

WINSTON-SALEM STATE UNIVERSITY INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

ASSURANCE OF COMPLIANCE WITH PUBLIC HEALTH SERVICE POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS

Last Updated: June 10, 2021

Winston-Salem State University, hereinafter referred to as Institution, hereby gives assurance that it will comply with the [Public Health Service Policy on Humane Care and Use of Laboratory Animals](#), hereinafter referred to as PHS Policy.

I. APPLICABILITY

This Assurance is applicable to all research, research training, experimentation, biological testing, and related activities, hereinafter referred to as activities, involving live, vertebrate animals supported by the Public Health Service (PHS) and conducted at this institution, or at another institution as a consequence of the subgranting or subcontracting of a PHS-conducted or supported activity by this institution.

"Institution" includes the following branches and major components of Winston-Salem State University: The applicable branches are all departments and components of Winston-Salem State University.

II. INSTITUTIONAL POLICY

- A. This institution will comply with all applicable provisions of the [Animal Welfare Act](#) and other Federal statutes and regulations relating to animals.
- B. This institution is guided by the ["U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."](#)
- C. This institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this institution will make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance as well as all other applicable laws and regulations pertaining to animal care, treatment, and use.

- D. This institution has established and will maintain a program for activities involving animals in accordance with the [Guide for the Care and Use of Laboratory Animals \(Guide\)](#) and the PHS Policy.

III. INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE

- A. The lines of authority and responsibility for administering the program and ensuring compliance with the PHS Policy are:

1. Dr. Erin Lynch, Associate Provost for Research, and Institutional Official (IO), with Numbers 2 and 3 reporting to the IO. Numbers 3-7 report their findings and recommendations to IACUC Chair. IACUC Chair reports needs identified to IO if university funds are required. Numbers 8 and 9 assists with maintaining IACUC records.
2. Dr. Jeffery Overholt, IACUC Chair
3. Dr. Calvert Jeffers, Jr., Veterinarian
4. Dr. Tennille Presley
5. Dr. Claudia Warren, IACUC Member
6. Dr. Morris Clarke, IACUC Member
7. Ms. Nicole Ramsey, non-affiliated IACUC Member
8. Mr. Vernon Shanks, Interim-Director, Office of Sponsored Programs
9. Dr. Islam Khan, Compliance Officer, Office of Sponsored Programs

- B. The qualifications, authority, and percent of time contributed by the veterinarian(s) that will participate in the program are:

Dr. Calvert B. Jeffers, Jr., has a D.V.M. with a specialty in small animal care from Tuskegee University 1972. He has been practicing veterinary medicine for 24 years. He owns the Boulevard Animal Hospital, which is a small animal practice located in Winston-Salem, NC.

Dr. Jeffers visits the laboratory periodically to personally inspect the animals and determine that the regulations in the [Guide](#) and the PHS Policy are being implemented. In addition, he is on call for dealing with any immediate health problems that may occur within the laboratory animals.

Dr. Jeffers will spend 2% of his total monthly effort toward his animal care, treatment, and use duties at this institution.

Dr. Jeffers has direct authorization to suspend all research activities involving animals immediately should he find during his inspection that the conditions under which the animals are maintained are not acceptable, the [Guide](#) and the PHS Policy are not being followed, and/or protocols are being used that do not have prior approval.

The investigator has been informed of Dr. Jeffers' authority in this regard. Should Dr. Jeffers terminate the research, he will inform the Chancellor and the IACUC Chair immediately. This information will be reported to OLAW in accordance with the Guide and the PHS Policy.

In the event that the primary attending veterinarian, Dr. Jeffers, is not available, Dr. Eugene Upshaw will serve as the attending veterinarian.

Dr. Upshaw graduated from Tuskegee University in 1987, receiving a D.V.M. degree. He has 17 years of experience as a veterinarian. His specialties include small animals, companion animals and farm animals. Dr. Upshaw has his own business, the Burlington Road Animal Hospital, located in Greensboro, NC.

C. This institution has established an Institutional Animal Care and Use Committee (IACUC), which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy at IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, position titles, specialties and institutional affiliations. This list is titled "Membership of the Institutional Animal Care and Use Committee."

D. The IACUC will:

1. Review at least once every six months the institution's program for humane care and use of animals, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual program evaluations are:
 - a. A meeting of IACUC members is convened every six months. A quorum will evaluate the animal care, treatment, and use program at WSSU using the Semiannual Program and Facility Review Checklist (Checklist) to review the various areas of the program.
 - b. No member will be involuntarily excluded from participating in any portion of the review.
 - c. The items used for review will be:
 - The Checklist
 - The Guide
 - The PHS Policy
 - d. Each IACUC member will utilize the Checklist during the program review. Data collected will be compiled, summarized, recorded, and reported to the IO with a copy to the Office of Sponsored Programs (OSP) and a copy kept by the IACUC chair.
 - e. Any deficiencies will be categorized as "minor" or "significant" and noted as such within the records and reports. See attached "Table 1: Minor and Significant Program or Facility Deficiencies."
 - f. The IACUC chair will notify the investigator of the deficiencies and discuss a plan of action for rectifying those deficiencies and a schedule for implementing that plan.
 - g. Plans and schedules for rectifying those deficiencies will be a part of the Semiannual Report (Report) submitted to the IO. A quorum will review and approve the Report to be submitted to the IO.
 - h. The program areas evaluated during the program review are:

- IACUC membership and functions
- IACUC records and reporting requirements
- Husbandry and veterinary care
- Personnel qualifications
- Occupational safety and health of personnel as it pertains to animal care, treatment, and use at WSSU
- The training programs for all involved with animal care, treatment, and use at WSSU (i.e., training for IACUC members, animal technicians, investigators, student participants, and other personnel involved in animal care, treatment, or use)

2. Inspect at least once every six months all of the institution's animal facilities, including satellite facilities, using the Guide as a basis for evaluation.

The IACUC procedures for conducting semiannual facility inspections are:

- a. A meeting is scheduled for the IACUC to inspect the animal facilities.
- b. Each member of the committee is given a copy of the Checklist.
- c. At the conclusion of the inspections, each member submits findings to the IACUC Chair.
- d. The IACUC Chair discusses the findings with the investigator. A report is issued regarding the results of the review. Significant deficiencies and minor deficiencies are noted.
- e. The investigator is notified in writing of the committee findings.
- f. The investigator in consultation with IACUC members will develop a plan of action, with a schedule for completion, to rectify the noted minor or significant deficiencies. This plan will become part of the Report to the IO (see D.3.).

3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy at IV.B.3. and submit the reports to Dr. Erin Lynch, Associate Provost for Research and IO. The IACUC process for developing reports and submitting them to the IO is:

- a. IACUC members will convene and review findings of the program evaluation (from D.1.) and facility review (from D.2.) processes.
- b. All findings will be summarized in the Report, which is reviewed and approved by IACUC members. The Report will include sections regarding program evaluation, facility review, and any minority views.
- c. The Report is submitted to the IO by the IACUC Chair. A copy is submitted to the OSP and the IACUC Chair keeps a copy. Records are maintained by the OSP and the IACUC Chair.

4. Review concerns involving the care and use of animals at the institution. The IACUC procedures for reviewing concerns are:

- a. Ways to report concerns relating to the welfare of animals and protocol noncompliance are addressed in the attached flyer, "How to Report Your Concerns Regarding Animal Care and Use," which is

- i. Posted on the OSP website and in each animal facility
 - ii. Distributed to investigators' laboratories during the semi-annual facility inspection so that it may be re-posted at that time
 - iii. Distributed at laboratory training sessions to all those involved with animals.
 - iv. Distributed during workshops, seminars, and other training sessions regarding laws, regulations, policies, and procedures involving animal care, treatment, and use
 - v. Distributed during the Safety Officer's training workshops (see F.), and
 - vi. Distributed at faculty orientation sessions presented by the OSPR.
 - b. These concerns come to the IACUC's attention in a number of ways:
 - i. By being reported to the IACUC Chair,
 - ii. By being reported to the OSP,
 - iii. By being reported to the attending veterinarian,
 - iv. By being reported to the investigator, and/or
 - v. By being reported to the animal care technician.

NOTE: These concerns may be reported in person, via telephone, via electronic mail, or in writing.
 - c. Reported concerns are handled according to the following:
 - i. As stated on the attached flyer, "How to Report Your Concerns Regarding Animal Care and Use," individuals shall be free to report concerns related to animal care, treatment, and use at WSSU without fear of reprisal.
 - ii. Any reported concerns will be forwarded in writing to the IACUC Chair and the IO (if they have not already been advised).
 - iii. The IACUC Chair will convene the committee and present the problem for discussion.
 - iv. IACUC will review the matter and make recommendations that will be conveyed to the IO and the attending veterinarian.
 - v. Depending on the nature of the concern, the IACUC Chair, the attending veterinarian, and/or the IO will take appropriate action(s) and ensure that there is no reprisal against the individual reporting the concern.
 - vi. Concerns that will be reported to OLAW by the IO are referenced in Table 3, "Concerns That Must Be Reported to OLAW." Actions taken regarding all concerns will be reported to OLAW by the IO as well.
5. Make written recommendations to Dr. Erin Lynch, Associate Provost for Research and IO, regarding any aspect of the institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are:
- a. The IACUC Chair forwards the summarized findings of the IACUC to the IO for review. All major and minor deficiencies are noted in a report to the IO.
 - b. Any required corrective action plans are included in this report.
6. Review and approve, require modifications in (to secure approval), or withhold approval of those activities related to the care and use of animals as set forth in the PHS Policy at IV.C. The IACUC procedures for protocol review are:
- a. The "Protocol Review Form" (see attached) is submitted by the investigator as projects are funded.

- b. The form is submitted to the IACUC Chair for distribution to all committee members for their review. The committee may determine that an outside consultant is needed to provide appropriate discipline-specific guidance and may then invite that consultant to participate in the review and approval process.
- c. IACUC members convene to discuss and decide whether to approve the protocol. The protocol may require modifications to secure approval. The IACUC Chair will notify the investigator in writing of any modifications required to secure IACUC approval. The investigator will then submit a revised protocol for review and approval.
- d. Absent members' comments may be presented for the purpose of discussion. However, absent members' votes may not be counted.
- e. The final decision whether to approve or withhold approval is sent in writing to the investigator with a copy sent to the OSPR and a copy kept by the IACUC Chair.
- f. If a protocol is not approved by the committee, at the request of the investigator the committee will interview the investigator and attempt to resolve any issues prior to written appeal to the IO.
- g. Upon written appeal to the IO, the following appeal process will be followed:
 - i. The IO will decide whether to obtain further information or assistance from other scientists or consultants.
 - ii. After further information or guidance is obtained, the protocol is then reviewed again by the IACUC and a final decision is made.
 - iii. The letter announcing the decision is forwarded to the investigator and to the IO. The IACUC Chair will keep a copy and forward a copy to the OSP.

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

- a. Requests for significant changes to an ongoing research project must be submitted in writing to the IACUC Chair.
- b. The IACUC Chair will submit the modification request to each member of the Committee. Note: Information on how the modified protocol deviates from the original is included within the request. Significant modification(s) noted as such per "Table 2: Minor or Significant Changes to an Ongoing Protocol" (see attached) will necessitate a new full committee review by the IACUC.
- c. An appropriate primary reviewer ("appropriate" based on individual disciplinary knowledge) is selected and authorized by the IACUC Chair to approve, require modifications in (to secure approval), or request full committee review of the modified protocol. The committee may determine that an outside consultant is needed to provide appropriate discipline-specific guidance and may then invite that consultant to participate in the review and approval process.
- d. Any IACUC member may within seven (7) business days request a full committee meeting and review, which the investigator is invited to attend.
- e. During a full committee meeting and review, a majority vote of the quorum present is required.
- f. The IACUC Chair will notify the investigator and the IO in writing of the final decision of the committee. Results of such decisions will also be recorded in IACUC minutes and

reports. Copies of these documents will be maintained in the OSP, with a copy kept by the IACUC Chair and a copy kept by the IO.

- g. If the investigator wishes to appeal the committee's decision, the request must be made in writing to the IACUC Chair with a copy to the IO. The appeal process above (see D.6.f-g.) is then followed.

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

- a. At the conclusion of the IACUC review, the IACUC Chair is responsible for notifying all investigators and the IO in writing of the decision to approve or withhold approval of the protocol that was submitted or to require modifications to secure IACUC approval (see D.6.c.).
- b. The letter announcing the decision is forwarded to the investigator and to the IO. The IACUC Chair will keep a copy and forward a copy to the OSPR.
- c. If the investigator wishes to appeal the committee's decision, the request must be made in writing to the IACUC Chair with a copy to the IO. The appeal process above (see D.6.f-g.) is then followed.

9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy at IV.C. 1-4. at least once every three years. The IACUC procedures for conducting continuing reviews are:

- a. Not less than once every three years, the IACUC will conduct continuing reviews of ongoing research protocols according to the review criteria and procedures listed in D.6.
- b. A continuing review of ongoing research protocols will be conducted throughout the life of each project using the attached "Protocol Review Form," which will be completed by the investigator in its entirety during each triennial review.
- c. Any minor or significant changes in ongoing protocols will be handled according to the procedures outlined in D.7.
- d. Any corrective action, up to and including suspension due to non-compliance, will be reported to OLAW.

10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6. The IACUC procedures for suspending an ongoing activity are:

- a. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.
- b. If the IACUC suspends an activity involving animals, the IACUC Chair will notify the investigator of that decision.
- c. The IO, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW.

- d. Documentation of this action will be recorded in the OSPR, with a copy kept by the IACUC Chair and a copy kept by the IO.
- E. The individuals authorized by this institution to verify IACUC approval of those sections of applications and proposals related to the care and use of animals are the IACUC Chair and the Director of Sponsored Programs.
- F. The occupational health and safety program for personnel who work in laboratory animal facilities or have frequent contact with animals is:
1. To ensure that health and safety issues pertaining to animal research are addressed, the University Compliance Officer, the University Safety Officer and the Institutional Biosafety Committee will collaborate to offer training (including training regarding the appropriate handling of hazardous agents) and conduct risk assessments. The Safety Officer is the responsible person for overseeing and/or administering the university's occupational health and safety program. The Safety Officer will ensure that medical evaluations are performed by appropriate medical personnel (e.g., personal physician and/or Student Health Service staff).
 2. Common Risks Associated with Animal Husbandry and Care – Personnel involved in the care and use of research animals work in an environment that presents a number of unique hazards from several sources:
 - Hazards related to the equipment, material and practices used in performing routine animal husbandry;
 - Hazards related directly or indirectly to animal contact; and
 - Hazards related to the techniques or materials that may be used during the course of animal experimentation.
 - a. Regardless of the source of hazard, several basic measures should be taken to reduce the risk of personal exposure. These include understanding the hazards likely to be encountered during animal care and use, using appropriate personal protective equipment, and demonstrating the technical proficiency necessary to accomplish experimental manipulations or animal care procedures in safe and humane fashion.
 - b. Training of personnel involved with the care, treatment and use of animals will be mandatory and will be performed annually. Training will include policies, laws, and regulations pertaining to health and safety for personnel involved with the care, treatment and use of animals—including safe work practices, good personal hygiene, proper protective clothing, appropriate use of research devices, and appropriate handling of hazardous agents—as well as appropriate actions to be taken in the event of injury.
 - c. Documentation of training performed will be noted in the annual report to OLAW.
 - d. Individual risk assessments will be performed. They will incorporate individual health histories, current health and safety concerns, the species of animals used, the extent of animal contact, and the experimental agents or procedures that will be

used in the animal studies. Based on this assessment, additional vaccinations or modifications in the use of personal protective equipment (PPE) might be recommended. In addition, consultation and close communication with medical professionals at Concentra Medical Center, our primary care provider for workplace injuries, will be performed to ensure that all concerns associated with animal handling are addressed.

3. Common Injuries Associated with Animal Husbandry and Care – Injuries and accidents possible in personnel working in animal laboratories include:

- Crush or lacerations from moving caging equipment and/or operating sanitation equipment
- Respiratory exposure to irritating vapors, aerosols, or particulates from working with disinfectants and bedding materials
- Skin irritation or contact dermatitis from exposure to chemicals used in cleaning, latex or talc allergy, or in experimental procedures used
- Needle stick exposures
- Musculoskeletal injuries (sprains, strains, or fractures) due to improper technique in lifting or moving equipment
- Slip and fall injuries

NOTE: Personal awareness of hazardous conditions or factors in the environment is critical to avoiding these types of injuries, and individuals should develop the habit of assessing the environments in which they work.

4. Animal-Related Hazards – Bites, scratches, and other injuries represent a significant portion of animal-associated hazards encountered by individuals with laboratory animal contact and are readily preventable through proper animal handling techniques and proper use of PPE. Animal bites should be regarded seriously even when they have caused little tissue damage. Personnel who have been bitten should seek prompt medical review of the wound and their tetanus immunization status by Concentra Medical Center's Staff. Animal bites will also prompt a review of the animal handling circumstances to ensure that proper animal handling techniques were used.

NOTE: Specific viral agents associated with rodents that can be involved as wound contaminants include rabies virus, hantavirus, and lymphocytic choriomeningitis. Numerous bacterial agents and at least one fungal agent have also been recorded as wound contaminants resulting in serious localized or systemic infections.

5. Animal-Related Allergy – An estimated 10 to 30 percent of individuals who work with laboratory animals may eventually develop allergy to laboratory animals manifested by reddened, itchy eyes, nasal symptoms and skin rashes. Asthma, which is characterized by cough, wheezing, chest tightness and shortness of breath, develops as a further complication in approximately 10 percent of individuals with animal-associated allergy.

NOTE: Rodents, rabbits, and cats are most often the source of laboratory-animal-associated allergy. Work practices, which minimize contact with animal proteins, reduce the risk for development of allergy. For example, various levels of PPE are available for personnel working with laboratory animals to reduce exposure to allergens. Allergy history is an important element of our medical evaluation conducted by Concentra Medical Center. Personnel who suspect that they are developing animal-associated allergy should consult with the Safety Officer to determine an allergy management strategy.

6. Zoonoses – Zoonoses are diseases that are transmissible from animals to humans. Laboratory animal species potentially harbor numerous zoonotic agents, including viruses, bacteria, fungi, protozoa, and internal and external parasites. Individuals who become ill and/or feel they have contacted a disease from a laboratory animal should consult with Concentra Medical Center's staff and notify the Safety Officer. Students may be referred to the WSSU Student Health Service if immediate assistance is needed.

NOTE: Modern conditions and care for most laboratory rodents have led to the eradication of zoonoses in most of these species. However, these animals can become contaminated through environmental sources, contact with wild rodents, or other infected animals. In most circumstances, only wild-caught, laboratory maintained rodents would be regarded as high risk for the transmission of zoonotic diseases. Two serious systemic viral zoonoses have been associated with the use of laboratory rodents. Lymphocytic choriomeningitis virus causes a flu-like disease with neurological complications, and hantavirus infection produces a disease marked by renal failure and respiratory complications. Other than the bite-associated bacterial infections from rodents (i.e., rat-bite fever), there are few bacterial zoonoses in this species. Rodents can also be a source of human ringworm infection (fungal). The dwarf tapeworm infestation of rodents also is capable of infecting humans. Health surveillance measures and the proper use of PPE when working with our laboratory animals are required. All unusual illnesses or conditions possibly related to animal contact will be reported to the Safety Officer.

- G. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein and the average daily inventory of animals, by species, in each facility is provided in the attached table, "Facility and Species Inventory."
- H. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is:
 1. All persons involved with animal care, treatment, and use at WSSU, including the IACUC, will be required to undergo the following training and/or instruction on an annual basis, upon being newly hired at the university, or prior to the initiation of a new protocol:
 - a. Lectures, seminars, and workshops designed to provide education and training relative to animal care, treatment, and use will be offered. Attendance at such training sessions will be recorded/documented and kept on file in the OSP, with a copy kept by the IACUC Chair and a copy kept by the investigator of the project.

- b. All persons involved with animal care, treatment, and use at WSSU will have access to the following documents either in electronic form via the OSP website or in hardcopy form at the OSP office:
 - i. The PHS Policy on Humane Care and Use of Laboratory Animals
 - ii. The Guide for the Care and Use of Laboratory Animals (published by the National Research Council).
 - iii. The ARENA/OLAW Institutional Animal Care and Use Committee Guidebook, 2nd Edition (and Addendum).
 - iv. The Animal Welfare Act.
 - v. The Office of Laboratory Animal Welfare (OLAW) website.
 - vi. The online NIH tutorial “PHS Policy on Humane Care and Use of Laboratory Animals Tutorial,” available at <http://grants.nih.gov/grants/olaw/tutorial> as of this writing.
 - c. All persons involved with animal care, treatment, and use at WSSU will attend professional development workshops, seminars, and other such training sessions regarding laws, regulations, policies, and procedures involving animal care, treatment, and use.
2. All persons who have hands-on involvement with animals (e.g., in a laboratory setting as an animal technician, student participant, or any other personnel involved in animal care, treatment, or use) will undergo additional training per the items below:

NOTE: The investigator will ensure appropriate training of all persons who have hands-on involvement with animals either in the investigator’s laboratory or involved with that investigator’s protocol.

- a. All persons who have hands-on involvement with animals will review documents and materials on, and become familiar with, animal care of the particular species being used.
- b. They will also review documents and materials on, and become familiar with, handling and restraint, blood collection, necropsy, and proper euthanasia of laboratory animals.
- c. Each person will be provided training pertaining to techniques and procedures not previously experienced.
- d. Once a person is deemed proficient in the animal species of interest, they will be given a certificate verifying having undergone training regarding that particular species.
- e. They will be provided training or instruction in the humane practice of animal care, treatment, and use, as well as training or instruction in research or testing methods that minimize the number of animals required to obtain valid results and minimize animal distress.

- f. Training will be provided on an as-needed basis depending upon the techniques and procedures to be used.
- g. A certificate will be provided to the individual and the IACUC Chair will retain copies of the certificates.
- h. Persons involved in the care, treatment, and use of animals will be provided species-specific instruction in accordance with 9 CFR part 2 before they are permitted to work with animals.

3. All training described above in H.1. and H.2. will be documented in the Semiannual Report.

IV. INSTITUTIONAL STATUS

As specified in the PHS Policy at IV.A.2, as Category 2, all of this institution's programs and facilities, including satellite facilities, for activities involving animals have been evaluated and by the IACUC and will be reevaluated by the IACUC at least once every six months, in accord with IV.B.1. and 2. of the PHS Policy, and reports prepared in accord with IV.B.3. of the PHS Policy.

All IACUC semiannual reports will include a description of the nature and extent of this institution's adherence to the Guide. Any departures from the Guide will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC evaluations will be submitted to Dr. Erin Lynch, Associate Provost for Research, and IO. Semiannual reports of IACUC evaluations will be maintained by this institution and made available to the Office of Laboratory Animal Welfare upon request. The most recent semiannual report of the IACUC is attached.

V. RECORD KEEPING REQUIREMENTS

A. This institution will maintain for at least three years:

1. A copy of this Assurance and any modifications thereto, as approved by PHS.
2. Minutes of IACUC 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 IACUC approval was given or withheld.
4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to Dr. Erin Lynch, Associate Provost for Research, and IO.
5. Records of accrediting body determinations.

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

VI. REPORTING REQUIREMENTS

- A. At least once every 12 months, the IACUC, through the Institutional Official, will report in writing to OLAW:
 - 1. Any change in the status of the institution (e.g., if the institution becomes accredited by AAALAC or AAALAC accreditation is revoked), any change in the description of the institution's program for animal care and use as described in this Assurance, or any changes in IACUC membership. If there are no changes to report, this institution will provide OLAW with written notification that there are no changes.
 - 2. Notification of the dates that the IACUC conducted its semiannual evaluations of the institution's program and facilities (including satellite facilities) and submitted the evaluations to Dr. Erin Lynch, Associate Provost for Research, and IO.
- B. The IACUC, through the Institutional Official, will provide the OLAW promptly with a full explanation of the circumstances and actions taken with respect to:
 - 1. Any serious or continuing noncompliance with the PHS Policy.
 - 2. Any serious deviations from the provisions of the Guide.
 - 3. Any suspension of an activity by the IACUC.
- C. Reports filed under VI.A. and VI.B. above shall include any minority views filed by members of the IACUC.

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institutional Official

Name: Harold L. Martin
Title: Chancellor
Address: Winston-Salem State University
Campus Box 19535
Winston-Salem, NC 27110
Phone: (336) 750-2041
Fax: (336) 750-2049
Signature:
Date:

B. PHS Approving Official

Name: Dr. Axel Wolff
Title: Senior Assurance Officer, Division of Assurance-OLAW, NIH
Address: National Institutes of Health
RKL1, Suite 360-MSC 7982
6705 Rockledge Drive
Bethesda, MS 20892-7982
Phone: (301) 594-2061
Fax:: (301) 402-7065
Date: April 2, 2004

C. Assurance Number: A3591-01

D. Effective Date of Assurance: April 2, 2004

E. Expiration Date of Assurance: March 21, 2009

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.