

Tuskegee University
Division of Research and Sponsored Programs
Office of Grantsmanship and Compliance
Animal Care and Use Committee

Operational Procedures and Policies Guide
for the Care and Use of Animals
in Research and Teaching

Approved by: **William L. Lester, Provost**

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CONTENTS

Preface	iv
Responsibilities When Using Vertebrate Animals in Research, Teaching, or Testing	
1. Introduction	1
2. Definitions	1
3. Approval for Use of Animals in Research, Teaching, and Testing	1
4. Student Research	2
5. The Review Process for Animal Use Approval	2
6. Relevant Training and Experience	2
7. Supervision of Personnel and Students	2
8. Deviations from Approved Protocols	3
9. Animal Facility Maintenance for Research	3
10. Acquisition of Animals	3
11. Policy on Sick Animals Housed in the Animal Facilities	4
12. Records Keeping for Animals Used in Research, Teaching, and Testing	4
13. Health and Safety Considerations	4
14. Who is at Risk	4
Tuskegee University Animal Care and Use Committee Policy and Procedures	
15. Animal Care and Use Committee Policy and Procedures	5
16. Public Health Service Policy	5
17. Guide for the Care and Use of Laboratory Animals	5
18. 2000 Report Veterinary Medical Association Panel on Euthanasia	5
19. Animal Welfare Regulations (AWR)	6
20. Tuskegee University Animal Care and Use Committee (TUACUC)	6
21. Responsibilities of the TUACUC	
1. Semiannual Reviews of Tuskegee University's Animal Care Program	7
2. Semiannual Reports to the Provost	7
3. Reports to the Office of Laboratory Animal Welfare (OLAW)	7
4. Reports to U.S. Department of Agriculture (USDA) and Animal and Plant Health Inspection Service (APHIS)	7
5. Review of Animal Care and Use Application Form	8
6. Monitoring and Possible Suspension of Ongoing Activities	8
7. Responding to Public Concerns	9
8. Records Keeping	9

Appendix A: Animal Care and Use Protocol Form.....	10-18
Appendix B: Terms for Approval or Disapproval of Application Form.....	19
Appendix C: Reference Materials	20
Appendix D: List of Approved Sources for Animal Purchase	21
Appendix E: Pain and Distress Classifications	22-23
Appendix F: Animal Subject Transfer or Census Change Form	24
Appendix G: Occupational Health for Animal Care Personnel.....	25-27
Documentation Form for Animal Care Personnel Occupational Health Program	28

PREFACE

The revised second edition of the Operational Procedures and Policies Guide for the Care and Use of Animals in Research or Teaching is designed to further the University's goal in teaching; testing and demonstration through the use of animals which must follow humane and scientifically appropriate procedures. This guide will support such efforts at Tuskegee University. The primary purpose of the document is to provide guidance to Tuskegee University investigators, on how to plan for and conduct animal experiments with the highest scientific and ethical principles that are humanly possible. The guide provides information regarding the University's Policies and Tuskegee University Animal Care and Use Committee's (TUACUC) policies and procedures to conduct research on animals.

In research fields today, technological advances occur daily. For this reason, this guide has been constructed in a manner which allows for the revision of any section without the need to re-write the entire guide. Continuous revision is essential. Researchers' suggestions for improvement are requested and appreciated. Please submit suggestions by e-mail to Felecia Moss-Grant fmgrant@tuskegee.edu Office of Grantsmanship and Compliance, Dr. Kunwar Srivastava srivastava@tuskegee.edu Veterinary Medicine, Department of Pathobiology or Dr. Pochana Reddy reddyg@tuskegee.edu Veterinary Medicine, Department of Pathobiology

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RESPONSIBILITIES WHEN USING VERTEBRATE ANIMALS IN RESEARCH, TEACHING OR TESTING

Introduction

All activities involving animals must be conducted in accordance with humane and ethical principles as established by federal laws, regulations, and guidelines pertaining to animal care and use. Tuskegee University has an Animal Welfare Assurance Number on file from the Office of Laboratory Animal Welfare (OLAW), and therefore follows the Public Health Service (PHS) Policy on the Humane Care and Use of Laboratory Animals. The information and the animal use application form in this guide conform to the PHS Policy and Animal Welfare Act (AWA) of the United States Department of Agriculture (USDA).

Definitions

- Animal — any live vertebrate animal (mammals, birds, fish, reptiles, and amphibians).
- Activities — research, teaching, training, experimentation, demonstration and related activities, whether in the laboratory or in the field.
- Principal Investigator — the faculty member or other investigator with primary responsibility for the oversight of the research, teaching, training, experimentation, observation and related activities.

Animals may not be acquired for use at Tuskegee University before approval is received from Tuskegee University Animal Care and Use Committee (TUACUC)

Approval for Use of Animals in Research, Teaching, and Testing

To obtain approval from the TUACUC, an Application for Animal Care and Use Form for the use of animals in teaching, research and testing must be completed. The completed Application for Animal Care and Use Form (original and seven copies) should be submitted to the Administrative Assistant (Mrs. M.B. Mitchell - 727-8234), Rm. 119, Williams-Bowie Hall, Tuskegee University. Application should be submitted a minimum of 21 working days prior to the committee's regular meeting date (last Friday of each month). Application received after that date may not be reviewed during that month. A copy of this form is provided in Appendix A. The application form can also be obtained through the website from the Office of Research and Sponsored Programs Grantsmanship and Compliance or the College of Veterinary Medicine Nursing, and Allied Health.

If there are any questions about the application form, please call Mrs. M. B. Mitchell, Administrative Assistant at 727-8234, or the TUACUC Chair. Dr. Gopal Reddy. After TUACUC review of the application form, the principal investigator will be informed of the results, within 7 working days.

Student Research

Students may not be designated as the investigators for animal activities; only a faculty member may serve as principal investigator. Students may serve as co-investigators on a project. Students intending to conduct research, demonstrations, or testing with animals, must involve a faculty member from the beginning stages of the research project.

The Review Process for Animal Use Approval

All applications are reviewed by the TUACUC at the regular meetings (the last Friday of each month). Approval/disapproval categories are defined in Appendix B. The TUACUC will not approve applications that have not received approval from: the Radiation Safety Committee, Biohazard Committee or Human Participant Review Committee. It is the responsibility of the principal investigator to acquire approval from the appropriate committees and to obtain approval from TUACUC.

Relevant Training and Experience

Investigators and other individuals involved in animal care and use at Tuskegee University will be required to become familiar with materials that are relevant and appropriate to their animal involvement. For example, investigators may be expected to be familiar with the Animal Welfare Regulations (AWR), the NIH Guide for the Care and Use of Laboratory Animals (Guide), the P1 Policy and the current Report of the AVM Panel on Euthanasia. Investigators must be able to demonstrate that they have had the training and experience necessary to humanely conduct the proposed teaching, demonstration, testing, or research activities.

In accordance with humane and ethical principles as established by federal laws, regulations, and guidelines pertaining to animal care and use, all new investigators who direct or conduct surgical procedures on rodents will be required to view the video, Basics of Aseptic Surgery and Anesthesia in Rodents, and read relevant sections of Recognition and Alleviation of Pain and Distress In Laboratory Animals. Mrs. M.B. Mitchell can be contacted to view the video.

Instructional and reference materials are maintained in the Comparative Medicine Resource Center. These materials may be borrowed by faculty, investigators and other individuals involved in animal care and use. See Appendix C for a list of the available materials. As a supplement to these materials, the TUACUC home page has extensive links to Web resources on animal care and use. Direct training with regards to special techniques will be provided by the TUACUC or attending veterinarian.

Supervision of Personnel and Students

In the event that individuals other than the principal investigator will be involved in the care and use of animals, the principal investigator is required to make arrangements with the attending veterinarian for the necessary training of these individuals. The principal investigator is responsible for the conduct of personnel and student researchers.

Deviations from Approved Protocols

Once a protocol is approved, no changes are permitted. Changes to the approved protocol must be approved by TUACUC

Examples of changes that must be reported immediately are listed below.

- Additions, deletions, or modifications of animal procedures as outlined in the original protocol.
- Personnel directly involved with animal care or use
- Species of animals
- Number of animals
- Anticipated levels of pain or distress
- Location of housing or use
- Surgical procedures
- Drug doses
- Method of euthanasia
- Disposal of remains

These changes/deviations in the protocol will be reviewed in the same way as a new proposal.

Animal Facility Maintenance for Research

The following information should be clearly posted on the door of the research animal facility:

- 1) a schedule describing the frequency in which all animal caging is changed.
- 2) a list of the names and telephone numbers of responsible emergency contact persons.
- 3) the address and telephone number of the Attending Veterinarian and the principal investigator.

Acquisition of Animals

Research Animals acquired for research should be purchased from reputable sources. The current approved sources are listed in Appendix D. Other suppliers of mammals may be suggested by researchers, but these will require pre-approval by the TUACUC.

If animals will be collected in the wild, the appropriate permits must be obtained. The living conditions for any wild animals must be appropriate for the species. Please contact the Comparative Medicine Resource Center or the Attending Veterinarian to ensure that all appropriate permits have been obtained for the animals collected in the wild. Under no circumstances any stray dog or cat is to be used in teaching, research, or testing activities.

Policy on Sick Animals Housed in the Animal Facilities

If an unexpected illness occurs, the investigator or his/her staff should contact the Attending Veterinarian for examination and consultation. Animals that are experiencing pain and distress (see Appendix E) or that are moribund will be referred to the Attending Veterinarian for a decision on euthanasia.

Record Keeping for Animals Used in Research, Teaching, and Testing

The Animal Welfare Regulations and the PHS Policy require that the species and numbers of animals used at Tuskegee University be closely monitored. This is accomplished by requiring investigators to fill out the Animal Subjects Transfer/Census Change Form (Appendix F) and send it to the Office of Comparative Medicine Resource Center, within three (3) days of the census change.

Individual research animals housed in the animal facilities should be appropriately identified by using color leg bards, tattoos, or cage cards; the cards should include the name of the principal investigator, date of arrival of animals, TUACUC protocol number and, if applicable, the date(s) of any surgical procedures conducted on the animal.

Health and Safety Considerations

The TUACUC publishes an educational document on Occupational Health for Animal Care Personnel (Appendix G). Any person who is placed “at risk” is required to read the document, visit the Tuskegee University assigned Health provider, complete and sign the documentation form and send it to Mrs. MB. Mitchell, Room 119, Williams-Bowie Hall, School of Veterinary Medicine, Tuskegee University.

Who is “at risk”?

Risk is determined by the species of animal, the amount of contact or exposure to the animals, the duties involved and the hazards potentially encountered while exposed to the animals. For example, an individual who handles rats (chance of being bitten) or cleans the rat cages (chance of air-borne disease or allergens) is at risk. An individual who is observing bird behavior on campus or observing fish in a fish tank is not at risk from the animals. Whether someone is “at risk” must be determined on an individual basis. If you are not sure whether an individual will be placed at risk, please discuss with the TUACUC chair or the Attending Veterinarian.

TUSKEGEE UNIVERSITY ANIMAL CARE AND USE COMMITTEE POLICY AND PROCEDURES

The Tuskegee University policies and procedures for the care and use of animals are based on federal laws, regulations, policies and guidelines as provided by federal agencies and other professional associations. Tuskegee University is a registered research facility with the United States Department of Agriculture. Tuskegee University has an Animal Welfare Assurance Number filed with the Office of Laboratory Animal Welfare (OLAW), and, therefore is required to follow the Animal Welfare Regulations and the Public Health Service Policy on the Humane Care and Use of Laboratory Animals. Copies of the documents mentioned are available at the College of Veterinary Medicine Library, and the Office of Comparative Medicine Resource Center.

Public Health Service Policy

The Public Health Service (PHS) Policy on the Humane Care and Use of Laboratory Animals was promulgated to implement the Health, Research and Extension Act of 1985 (Public Law 99-158, November 20, 1985, Animals in Research'. The PHS Policy is administered by the Office of Laboratory Animal Welfare (OLAW) of the National Institutes of Health (NIH). This policy is applicable to all PHS-conducted or supported activities involving animals. Tuskegee University does conduct PHS-supported animal activities and has an Assurance Number filed with OLAW.

The PHS Policy describes the requirements and responsibilities of the TUACUC in overseeing animal care and use in research, teaching, and testing at Tuskegee University.

The Guide for the Care and Use of Laboratory Animals

The Guide was prepared by the Institute of Laboratory Animal Resources of the National Research Council revised in 1996. The PHS Policy requires institutions to use the Guide as a basis for developing and implementing an institutional program for activities involving animals. The Guide addresses several areas of concern that arise in animal research, including the role of the TUACUC in monitoring the care and use of animals, the use of physical restraint, surgical procedures, food or fluid restriction, occupational health and safety of animal care personnel, housing of animals and veterinary medical care.

2000 Report of the American Veterinary Medical Association (AVISIA) Panel on Euthanasia

The PHS Policy states that methods of euthanasia will be consistent with the recommendations of this panel. The report was published in the Journal of the American Veterinary Medical Association, March 1, 2000 (Vol. 281, No. 5). For more information on the AVISIA, go to the Office of Grantsmanship and Compliance website.

The Animal Welfare Regulations (AWR)

The AWR are the principal federal rules governing the sale, purchases, handling, transport and use of animals

(The Animal Welfare Act) The U. S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS)/Animal Care (AC) implements the AWR. Tuskegee University has USDA regulated animal activities and is a Registered Research Facility. For more information on the AWR, go to the Office of Grantsmanship and Compliance Website.

The Tuskegee University Animal Care and Use Committee (TUACUC)

1. The TUACUC charge is to implement federal guidelines as required by law concerning animal care and use.

2. The Provost who appoints all committee members including the Chair is the Institutional Official for Tuskegee University.

3. Membership

- a. One doctor of veterinary medicine knowledgeable in laboratory animal medicine.
- b. Three members who have had experience in research involving animals.
- c. One member whose primary concerns are in a non-scientific area.
- d. One individual who is not affiliated with the University in any way other than as a member of the TUACUC, and is not a member of the immediate family of a person who is affiliated with the University. (Note: c and d may be one individual)
- e. The Chair will be appointed by the Provost from the three faculty members with animal research experience.
- f. Member replacement: A member who is unable to attend regular meetings up to six times or complete his/her term may be replaced by the Provost (Institutional Official) in order to maintain the committee membership.

4. Meeting schedule: Monthly, the last Friday of the month.

5. Reports to: Provost, Institutional Official for Tuskegee University.

A list of the current members of the TUACUC may be obtained from the Administrative Assistant, Comparative Medicine and Resource Center (CMRC). 727-8234. the College of Veterinary Medicine, Nursing, and Allied Health, or the Division of Research and Sponsored Programs, Grantsmanship and Compliance website.

Responsibilities of the TUACUC

1. Semiannual Reviews of Tuskegee University's Animal Care Program

The PHS Policy and USDA AWR require that the TUACUC review the institution's program for humane care and use of animals at least once every six months using the Guide for the Care and Use of Laboratory Animals as a basis for evaluation. This review must include an inspection of Tuskegee University's animal facilities, including any satellite facilities.

2. Semiannual Reports to the Provost

Upon completion of each review, the TUACUC will submit a report to the Provost.

These reports will:

- 1) contain a description of the nature and extent of Tuskegee University's adherence to the Guide and PBS Policy;
- 2) identify and justify any departures from the Guide and P Polio';
- 3) distinguish significant deficiencies (those that may be a threat to the health or safety of animals) and minor deficiencies, and provide a reasonable and specific plan for correcting each deficiency; and
- 4) include recommendations to the Provost regarding any aspect of Tuskegee University's animal care program facilities or personnel training.

Note: The responsible investigator, dean, or director must respond in writing indicating how and when deficiencies are corrected and the steps taken to prevent future deficiencies.

3. Reports to Office of Laboratory Animal Welfare (OLAW)

Following approval of an animal welfare assurance by OLAW, the TUACUC, through the Provost, will submit annual reports to OLAW on or before its anniversary date. These reports will include any changes in Tuskegee University's animal care program, TUACUC membership, and the addition or deletion of an animal facilities. The TUACUC is obliged by its Assurance Number to promptly inform OLAW of any serious or continuing noncompliance with PHS Policy, any serious deviations from provisions of the Guide, and any suspension of an activity by the TUACUC. All reports to OLAW will include majority and minority views filed by members of the TUACUC.

4. Reports to U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS)

Tuskegee University houses animals covered under the Federal Animal Welfare Act.

Therefore, TUACUC submits annual reports, signed by the Provost, the Institutional Official, to the USDA Animal and Plant Health Inspection Service before December 1.

5. Review of Animal Care and Use Application Form

Any use of animals for research, teaching and testing at Tuskegee University must be reviewed and approved by the TUACUC prior to initiating any activity related to animal use. The faculty member or principal investigator having primary responsibility for a project involving animals will submit to the Administrative Assistant of the Comparative Medicine and Resource Center, a completed Animal Care and Use protocol for Research, Teaching, Testing, or Demonstration. A copy of this application form is included (Appendix A) and is also available at the Division of Research and Sponsored Programs website. In reviewing the form, TUACUC will consider these important elements:

- 1) the rationale for the choice of species and number of animals to be used, including evidence of consideration of 'the three R's (reduction in the number of animals needed, refinement of procedures to maximize the value of the research, and replacement with non-animal models).
- 2) the anticipated level of pain or discomfort to be experienced by the animals and methods used to minimize pain or discomfort.
- 3) the living conditions of the animals, including housing, feeding, and non- medical care.
- 4) provisions for medical care, if such care is needed.
- 5) knowledge demonstrated by personnel, including basic needs of the species, use of aseptic surgical methods and procedures, proper pre- and post- surgical care, and personnel health and safety issues.
- 6) the disposition of animals at the end of the project.
- 7) whether consideration was given to alternatives to the painful procedures.

Animals may not be acquired for use at Tuskegee University before approval is received from the TUACUC. New application forms will be reviewed by the TUACUC during monthly meetings.

6. Monitoring and Possible Suspension of Ongoing Activities

As part of the monthly review process, or through visits to Tuskegee University's animal care facilities at other times, members of the TUACUC note whether adherence to approved protocols is being maintained. If serious problems are noted, the TUACUC may convene to consider suspension of an activity. If the TUACTJC votes to suspend the activity, the TUACUC Chair will meet with the responsible faculty member or principal investigator to state the reasons for the suspension and necessary corrective actions. If the activity is funded by PHS, a report will be forwarded to OLAW.

Ongoing activities will be reviewed by the TUACUC annually to ensure that significant departures from approved protocols have not occurred. The TUACUC Chair along with a designee will meet with the investigator to review the original protocol and discuss departures. Long-term activities will be subject to full review by the TUACUC every three years for OLAW and annually for USDA. A new application form is required for this review, except for teaching protocols. The procedure for these reviews will be the same as for initial applications.

7. Responding to Public Concerns

TUACUC should be prepared to answer questions regarding Tuskegee University's animal care policy posed by members of the University community or the general public. The TUACUC will investigate any accusations regarding violations of federal regulations, determine whether the accusations are valid and take corrective action or suspension of an ongoing activity if necessary. No University employee, student, or TUACUC member will be discriminated against or be subject to any reprisal for reporting violations of federal regulations. Procedures for reporting animal care concerns will be posted throughout the animal facility.

8. Record Keeping

The Administrative Assistant and the Attending Veterinarian will maintain, and provide copies of the following documents to the Office of the Provost

- 1) The University's Animal Welfare Assurance Number;
- 2) Minutes of TUACUC 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 TUACUC approval was given or withheld;
- 4) Records of semiannual TUACUC reports and recommendations (including minority views) submitted to the Provost.

Records shall be maintained for three years. Records that relate directly to applications, proposals, and proposed significant changes in ongoing activities reviewed and approved by the TUACUC shall be maintained for the duration of the project and for an additional three years following completion of the project. The records shall be accessible for inspection and copying by authorized OLAW or USDA inspectors at reasonable times. A copy of all the above documents will also be on file in the Office of the Director, Comparative Medicine Resource Center.