

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

Lehigh 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 *Lehigh University*:

Lehigh University
Office of Research and Sponsored Programs
526 Brodhead Avenue
Bethlehem, PA 18015

II. INSTITUTIONAL POLICY

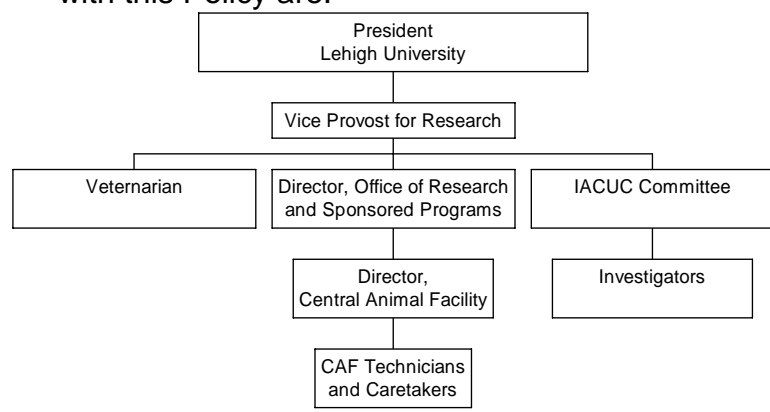
- A. This institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- B. This institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and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

III. INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE

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



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

B.S. – Animal Bioscience – 1981 Pennsylvania State University

VMD – School of Veterinary Medicine – 1986 University of Pennsylvania

General Practitioner for 18 years

She is in a Multi-Doctor Practice with several clinicians with special interest in laboratory animals.

The veterinarian has the ultimate authority on administration of all veterinary procedures to animals in the facility other than procedures that are described in the IACUC-approved protocols. Other than the procedures approved in the protocols, no veterinary care is provided other than that specifically sanctioned by the veterinarian. In addition she serves on the IACUC committee according to the following:

Veterinarian’s Authority and Responsibility (from LU Policy and Procedure Manual for Institutional Animal Care and Use)

3.3.3 Consulting Veterinarian

3.3.3.1 Maintains liaison with the Directors of the CAF and ORSP, on all matters related to animal care and use at LU.

3.3.3.2 Serves as advisor on all veterinary matters at LU.

- 3.3.3.3 Assists research personnel in meeting established standards.
- 3.3.3.4 Provides current information on legislation, licensing, registration, accreditation, other matters pertaining to care and the use of animals in teaching and research.
- 3.3.3.5 Maintains liaison with pertinent professional, governmental, licensing, regulatory, accrediting, and funding agencies.
- 3.3.3.6 Helps implement and maintain institutional policies and standards that meet or exceed the requirements of regulatory and accrediting agencies.
- 3.3.3.7 Assists in the acquisition and maintenance of required licenses, registrations, permits, certificates, and accreditation for LU.
- 3.3.3.8 Participates in necessary record keeping and the preparation of reports for regulatory, accrediting, and funding agencies.
- 3.3.3.9 Is involved in updating LU policies and procedures for the care and use of laboratory animals.
- 3.3.3.10 Provides guidelines and assistance for investigators on the selection and use of anesthetics, analgesics, and tranquilizers.
- 3.3.3.11 Serves on the IACUC and:
 - 3.3.3.11.1 Participates in scheduled inspection of animal care and facilities.
 - 3.3.3.11.2 Advises and reports on issues involving laboratory animals.
 - 3.3.3.12 Provides veterinary and professional consultation services on the design, construction, and maintenance of the animal facility, and prospective planning of project protocols involving animals.
 - 3.3.3.13 Provides veterinary clinical-pathological services for disease prevention and control, quarantine and isolation, and monitoring the health status of animals.
 - 3.3.3.14 Assists in training of personnel in the proper care and use of laboratory animals, as well as proper health and safety measures. (See Appendix 1)
 - 3.3.3.15 Ensures the surveillance of the animal facility so that proper animal care and use processes are maintained, and that deficiencies are corrected. (The veterinarian or designated animal health technician may intervene to order or provide appropriate veterinary care.)
 - 3.3.3.16 Establishes and maintains liaison and effective working relationships with other administrators and staff concerned with animal facilities, care, use, and personnel.
 - 3.3.3.17 Is involved in all new protocol reviews or renewals with changes in scope.
 - 3.3.3.17.1 To ensure that proposed animal stock/strain can be obtained from eligible supplier, or to initiate steps to determine eligibility where required.
 - 3.3.3.17.2 To ensure that biohazards to animals and animal-care staff, if any, are adequately addressed in terms of containment.
 - 3.3.3.17.3 To ensure that humane issues have been considered and appropriately addressed.
 - 3.3.3.17.4 To ensure that sufficient room and cage space are available to quarantine/condition and house animals for the proposed study.
 - 3.3.3.17.5 To ensure in conjunction with the University Safety Officer that the protocol addresses the acceptable handling and disposal of biohazardous materials.

The veterinarian contributes to the program by performing the duties described above. Since we are a small facility, the main responsibilities are approving protocols, attendance at biannual IACUC meetings and inspections, and by occasional consultation as needed. Typically she is asked to provide between 3-10 telephone consultations, 0-3 necropsies, and 0-3 unplanned visits to the animal facility per year. Thus, we estimate that the veterinarian is required to spend approximately 1% of her total working time contributing to our program.

Our veterinarian is a partner at, a large local veterinary practice. In the case of absence, several licensed, experienced veterinarians are on call to take care of Lehigh University's veterinary needs.

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.

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:

The IACUC members meet together in Lehigh University's Office of Research and Sponsored Programs or at the Central Animal Facility at least once every six months to review the institution's program for humane care and use of animals us The Guide as the basis for evaluation. Problems and potential problems are discussed and new procedures and policies are implemented by endorsement of the animal facility director and a majority vote.

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:

After the above-described meeting, all members of the IACUC committee walk through the Central Animal Facility, including the animal rooms, surgery, wash rooms, restrooms, drug lockers, and storage rooms. The inspection includes items on the checklist. The level of cleanliness of each area, any violations and problems are recorded. All members sign to acknowledge the record of the inspection.

2. Prepare reports of the IACUC evaluations as set forth in the PHS Policy at IV.B.3. and submit the reports to *Bruce E. Koel, Vice Provost for Research*. The IACUC process for developing reports and submitting them to the Institutional Official is:

Immediately after the semiannual IACUC meeting and inspection of the animal facility and laboratories, the Executive Secretary of the IACUC prepares a draft report. The draft report is submitted to the IACUC for comment and review. The final report is submitted, along with written recommendations regarding any aspects of the institution's animal program, facilities or personnel training to the Vice Provost for Research.

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

Concerns can be most easily brought to the attention of the Manager or the Director of the Central Animal Facility, who can easily correct most problems. Concerns that cannot be addressed by the Manager or Director may be brought from any source to the attention of the IACUC by contacting any IACUC member, or the Executive Secretary of the IACUC and submitting a written, oral or email statement. Concerns are

reviewed at the next IACUC meeting. An emergency meeting is called if necessary. In all cases the source of the report must be identified to the IACUC in order to determine the accuracy and to gauge the legitimacy of the report. The identity of the person reporting the concern will be kept confidential within the IACUC upon request. Any person who reports a legitimate concern to the IACUC is guaranteed the right to be heard without reprisal.

5. Make written recommendations to *Bruce E. Koel, Vice Provost for Research* regarding any aspect of the institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are

Immediately after the semiannual IACUC meeting and inspection of the animal facility and laboratories, the Executive Secretary of the IACUC prepares a draft report. The draft report is submitted to the IACUC for comment and review. The final report is submitted, along with written recommendations regarding any aspects of the institution's animal program, facilities or personnel training to the Vice Provost for Research.

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

In order to submit a protocol for review, protocol forms) must be completed and signed by the principle investigator (PI) and sent to the Executive Secretary of the IACUC committee. The Executive Secretary copies and distributes the completed protocol forms to all members of the IACUC for review. Any of the IACUC members may require that the PI address specific questions or modify the protocol by submitting a revised protocol form or by attaching an addendum. The revised protocol or addended protocol is resubmitted to all IACUC members. In order to gain IACUC approval, all participating IACUC members must approve the protocol. Approval is withheld if one participating IACUC member fails to grant approval. The notice of approval must be signed by the chair of the IACUC. An IACUC member other than the chair may be designated by the chair to sign under special circumstances. Access to the Central Animal Facility is allowed only to PI's that have a current IACUC-approved protocols on file.

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:

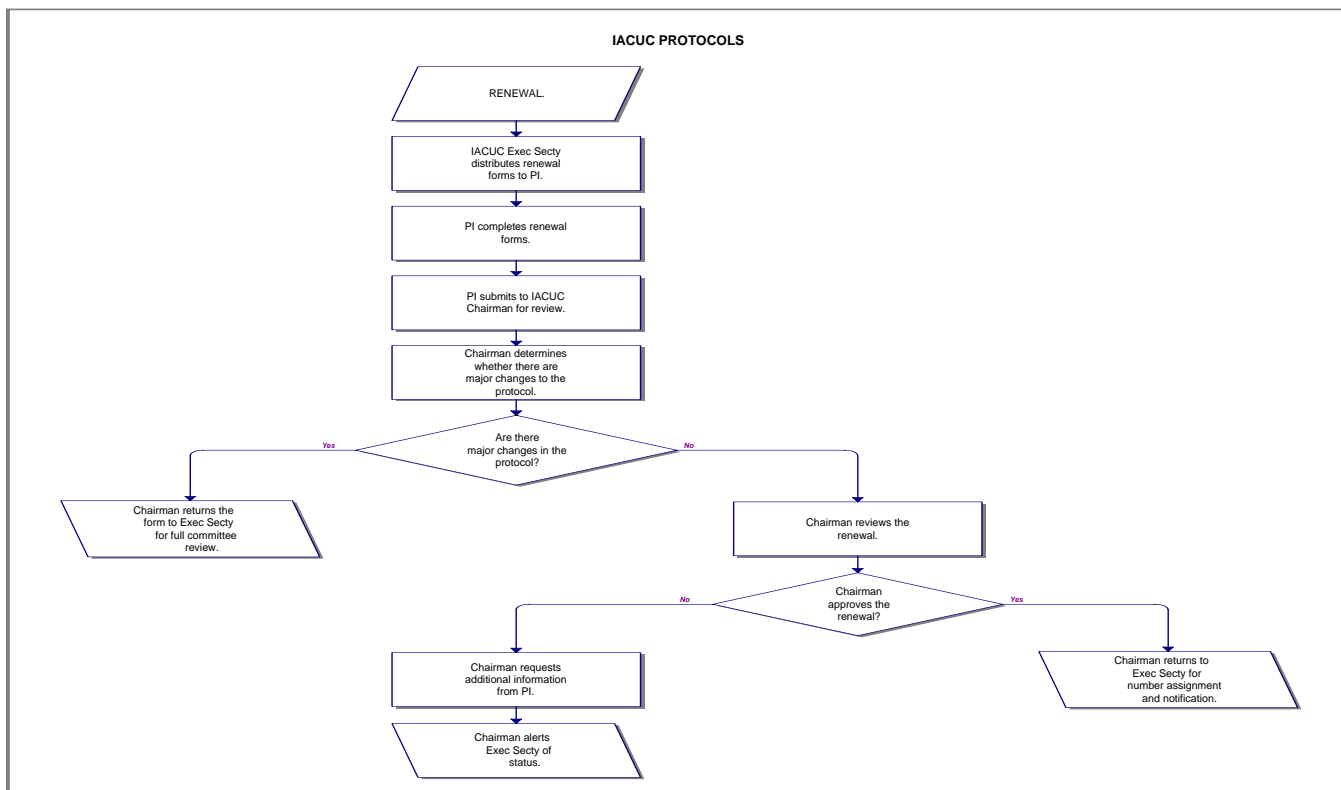
In the case of significant changes to a protocol, the Principal Investigator (PI) must either submit the revised protocol on a separate protocol form, or attach an addendum to the original protocol. The addendum must fully documents the proposed changes. These are submitted to the Executive Secretary who copies and distributes the completed protocol forms to all members of the IACUC for review. Any of the IACUC members may require that the PI address specific questions or modify the protocol by submitting a revised protocol form or by attaching an addendum. The revised protocol or addended protocol is resubmitted to all IACUC members. In order to gain IACUC approval, all participating IACUC members must approve the protocol. Approval is withheld if one participating IACUC member fails to grant approval. Access to the Central Animal Facility is allowed only to PI's that have a current IACUC-approved protocol on file.

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:

After full IACUC approval, investigators receive both an e-mail and a hard copy of the approval notice from the Executive Secretary. The notice of approval is signed by the Executive Secretary of the IACUC after Committee approval.

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 review are:

Renewals of existing protocols are required annually. A two-page renewal form is completed by the Principal Investigator (PI) and forwarded by the Executive Secretary to the Chairperson of the IACUC for review. Renewals will be subjected to a full committee review if there are major changes or if the proposal is more than three years old.



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:

*PI will receive written notification by the Executive Secretary and verbal notification by the Director of the Central Animal Facility that the IACUC has voted to suspend an activity involving animals in accordance with specifications set forth in The **Guide**, Section IV.C.6.*

E. The individual(s) authorized by this institution to verify IACUC approval of those sections of applications and proposals related to the care and use of animals is/are

*Chairperson, IACUC
Director, Central Animal Facility*

F. The occupational health and safety program for personnel who work in laboratory animal facilities or have frequent contact with animals is:

The following health and safety program applies to the Central Animal Facility and its users (from LU's Policy and Procedure Manual for Institutional Animal Care and Use.)

1. Occupational Health Program

A pre-employment physical, conducted by the individual's private physician, is required for all employees with significant animal exposure such as students, volunteers, etc.

1.1.1 This includes a TB tine test, and tetanus inoculation or tetanus booster as needed (unless the employee can show that a booster has been received within the last five (5) years).

1.2 Animal-care personnel and volunteers shall also receive the following preventive measures as indicated:

1.2.1 Tetanus Booster - Every ten years, or as needed, following injury.

1.3 A continuing education program will be provided for CAF personnel who will give information regarding such things as personal hygiene, zoonosis, and occupational hazards.

1.4 Records (incident reports of personnel injuries (bites, etc.) will be kept in the CAF.

1.4.1 All such injuries will be referred immediately to the Employee Health Service (See Appendix 8: Emergency Referral Form and Incident Report)

*1.4.2 A written report will be submitted to the attending physician, the CAF Supervisor, the Chairman of the IACUC.**

1.5 All used needles, syringes, surgical blades, or other sharp instruments are to be placed in puncture-proof containers for disposal. Anyone injured by a potentially contaminated needle or surgical instrument shall report it to the CAF Supervisor, who will, in turn, notify the veterinarian.

1.6 All persons who handle animals and animal-related materials must wash hands before, after, and between visits to animal room; before eating; and after visiting toilet facilities.

1.7 Personnel are to notify CAF Supervisor of other suspected personnel health and safety hazards.

1.7.1 These include sores or lesions on the skin, diarrhea, respiratory symptoms (wheezing, cough, chest pain, and fever).

1.7.2 Every precaution shall be used to prevent spreading, not only to other workers, but also to the laboratory animal population.

1.8 All CAF personnel will wear proper uniforms and foot covering, gloves, etc., to perform their work in a safe manner.

1.8.1 Daily clean changes of uniforms will be required.

1.8.2 All employees are encouraged to take showers at the start and end of the workday.

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.

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

All new Central Animal Facility Users, including PI's, students, technicians, and workstudy students report to the Manager of the Central Animal Facility for a one-day training session. Training includes education in humane care and use of laboratory animals, how to recognize pain and distress in laboratory animals, and employee health and safety according to PHS guidelines. New users are provided access to the Lehigh University Policy and Procedure Manual for Institutional Animal Care and Use online, as well as a hard copy of the condensed version of the Lehigh University Animal Facility Rules. Immediately after the training session, new users must pass a test with a score of 100%. The test covers all of the rules and guidelines for the animal facility. Every third year, all users must pass a renewal retest of the animal facility rules and regulations. A score of less than 100% requires a refresher course arranged through the Manager of the Central Animal Facility. Training and testing is documented by the Manager of the Central Animal Facility.

All PI's are required to train their own laboratory personnel in experimental design and methods, especially in research methods that minimize the number of animals required and to limit pain and/or distress in laboratory animals.

IV. INSTITUTIONAL STATUS

As specified in the PHS Policy at IV.A.2., as Category 1, all of this institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated and accredited by The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). All of this institution's programs and facilities (including satellite facilities) for activities involving animals have also been evaluated 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 *Bruce E. Koel, Vice Provost for Research*. Semiannual reports of IACUC evaluations will be maintained by this institution and made available to the Office for Protection from Research Risks (OPRR) upon request.

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 *Bruce E. Koel, Vice Provost for Research*.
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 OPRR 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 OPRR:

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 OPRR 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 *Bruce E. Koel, Vice Provost for Research*.

B. The IACUC, through the Institutional Official, will provide the OPRR 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: Bruce E. Koel

Title: Vice Provost for Research

Address: Lehigh University, 526 Brodhead Avenue, Bethlehem, PA 18015

Phone: (610) 758-3021

Fax: (610) 758-5994

Signature: _____

Date:

B. PHS Approving Official

Name:

Title:

Address:

Phone:

Fax:

Signature:

Date:

C. Effective Date of Assurance:

D. Expiration Date of Assurance: