



QUILLEN
COLLEGE *of* MEDICINE
EAST TENNESSEE STATE UNIVERSITY

University Committee on Animal Care

Policies and Procedures for the University Committee on Animal Care at East Tennessee State University

ETSU UCAC Policies & Procedures
Approved: September 21, 2001
Revised and approved: September 14, 2021

INTRODUCTION

In accordance with the Animal Welfare Act (Public Law 89-544, 1966, as amended, (P.O. 91-579, P.O. 94-279 and P.O. 99-198) 7 U.S.C. 2131 et. seq.), and the Health Research Extension Act (P. L. 99-158)*, East Tennessee State University (ETSU) is responsible for establishing and maintaining proper measures to ensure appropriate care and use of all animals involved in teaching, research, research training and biological testing activities at ETSU.

To conduct this responsibility effectively, ETSU maintains the University Committee on Animal Care (UCAC) as a Standing Committee. The UCAC is charged with the regulation of animal care and use in all programs associated with the University including: 1) ascertain compliance with applicable federal regulations and guidelines, 2) act as the internal certifying agency for the University concerning animal care and welfare, 3) make recommendations and suggest policies for the administration of the Division of Laboratory Animal Resources (DLAR) regarding animals in research and teaching programs, 4) conduct forums as appropriate, on the needs for uses of and policies pertaining to research using animals.

* Implementing regulations for the Animal Welfare Act are published in the Code of Federal Regulations (CFR), Title 9, Chapter 1, Subchapter A, Parts 1, 2, and 3, and are administered by the U.S. Department of Agriculture (USDA). The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals was promulgated to implement the Health Research Extension Act. The Office of Laboratory Animal Welfare (OLAW) at the National Institutes of Health has responsibility for the administration and coordination of the PHS Policy.

TABLE OF CONTENTS

1. PURPOSE	4
2. AUTHORITY	4
3. THE UCAC	4
4. FUNCTIONS OF THE UCAC	7
5. PROTOCOL REVIEW	9
6. DLAR OFFICE FUNCTIONS	16
7. DEFINITIONS AND PUBLICATIONS	17

1. **PURPOSE**

The purpose of the University Committee on Animal Care (UCAC) is to oversee and evaluate the institution's animal care program, procedures, and facilities to ensure that they are consistent with the applicable regulations and guidelines governing animal subjects.

2. **AUTHORITY**

- 2.1. At ETSU, all research, teaching and testing activities that involve the use of vertebrate animals must be approved by the UCAC (9 CFR, Ch. 1, ' 2.31).
- 2.2. 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 (9 CFR, Ch.1, ' 2.32, (d) (8).
- 2.3. The UCAC is authorized to suspend, by majority vote of a quorum present at a convened meeting, a previously approved activity involving animals if it determines that the activity is not being conducted in accordance with the Animal Welfare Act, the PHS Policy or the NRC Guide (9 CFR, Ch.1, ' 2.32, (d) (6).

3. **THE UCAC**

- 3.1. **Voting membership**: The Institutional Official of ETSU will appoint the members of the UCAC, qualified through their experience and expertise, to assess ETSU's animal program, facilities, and procedures.

To comply with Federal regulations and guidelines, the UCAC will consist of no less than five members:

- 3.1.1. at least one member will be a Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at ETSU;
- 3.1.2. at least one practicing scientist experienced in research involving animals;
- 3.1.3. at least one member whose primary concerns are in a nonscientific area;
- 3.1.4. at least one member from James H. Quillen VA
- 3.1.5. one public member to represent general community interests in the proper care and use of animals. This member will not be a laboratory-animal user, will not

be affiliated with ETSU, or be a member of the immediate family of a person who is affiliated with ETSU.

An individual who meets the requirements of more than one of the above categories may fulfill more than one requirement. However, the UCAC must consist of at least five members.

- 3.2. Non-voting Ex Officio members: The Vice Provost for Research and Sponsored Programs at ETSU and one representative from the VA Research Office will be non-voting, ex officio members of the UCAC
- 3.3. Alternates: At least one Faculty (scientist) alternate and one Community member alternate will be appointed. The alternate will receive UCAC training or orientation similar or identical to what is provided to regular UCAC members. The alternate is expected to vote his/her conscience as opposed to representing the position of the regular member. The alternate may attend UCAC meetings and participate in other UCAC activities even when the regular member is present; however, an UCAC member and his/her alternate may not contribute to a quorum at the same time or act in an official committee member capacity at the same time. The appointed alternates will be listed in the UCAC roster.
- 3.4. Chair and Vice Chair: The UCAC will elect a Chair and a Vice Chair from the voting membership of the committee; neither the appointed alternates nor the Director of the DLAR may be appointed Chair or Vice Chair of the UCAC. In the Chair's absence, the Vice Chair has signatory authority and may act in all matters concerning the functions of the UCAC.
- 3.5. Length of appointment: The term of appointment to the UCAC for voting members and alternates, except for ex officio members, will be three (3) years.
- 3.6. Attendance: Attendance at the meetings of the UCAC is crucial. If a voting member or his/her alternate has been unable to attend at least 50% of the regularly scheduled meetings of the UCAC during one year, the Chair of the UCAC may ask for the resignation of that voting member and a new voting member will be appointed.
- 3.7. Frequency of meetings: The UCAC will meet monthly. At the discretion of the Chair, regular meetings may be cancelled due to lack of business or additional meetings may be called.
- 3.8. Quorum and recording of votes: A quorum will consist of a majority (51%) of the voting members of the UCAC. At a convened meeting, approval of a proposed activity may be granted only with the approval vote of a majority of the quorum present. The recording of the vote will denote the number of votes for, opposed and abstained.

- 3.9. Minutes: Minutes of the meetings will be sent to the Chairman for review. The UCAC will vote to approve the minutes at the next convened meeting. Approved minutes of UCAC activities will be routed to the Vice Provost for Research and Sponsored Programs, the Vice President for Health Affairs, the Provost, and forwarded to Sherrod Library. A copy will be maintained in the office of the DLAR.
- 3.10. Compensation: Members of the UCAC will not be compensated for their service on the UCAC or its subcommittees.
- 3.11. Liability: ETSU assures that the members of the UCAC, state employees and volunteers, who have obtained an approved statement of Understanding/Agreement from Human Resources, are covered under the Tennessee liability programs for their participation in the actions of the UCAC.
- 3.12. Conflict of interest: No member may participate in the UCAC 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.
- 3.13. Institutional Official: The Vice Provost for Research and Sponsored Programs will function as the Institutional Official at ETSU. He/she will be authorized to legally commit on behalf of ETSU that the requirements of the Animal Welfare Act, the USDA regulations and the PHS Policy on Humane Care and Use of Laboratory Animals are met. He/she will also have the authority to appoint UCAC members
- 3.14. Reporting at ETSU: The UCAC will report to the ETSU President through the Vice Provost for Research and Sponsored Programs, the Vice President for Health Affairs and the Vice President for Academic Affairs and will be advisory to the Director of the DLAR.
- 3.15. Reports to Federal funding agencies: If the UCAC suspends a research or teaching activity involving animals, 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 to USDA, OLAW, and any Federal agency funding that activity.

Failure to adhere to an established plan or schedule to correct a significant deficiency, that may be a threat to the health or safety of animals, will be reported in writing within 15 business days by the UCAC, through the Institutional Official at ETSU, to the USDA, OLAW and any federal agency funding the related activity. Any serious non-compliance issue will be reported in writing to OLAW.

- 3.16. Policies: The UCAC will request that policies, standards, procedures, guidelines, and

manuals relating to the animal care program, facility maintenance, and personnel training at ETSU be established to ensure humane care and concern by faculty, staff, and students. The Committee will review from time to time content and implementation of the policies, and guidelines adopted for ETSU and may change or amend these, if necessary, by a majority vote of the committee members when a quorum is present at a convened meeting.

Meetings of the UCAC will be conducted according to Robert's Rules of Order.

3.17. Staff: The UCAC will be supported administratively by the office staff of the DLAR.

4. FUNCTIONS OF THE UCAC

4.1. Semiannual program review: the UCAC will review, at least once every six months, ETSU's program for humane care and use of animals, using the Animal Welfare Act, and the NRC Guide for the Care and Use of Laboratory Animals (NRC Guide) as a basis for evaluation;

4.2. Semiannual inspection: the UCAC will inspect, at least once every six months, all of ETSU's animal facilities, including animal study areas, using the Animal Welfare Act and the NRC Guide as a basis for evaluation. Animal areas containing free-living wild animals in their natural habitat need not be included in such inspection.

4.2.1. The UCAC may determine the best means of conducting evaluations of ETSU's programs and facilities, however, the UCAC remains responsible for the evaluations and reports as required by the Animal Welfare Act and the NRC Guide. No UCAC member wishing to participate in any evaluation conducted under this policy may be excluded.

4.2.2. For areas housing non-Animal Welfare Act (AWA)-regulated species, the UCAC may use as few as one qualified individual or ad hoc consultant, who need not be an UCAC member or institutional employee, to conduct the facility inspections. Qualified individuals should have training and a working knowledge of the PHS Policy, *Guide*, and the AWRs to appropriately evaluate the facilities and identify deficiencies and animal welfare issues.

4.2.3. For areas housing AWA-regulated species, the UCAC may use subcommittees composed of at least two committee members and may also invite ad hoc consultants to assist in conducting the inspections. UCAC members involved in these inspections are not required to inspect together and may each inspect different parts of the facility.

- 4.3. Semiannual report to the Institutional Official: The UCAC will submit reports of the above evaluations to the Institutional Official at ETSU:
 - 4.3.1. The reports will be reviewed and signed by a majority of the UCAC members and will include any minority views. The reports will be updated at least once every six months upon completion of the required semiannual evaluations. Copies of the reports will be maintained by the office of the DLAR and will be made available to officials of the USDA and other federal funding agencies for inspection and copy upon request.
 - 4.3.2. The reports will contain a description of the nature and extent of ETSU's adherence to the Animal Welfare Act and the NRC Guide and will identify specifically any departures from the provisions of the Animal Welfare Act and the NRC Guide and will state the reasons for each departure.
 - 4.3.3. The reports will distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, with reference to the Animal Welfare Act and the NRC Guide and in the judgment of the UCAC and the Institutional Official at ETSU, is or may be a threat to the health or safety of the animals.
 - 4.3.4. If program or facility deficiencies are noted, the reports will contain a reasonable and specific plan and schedule with dates for correcting each deficiency. Any failure to adhere to the plan and schedule which results in a significant deficiency remaining uncorrected will be reported in writing within 15 business days by the UCAC, through the Institutional Official at ETSU, to the USDA, OLAW and any federal agency funding that activity.
- 4.4. Noncompliance reports: The UCAC will review, and, if warranted, investigate concerns involving the care and use of animals at ETSU resulting from public complaints and from reports of noncompliance received from laboratory or research facility personnel or employees.
- 4.5. Recommendations for improvements: The UCAC will make recommendations to the Institutional Official at ETSU regarding any aspect of ETSU's animal program, facilities, or personnel training.
- 4.6. Animal study protocol review: The UCAC will review all proposals for research, teaching and testing protocols using experimental animals. The UCAC will approve, require modifications in (to secure approval), or withhold approval of those components of proposed activities or of proposed changes regarding the care and use of animals, as specified in the Animal Welfare Act and the NRC Guide. The Committee will recommend alternatives to animal use where feasible, and guard against unnecessary repetitious experimentation.

5. **PROTOCOL REVIEW**

5.1. Policies

In order to approve proposed activities or proposed significant changes in ongoing activities, the UCAC will conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with the Animal Welfare Act, the NRC Guide, and the PHS Policy unless acceptable justification for a departure is presented in writing. The UCAC will determine that the proposed activities or changes in ongoing activities meet the following requirements:

- 5.1.1. Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals.
- 5.1.2. The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources, e. g. MedLine, Agricola, or the Animal Welfare Information Center, used to determine that alternatives were not available.
- 5.1.3. The principal investigator has provided written assurance that the activities do not unnecessarily duplicate previous experiments.
- 5.1.4. Procedures that may cause more than momentary or slight pain or distress to the animals will:
 - 5.1.4.1. be performed with appropriate sedatives, analgesics or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator, and will continue for only the necessary period of time;
 - 5.1.4.2. involve, in their planning, consultation with the attending veterinarian or his or her designee;
 - 5.1.4.3. not include the use of paralytics without anesthesia.
- 5.1.5. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.
- 5.1.6. The animals' living conditions will be appropriate for the species in accordance

with the Animal Welfare Act and the NRC Guide and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by the attending veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.

- 5.1.7. Medical care for animals will be available and provided as necessary by a qualified veterinarian.
- 5.1.8. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
- 5.1.9. Activities that involve surgery include appropriate provision for pre-operative and post-operative care of the animals in accordance with established veterinary medical and nursing practices. All survival surgery will be performed using aseptic procedures, including gloves, masks, sterile instruments, and aseptic techniques. Major operative procedures on non-rodent mammals will be conducted only in facilities intended for that purpose which shall be operated and maintained under aseptic conditions. Non-major operative procedures and all surgery on rodents do not require a dedicated facility, but must be performed using aseptic procedures. Operative procedures conducted at field sites need not be performed in dedicated facilities, but must be performed using aseptic procedures.
- 5.1.10. No animal will be used in more than one major operative procedure from which it is allowed to recover, unless:
 - 5.1.10.1. justified for scientific reasons by the principal investigator, in writing.
 - 5.1.10.2. required as routine veterinary procedure or to protect the health or well-being of the animal as determined by the attending veterinarian.
 - 5.1.10.3. in other special circumstances as determined by the Administrator of APHIS, USDA on an individual basis. Written requests and supporting data will be sent to the Administrator, APHIS, USDA, 4700 River Road, Riverdale MD 20737-1234. Tel. 202-720-3668
- 5.1.11. Methods of euthanasia used will be in accordance with the definition of the term set forth in the USDA regulations and the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia, unless a deviation is justified for scientific reasons, in writing, by the investigator.

5.2. Procedures

- 5.2.1. Animal study protocol approval process: The principal investigator will submit an

Animal Study Protocol form with all pertinent information to the office of the DLAR. The Animal Care and Use Coordinator will conduct a preliminary review and may suggest modifications (to secure approval) for adherence to applicable guidelines. Prior to UCAC review, each member of the UCAC will be provided with a copy of the Animal Study Protocol. Protocols may be approved by:

- 5.2.1.1. Approval at a convened meeting: 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.
- 5.2.1.2. Approval by a designated reviewer: In special circumstances the UCAC may use the designated reviewer procedure. All UCAC members will receive a list of the proposed activities. Within one week 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 Animal Care and Use Coordinator or the Chair 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 approve the protocol, request additional information from the PI to approve it, or refer it for full UCAC review.

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 reapproval or notification by a convened meeting.

No member may participate in the UCAC 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.

- 5.2.2. Review of PHS-supported activities involving live, vertebrate animals: There are three options for submitting verification of UCAC approval for competing PHS applications involving the use of animals:

- 5.2.2.1. Submission of the UCAC approval letter at the time of grant / contract submission;
- 5.2.2.2. Submission of the UCAC approval letter within 60 days from the

application / proposal receipt date at NIH but before peer review;

- 5.2.2.3. Just in time review by the UCAC: For competing PHS applications or proposals, verification of UCAC approval may be filed with the granting agency at any time prior to award unless specifically required earlier by the funding component. It is the responsibility of the Principal Investigator (PI) to secure UCAC approval in time to accept a PHS award. Under no circumstances may the UCAC be pressured to approve an animal study protocol or be overruled on its decision to withhold approval.
- 5.2.3. Limits of protocol review: Except as specifically authorized by ETSU Policies and USDA regulations, the UCAC will not prescribe methods or set standards for the design, performance, or conduct of actual research or experimentation by a research facility (9CFR, Ch. 1, ' 2.31,(a)) . Although not intended to conduct peer review of research proposals, the UCAC may include consideration of the U.S. Government Principles for the Utilization and Care of Vertebrate Animal in Testing, Research and Training in its proposal review process. The Principles suggest an evaluation of the relevance of a procedure to human and animal health, the advancement of knowledge or the good of society, and the conduct of scientifically valuable research (OLAW).
- 5.2.4. Use of exogenous substances in animals or in an animal housing facility: It is the responsibility of the principal investigator to insure that all individuals who may come in contact with the project and the animals used are aware of any hazard involved. Any use of potentially hazardous exogenous substances or hazardous agents in animals or in the ETSU animal facilities must be reviewed by the UCAC. The University Biosafety Committee will review the agents and make recommendations to the principal investigator.
 - 5.2.4.1. Toxins, carcinogens, test substances: The use of hazardous substances in animals must be approved by the University Biosafety Committee. Written approvals must be included with the animal study protocol.
 - 5.2.4.2. Radioactive or recombinant DNA material: Use of radioisotopes must be approved by the ETSU Radiation Safety Officer. The use of recombinant DNA material must be approved by the ETSU Institutional BioSafety and Chemical Safety Committee. Written approvals must be included with the animal study protocol.
 - 5.2.4.3. Cells, tissue, or other biological material: These must be tested for contamination with human and/or animal viruses. Test results must be submitted to the Attending Veterinarian before the material may be

introduced into animals.

5.2.5. Consultants: The UCAC may invite consultants to assist in the review of complex issues arising out of its review of proposed activities. Consultants may not approve or withhold approval of an activity, and may not vote with the UCAC unless they are also members of the UCAC.

5.2.6. Disposition of a protocol: As the result of the review of an animal study protocol or an amendment of a previously approved protocol the UCAC may:

5.2.6.1. approve the proposal as submitted,

5.2.6.2. request modifications/clarification to secure approval

5.2.6.3. withhold approval

A protocol in which approval is withheld is returned to the principal investigator with a written explanation of the reason(s) for the withholding.

5.2.7. Notification of principal investigator and others: The UCAC will notify the principal investigator, 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 decides to withhold approval of an activity, it will include in its written notification a statement of the reasons for its decision and give 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.

5.2.8. Protocol Amendment: Any changes or modifications to an approved animal study protocol require the prior approval by the UCAC. 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 Animal Care and Use Coordinator. The amendment may be approved by:

5.2.8.1. Approval at a convened meeting: Approval of a protocol amendment may be granted by the UCAC after review, at a convened meeting of a quorum of the UCAC, and with the approval vote of a majority of the quorum present.

- 5.2.8.2. Approval by a designated reviewer: The UCAC may allow the designated reviewer procedure for an amendment to a previously approved protocol. For this process, all members of the UCAC will be provided with the amendment request. Within one week of any UCAC member may request full committee review. This request should be sent to the Animal Care and Use Coordinator or the Chair by email or by mail. If no UCAC member calls for a full-committee review, the UCAC Chair can refer the amendment in question to a designated reviewer. The Chair may select one or more UCAC members, qualified to review the amendment, who will act on behalf of the entire UCAC to approve the amendment, request additional information from the PI to approve it, or refer it for full UCAC review. The principal investigator will be notified in writing of the decision of the UCAC.
- The designated reviewer(s) cannot withhold approval, however; but must in such cases refer the protocol amendment for full-committee review. The designated-reviewer approval has equal validity to full-committee review approval and does not require subsequent reapproval or notification by a convened meeting.
- 5.2.8.3. Approval of changes in personnel: Changes in personnel, other than the Principal Investigator, are classified as a “minor” change. As such the UCAC hereby authorizes 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.
- 5.2.9. Periodic review of animal study protocols: The UCAC will conduct continuing reviews of each previously approved activity involving the care and use of animals at appropriate intervals as determined by the UCAC but not less frequently than annually. The UCAC will conduct a complete review of all activities related to the care and use of animals in accordance with the above described policies and procedures at least once every three (3) years.
- 5.2.10. Post-approval monitoring of animal study protocols: After the UCAC has approved a protocol, it will monitor that procedures are carried out in the laboratory or classroom as described in the protocol in several ways: annual review of approved protocols, semiannual inspections of the animal use laboratories, limiting the purchase of animals through the DLAR office, documentation of numbers of animals used, and by investigating non-compliance reports.

- 5.2.11. Suspension of an activity: The UCAC may suspend an activity that it previously approved if it determines 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.
- 5.2.12. Report of a suspension: If the UCAC suspends an activity involving animals, 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 to USDA and any Federal agency funding that activity.
- 5.2.13. Review of animal related activities by ETSU officials: Activities and proposed significant changes in ongoing activities that have been approved by the UCAC may be subject to further appropriate 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.
- 5.2.14. Content of an animal study protocol: A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following:
- 5.2.14.1. Identification of the species and the approximate number of animals to be used.
 - 5.2.14.2. A rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used.
 - 5.2.14.3. A complete description of the proposed use of the animals.
 - 5.2.14.4. A description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, including provision for the use of analgesic, anesthetic, and tranquilizing drugs where indicated and appropriate to minimize discomfort and pain to animals.
 - 5.2.14.5. A description of any euthanasia method to be used.
- 5.2.15. Record keeping: A copy of all approved protocols and amendments to the protocols will be maintained in the office of the DLAR for the duration of the activity and an additional three years after completion of the activity. All records will be accessible for inspection and copying by authorized USDA or funding federal agency representatives at reasonable times and in a reasonable manner.

5.2.16. Animal studies at collaborating institutions: An animal study may involve a partnership between collaborating institutions. If the other institution has a current PHS Assurance on file with the OLAW and is registered as a research animal facility with the USDA, ETSU and the other institution may exercise discretion in determining which institutional animal care and use committee (IACUC) reviews the research protocol(s) and under which institutional program the research will be performed. However, the procedures performed on animals housed and/or used at ETSU must be approved by the UCAC.

If the UCAC defers the protocol review to the other IACUC, documentation of the review must be maintained by the UCAC at ETSU.

It is imperative that the UCAC is informed about any significant questions or issues raised during a semiannual program inspection by the IACUC of the other institution housing a collaborative research activity for which that IACUC bears some responsibility. It will be the responsibility of the principal investigator to keep the ETSU UCAC informed.

6. DLAR OFFICE FUNCTIONS

- 6.1. UCAC Handbook and training of UCAC members and alternates: The Animal Care and Use Coordinator will be responsible for maintaining written UCAC policies and procedures, and for informing investigators of these policies and procedures. Before their first UCAC meeting the Animal Care and Use Coordinator will conduct an orientation for newly appointed UCAC members and alternates. During this session a copy of the UCAC Handbook, including UCAC Policies and Procedures and appropriate publications, will be given to each new member and the content of the Handbook will be reviewed.
- 6.2. Recordkeeping: The DLAR staff will be responsible for maintaining UCAC files and record keeping systems in accord with 9 CFR, ch.1, ' 2.35. This will include maintaining a computer database of approved protocols, meeting minutes, correspondence, protocol files, copies of USDA and OLAW regulations, NIH guidelines, etc. Documentation maintained by the DLAR staff must support successful USDA inspections and AAALAC Int. accreditation site visits.
- 6.3. UCAC web site: The DLAR staff will maintain the UCAC web site providing full text access to policies and guidelines, animal study protocol forms and other information relevant to the use of animals at ETSU.
- 6.4. Processing animal study protocols: The Animal Care and Use Coordinator will receive

from the investigators the research protocols which involve the use of animals, will ensure that the protocols have been properly completed, will distribute the protocol to all UCAC members, will inform the investigators of the approval/denial of a research protocol by the UCAC and/or required modifications to the application, and will return all approval withheld protocols to the investigators..

- 6.5. UCAC meetings: The Animal Care and Use Coordinator will organize the monthly UCAC meetings, and will prepare and distribute the material to all UCAC members for use during the meetings, including the agenda for the meeting, minutes of the previous meeting, the animal study protocols and amendments submitted for UCAC review, and other information and materials relevant to agenda items.
- 6.6. Annual protocol surveillance: The Animal Care and Use Coordinator will initiate requests for and monitor responses to the annual protocol surveillance.
- 6.7. Semiannual program review: The Animal Care and Use Coordinator will prepare all material for the semiannual program and facility reviews, will set up the reviews, will monitor the progress of compliance with policies, and will submit the report on these reviews to the UCAC.
- 6.8. Semiannual report to Institutional Official: The Animal Care and Use Coordinator will prepare the semiannual report on the status of the animal care and use program for the UCAC, will secure signatures by all UCAC members and will forward the completed report to the ETSU Institutional Official.
- 6.9. Annual reports to USDA, OLAW, and AAALAC: The Animal Care and Use Coordinator will prepare the annual reports to these agencies to comply with their requirements.
- 6.10. Renewal of USDA license, OLAW letter of assurance, and AAALAC program description: The Animal Care and Use Coordinator will maintain and submit through the Office of the Institutional Official all necessary documents to maintain ETSU's research facility registration, the NIH Assurance, and AAALAC accreditation.
- 6.11. New information to UCAC: The Director of the DLAR will make available to UCAC members all changes in laws and standards pertaining to animal care and use.
- 6.12. Post-approval monitoring of animal study protocols: The DLAR staff will only place an order for animals if the animal use is linked to an approved protocol and will monitor the number of animals used for each protocol.

7. DEFINITIONS AND PUBLICATIONS

AAALAC: Association for Assessment and Accreditation of Laboratory Animal Care International.

Animal: Any live, vertebrate animal used or intended for use in research, research training, experimentation or biological testing or for related purposes.

Animal Facility: Any and all buildings, rooms, areas, enclosures, or vehicles including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours.

Animal Welfare Act: Public Law 89-544, 1966, as amended, (P.O. 91-579, P.O. 94-279 and P.O. 99-198) 7 U.S.C. 2131 et. seq. Implementing regulations are published in the Code of Federal Regulations (CFR), Title 9, Chapter 1, Subchapter A, Parts 1, 2, and 3, and are administered by the U.S. Department of Agriculture.

Animal Welfare Assurance or Assurance: The documentation from an institution assuring institutional compliance with the PHS Policy on Humane Care and Use of Laboratory Animals.

Attending Veterinarian: A person who has graduated from a veterinary school and has received training and/or experience in the care and management of the species being attended, and who has direct or delegated authority for activities involving animals at ETSU.

DLAR: Division of Laboratory Animal Resources at ETSU

Field study: Any study conducted on free-living wild animals in their natural habitat. This term excludes any study that involves an invasive procedure, harms or materially alters the behavior of an animal under study.

Guide: Guide for the Care and Use of Laboratory Animals, Institute of Laboratory Animal Resources, National Research Council, National Academy Press, Washington, 1996, ISBN 0-309-05377-3 or succeeding released editions.

Institutional Official: An individual at a research facility who is authorized to legally commit on behalf of the research facility that the requirements of USDA and PHS will be met. At ETSU the Vice Provost for Research acts as the Institutional Official.

OLAW: Office of Laboratory Animal Welfare is located in the Office of Extramural Research (OER) at the National Institutes of Health (NIH). OLAW oversees the implementation of the PHS Policy on Humane Care and Use of Laboratory Animals involved in research conducted or supported by any component of the Public Health Service

PHS: Public Health Service at the National Institutes of Health (NIH).

Principal investigator (PI): ETSU faculty member responsible for a proposal to conduct research

involving animals.

2020 Report of the AVMA Panel on Euthanasia: Journal of the American Veterinary Medical Association, Vol. 218, No. 5, 669-695.

Robert's Rules of Order: H. M. Robert III, W. J. Evans, D. H. Honeman, T.J. Balch (editors). HarperCollins Publ. 10th edition, 2000. ISBN 0738203076

Quorum: A majority of the voting members of the University Committee on Animal Care (UCAC).

Study area: Any building or room in which animals are housed for more than 12 hours.

UCAC: University Committee on Animal Care at ETSU

USDA: United States Department of Agriculture. Within the USDA the Animal and Plant Health Inspection Service (APHIS), Animal Care (AC) is responsible for implementing the regulations to the Animal Welfare Act.