



University Committee on Animal Care

Policy and Procedures for Noncompliance with Animal Care and Use Policies

Purpose

The purpose of this policy is to provide guidance to the University Committee on Animal Care (UCAC), faculty, staff, and students on how allegations of noncompliance with animal care and use will be submitted, reviewed, and processed.

Policy

East Tennessee State University (ETSU) advocates the finest care and humane use of animals used by its faculty, staff and students in research projects. Everyone at ETSU has a responsibility to report potential noncompliance with animal care and use policies.

This policy pertains to activities involving animals that are reviewed by the UCAC of ETSU, including field studies. Per regulatory requirements (USDA 9 CFR 2.31 (c)(1)-(8) and 2.31 (d) (5)-(7) and PHS Policy IV.B.1-8) the UCAC is charged to review allegations of noncompliance with animal care and use within the institution. The UCAC is empowered to inspect laboratories, procedure areas, animal housing areas, and to sequester any pertinent research records or training records in the course of their investigations.

For VA Animal Studies the IACUC will follow the reporting and review requirements per VHA Directive 1058.01

No facility employee, member of the UCAC, laboratory personnel or student shall be discriminated against, or be subject to any reprisal, for reporting noncompliance with ETSU animal care and use guidelines and policies.

Definitions

Noncompliance with animal care and use policies (Noncompliance) is defined as using animals in research or teaching in a manner that disregards or violates federal, state, or local regulations and guidelines, and/or ETSU policies.

Mistreatment is physical or psychological, wrongful or abusive treatment of an animal and is considered a noncompliance.

Procedures

Allegations of Noncompliance may be received from any source, including external complaints, internal complaints, random and directed site visits, and investigator self-reporting. The UCAC encourages the principal investigator (PI), other faculty, staff, students, volunteers and visitors to report instances of alleged Noncompliance, especially when animal or human health and welfare are in question.

Allegations of Noncompliance should be directed verbally or in writing to the Chair of the UCAC (c/o Division of Laboratory Animal Resources, PO Box 70418) or to the Director of the Division of Laboratory Animal Resources (PO Box 70418 or Tel.: 423-439-6783). Reports may be anonymous.

In an emergency, the Attending Veterinarian should be contacted immediately by calling 423-439-6783 or outside regular work hours by calling Campus Security, 423-439-4480, who will contact the

veterinarian. If needed, the Attending Veterinarian or his/her designee will take any necessary action immediately.

Allegations of Noncompliance received in the Office of the Division of Laboratory Animal Resources (DLAR) will be forwarded to the Chair of the UCAC. Receipt of the complaint will be acknowledged in writing if the complainant has identified him/herself. The process followed after the allegation is received by the Chair of the UCAC will be determined by the seriousness of the allegations and the probability or occurrence of harm to the animal(s).

Inquiry into allegations of Noncompliance will be initiated within five working days of receipt of the allegation by the Chair of the UCAC. The Chair of the UCAC or his/her designee, one additional member of the UCAC, and a representative of the veterinary staff will notify the principal investigator in writing, conduct the inquiry, and make a determination as to the severity of the instance(s) of Noncompliance. The inquiry will be completed within 30 working days of receipt of the allegation by the Chair of the UCAC.

Determination of Minor Noncompliance

If Noncompliance is found and is minor in nature, the inquiry committee will see that the Principal Investigator (PI) and her/his staff working with laboratory animals become compliant. Such actions will be reported in writing to the UCAC at its next scheduled meeting and will be recorded in the minutes of the UCAC meeting. Repeated or continuing minor Noncompliance may warrant further action as described below. Instances of Minor Noncompliance do not have to be reported specifically to the Vice Provost for Research (Institutional Official) who receives the minutes of the UCAC meetings, or to federal agencies or research sponsors.

Examples of Minor Noncompliance Issues (not reportable)

- Incomplete or inaccurate controlled substance logs or inappropriate storage of controlled substances.
- Animal death or injuries relating to manipulations that fall within parameters described in the UCAC-approved protocol
- Death of an animal that has reached the end of its natural life span
- Death or failure 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;
- 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).

Determination of Serious Noncompliance

If the inquiry committee determines that Serious Noncompliance has occurred (for examples see below) it will provide a detailed report to the UCAC within 10 working days of receipt of the allegation by the Chair of the UCAC. The Chair of the UCAC will inform the Vice Provost for Research of the instance of Serious Noncompliance and the UCAC will conduct a thorough examination of the episode of Non-compliance. To accomplish this, the Chair of the UCAC or his/her designee will appoint a subcommittee, including a representative of the veterinary staff and the Vice Provost for Research, to perform a thorough review of the episode of Serious Noncompliance and suggest corrective actions or

penalties. The results will be presented, in writing, to the full UCAC at the next scheduled meeting, or at a called meeting if the allegations are deemed to be serious. When determining the appropriate corrective action or penalty the UCAC will consider the extent to which harm to an animal resulted from the incident(s), the extent to which the incident was self-reported and the proactive corrective action(s) taken in response to the incident(s) by the PI or staff, and the extent to which the incident(s) represented a continuing or repeated violation. While the UCAC will consider self-reporting and corrective actions taken by the PI in evaluating the Noncompliance, these will not impact on the reporting to regulatory agencies. Discussion and voting pertaining to Noncompliance issues must be documented in the meeting minutes.

Examples of Serious Noncompliance Issues Posing Risk of Immediate Harm to an Animal or Deviation from the Approved Animal Study Protocol (reportable):

- Insufficient anesthesia, insufficient analgesia, inappropriate post-operative care, or improper euthanasia which results in pain or distress to the animal or premature death of an animal.
- Failure to ensure death of animals after euthanasia, e.g. failed euthanasia with CO₂.
- 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.
- Maintenance of animals beyond the humane endpoints specified in the approved protocol.
- Conducting animal-related activities or procedures without UCAC review and approval, including implementing significant change to an UCAC-approved protocol without prior UCAC approval or conducting animal-related activities beyond the expiration date established by the UCAC or using additional animals beyond the number approved by the UCAC.
- Use of procedure or housing area(s) which have not been approved by the UCAC.
- Failure of animal care and research personnel to carry out veterinary orders, e.g. treatments.
- Chronic failure to provide space for animals in accordance with recommendations of the Guide unless the UCAC has approved a protocol-specific deviation from the Guide based on written justification.

Examples of Serious Noncompliance Programmatic Issues (reportable):

- UCAC suspensions or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the PHS Policy, Animal Welfare Act, the Guide, or ETSU's Animal Welfare Assurance.
- Failure to correct serious deficiencies identified in previous UCAC semiannual evaluations in a timely manner.
- Conditions that jeopardize the health or well being of animals, including accidents, natural disasters and mechanical failures resulting in actual harm or death of animals.
- Conducting official UCAC business requiring a quorum in the absence of a quorum.

A written report on the results of the investigation will be sent to: the person(s) making the allegation, if known, the PI involved, the departmental chair, the dean of the college, the Vice President / Provost of the involved unit and the Vice Provost for Research as the Institutional Official. A serious noncompliance finding as well as a suspension of a previously approved protocol must be reported

through the Institutional Official to the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC), to the USDA, if regulated species are involved, to the Office of Laboratory Animal Welfare (OLAW) at NIH, the federal agency that may be sponsoring the research or to the private entity sponsoring the research if this is required by the entity.

Instances of Noncompliance that May Constitute Scientific Misconduct

ETSU Faculty Handbook Policy 1.2. F. Misconduct in Scholarship and Research §1/16.2.6 states that “Deliberate and repeated violation of Federal, State, local, or University regulations governing conduct of research, including, but not limited to, guidelines for the protection of human subjects; protection of animal subjects; use of recombinant DNA; use and disposal of radioactive material; and use and disposal of hazardous chemicals and/or biological materials” can constitute as Scientific Misconduct.

A finding of Serious Noncompliance as defined above does not necessarily entail Scientific Misconduct. However, if the UCAC finds that the finding of Serious Noncompliance is a “deliberate and repeated violation” of policies involving the use of animals in research it may request in writing that the Vice Provost for Research act according to ETSU Policy 1.16 to determine if Scientific Misconduct has occurred.

Time Frame for Reporting to the Agencies

ETSU should notify the appropriate agencies promptly and without delay. However, since federal policies require a full explanation of circumstances and actions taken, an authorized institutional representative should provide a preliminary report to the agencies as soon as possible, but at least within 5 (five) working days, and follow up with a thorough report once action has been taken. Preliminary reports may be in the form of a fax, email or telephone call. Reports should be submitted as situations occur, and not collected and submitted in groups or with the annual report to the agencies.

Approved by the ETSU University Committee on Animal Care: October 20, 2005

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