

# **EAST TENNESSEE STATE UNIVERSITY**

## **Animal Welfare Assurance**

### **Assurance of Compliance With the Public Health Service Policy for the Humane Care and Use of Laboratory Animals (October 2018)**

**OLAW Assurance: A3203-01**

I, William R. Duncan, Ph.D. as named Institutional Official for animal care and use at East Tennessee State University, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

#### **I. Applicability of Assurance**

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS and/or NSF. This Assurance covers only those facilities and components listed below

- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name: All departments and schools at East Tennessee State University who use vertebrate animals for research, teaching or testing and are physically located on the ETSU campus in Johnson, Tennessee. There are no covered off-campus facilities and / or other covered components.
- B. The following are other institution(s), or branches and components of another institution:  
None / Not applicable.

#### **II. Institutional Commitment**

- A. ETSU will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- B. ETSU is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."

- C. ETSU acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, ETSU will make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance as well as all other applicable laws and regulations pertaining to animal care and use.
- D. ETSU has established and will maintain a program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals (Guide, 8<sup>th</sup> ed.).
- E. ETSU agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (UCAC) approval.

### **III. Institutional Program for Animal Care and Use**

- A. A diagram of the lines of authority and responsibility for administering the program and ensuring compliance with this Policy is attached as Appendix 1.
- B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

1. Name: Gregory A. Hanley, Attending Veterinarian and Director of the Division of Laboratory Animal Resources (DLAR),

Qualifications

- Degrees: DVM, University of Florida; PhD; DACLAM
- Training or experience in laboratory animal medicine or in the use of the species at the institution: Dr. Hanley has more than 25 years' experience in laboratory animal medicine. He is a voting member of the University Committee on Animal Care (UCAC).

Authority: Dr. Hanley has direct program authority and responsibility for the Institution's animal care and use program including access to all animals.

Time contributed to program: Dr. Hanley is a full time employee of ETSU and commits 100% of his time to ETSU's animal care and use program.

2. Provisions for Back-up Veterinary Care: During the absence of the Attending Veterinarian, Tammy Ozment, DVM (Univ. Tenn. 1998), PhD, Research Assistant Professor in the Department of Surgery, provides clinical care of the animals. Dr. Ozment has more than 20 years' clinical experience and 20 years' experience in

experimental surgery. She makes herself available for consultation and veterinary care. Dr. Ozment is a full time employee of ETSU. Approximately 10 percent of her time is contributed to the animal care and use program.

C. ETSU has established an Institutional Animal Care and Use Committee, called the University Committee on Animal Care (UCAC). The UCAC at this Institution is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The President, as Chief Executive Officer (C.E.O.), appoints the members of the UCAC. The UCAC consists of at least five members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Part VIII is a list of the names, degrees, position titles, specialties and institutional affiliations of the UCAC members.

D. The UCAC will:

**1. Review at least once every six months the Institution's program for humane care and use of animals, using the Guide as a basis for evaluation. The UCAC procedures for conducting semiannual program reviews are as follows are:**

- The UCAC has developed a checklist for the program review (following the OLAW sample checklist).
- This program review is accomplished by the full UCAC at a convened meeting at least once every six months—generally in October and in April of each year.
- The evaluation will include, but not necessarily be limited to, a review of the following:
  - a) UCAC Membership and Functions;
  - b) UCAC Records and Reporting Requirements;
  - c) Husbandry and Veterinary Care (all aspects);
  - d) Personnel Qualifications (Experience and Training);
  - e) Occupational Health and Safety; and
  - f) Disaster Planning
  - g) PHS Assurance
- If program deficiencies are noted during the review, they will be categorized as significant or minor and that the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency.
- A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel.
- No member will be involuntarily excluded from participating in any portion of the

reviews.

**2. Inspect at least once every six months all of the Institution's animal facilities, including satellite facilities and animal surgical sites, using the Guide as a basis for evaluation. The UCAC procedures for conducting semiannual facility inspections are as follows:**

- A subcommittee of the UCAC of at least two voting members tours and inspects every area an animal is utilized including all ETSU animal housing facilities, including satellite facilities, animal surgery area, and the research laboratories where animals are used.
- Checklists for these inspections were developed and are used.
- If deficiencies are noted during the inspection, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel.
- No UCAC member wishing to participate may be involuntarily excluded from any portion of the inspections.

**3. Prepare reports of the UCAC evaluations according to PHS Policy IV.B.3. and submit the reports to the Institutional Official. The UCAC procedures for developing reports and submitting them to the Institutional Official are as follows:**

- The program reviewers and facility inspectors convey their findings to the AV, who in-turn drafts the reports.
- The reports contain a description of the nature and extent of ETSU's adherence to the Animal Welfare Act and the Guide and identify specifically any departures from the provisions of the Animal Welfare Act and the Guide and state the reasons for each departure. If no departures are noted the report will so state.
- Approved departures must be approved as part of a protocol, protocol amendment, or other written document, using either FCR or DMR as delineated below in Section III.D.6.

- Departures from the provisions of the Guide that are not UCAC approved are considered deficiencies and addressed as such, i.e., the UCAC will develop a reasonable plan and schedule for discontinuing the departure or for having the departure properly reviewed and approved.
- If program or facility deficiencies are noted, the reports will contain a reasonable and specific plan and schedule with dates for correcting each deficiency. Deficiencies will be designated as either minor or significant. Significant deficiencies are those that are or may be a threat to the health and/or safety of the animals.
- All of the institution's facilities are accredited by AAALAC International.
- The written reports of the semiannual program review and the animal housing facility and laboratory inspections are reviewed by the full UCAC.
- These reports are included with the semiannual report (signed by the majority of the UCAC members) to the Institutional Official and will include any minority opinions. And, if there are no minority opinions, the reports will so state.
- Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected will be reported in writing in a timely manner by the UCAC, through the Institutional Official at ETSU, to the USDA, to OLAW and to other federal agencies funding that activity.
- Deficiencies will be tracked by the AV to ensure that that are appropriately resolved.

**4. Review concerns involving the care and use of animals at the Institution. The UCAC procedures for reviewing concerns are as follows:**

- The UCAC has developed a Policy for Noncompliance with Animal Care and Use Policies (Whistleblower Policy). This Policy is discussed during the orientation of new animal users, posted on both the public web site and throughout the animal facilities.
- Concerns of faculty, staff, students, and others concerning the use and care of animals at ETSU may be communicated in writing or orally to any member of the UCAC or the DLAR Office.
- The UCAC will review, and, if warranted, investigate these issues and their

resolution.

- A written report on the results of the investigation will be sent to those primarily involved including the individual communicating the concern, the Principal Investigator and the Institutional Official.
- It is ETSU policy that no employee or student shall be discriminated against or be subject to any reprisal for, in good faith reporting an animal welfare concern or for reporting non-compliance with ETSU animal care and use guidelines.

**5. Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:**

- Recommendations regarding any aspects of the institution's animal program or facilities are discussed and developed by the Committee.
- In addition to the reports of the UCAC's evaluations (program review and facility inspection), various other types of correspondence that may be used for delivering the written recommendations to Institutional Official. For example, UCAC meeting minutes, separate letter, etc.
- Written recommendations are reviewed by the Committee, revised as appropriate, and then submitted to the IO.
- Recommendations from the UCAC regarding any aspect of the animal care and use program, facilities or personnel training are also communicated to the Vice Provost for Research and Sponsored Programs in writing.

**6. Review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals according to PHS Policy IV.C.1-3. The UCAC procedures for protocol review are as follows:**

- ETSU policy requires that all activities involving the use of vertebrate animals in research, instruction, or testing, regardless of the source of funds, be reviewed and approved by the UCAC prior to initiation. Principal investigators cannot procure animals without an active approved protocol.

**Submission, Pre-review, and Distribution**

- The principal investigator submits either a hard or electronic version of the Animal Study Protocol form with all pertinent information to the office of the DLAR.
- One member of the UCAC, designated by the chairman, may conduct a preliminary review and may suggest modifications (to secure approval) for adherence to applicable guidelines.
- Prior to each UCAC meeting every member is provided via email the agenda which includes the protocols up for review as well as any additional items that warrant UCAC review.

#### **Animal study protocol approval process:**

- No member may participate in the UCAC review or approval of an activity in which that member has a conflicting interest (e.g., is personally involved in the activity), except to provide information requested by the UCAC, nor may a member who has a conflicting interest contribute to the constitution of a quorum.
- The UCAC may invite consultants to assist in reviewing complex issues. Consultants may not approve or withhold approval of an activity or vote with the UCAC unless they are also members of the UCAC.
- UCAC meetings are conducted in person.
- Any use of telecommunications will be in accordance with NIH Notice NOT-OD-06-052 of March 24<sup>th</sup>, 2006, entitled Guidance on Use of Telecommunications for UCAC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals.
- Prior to the review, each UCAC member will be provided with a list of proposed activities/projects to be reviewed and written descriptions of activities/projects (protocols) that involve the care and use of animals shall be provided or available to all UCAC members, and any member of the UCAC may obtain, upon request, full committee review (FCR) of those protocols.

#### **Full-Committee Review (FCR)**

- If FCR is requested, approval of those protocols may be granted only after review at a convened meeting of a quorum of the UCAC and with the approval vote of a majority of the quorum present.
- Approval by the UCAC of the activities involving the use of animals may be

granted after review, at a convened meeting of a quorum of the UCAC, and with the approval vote of a majority of the quorum present.

- A quorum will consist of a majority (51%) of the voting members of the UCAC. The recording of the vote will denote the number of votes for, opposed and abstained.
- Possible outcomes of FCR include: Approval, Require Modifications (to secure approval) or Approval Withheld.
- Review of Required Modifications Subsequent to FCR. When the UCAC requires modifications (to secure approval), of a protocol, such modifications are reviewed as follows:
  - a. FCR or DMR following all applicable procedures as delineated in the PHS Policy and elsewhere in Part III.D.6 of this Assurance.

Or

- b. DMR if approved unanimously by all members at the meeting at which the required modifications are developed / delineated As required, for this process, each UCAC member has agreed in advance, in writing, that the quorum of members present at a convened meeting may decide by unanimous vote to use designated member review subsequent to full committee review when a modification if needed to secure approval. However, any member of the UCAC may, at any time, request to see the revised protocol and/or request FCR of the protocol.

### **Designated-Member Review (DMR)**

- The UCAC may also use the designated reviewer procedure.
- Written descriptions of activities/projects (protocols) that involve the care and use of animals shall also be provided or available to all UCAC members
- Within five full working days any member of the UCAC may request that the protocol be reviewed by the full committee at the next UCAC meeting. The request for full UCAC review should be sent to the DLAR Office or to any UCAC member by email or by mail.
- If no UCAC member requests full-committee review, then the UCAC Chair can refer the protocol in question to a designated reviewer. The Chair may select one or more UCAC members, qualified to review the specific protocol, who will act on behalf of the entire UCAC to 1) approve the protocol, 2) require modifications (to

secure approval), or 3) refer it for full UCAC review.

- Records of polling of members to obtain concurrence to use the DMR method are recorded in the minutes of the next convened UCAC meeting
- Other UCAC members may provide the designated reviewer(s) with comments and/or suggestions for the reviewer's consideration only.
- After all required modifications are made, a final revised protocol, i.e., an identical document with all required modifications included, is submitted to all designated reviewers for review and approval
- If more than one designated reviewer is assigned, any decisions made by the designated reviewers must be unanimous; if not, the protocol will be referred for FCR.
- The designated reviewer cannot withhold approval, however; but must in such cases refer the protocol for full-committee review. The designated-reviewer approval has equal validity to full-committee review approval and does not require subsequent re-approval or notification by a convened meeting.
- No other processes or procedures for special or expedited reviews exist.
- In order to approve proposed protocols or proposed significant changes in ongoing protocols, the UCAC will conduct a review [by FCR or DMR] of those components related to the care and use of animals and determine that the proposed protocols are in accordance with the PHS Policy. In making this determination, the UCAC will confirm that the protocol will be conducted in accordance with the Animal Welfare Act insofar as it applies to the activity, and that the protocol is consistent with the Guide unless acceptable justification for a departure is presented. Further, the UCAC shall determine that the protocol conforms to the institution's PHS Assurance and meets the following requirements:
  - a. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
  - b. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
  - c. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

- d. The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.
- e. Medical care for animals will be available and provided as necessary by a qualified veterinarian.
- f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
- g. Methods of euthanasia used will be consistent with the current American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals unless a deviation is justified for scientific reasons in writing by the investigator.

**7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities according to PHS Policy IV.C. The UCAC procedures for reviewing proposed significant changes in ongoing research projects are as follows:**

- Using the forms provided on the web site, the principal investigator will submit a written amendment to the previously approved animal study protocol if it becomes necessary to modify the experimental procedures, the anesthesia, analgesia or euthanasia procedures, if additional animals are needed or if there will be a change in personnel handling the animals.
- The request for approval of an amendment to an approved protocol is submitted in writing to the UCAC through the DLAR office.
- Review and approval of significant changes will be handled in the same manner as new protocols. That is, by FCR or DMR. See Part III.D.6. above.
- Examples of changes considered to be significant include, but are not limited to, changes:
  - a. in the objectives of a study
  - b. from non-survival to survival surgery;
  - c. resulting in greater discomfort or in a greater degree of invasiveness;
  - d. in the species or in approximate number of animals used<sup>1</sup>;

- e. in Principal Investigator;
- f. in anesthetic agent(s) or the use or withholding of analgesics;
- g. in the method of euthanasia; and
- h. in the duration, frequency, or number of procedures performed on an animal
- i. in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC
- j. that impact personnel safety.

<sup>1</sup>Changes of less than 10% in the approximate number of animals used of mice of the genus *Mus* and rats of the genus *Rattus* that are bred for use in research may, at the UCAC's discretion, be considered minor (not significant).

- Changes in personnel, other than the Principal Investigator, are classified as a "minor" change. As such the UCAC has authorized the Attending Veterinarian to function as a designated reviewer for personnel changes. The Attending Veterinarian will ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in applicable occupational health and safety programs, and meet other criteria as required by the UCAC.

**8. Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure UCAC approval according to PHS Policy IV.C.4. The UCAC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:**

- The UCAC notifies the principal investigator (via letter), the Vice Provost for Research and Sponsored Programs (the IO), the Vice President for Health Affairs, and the Vice President for Academic Affairs, in writing, of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure UCAC approval.
- If the UCAC's decision is to require modifications to secure approval, the required modifications are delineated in the written notification.
- If the UCAC decides to withhold approval of an activity, it includes in its written notification a statement of the reasons for its decision and gives the principal investigator an opportunity to respond in person or in writing. The UCAC may reconsider its decision, with documentation in UCAC minutes, in light of the information provided by the principal investigator.

**9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the UCAC, including a complete review at least once every three years according to PHS**

**Policy IV.C.1.-5. The UCAC procedures for conducting continuing reviews are as follows:**

- **Post-approval Monitoring** - Every year approved animal activities are reviewed by the UCAC via the Annual Surveillance method. Additionally all animals must be acquired through DLAR enabling monitoring of the number of animals used. Animal activities are also monitored by the UCAC during the semiannual inspections where the records on experimental procedures, anesthesia, analgesia, euthanasia and personnel are reviewed for consistency with the approved animal activity. Lastly, the trained DLAR staff performs day-to-day observation and monitoring of animal conditions and of animal research activities in the animal facilities.
- The UCAC conducts continuing reviews of each previously approved activity involving the care and use of animals at intervals determined by the UCAC but not less frequently than annually.
- **USDA Regulated Species** – Every year approved animal activities are reviewed by the UCAC via the Annual review process. The DLAR office initiates the review by sending a letter to the PI notifying them of the impending deadline. The PI completes the Annual Surveillance form with any changes proposed for the coming year. If changes are proposed the PI must submit the necessary forms for the addenda to the protocol. The completed Annual Surveillance form is submitted to the UCAC for review and approval.
- **Non-USDA Regulated Species** – Every year approved animal activities are reviewed by the UCAC via the Annual review process. The DLAR office initiates the review by sending a letter to the PI notifying them of the impending deadline. The PI completes the Annual Surveillance form with any changes proposed for the coming year. If changes are proposed the PI must submit the necessary forms for the addenda to the protocol. The completed Annual Surveillance form is submitted to the UCAC for review and approval.
- Protocols are approved for a maximum of 36 months.
- If activities will continue beyond the expiration date, prior to expiration of the original or preceding protocol a new protocol must be submitted, reviewed, and approved Part III.D. 6 and III.D.8 apply.

**10. Be authorized to suspend an activity involving animals according to PHS Policy IV.C.6. The UCAC procedures for suspending an ongoing activity are as follows:**

- The UCAC 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.1.a.-g. of the PHS Policy or that the activity is not being conducted in accordance with the description of that activity provided by the principal investigator and approved by the UCAC.

- The UCAC may suspend an activity only after review of the matter at a convened meeting of a quorum of the UCAC and with the suspension vote of a majority of the quorum present.
- If the UCAC suspends an activity involving animals, or any other institutional intervention results in the temporary or permanent suspension of an activity due to noncompliance with the Policy, Animal Welfare Act, the *Guide*, or the institution's Assurance, the Institutional Official at ETSU in consultation with the UCAC, will review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation,, in writing, to USDA, OLAW and/or any other Federal agency funding that activity. Preliminary reports may be made verbally.
- Activities that have been approved by the UCAC may be subject to further review and approval by officials of ETSU. However, those officials may not approve an activity involving the care and use of animals if it has not been approved by the UCAC.

E. The risk-based occupational health and safety program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals is as follows:

1. Administration/management.

- The purpose of the occupational health and safety program at ETSU is to provide information on the risk of working with animals, including zoonotic diseases; to foster the prevention of occupationally acquired illnesses and injuries; to determine each individual's physical fitness to perform the duties of his/her position satisfactorily and without risk to the health and safety of fellow employees, students and visitors; to offer occupationally indicated immunizations and tests; and to provide a mechanisms for reporting and treatment of work related injuries and illnesses.
- At ETSU, the Office of Health & Safety, the Office of Radiation Safety and the Department of Internal Medicine are responsible for administering the following occupational health and safety programs: Occupational Health Care Program, Workers' Compensation Program, Chemical Hygiene Plan, Hazardous Chemical Right-to-know Program, Hazardous Waste Management, Emergency Preparedness Plan, Bloodborne Pathogen Exposure Control, and Radiation Safety. The Department of Internal Medicine Medical Director is responsible for and is involved

in the planning and monitoring of the occupational health and safety program at ETSU.

## 2. Scope.

- All ETSU personnel who work in laboratory animal facilities or who have recurrent contact with vertebrate animals or their viable tissues, body fluids, or wastes must be familiar with and participate in the program. This includes faculty, staff, students, visitors and volunteers.
- Participants are identified to be enrolled in the occupational health and safety program by their inclusion on an UCAC protocol. Participants must complete a Health Assessment form initially and submit a Health Assessment update annually.

## 3. Health Histories and Evaluations.

- Occupational health care services are provided by the Department of Internal Medicine. The Risk Inventory form and the Health Assessment form provided by each participant are reviewed.
- Medical services for all personnel exposed to vertebrate animals at ETSU include:
  - a. Annual risk inventory and health assessment.
  - b. Education and training provided by the PI, the Department of Internal Medicine, and the Attending Veterinarian and through written material made available on the ETSU web site.
  - c. Personal protection, including personal hygiene, protective clothing and devices, hearing protection and eye protection.
  - d. Review of status of tetanus prophylaxis
  - e. Animal related allergy consultation.
  - f. Assessment and treatment of work related illnesses and injuries.
- Additional medical services for personnel working with large animals, including cats, dogs and farm animals:
  - a. Hearing tests
- Additional services for personnel with substantial (> 15 hours per week) exposure to animals in the animal housing facilities:
  - a. Pre-employment health physical examination.

## 4. Hazard Identification and Risk Assessment.

- A critical component of the program is the identification of potential hazards. The animal study protocol review process provides an opportunity for identifying the

hazards as well as the personnel who will be involved in a research activity and therefore the persons potentially exposed to the associated hazards.

- Review of proposed animal use by the UCAC includes review of information on the potential hazards involved in the proposed research protocol (Risk Inventory).
- The Risk Assessment is an ongoing critical assessment and includes both the protocol related risks as well as the risks posed by the research animals and other potential hazards (e.g. animal bites, exposure to allergens, chemical cleaning agents, wet floors, ladder use etc.). Critical components of the Risk Assessment include, but are not limited to:
  - Evaluation of the appropriate design and operation of facilities and use of appropriate safety equipment, ongoing review of standard operating procedures and provision of appropriate PPE during the annual safety inspection conducted by Environmental Health and Safety (EH&S).
  - The Institutional Biological and Chemical Safety Committee continually reviews the risks associated with the experimental use of animals including biological agents, chemical agents, radiation and physical hazards.
  - Ongoing review of appropriate policies regarding personal hygiene by EH&S and the UCAC.
  - Yearly review of Health Assessment and Risk Inventory surveys by physicians in the Department of Internal Medicine including; immunizations, procedures for reporting bites, scratches and injuries, laboratory animal allergies and zoonotic diseases.
  - UCAC periodic review of the ETSU Occupational Health and Safety Program for Personnel Exposed to Vertebrate Animals.
  - Ongoing review of the Emergency Preparedness and Response Plan by the UCAC and EH&S.
  - Personnel training requirements are continually reviewed by the UCAC focusing on PPE, hazard identification, zoonosis, chemical, biologic, and physical hazards and handling of waste materials.
  - The UCAC does a semiannual review of the Institutional Policies and Responsibilities Checklist, which includes personnel qualifications, and training as well as occupational health and safety of personnel.
- In addition, hazard review and risk assessment is accomplished after obtaining the advice or approval from the appropriate offices or committees.

## 5. Procedures in Place to Alleviate Hazards and Minimize Risks.

- During orientation and training personnel are trained regarding zoonoses, chemical safety, microbiologic and physical hazards (including those related to radiation and allergies), unusual conditions or agents that might be part of experimental procedures (including the use of genetically engineered animals and the use of human tissue in immunocompromised animals), handling of waste materials, personal hygiene, and other considerations (e.g., precautions to be taken

during personnel pregnancy, illness, or decreased immunocompetence) as appropriate to the risk imposed by their workplace. Several procedures are in place to alleviate hazards and minimize risks including the following; engineering methods or controls, institutional policies, training (e.g., regarding: allergies, zoonoses, specific chemical and physical hazards, etc.), use of personal protective equipment and personal hygiene requirements.

- Appropriate personal hygiene and personnel protection policies are in place and enforced. The Institution provides suitable attire and PPE for use in the animal facility and laboratories where animals are used. Soiled attire is either disposed of or laundered by the Institution. Personnel must wash and/or disinfect hands and change clothing as often as necessary to maintain good personal hygiene. Outer garments worn in the animal rooms must not be worn outside the animal facility unless covered. Personnel are not permitted to eat, drink, use tobacco products, apply cosmetics, or handle or apply contact lenses in rooms and laboratories where animals are housed or used.

6. Immunizations.

- All ETSU personnel who work in laboratory animal facilities or who have contact with vertebrate animals or their viable tissues, body fluids, or wastes are required to have up to date tetanus immunization. The institution does not provide this service.

7. Precautions taken during pregnancy, illness or decreased immunocompetence.

- Personnel are prompted to provide answers regarding pregnancy and immune status on the Annual Health Assessment form. Additionally they are instructed to inform Internal Medicine anytime there are changes to pregnancy or immune status. The Department of Internal Medicine will perform a risk assessment with this information and provide appropriate education and training.

8. Provisions for personnel who are not involved in animal care and/or use but nevertheless need to enter areas when animals are housed or used.

- Housekeeping personnel do not enter areas where animals are housed or used. Maintenance personnel are always escorted by a DLAR staff member when entering the animal facility. Additionally they are enrolled in their own Occupational Health Program which addresses animal exposures.

9. Availability and procedures for treatment of bites, scratches, illness or injury.

- An individual is required to promptly report all work-related injuries and illnesses to his/her supervisor or instructor. Appropriate first aid should be administered immediately.

- Registered students injured by an animal during teaching or research activities should report to the Student Health Service in Nicks Hall, tel. 439-4225, for medical evaluation and treatment.

- ETSU employees and student workers needing medical attention should seek medical treatment from a physician who is authorized to treat injuries for ETSU employees or students. Life threatening emergencies should be directed to the Johnson City Medical Center Emergency Room.

#### 10. Procedures/program for reporting and tracking injuries and illnesses.

- All accidents and injuries occurring on ETSU owned or leased property must be documented via the Illness/Injury Report Form. Copies are sent to Public Safety, ETSU Legal Consul Office and the Environmental Health and Safety Office (EH&S). EH&S monitors the reports for any required follow-up and looks for trends that would indicate additional actions to be taken.

F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein, and the average daily inventory of animals by species, in each facility is provided in Part X., Facility and Species Inventory.

G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

##### 1. UCAC Members

- UCAC members receive all the training listed below.
- UCAC members receive copies of following:
  - a. the PHS Policy on Humane care and Use of Laboratory Animals;
  - b. the National Research Council (NRC) Guide for the Care and Use of Laboratory Animals; and
  - c. the Institutional Animal Care and Use Guidebook.
  - d. Animal Welfare Assurance
  - e. AVMA Guidelines for Euthanasia
  - f. CITI Training "Working with the IACUC". – provides instruction on research or testing methods that minimize the number of animals required to obtain valid results as well as the minimization of distress.
- Each UCAC member undergoes an orientation session with the Attending Veterinarian where the above listed documents are discussed.
- Typically a portion of each UCAC meeting is devoted to continuing education where UCAC members are brought up to date on any recent changes in regulatory

guidelines.

## **2. Animal Care and Use Personnel**

- All faculty, staff, students and volunteers wishing to use animals in research and teaching at ETSU will be provided with a copy of this Assurance following their required tour of the animal facilities.
- A training database is maintained by the UCAC administration office. Prior to protocol review the UCAC secretary verifies that all personnel have completed their required training. Additionally the protocol form specifically asks about training of all personnel and this information is reviewed by the UCAC during protocol deliberations.
- On-the-job training and classroom teaching for DLAR personnel is ongoing and is the duty of the Assistant Director.
- Instructional material is based on but not limited to the manuals published by AALAS. Participation in the training program by all animal care personnel is mandatory.
- The staff attends local and national AALAS meetings whenever possible.
- All faculty, staff, students and volunteers wishing to use animals in research and teaching at ETSU are required to complete an on-line training course and exam. [[www.citiprogram.org](http://www.citiprogram.org); Working with the UCAC (Non-VA Version)]. This training includes methods that minimize the number of animals required to obtain valid results and minimize animal distress.
- Additionally a tour of the animal housing facilities is required before they can use/handle animals.
- Participants receive written material, including a copy of the DLAR standard operation procedures for the care and maintenance of the animal species to be used and a copy of the Occupational Health and Safety Program for Personnel Exposed to Vertebrate Animal.
- One-on-one training in handling of animals and other procedures, including use of analgesics and anesthetics, is available to faculty, staff, and students and is provided by the DLAR staff as needed or requested,.
- Anesthesia, analgesia, and tranquilization of animals is discussed in depth with the principal investigator during the developmental phase of an animal study protocol if the procedures may cause more than momentary pain or distress.

- A listing of anesthesia and analgesia methods with route of application and dosages was compiled by the Attending Veterinarian and is provided to faculty members and research staff using animals for research and teaching.
- The DLAR has developed an unrestricted web site on the ETSU server: [www.etsu.edu/animals/dlar](http://www.etsu.edu/animals/dlar). Information on the animal care and use program at ETSU and all UCAC policies are available in full text on this site. Forms used in the animal use review process are available in Adobe pdf or downloadable in common word processing formats. More information will be added as it is developed. Faculty and staff are encouraged to visit the web site often.
- In addition, throughout the year informational emails are sent to all personnel involved with the use of animals at ETSU.
- The training delineated above includes training or instruction on research or testing methods that minimize the numbers of animals required to obtain valid results and limit animal pain or distress as well as other requirements delineated in 9 CFR, Part 2, Subpart C, Section 2.32(c). Specifically, as applicable, training and instruction of personnel includes guidance in at least the following areas:
  1. Humane methods of animal maintenance and experimentation, including:
    - a. The basic needs of each species of animal;
    - b. Proper handling and care for the various species of animals used by the facility;
    - c. Proper pre-procedural and post-procedural care of animals; and
    - d. Aseptic surgical methods and procedures;
  2. The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress;
  3. Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility;
  4. Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act;
  5. Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information:
    - a. On appropriate methods of animal care and use;

- b. On alternatives to the use of live animals in research;
- c. That could prevent unintended and unnecessary duplication of research involving animals; and
- d. Regarding the intent and requirements of the Animal Welfare Act and USDA-APHIS Regulations

#### **IV. Institutional Program Evaluation and Accreditation**

- A. All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the UCAC within the past six months and will be reevaluated by the UCAC at least once every six months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to PHS Policy IV.B.3. All UCAC semiannual reports will include a description of the nature and extent of this Institution's adherence to the PHS Policy and the Guide. Any departures from the Guide will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the UCAC's evaluations will be submitted to the Institutional Official. Semiannual reports of UCAC evaluations will be maintained by this Institution and made available to the OLAW upon request.
- B. This Institution is Category 1 — accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) . As noted above, reports of the UCAC's semiannual evaluations (program reviews and facility inspections) will be made available upon request.

#### **V. Record Keeping Requirements**

- A. ETSU will maintain for at least three years:
  - 1. A copy of this Assurance and any modifications made to it, as approved by PHS.
  - 2. Minutes of UCAC meetings, including records of attendance, activities of the committee, and committee deliberations.
  - 3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether UCAC approval was granted or withheld.
  - 4. Records of semiannual UCAC reports and recommendations (including minority views) as forwarded to the Institutional Official, William Duncan, Ph.D., Vice Provost for Research and Sponsored Programs.
  - 5. Records of accrediting body determinations.

- B. ETSU will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the UCAC for the duration of the activity and for an additional three years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

## VI. REPORTING REQUIREMENTS

- A. The Institutional reporting period is the calendar year (January 1 – December 31). The UCAC, through the Institutional Official, will submit an annual report to OLAW by January 31 of each year. The annual report will include:
  - 1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked)
  - 2. Any change in the description of the Institution's program for animal care and use as described in this Assurance
  - 3. Any change in the UCAC membership
  - 4. Notification of the dates that the UCAC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, William Duncan, Ph.D., Vice Provost for Research and Sponsored Programs
  - 5. Any minority views filed by members of the UCAC
- B. The UCAC, through the Institutional Official, will provide the OLAW promptly with a full explanation of the circumstances and actions taken with respect to:
  - 1. Any serious or continuing noncompliance with the PHS Policy.
  - 2. Any serious deviations from the provisions of the Guide.
  - 3. Any suspension of an activity by the UCAC.
- C. Reports filed under VI.A. and VI.B. above shall include any minority views filed by members of the UCAC.

## VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official	
Name: William Duncan, Ph.D.	
Title: Vice Provost for Research and Sponsored Programs	
Name of Institution: East Tennessee State University	
Address: (street, city, state, country, postal code)	
Campus Box 70565 Johnson City, TN 37614	
Phone: 423-439-6000	Fax: 423-439-6050
E-mail: DUNCANW@etsu.edu	
Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.	
Signature: <i>William R. Duncan</i>	Date: 10/12/18

### B. PHS Approving Official (to be completed by OLAW)

Doreen H. Bartlett  
 Senior Assurance Officer, Division of Assurances  
 Office of Laboratory Animal Welfare (OLAW)  
 National Institutes of Health  
 6700B Rockledge Drive Suite 2500 MSC 6910  
 Bethesda, MD 20892  
 bartletd@od.nih.gov  
 301-496-7163

Signature: Doreen H. Bartlett - S	<small>Digitally signed by Doreen H. Bartlett - S Date: 2018.10.12 13:02:37 -04'00'</small>	Date: October 12, 2018
Assurance Number: D16-00127 (A3203-01)		
Effective Date: October 12, 2018	Expiration Date: October 31, 2022	

## VIII. Membership of the UCAC

Date: May 2018			
Name of Institution: East Tennessee State University			
Assurance Number: A3203-01			
UCAC Chairperson			
Name*: Doug Thewke			
Title*: Assoc. Prof		Degree/Credentials*: Ph.D.	
Address*: (street, city, state, zip code)			
East Tennessee State University Department of Biomedical Sciences PO Box 70582 Johnson City, TN 37614			
E-mail*: thewke@etsu.edu			
Phone*: 423-439-2131		Fax*: 423-439-6766	
UCAC Roster			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
Member #26	PhD	Assoc. Professor	Scientist
" " 30	PhD	Asst. Professor	Scientist
" " 23	MD	Humane Society Rep/MD	Nonaffiliated
" " 6	PhD	Asst. Prof.	Scientist
" " 7	PhD	Assoc. Prof.	Scientist
Greg Hanley	DVM, PhD	Attending Vet	Veterinarian
Member #9	BS	Asst. Dir.	Scientist
" " 10	DVM, PhD	Asst. Prof.	Scientist
" " 31	PhD	Assoc. Professor	Scientist
" " 12	PhD	Professor	Scientist
" " 17	MD, PhD	Professor	Scientist
" " 28	RN	Nurse	Alternate Nonaffiliated
" " 37	MBA	Assoc. Dir. Bldg. Mnt.	Nonscientist
" " 38		Const. Mgmt. Dir.	Alternate Nonscientist
" " 32	PhD	Asst. Prof.	Alternate Scientist

\* This information is mandatory.

\*\* Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must

be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

\*\*\* List specific position titles for all members, including nonaffiliated (e.g., banker, teacher, volunteer fireman; not "community member" or "retired").

\*\*\*\* PHS Policy Membership Requirements:

<i>Veterinarian</i>	veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals at the institution.
<i>Scientist</i>	practicing scientist experienced in research involving animals.
<i>Nonscientist</i>	member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).
<i>Nonaffiliated</i>	individual who is not affiliated with the institution in any way other than as a member of the UCAC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

All members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Non-voting members and alternate members must be so identified.

## IX. Other Key Contacts (optional)

If there are other individuals within the Institution who may be contacted regarding this Assurance, please provide information below.

Contact #1	
Name: Gregory A Hanley	
Title: Director, DLAR	
Phone: 423-439-6783	E-mail: Hanley@etsu.edu
Contact #2	
Name:	
Title:	
Phone:	E-mail:

## X. Facility and Species Inventory

[illegible]

Unless otherwise indicated, mice and rats means mice of the genus mus and rats of the genus rattus that are purposely bred for research.

# East Tennessee State University Laboratory Animal Care and Use Program

