

WINSTON-SALEM STATE UNIVERSITY



WINSTON-SALEM
STATE UNIVERSITY

INSTITUTIONAL ANIMAL CARE AND
USE COMMITTEE (IACUC)
PROCEDURES

I. BACKGROUND AND ORGANIZATION

A. INTRODUCTION & PURPOSE

Winston-Salem State University is committed to the humane care and use of animals in activities related to research, testing and teaching. The University has adopted on an institution-wide principles regarding animal care as stated in the Animal Welfare Act (AWA) and the *NIH Guide for the Care and Use of Laboratory Animals*. All research involving vertebrate animals that is conducted or authorized under the jurisdiction of Winston-Salem State University is subject to review by the IACUC.

Winston-Salem State University's Institutional Animal Care and Use Committee (IACUC) is the committee responsible for ensuring the protection and care of vertebrate animals being used in research studies at Winston-Salem State University. The IACUC is charged with this task while facilitating animal research in ways consistent with long-standing ethical principles and federal, state and university regulations. All research projects or instructional practices that involve animal subjects must be reviewed and approved by the IACUC prior to initiation.

B. LINES OF AUTHORITY AND CHARGE

The IACUC was established in accordance with the Animal Welfare Act and the Health Research Extension Act under the authority of the Chancellor to ensure the humane care and use of animals for research and education at the University under optimum conditions, which, at a minimum, comply with all pertinent laws. The IACUC is staffed by the Office of Sponsored Programs, which is under the authority of the Provost and Vice Chancellor for Academic Affairs

C. DEFINITIONS & ACRONYMS

The IACUC uses the following definitions and acronyms in reference to its activities:

AAALAC – Association for Assessment and Accreditation of Laboratory Animal Care.

Animal – An unqualified use of the term “animal” refers to live vertebrates beyond the fetal stage (mammals) or that have hatched (other vertebrates). The IACUC does not regulate activity associated with non-vertebrate animals.

Animal Use – Any contact with live vertebrates, including care and handling, for research or teaching purposes is classified as “animal use” and is governed by the IACUC.

Application – This refers to the IACUC Protocol Application for Animal Use. The term indicates that the protocol has not yet been approved.

APHIS – Animal and Plant Health Inspection Service.

Attending Veterinarian – Winston-Salem State University Attending Veterinarian serves on the IACUC, has delegated authority for all protocols, animal facilities and all animals at the

university. The Attending Veterinarian is available to make recommendations and provides veterinary care.

AWA – Animal Welfare Act of 1966. This term is normally used to both the Act itself and the resulting regulations. The AWA governs use of USDA-covered species (all mammals and birds except mice, rats and birds bred for research purposes).

Compliance Officer – The Compliance Officer monitors compliance and corrective actions and submits IACUC reports.

Designated Reviewer(s) – An individual or individuals granted the authority by the Chair or IACUC to review and, at their discretion, approve modified or revised Applications or protocols, or to match grants to protocols.

The Guide – The Guide for the Care and Use of Laboratory Animals is published by the National Academy of Sciences under the auspices of the National Research Council (NRC), and serves as a standard for laboratory animal welfare.

IACUC – Institutional Animal Care and Use Committee.

Investigator – Any faculty member using animals (live vertebrates) in research or teaching is classified as an Investigator for IACUC purposes. In addition, any other person serving as Principal Investigator on a research grant is also considered an Investigator, regardless of whether they will have physical contact with animals.

NIH – The National Institutes of Health, a part of the U.S. Department of Health and Human Services, is the primary Federal agency for conducting and supporting medical research.

Noncompliance – Any action or inaction that does not follow the procedures or design specified in an approved protocol, and/or that violates animal welfare regulations, or Winston-Salem State University IACUC Policies and Procedures.

NRC – National Research Council

OLAW – Office of Laboratory Animal Welfare

PHS – Public Health Services, an agency that serves as the office of Surgeon General, includes agencies whose mission is to improve the public health.

PHS Policy – Public Health Service Policy on Humane Care and Use of Laboratory Animals.

Principal Investigator – When submitting a Protocol Application for Animal Use, a single individual must be listed as Principal Investigator (PI). In the case of projects funded by government sources, this individual must be the same as the Principal Investigator on the grant. Any other Investigators involved with the project must be listed on the Protocol Application as Co-Investigators.

PTCRC – The Piedmont Triad Center for Research

Protocol – Normally refers specifically to a protocol that has been approved by the IACUC, as opposed to an Application submitted for review.

USDA – U.S. Department of Agriculture

D. THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

Winston-Salem State University process for reviewing all research and research training activities involving vertebrate animals is carried out by the Institutional Animal Care and Use Committee (IACUC). The IACUC is authorized to request modifications, approve, withhold approval, or suspend animal research and teaching projects.

In addition to reviewing specific research projects, the IACUC also carries out other federally mandated functions such as: review and report on the overall animal program and inspect and evaluate all of the animal facilities at least once every six months; review and investigate legitimate concerns involving the care and use of animals at the institution; and make recommendations to the Institutional Official regarding any aspect of the research, animal program, facilities or personnel training.

All projects (with or without internal or external funding) which involve the use of vertebrate animals must undergo IACUC review and receive approval prior to initiation. Investigators are recommended to consult with the attending veterinarian about the project and submit a completed Animal Use Protocol Form (application) to the IACUC for review by the Committee.

The Committee is comprised of non-scientific/lay/non-affiliated members as well as scientific/affiliated members, to ensure a balance of professional expertise and community perspective. All committee members participate in the review process. IACUC policies and procedures are designed to ensure that the review is conducted with thoroughness, consistency and objectivity in a manner allowing each member to exercise independent judgment. No member is assigned to serve as a primary reviewer or is permitted to vote on any matter in which that member has a conflicting interest.

IACUC Meetings

Meetings are routinely every six months. The IACUC will call a meeting when materials for review are submitted. The Compliance Officer will initially review each protocol. In consultation with the Compliance Officer, the IACUC will decide as to the type of review a proposal receives (executive or full committee), which is based on the expected level of animal discomfort and types of procedures. The agenda is sent to members approximately one week prior to a meeting. Protocols are placed on the agenda as they come in. A quorum is considered to be one more than one half the total number of regular voting members and at least one non-scientist must be present. If less than one-half the total number of regular voting members are not present, ex officio members with voting privileges may be included to constitute a quorum.

If the Committee Chair has a conflict of interest or is unavailable, a majority vote with a quorum from the IACUC with the chair excusing him/her will be appropriate. Included in this vote shall be the designation of a specific person to sign the protocol.

Once approved, each protocol is reviewed at least annually or more frequently if deemed appropriate or necessary by the IACUC and if active long enough, a renewal of ongoing projects is required every three years.

A research project that is identical to an already approved project in regard to specific aims, hypothesis, and animal species and use, may be given approval by the Committee Chair. This approval is reported at a regularly scheduled meeting.

Protocols not requiring direct use of live animals, i.e. using animal material obtained from slaughterhouses or other specified sources, receive approval by the Committee Chair.

IACUC Membership

Members shall be of varying professional and personal backgrounds and shall demonstrate a genuine interest in and commitment to the purpose of the Committee. Membership shall include one Doctor of Veterinary Medicine, one practicing scientist, one member whose primary concerns are in a nonscientific area, one individual who is not affiliated with the institution in any way other than as a member of the IACUC, an Ex Officio member (OSP staff person).

Every effort will be made to schedule meetings to accommodate as many members as possible. Each member of the committee was chosen because of their expertise in their particular field. It is the members' professional responsibility to attend meetings and participate. Meetings are routinely held every six months. Additional meetings will be scheduled as needed. Failure to attend at least 50% of these meetings will result in removal and replacement of the committee member.

For a more detailed description of committee membership, refer to the *Guide for the Care and Use of Animals*.

Contacting the IACUC

The IACUC Chair, the Director of the Office of Sponsored Programs and the Compliance Officer serves as the point of contact for information regarding the IACUC.

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(336) 750-3247
overholtjl@wssu.edu

Vernon Shanks, Interim Director
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C117 Anderson Center
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shanksvl@wssu.edu

Islam Khan, PhD, Compliance Officer
Office of Sponsored Programs
C125 Anderson Center
(336) 750-2982
khaniu@wssu.edu

All correspondence, including that directed to the Chair or other specific members of the Committee, should also be sent to the Compliance Officer.

E. RESPONSIBILITIES

Institutional Animal Care and Use Committee

1. Review, as required by Federal regulation, the University's program for humane care and use of animals;
2. Inspect, as required by Federal regulation, all of the University's animal facilities;
3. Prepare reports of IACUC evaluations conducted as required above and submit the reports to the Institutional Official;
4. Review concerns involving the care and use of animals at the University;
5. Make recommendations to the Institutional Official regarding any aspect of the University's animal program, facilities, or personnel training;
6. Review proposed and ongoing research projects for compliance with University and Federal policies;
7. Modify or suspend research activities which are inconsistent with University and Federal policy on the humane care and use of animals;
8. Oversee training programs for personnel involved in animal care and research;
9. In consultation with administrators, prepare reports as required by federal policy to sponsoring agencies on the status of the University's animal-related programs.

Principal Investigator

1. The Principal Investigator must sign the Protocol for Animal Use, thereby certifying the accuracy of the information upon which the IACUC bases its decision to approve or withhold approval of the protocol.
2. The Principal Investigator is responsible for the proper and ethical conduct of the study as well as the humane treatment of the animals used.
3. In addition, it is the responsibility of the Principal Investigator to ensure that all personnel handling animals (including technicians and students) are properly trained.

Office of Sponsored Programs (Compliance Officer)

1. Provide the necessary liaison between Principal Investigators, the Institutional Animal Care and Use Committee, granting agencies, and regulatory agencies.
2. Serve as the administrator for the Institutional Animal Care and Use Committee.
3. Provide all necessary documentation, forms, regulatory guidelines and regulations, etc. for Principal Investigators

II. REGULATIONS, GUIDELINES AND STANDARDS

The Winston-Salem State University Institutional Animal Care and Use Committee (IACUC) has an Assurance on file with the Office for Protection from Research Risks in accordance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, for institutions which have research sponsored by the PHS. The Committee is governed by the USDA Animal Welfare Act as documented in the Code of Federal Regulation Title 9, Subchapter A Parts 1, 2 and 3 (<https://www.nal.usda.gov/awic/final-rules-animal-welfare-9-cfr-parts-1-2-and-3>). The IACUC applies the standards set forth in the *Guide for the Care and Use of Laboratory Animals*.

III. ANIMAL PROTOCOL SUBMISSION AND REVIEW

A. SCOPE

The Winston-Salem Animal Use Protocol Form must be completed and **approved** for all work involving the use of vertebrate animals at Winston-Salem State University regardless of the source of funding or the intended use (e.g., research, teaching or testing) of the animals.

B. PROTOCOL REVIEW PROCESS AND CRITERIA FOR REVIEW

Types of Review/Overview of the Application Process

The process for reviewing and approving programs using animals begins with the completion of Winston-Salem Animal Use Protocol Form. Information required for the Protocol is consistent with requirements detailed in the Public Health Service Policy on Humane Care and Use of Laboratory Animals, and the Animal Welfare Regulations. A consultation with the University Veterinarian is recommended for all proposals involving the use of animals prior to the protocol's approval.

The principal investigator is requested to submit two (2) copies to the Compliance Officer. One electronic copy and 1 copy with all appropriate signatures of the application materials should be sent to the attention of:

Islam Khan, PhD, Compliance Officer
Office of Sponsored Programs
C125 Anderson Center
(336) 750-2982
khaniu@wssu.edu

There are two types of Committee review: full or executive. Determination of the type of review is usually based upon the expected level of animal pain or discomfort and types of procedures (see Appendix 1). The following steps are involved in the review process:

Step 1: *Submission of the Protocol.* The investigator must complete Winston-Salem State University IACUC Application for Approval of Research Involving Vertebrate Animals through online system *Cayuse Animal Oversight*.

Step 2: *Initial Review.* Following the receipt of a Protocol by the Compliance Officer, the type of review a proposal will receive (executive or full committee) based on the expected level of animal discomfort and types of procedures will be verified. Completeness of the protocol is also checked at this time.

Step 3: *Review.* The IACUC considers new protocols requiring full committee review, and a meeting is scheduled. Possible outcomes of the Committee's review include approval, approval pending modification(s) and/or clarification(s) or disapproval.

a. FULL REVIEWS – The Committee reviews the protocols prior to the meeting and comments on any concerns or points requiring clarification and/or stipulations. The protocol is then open for discussion by the Committee, which includes the University Veterinarian.

b. EXECUTIVE REVIEW - The chair alone (or his designee from the Committee) reviews and approves protocols falling in this category. This category includes continuing reviews, previously approved protocols that have been resubmitted or identical protocols submitted to different funding agencies, protocols with no direct animal use, e.g. funds will be used for salary support only (on a previously approved protocol), or use of shared animal products or slaughterhouse materials.

Step 4: *Investigator Notification.* If a protocol receives approval, the investigator is provided with a Letter of Approval certifying the approval. In cases where the IACUC requires clarification(s) or modification(s), the investigator is notified by the Compliance Officer. In such cases, the approval is issued following receipt of an acceptable response from the investigator. In cases of a tabled or disapproved protocol, the investigator is notified by the Chair and advised as to available options.

Criteria for Review

All proposed activities are reviewed to ensure that the following federal requirements for granting IACUC approval are met:

a. **ACTIVITIES** -- All activities involving animals must be in accord with USDA Regulations/PHS Policy

b. **PAIN/DISTRESS** -- Must avoid/minimize discomfort/distress/pain. If pain/distress is caused, appropriate sedation, analgesia or anesthesia will be used. Attending veterinarian must be involved in planning. Use of paralytics is prohibited. Animals with chronic/severe unrelievable pain will be painlessly killed.

c. **ALTERNATIVES** -- The PI has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animal and has provided a written narrative description of the methods and sources, e.g., the Animal Welfare Information Center, used to determine that alternatives were not available.

d. **RATIONALE AND METHODS** -- All proposals must include:

- Identification of the species and the approximate number of animals to be used;
- A rationale for involving animals and for the appropriateness of the species and numbers of animals to be used;
- A complete description of the proposed use of the animals;
- A description of procedures designed to assure that discomfort and pain to animals will be limited to that which is non avoidable 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; and
- A description of any euthanasia method to be used.

e. **DUPLICATION** -- Assurance that activities do not unnecessarily duplicate previous efforts must be provided.

f. **SURGERY**-- Requirements for sterile surgery and pre/post operative care must be met. You cannot use one animal for several major operative procedures from which it will recover, without meeting specified conditions.

g. **EUTHANASIA**--The euthanasia method must be consistent with USDA Regulations/AVMA recommendations

h. **HOUSING/HEALTH** -- Animal living conditions must be consistent with standards of housing, feeding and care directed by veterinarian or scientist with appropriate expertise. Medical care must be provided by qualified veterinarian.

i. **QUALIFICATIONS** --Personnel must be appropriately trained and qualified. Completion of the Winston-Salem State University approved training program is required for all individuals working with animals or identified on a protocol.

j. DEVIATION FROM REQUIREMENTS --Must be justified for scientific reasons, in writing.

The Committee's review process always includes a check for compliance with all applicable IACUC or institutional policies and procedures.

C. CONTINUING REVIEW, AMENDMENTS AND TERMINATION OF PROTOCOLS

Continuing Review and Three-Year Renewal of Ongoing Projects

Animal research protocols are approved for a three-year term, subject to continuing review at least annually.

Continuing Review Process:

The principal investigator is notified by email by the Compliance Officer prior to the anniversary date of the last review indicating that the continuing review is due. The investigator must complete and return an IACUC Continuing Review or Termination of IACUC Approval Form, which is then reviewed by a Committee Chair. Upon recommendation of the Committee Chair, the protocol is either approved outright for period of time up to an additional year or a protocol modification requested and the normal review process resumes.

Three-Year Renewal:

At the end of the third year of a protocol, the investigator must resubmit it for Committee review in order to continue research activities. A new *Animal Use Protocol Review Form* must be submitted; this form undergoes the same review process as any new protocol. The renewal should include all previous modifications or amendments made to the protocol since its original approval.

Request for Amendment to Previously Approved Protocol

Review of any changes to previously approved research is required by federal regulation and is an essential element of the continuing review of research involving vertebrate animals. Federal regulations mandate that changes cannot occur until after review and approval.

The IACUC recognizes that research is a continuous process and that changes in the conduct of the research are necessary. However, no changes to an approved protocol should be implemented until the IACUC has reviewed and approved the changes.

The determination of whether a proposed amendment is "significant" versus "minor" falls to the IACUC chair, in consultation with the University Veterinarian as necessary.

When to Request

Requests for approval of modifications may be submitted at any time. Complete an Animal Use

Protocol Review form with the “Revised” box checked. The changes must be approved, before any changes can be implemented in the conduct of the protocol. NOTE: If the amendment involves the use of hazardous materials this requires additional review by other committees. The approval by the other committees is required prior to implementation.

How to Request an Amendment to Approved Protocol

The Animal Use Protocol form is intended to capture all of the required elements for a significant review of proposed amendments. When submitting amendments, you are required to complete this form, modify the applicable pages of the protocol form and attach all supporting documents (i.e., revised protocol form pages, literature searches, etc.) Forward the signed copies to the Compliance Officer.

Documentation:

Once approved, the IACUC will return a signed Animal Use Protocol form. Proof of the amendment/change approval must be kept by the PI (perhaps in a Research Regulatory Binder) as evidence that the IACUC has approved the change.

Note: A copy of the approval will be kept on record by Office of Sponsored Programs for inclusion in their protocol files.

Protocol Follow-up/Monitoring Process

An integral part of Winston-Salem State University’s program for the care and use of animals is meaningful monitoring of protocols which have been approved by the IACUC. Each protocol submitted to the IACUC requires the Principal Investigator (PI) to sign an assurance that the protocol accurately reflects the procedures and care which affect research animals in any way. Protocol-monitoring is an ongoing process which ascertains that investigators are adhering to their protocol and documenting that adherence.

The University veterinarian is responsible for the thoroughness and accuracy of the protocol follow-up process. Compliance will be monitored during both scheduled and unscheduled visits to the animal and laboratory facilities. If assistance is required with this monitoring, the University veterinarian may draw on technical staff or members of the IACUC for help in reviewing animal and laboratory records. The goal is to review each research laboratory (which may involve multiple protocols) every six months.

At a minimum, the protocol follow-up process will address the following areas:

1. Protocol: up-to-date, agrees with procedures used by researchers
2. Personnel: listed in the protocol, verify adequacy of training by actual observation of procedures
3. Records: animals identified, activities documented, proper surgery & anesthesia records, animal observation documented, unscheduled deaths or other health problems documented and veterinarians notified

4. Animal housing & care: housing conditions documented regularly, biosecurity issues addressed appropriately, animals are healthy, good access to quality food and water, appropriate animal density.
5. Laboratory: locations stated correctly in protocol, lab maintained in proper condition, correct storage of pharmaceuticals and other chemicals

The University Veterinarian will instruct laboratory personnel as to the correction of any noncompliance areas identified in the process. The PI and the IACUC will receive a written report of the visit. It is the responsibility of the PI to correct deficiencies in a timely manner. It is the responsibility of the IACUC will confirm with the PI that corrections have been made and adequately documented.

The IACUC is considering additional elements for the process such as monthly self-inspections. This protocol will be amended as further utilization and evaluation of the monitoring process occurs

Termination of IACUC Protocols

It is the responsibility of the investigator to notify the IACUC when a project is completed by completing an IACUC Continuing Review or Termination of IACUC Approval Form. Projects that have been completed, withdrawn or terminated are closed immediately upon notification. The Office of Sponsored Programs is notified by the Compliance Officer of all closures. All animal use on a specified protocol is stopped. No further purchase of animals can be made under the specified protocol number. All closed projects are filed in the Office of Sponsored Programs for a 3-year period from date of closure.

IV. OTHER IACUC STANDARD OPERATING PROCEDURES

A. Semiannual Review of Program and Facilities and Protocol Monitoring

Twice each year the IACUC conducts a complete review of Winston-Salem State University's Animal Care and Use Program and inspects facilities where animals are housed and/or used. The *NIH Guide for the Care and Use of Laboratory Animals* (<https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf>) and Animal Welfare Regulations are the principal documents used by the IACUC in its evaluations. Researchers who house animals in their laboratories over 12 hours should expect visits by the subcommittee of the IACUC at approximately 6-month intervals. In addition to looking at the research facilities during the semiannual inspection, IACUC members will conduct protocol monitoring visits at least annually. Members will meet with the investigators and their staff to discuss animal use procedures described in the applicable protocol(s), inspects drugs and materials intended for *in vivo* use, and inspect the research animal records.

B. Committee Training

Instructions for using the Research Training website

Winston-Salem State University is registered with the [CITI Program website](#). To access their training module(s):

- New users should enter identifying information (log in info for WSSU) and follow the instructions
 - IACUC committee members take the "Essentials for IACUC members" course
 - RESEARCHERS should take Basic course depending on the type of vertebrate animals being used in their current research.
- Completed training program(s) will be automatically documented by the website, and a copy of training certification(s) will be maintained in the Office of Sponsored Programs.
- If problems are encountered, contact the Compliance Officer at (336) 750-2982 or khaniu@wssu.edu.

Training Session for New IACUC Members

A meeting will be scheduled with new members and the OSP staff, the University Veterinarian, the Compliance Officer and the IACUC chair. The purpose of this meeting is to discuss committee functions in light of the apprentice experience. Some aspects of the committee's history, the Animal Welfare Act and the Public Health Service Guidelines will be reviewed.

V. IACUC POLICIES AND GUIDELINES FOR USE IN REVIEW OF PROTOCOLS AND CARE OF ANIMALS

A. HAZARDOUS AGENTS

In accordance with the National Institutes of Health (NIH) "Guidelines for Research Involving Recombinant DNA Molecules" revised April 2019 (https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf) and other relevant [federal regulation regarding SARS-CoV-2](#), Winston-Salem State University has established the Institutional Biosafety Committee (IBC). The Committee is charged with reviewing all research projects and activities involving recombinant DNA (as outlined in the "Guidelines") to assure that specific practices for constructing and handling (i) recombinant DNA molecules and (ii) organisms and viruses containing recombinant DNA molecules, as specified in the "Guidelines," are followed. The IBC was established by the authority of the Chancellor and define the basic policies, procedures and standards by which research involving recombinant DNA will be reviewed to provide for the safe conduct of recombinant DNA research. The authority of the IBC to disapprove, suspend or terminate a study involving recombinant DNA use may not be overridden. The Committee has the authority to require the immediate, temporary cessation of any University activity should it determine that such activity represents a substantial and immediate threat to human health or the environment. The Provost reviews such actions.

All protocols involving the use of infectious agents are reviewed by an IBC member with the appropriate expertise.

B. ANIMAL RESEARCH INVOLVING BIOHAZARDOUS MATERIAL POLICY AND PROCEDURES

It is the IACUC's responsibility to pay particular attention to animal use proposals using potentially hazardous materials, including, radioactive substances, infectious microorganisms and hazardous chemicals. Each of these substances has the potential to cause harm to animals as well as those caring and working with the animals. Some hazardous materials are strictly controlled by federal, state and local regulations and often an institution has specific committees concerned with all instances of hazardous material use. Winston-Salem State University has established specific biosafety committees composed of professional staff and faculty with expertise in handling chemical, biological and radiological agents. These committees include: 1.) the Institutional Biosafety Committee, and 2.) Office of Sponsored Programs. It is the IACUC's expectation that the biosafety committee will review and assess potential hazards associated with animal use. The IACUC committee is charged with ensuring or being assured that appropriate review and follow-up is being performed. The Principal Investigator is responsible for complying fully with this policy on biohazardous use involving animals.

C. ANIMAL TISSUE USE

Principles: An investigator is to use the minimum number of animals to get reliable results. Sharing tissue is highly encouraged because using shared tissue should reduce the total number of animals. It is also important identify the source of all animal products to ensure the safety of all personnel.

Tissues derived from animals listed on an investigator's own protocol

The investigator must have a standard live animal use protocol approved by the IACUC. The protocol must include details concerning the tissue to be used, how it will be acquired, etc.

Tissues not derived from live animals

When tissue is to be obtained from a dead animal whose death was not due to the need for the tissue, the tissue used must be obtained from an acceptable source. Such sources include an in-house animal that was euthanized for other purposes. The animal must be listed either on a protocol approved by the IACUC for the sharing of the tissue, or on an IACUC approved protocol from another institution.

D. ENSURING PROPER OCCUPATIONAL HEALTH

It is the policy of the IACUC to ensure all personnel working with animals adhere to the recommended procedures stated in the Guide for the Care and Use of Laboratory Animals and the Occupational Health and Safety in Care and Use of Research Animals

E. POLICY FOR RECEIVING BIOLOGICAL AGENTS (OTHER THAN ANIMALS) THAT WILL BE USED IN ANIMAL RESEARCH

Tumors, cells, sera or other body fluids derived from **humans** and used in live animals may potentially carry disease that could infect research and animal care personnel. If any of these agents are to be used, they need to be described as a biohazard in the Animal Care and Use Protocol and discussed with the University Veterinarian. Tumors, cells, sera or other body fluids derived from **animals** are potential sources of animal and/or human disease. There is a special concern with rodent viruses that could spread throughout the animal facilities (and have done so at other institutions). If you are using any of these agents, contact the Compliance Officer.

F. ORDERING ANIMALS

A current IACUC approval is required before animals can be purchased or housed. Contact the Compliance Officer for procedures for ordering animals or arranging for housing.

Table 1: Minor and Significant Program or Facility Deficiencies

The term “significant deficiencies” refers to any facility or program deficiency that is or may be a threat to the health or safety of animals.

Significant program or facility deficiencies may include:

- Accidents and natural disasters that cause injury, death, or severe distress to animals;
- Failures in heating, ventilating, and air conditioning systems and their associated electrical systems;
- Inoperative watering systems;
- General power failures of sufficient duration to affect critical areas such as isolators, barriers, surgical suites, and intensive care units;
- IACUC’s deviation from commitments stated in the Institutional Assurance (e.g., the animal research proposal review process, veterinary care, or institutional training programs, inadequacies of which may pose real or potential threats to the health or safety of animals);
- Repeated detection of minor, area-specific problems that may indicate substantial program deficiencies resulting from a failure to develop effective policies or plans or to take corrective actions to prevent recurrences; and/or
- Any other facility or program deficiency that is or may be a threat to the health or safety of animals.

Minor deficiencies in animal facilities include:

- Infrequent findings of peeling or chipped paint;
- Burned-out light bulbs;
- Missing floor drain covers; and
- Similar problems for which immediate solutions generally are not necessary to protect life or prevent distress.

NOTE: This table is not intended to address specifically all situations encountered by the IACUC or other program or facility reviewers. For situations not addressed in this table, refer to the Guide and the PHS Policy.

Table 2: Minor or Significant Changes to an Ongoing Protocol

The following are considered minor changes to an ongoing protocol at WSSU involving the care and use of animals:

- Personnel Changes (except a change of investigator)
- Title Changes/Funding Changes
- Investigator transfers
- Change in number of animals (if less than 25% of the approved number and not in Pain Category E – some exceptions to the 25% limit may be made for the addition of transgenic lines)
- Additional drugs under item H of protocol if procedures are the same and drugs are not used to induce toxicity
- Change of anesthetic agent if switch is to an approved regimen for the species
- Change of strain of animals within a species (e.g., different knockouts or Sprague Dawley to Wistar)
- Increase in duration of experiment if not a post-surgical protocol (e.g., follow animals for effects of drug from 2 weeks to 4 weeks or monitor spontaneous tumor development from 4 months to 8 months)
- Method of bleeding, if IACUC-approved method
- Method of euthanasia (not including physical euthanasia)
- Minor changes in behavioral/observation procedures (e.g., increasing observation period for locomotor activity from 5 to 10 minutes)

Because the above are common changes that are usually benign without pain or suffering, the IACUC Chair may approve such changes without consulting the entire committee.

Requested changes not addressed on the above list will be considered “significant” and require a review performed by the entire IACUC.

Table 3: Concerns That Must Be Reported to OLAW

The following concerns must be reported to OLAW:

- a. Non-compliance with IACUC-approved protocols
- b. Initiating unapproved animal work
- c. Deviation from the approved WSSU Assurance of Compliance with PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy)
- d. Animal activities conducted by unauthorized or unqualified individuals
- e. Ongoing, unresolved problems in animal care and use
- f. Shortcomings in the animal care program that jeopardize the health and well being of animals or cause their death
- g. The IACUC's suspension of any animal activities by the IACUC (temporary or permanent interruption of activities involving animals)

Winston-Salem State University investigates all allegations falling into these categories and reports non-compliance to the Office of Laboratory Animal Welfare.