**ENVIRONMENTAL HEALTH AND SAFETY**
**STANDARD OPERATING PROCEDURES**

**SOP No. 15.99.05.W1.07AR Potential Non-Compliance in the Course of Vertebrate Animal Care and Use Research**
Approved: November 20, 2013
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Environmental Health and Safety at WTAMU is composed of two distinct but integrated environmental safety departments that report to the Vice President of Research and Compliance. Academic and Research Environmental Health and Safety (AR-EHS) is responsible for research and academic related compliance, which includes laboratory and academic research and the associated compliance committees. Fire and Life Safety (FLS-EHS) is responsible for fire related compliance and conducts fire and life safety inspections of campus buildings and assists with the testing all fire detection and suppression systems. General Safety (GHS-EHS) promotes safe work and health practices, to all faculty, staff, students, and visitors. Examples of General Health and Safety components include: office safety, proper lifting techniques, trip and fall prevention.

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## 1. PURPOSE

West Texas A & M University's animal care and use program adheres to the standards set forth in the Public Health Service (PHS) Policy and the Animal Welfare Act Regulations (AWA). The purpose of this guideline is to describe the process that will be observed by the Institutional

Animal Care and Use Committee (IACUC) when considering matters relating to the care and use of animals.

## 2. SCOPE

This procedure applies to all faculty, staff and students, affiliated researchers or other affiliated individuals who are involved in vertebrate animal research being conducted under the auspices of West Texas A&M University regardless of the location of the research and regardless of the source of funding or whether the research is funded or unfunded.

## 3. DEFINITIONS

3.1. **Noncompliance** is a failure (intentional or unintentional) to comply with applicable federal regulations, state or local law, the requirements or determinations of the IACUC (including failure to follow approved protocol), System policies or regulations, university rules or procedures in the conduct of animal research. Noncompliance can result from action or omission. Noncompliance may be non-serious (minor) or serious, and may also be continuing (see below).

3.1.1. **Non-serious** or **minor noncompliance** is noncompliance that does not increase risk to animals, compromise animals' rights or welfare, or affects the integrity of the research/data or the institutional animal care program. Examples of minor noncompliance may include, but are not limited to: lapses in continuing IACUC approval, minor changes in or deviations from an approved protocol, or administrative errors.

3.1.2. **Serious noncompliance** is noncompliance that a reasonable investigator should have foreseen that would increase risk to animals, compromise animals' rights or welfare, or affects the integrity of the research/data or institutional animal care program. Examples of serious noncompliance may include, but are not limited to: conducting or continuing animal research without IACUC approval; failure to report or review serious adverse events, unanticipated problems, or substantive changes in research; or inappropriate oversight of the research to insure the safety of animals and the integrity of the research/data.

3.1.3. **Continuing noncompliance** is noncompliance (serious or non-serious) that is a pattern of repeated actions or omissions taken by an investigator that indicates a deficiency in the ability or willingness of an investigator to comply with animal protection requirements that may affect animals or the validity of the research and suggest the potential for future noncompliance without intervention. Examples of continuing noncompliance may include, but are not limited to: repeated failures to provide or review progress reports resulting in lapses of IACUC approval, inadequate oversight of ongoing research, or failure to respond to or resolve previous allegations or findings of noncompliance.

3.2. **A report of potential noncompliance** is an unconfirmed written report of noncompliance.

3.3. Actions taken to avoid the occurrence of adverse events or unanticipated problems, if deviating from approved Protocol, must also be reported in accordance with this procedure.

## 4. GENERAL PROCEDURE

4.1. Anyone may report potential noncompliance involving animal research verbally or in writing to the Institutional Animal Care and Use Committee or the Research Compliance Officer. Reports of potential noncompliance should contain sufficient information to determine whether the report is sufficiently credible and specific so that potential evidence of noncompliance may be identified and acted upon. If the IACUC Chair, in consultation with the Research Compliance Officer, determines that the report of potential noncompliance is unjustified (i.e. no basis in fact) or that the complaint is a minor administrative issue that is able to be resolved by the IACUC Chair and does not represent noncompliance, no further action is taken.

4.2. The IACUC Chair will process all reports of potential non-compliance and findings of noncompliance, whether these reports arise internally (e.g., from WTAMU faculty, staff, the IACUC, or investigator self-reports) or from outside the University (e.g., research participants or regulators).

4.3. Reports of potential noncompliance will remain confidential to the extent permitted by Texas law, consistent with the need to conduct an adequate investigation.

4.4. Actions undertaken in response to a report of potential noncompliance or a finding of noncompliance will be completed in a timely manner, based on the circumstances or seriousness of the potential noncompliance.

4.5. If the report of potential noncompliance involves an Investigator of another University or research facility, the appropriate institutional official from that university will be notified either verbally or in writing by the IACUC Chair or Chief Research Officer. The communication will be documented and added to the IACUC files of the associated case.

## 5. INITIAL INQUIRY

5.1. The IACUC Chair will notify the IACUC Committee on all reports of potential noncompliance or findings or noncompliance – unless as exempted in section 4.1 of this document. The Research Compliance Officer – along with the IACUC Chair - will consult, as necessary, with the Office of General Counsel, on reports of potential noncompliance or findings of noncompliance.

5.1.1. Any individual with a potential conflict of interest may not participate in any investigations related to IACUC noncompliance. If the IACUC Chair has a conflict of interest and must be recused, the IACUC will assign a chair from the current IACUC committee membership.

5.2. The Investigator(s), as applicable, shall be informed of a report of potential noncompliance and/or contacted for a response during the initial inquiry, unless the available information and the nature of the potential noncompliance dictate otherwise.

5.3. In the initial inquiry, the IACUC Chair will gather information related to the report of potential noncompliance and forward the information to the IACUC for review and determination.

5.4. Possible outcomes of the initial inquiry include:

5.4.1. Dismissal of the allegation

5.4.2. Referral to other appropriate University process

5.4.3. No further action required

5.4.4. Corrective action(s) required (i.e., for minor violations)

5.4.5. Review by convened IACUC

5.5. When further investigation or convened IACUC review is not warranted, the Investigator(s) and Research Compliance Officer will be notified in writing within 14 business days by the IACUC Chair of the outcome of the initial inquiry - and within 30 business days to PHS or APHIS (as applicable for regulated research), any other sponsoring federal department or agency, and others (e.g., Office of Sponsored Research, Environmental Health and Safety) as necessary. The determination will be documented in a report reviewed and approved by the IACUC.

5.5.1. University Administration, including the Investigator(s)' Dean, and/or the Department Head (or equivalent) may also be informed of the outcome of the inquiry, at the discretion of the IACUC Chair or Research Compliance Officer.

5.6. Initial inquiries should be completed within 30 business days of receipt of the report of potential noncompliance or the finding of noncompliance, depending on the nature of the potential noncompliance.

## 6. INVESTIGATION: CONVENED IACUC

6.1. Unless the initial inquiry has resolved the noncompliance question, reports of potential noncompliance are forwarded to a convened IACUC for review and action.

6.1.1. Any individual with a potential conflict of interest may not participate in the investigation. If the IACUC Chair has a conflict of interest and must be recused, the IACUC committee will assign a chair from the current IACUC committee membership.

6.1.2. At least one IACUC member should possess related expertise appropriate for review of the report of potential noncompliance; additional IACUC members or external consultants may also be included as determined necessary by the IACUC Chair.

6.1.3. The IACUC committee will be assisted by the Research Compliance Officer and, as necessary, advised by TAMU System Office of General Counsel.

6.1.4. The IACUC committee will meet as necessary to ensure timely review of the reports of potential noncompliance.

6.1.5. The IACUC Chair will lead and/or facilitate the discussion. All available materials collected and/or associated with the noncompliance investigation will be distributed to all scheduled attendees in advance of the meeting.

6.1.6. The Investigator(s) may respond in person to the IACUC at the convened meeting during which the noncompliance review will take place. The IACUC Chair will be responsible for providing the Investigator(s) with reasonable notice of the meeting including notice that the Investigator(s) may address the IACUC about the matter under review at the meeting.

6.1.7. A personal advisor or legal counsel may accompany the Investigator(s), but the advisor or legal counsel may not participate in the discussion.

6.1.8. The IACUC will make final determinations in closed session by majority vote of a quorum of the members at the convened meeting.

6.1.9. The convened IACUC should, as appropriate:

- 6.1.9.1. Clearly describe the noncompliance, if any
- 6.1.9.2. Determine whether the noncompliance is serious and/or continuing
- 6.1.9.3. Consider the cause of the noncompliance
- 6.1.9.4. Assess the adequacy of corrective actions for future compliance
- 6.1.9.5. Consider the allow ability of data use
- 6.1.9.6. Determine if any harm to animals has occurred

6.2. The Investigator(s) and Research Compliance Officer - and within 30 business days to PHS or APHIS (as applicable for regulated research), any other sponsoring federal department or agency, and others (e.g., Office of Sponsored Research, Environmental Health and Safety) as necessary - will be informed in writing of the outcome and report (described below) of potential noncompliance and investigation by IACUC Chair.

6.3. The Investigator(s), other members of the research staff, and/or others may be interviewed and/or an audit completed of the Investigator(s)' research conducted during the investigation, as necessary. The IACUC committee will consider materials and recommendations from the initial inquiry, the Investigator' response, and other information relevant to the investigation (e.g., interviews, audit reports, literature searches, etc.).

6.4. A summary report that includes the report of potential noncompliance, information considered by the IACUC committee, and its conclusions will be prepared by the IACUC Chair.

6.5. Possible outcomes of the investigation include:

- 6.5.1. Dismissal of the report of potential noncompliance.
- 6.5.2. Referral to other appropriate University process
- 6.5.3. No further action required
- 6.5.4. Corrective action(s) required

6.6. The Investigator(s) will be given an opportunity to respond to the IACUC Committee's findings in writing within 14 business days of receipt of the report.

6.7. University Administrators', including but not limited to the Investigator(s)' Dean, and/or the Department Head (or equivalent) may also be informed, at the discretion of the Chair of the IACUC and Research Compliance Officer.

6.8. Investigations should be completed as expedited as possible, depending on the nature of the potential noncompliance and the complexity of the investigation.

## 7. CORRECTIVE ACTIONS

7.1. Corrective action(s) will be based on the nature of the noncompliance, degree to which animals were placed at risk, occurrence of previous noncompliance, etc. The range of possible corrective actions that the IACUC Chair and IACUC committee may consider includes, but is not limited to:

7.1.1. Modification(s) of the research
7.1.2. Monitoring of the research (including audits)
7.1.3. Education or mentoring for the Investigator(s)
7.1.4. Additional reporting (e.g., more frequent continuing review)
7.1.5. Additional resources to support the investigator's research activities
7.1.6. Limitations (e.g., restriction to co-investigator status) on research activities or use of research data
7.1.7. Suspension of IACUC approval for one or more of the Investigator(s)' studies
7.1.8. Termination of IACUC approval for one or more of the Investigator(s)' studies.
7.1.9. Notification of the Investigator(s) department and college administration. College or departments may seek corrective actions appropriate to TAMUS policies and University procedures.

7.2. If the Investigator(s) do not comply with the required corrective action(s) within the time specified in the corrective action plan, additional action may be required, including reporting of the lack of compliance to the appropriate university supervisor for further action in accordance with the WTAMU faculty handbook and/or TAMUS policies and University procedures for personnel responsibilities and obligations.

## 8. APPEALS

8.1. The convened IACUC will review an Investigator's request for reconsideration or appeal of a determination of noncompliance and/or corrective actions as warranted by the presentation of new information or unusual circumstances.

8.2. All investigator petitions must be made within 30 business days of his/her receipt of notification of the IACUC's findings.

8.3. The IACUC will review an Investigator's request or appeal within 30 business days, and the Investigator will be notified in writing of the IACUC's decision within 14 business days of the review.

## 9. RECORD RETENTION

No official state records may be destroyed without permission from the Texas State Library as outlined in Texas Government Code, Section 441.187 and 13 Texas Administrative Code, Title 13, Part 1, Chapter 6, Subchapter A, Rule 6.7. The Texas State Library certifies Agency retention schedules as a means of granting permission to destroy official state records.

West Texas A & M University Records Retention Schedule is certified by the Texas State Library and Archives Commission. West Texas A & M University Environmental Health and Safety will follow Texas A & M University Records Retention Schedule as stated in the Standard Operating Procedure 61.99.01.W0.01 Records Management. All official state records (paper, microform, electronic, or any other media) must be retained for the minimum period designated.

## 10. TRAINING

West Texas A & M University Environmental Health and Safety will follow the Texas A & M University System Policy 33.05.02 Required Employee Training. Staff and faculty whose required training is delinquent more than 90 days will have their access to the Internet terminated until all trainings are completed. Only Blackboard and Single Sign-on will be accessible. Internet access will be restored once training has been completed. Student workers whose required training is delinquent more than 90 days will need to be terminated by their manager through Student Employment.

## 11. REFERENCES AND RELATED MATERIALS

Code of Federal Regulations: Title 9: Part 4 Rules of Practice governing proceedings under the Animal Welfare Act (AWA)
Code of Federal Regulations: Title 9: Part 11 Horse Protection Regulations
Code of Federal Regulations: Title 9: Part 12 Rules of Practice governing proceedings under the Horse Protection Act
Public Health and Human Services: Subpart 370.4 – Acquisitions Involving the Use of Laboratory Animals
American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals

## Related Statutes, Policies, or Requirements

## Contact Office

WTAMU Environmental Health and Safety
(806) 651-2270

## Appendix A

### Animal and Plant Health Inspection Service (APHIS)

### APHIS Questions and Answers: Inspection Procedures in Response to an Incident or Adverse Event

**Date: May 2012**

**Q. What is an incident or adverse event?**
**A.** Incidents and adverse events at facilities regulated under the Animal Welfare Act (AWA) include but are not limited to: floods, fires, or other facility disasters; animal mishandling or escapes; attacks and fighting between animals as a result of incompatibility; human injury as a result of an animal attack; failures in HVAC systems, automatic feeders, or watering systems; and injury or death related to cage washers, environmental enrichment devices, and squeeze or guillotine mechanisms.

**Q. Should incidents and adverse events be reported to Animal Care by the licensee/registrant? A.** There is no regulatory requirement that licensees or registrants report incidents or adverse events to Animal Care (a division of the U.S. Department of Agriculture [USDA], Animal and Plant Health Inspection Service [APHIS]), with the exception of an event that results in the suspension of a protocol at a research facility. Licensees and registrants may choose to report incidents or adverse events in order to advise Animal Care of the situation, provide documentation of their corrective actions, and demonstrate their good faith intention to comply with the AWA and regulations.

**Q. Will incidents and adverse events be cited as noncompliance items (NCIs) on an Animal Care inspection report?**
**A.** These types of events will not be cited as NCIs if (1) the licensee/registrant found the problem in a timely manner, (2) the incident or adverse event was not reasonably foreseeable, (3) the licensee/registrant took timely and appropriate corrective action to prevent a recurrence, (4) there is not an ongoing pattern of violations at the facility, and (5) there were no serious animal welfare impacts as a result of the event. However, if there were serious animal welfare impacts, the problem was not identified and/or corrected in a timely manner, the incident was reasonably foreseeable, or there is an ongoing pattern of violations, Animal Care will cite the event as an NCI.

**Q. Will incidents and adverse events that are cited get a correction date?**
**A.** An NCI that resulted in serious animal welfare impacts will be assigned a correction date. If applicable, the inspector may document on the inspection report that the NCI was corrected during the inspection. If the citation is a repeat of a previous citation, the NCI will be listed as a Repeat NCI on the report, and no correction date will be given.

**Q. Will Animal Care inspections in response to incidents or adverse events be announced?**
**A.** Routinely, Animal Care conducts unannounced inspections to determine if facilities are in compliance with the AWA regulations and standards. In an effort to ensure that a facility has appropriate personnel and documentation available, Animal Care may conduct an announced visit to evaluate an incident or adverse event. These post-incident visits do not, however, take the place of regular, unannounced compliance inspections.

**Additional Information**
For more information about the AWA and its regulations and standards, visit the APHIS Animal Care Web site at **www.aphis.usda.gov/animal_welfare.** You can also contact the program's headquarters office at:

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Riverdale, MD 20737-1234

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Fax: (301) 734-4978
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