowered to reactivate the protocol at his/her discretion or it can vote that the Committee itself must approve reactivation. Protocols will be reactivated only after violations have been corrected.
2. As noted above, the IACUC Chair, the AV and the IO each retains the statutory authority to temporarily halt animal care and use activities, even those conducted under a previously approved protocol, in the event that those activities may present an unexpected or more severe than expected danger to animal health or well being. These administrative suspensions are temporary and are valid until the IACUC is able to take up the issue of concern and propound new guidance or approvals, or withdrawal of approval, or other suspensions as indicated by IACUC deliberation and decision.

E. Reporting noncompliance, deviations from the Guide and suspensions

1. Circumstances that must be reported to OLAW by the Institutional Official, are:
- serious or continuing noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals ("the PHS Policy");
 - serious deviations from the NRC-ILAR's Guide for the Care and Use of Laboratory Animals ("the Guide"); and
 - suspensions of protocols by the IACUC.

F. Allowable charges to NIH grants during periods of non-compliance

1. "The Office of Management and Budget Cost Principles and the NIH Grants Policy Statement (NIHGPS) do not permit charges to grant awards for the conduct of live vertebrate animal activities during periods of time that the terms and conditions of the NIHGPS are not upheld. In cases where charges have been made for unauthorized animal activities, appropriate adjustments must be made to the grant to remove those charges." Therefore, if the incident relates to conduct of non-approved procedures on a protocol being funded with NIH funds, charges to the grant related to the animal activities related to the incident will require removal. The PI will need to work with the



facility staff to determine the amount of the charges. The IACUC office will work with Sponsored Financial Services (SFS) and the PI to process the financial transaction and report it to the funding agency as required.

Regulatory Mandates and Guidelines

A. Federal Requirements Regarding the Reporting of Animal Care and Use Concerns: USDA – Animal Welfare (9 CFR Ch.1)

1. Part 2 - Subpart C 2.31 (c) IACUC Functions. With respect to activities involving animals, the IACUC, as an agent of the research facility shall:

(4) Review, and if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees;

2. 2.31 (d)

(6) The IACUC may suspend an activity that it previously approved if it determines that an activity is not being conducted in accordance with the description of that activity provided by the principal investigator and approved by the Committee. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present;

(7) If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any federal agency funding that activity.

3. 2.32 Training and Instruction of personnel must include

(4) Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care or treatment reported by any employee of the facility. No facility employee, Committee members, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations or standards under the Act. 4.

4. 2.33 (2) Each research facility shall assure that the attending veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use. (USDA provides the authority and responsibility to the attending veterinarian to temporarily suspend an activity involving animals.)

B. Public Health Service (Implementation of Public Law 99-158)

1. B. Functions of the IACUC

•4. Review concerns involving the care and use of animals at the Institution;

2. C. IACUC Review of PHS-conducted or Supported Research Projects

•6. The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, the institution's Assurance, or IV.C.l.a-g of this Policy. The IACUC may suspend an activity only after a review of the matter at a convened meeting of a quorum of the IACUC and with the Suspension vote of a majority of the quorum present.

•7. If the IACUC suspends an activity involving animals, the Institutional Official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW

3. F. Reporting Requirements

•3. The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

a. any serious or continuing noncompliance with this Policy;

b. any serious deviation from the provisions of the Guide;

c. any suspension of an activity by the IACUC

C. Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals



1. <http://grants.nih.gov/grants/guide/notice-files/not-od-05-034.html>

2. *Examples of reportable situations:*

- conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals;*
- conduct of animal-related activities without appropriate IACUC review and approval;*
- failure to adhere to IACUC-approved protocols;*
- implementation of any significant change to IACUC-approved protocols without prior IACUC approval as required by IV.B.7.;*
- conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete review under IV.C is required at least once every three years);*
- conduct of official IACUC business requiring a quorum (full Committee review of an activity in accord with IV.C.6) in the absence of a quorum;*
- conduct of official IACUC business during a period of time that the Committee is improperly constituted;*
- failure to correct deficiencies identified during the semiannual evaluation in a timely manner;*
- chronic failure to provide space for animals in accordance with recommendations of the Guide unless the IACUC has approved a protocol-specific deviation from the Guide based on written scientific justification;*
- participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as required by IV.C.1.f;*
- 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);*
- failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);*
- failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO₂);*
- failure of animal care and use personnel to carry out veterinary orders (e.g., treatments); or*
- IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the Guide, or the institution's Animal Welfare Assurance.*

3. *OLAW recognizes that there may be levels of morbidity and mortality in virtually any animal-related activity, including those associated with the care and use of animals in research, testing, and teaching that are not the result of violations of either the Policy or the Guide. OLAW offers the following examples of situations which may not meet the threshold for reporting, based on consideration of the circumstances by the IACUC.*

Examples of situations not normally required to be reported:

- death of animals that have reached the end of their natural life spans;*
- death or failures of neonates to thrive when husbandry and veterinary medical oversight of dams and litters was appropriate;*
- animal death or illness from spontaneous disease when appropriate quarantine, preventive medical, surveillance, diagnostic, and therapeutic procedures were in place and followed;*
- animal death or injuries related to manipulations that fall within parameters described in the IACUC approved protocol; or*
- infrequent incidents of drowning or near-drowning of rodents in cages when it is determined that the cause was water valves jammed with bedding (frequent problems of this nature, however, must be reported promptly along with corrective plans and schedules).*

History:

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