

LEHIGH UNIVERSITY
Animal Welfare Assurance A3877-01
ANIMAL WELFARE ASSURANCE
in accordance with the PHS Policy for
Humane Care and Use of Laboratory Animals

I, Bruce E. Koel, as named Institutional Official for animal care and use at Lehigh University, hereinafter referred to as Institution, by means of this document, provide assurance that this Institution will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

I. APPLICABILITY OF ASSURANCE

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 Lehigh University:

Lehigh University

Office of Research and Sponsored Programs
526 Brodhead Avenue
Bethlehem, PA 18015
Building: 111-Iacocca Hall
Contact Person: Central Animal Facility (CAF) Interim Director
Phone: 610.758.6359

"Institution" also includes the following: None

II. INSTITUTIONAL COMMITMENT

A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.

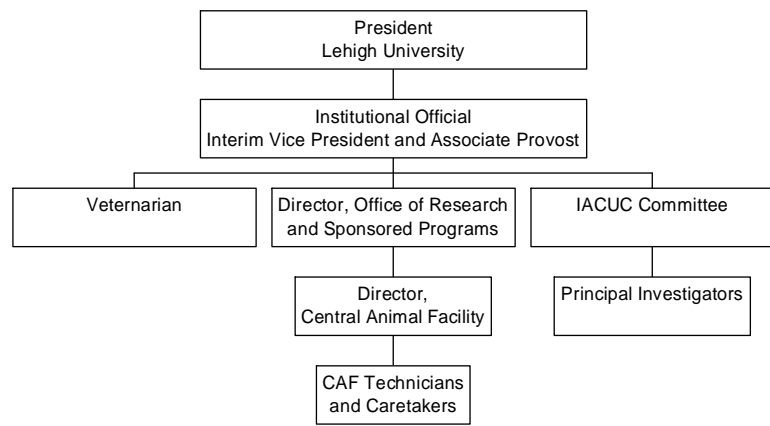
B. This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."

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 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 as follows:



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

Qualifications:

- Degrees:
 - a. *B.S. – Animal Bioscience – 1981 Pennsylvania State University*
 - b. *VMD – School of Veterinary Medicine – 1986 University of Pennsylvania*
- Training and experience in laboratory animal medicine: Primary Veterinarian has been a general practitioner for 23 years. She has worked with the species housed at the university since October 1995

Authority: Primary Veterinarian has delegated program authority and responsibility for the Institution’s animal care and use program. Primary Veterinarian has access to all animals in the facility and provides guidance and oversees all aspects of animal care and use. In addition, provides guidance/oversight on handling, immobilization, sedation, analgesia, anesthesia, euthanasia, surgery programs and postsurgical care. Primary Veterinarian maintains liaison with the Director of the Central Animal Facility, the Office of Research and Sponsored Programs and the Institutional Official, on all matters relating to animal care and use at Lehigh University.

Time Contributed to Program: Part-time employee. Primary Veterinarian is present at the university approximately 1-2 hours per month on average during which 100% of her efforts are focused on the animal care and use program.

In the event that the Primary Veterinarian is unavailable, there are three others available to provide back-up veterinary support to ensure adequate veterinary care of research animals:

C. The Institutional Animal Care and Use Committee (IACUC) at this Institution is properly appointed in accordance with the PHS Policy IV.A.3.a and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy, Section IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations

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 reviews are as follows:

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 using the Guide as the basis for evaluation. Challenges or issues are discussed and procedures and policies are developed or amended and implemented by endorsement of the Central Animal Facility Director, a majority vote of the IACUC and forwarded to the Institutional Official for review/approval. The Institutional Official is made aware of the issues and recommended resolutions in the Report to the Institutional Official. OLAW's Sample Semi-Annual Program Review Checklist has been adapted for use in the review process and supplements our current form.

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 as follows:

As part of this review, the members of the IACUC committee proceed to the Central Animal Facility for a complete review of the overall facility including food supply room, cage washing areas, records, each animal suite, surgery rooms, each cage housing the species in our facility, review of patient records, and any investigator laboratories outside of the Central Animal Facility which are utilized for animal research. Investigators are permitted to take animals to their laboratories for no longer than 24 hours.

A checklist is utilized for this review noting any deficiencies found in the facility inspection. Any deficiencies found are reported directly after the inspection to the Central Animal Facility Director and Manager. There is a "correct by date" assigned. This information is also provided to the Institutional Official and the Dean of the College of Arts and Sciences who has responsibility for the Department of Biological Sciences and is included in the formal Report to the Institutional Official.

The Executive Secretary, along with the Central Animal Facility Director and Manager are charged with ensuring timely correction of any issues noted. The Executive Secretary and the Institutional Official are charged with reporting any issues not resolved within 15 days of the timetable for correction of deficiencies.

3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy IV.B.3 and submit the reports to the Institutional Official.

The IACUC utilizes the OLAW sample format letter for reporting to the Institutional Official. The report summarizes the Committee's findings at the semiannual meeting including any minority views, departures from the Guide or PHS policy and reasons for departure, and any deficiencies – minor or significant. Immediately after the semiannual meeting and inspection, the Executive Secretary of the IACUC prepares a draft report for IACUC member review, correction and/or approval.

The final report is submitted to the Institutional Official along with written recommendations regarding any aspects of the institution's animal use program, facilities or personnel training after being signed by a quorum of the IACUC members. A correction date is assigned to issues which must be resolved.

As stated in item 2, the Executive Secretary, along with the Central Animal Facility Director and Manager are charged with ensuring timely correction of any issues noted. The Executive Secretary and the Institutional Official are charged with reporting any issues not resolved within 15 days of the timetable for correction of deficiencies.

Signatures of the IACUC Committee voting members indicating their approval of the report are retained on file by the Executive Secretary and is available for review upon request.

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

Signs are posted in the Central Animal Facility with steps to follow should anyone have concerns involving animal care and use, researchers, staff providing care or the facility. Conditions that reportedly jeopardize the health or well-being of animals are evaluated immediately.

The Director of the Central Animal Facility is authorized to temporarily halt procedures which he/she believes do not comply with institutional policies until the IACUC can be convened to consider the matter formally.

Emergency meetings may be necessary in these cases to ensure prompt consideration of concerns. 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.

Upon receipt of a concern, the IACUC Chair convenes a meeting of a quorum of the IACUC. After initial review of the complaint the IACUC would determine whether it requires further investigation and immediate action, further investigation but no immediate action, or no action. Once this decision has been made, the IACUC would determine which individuals or other institutional or non-institutional offices would require notification at this time. The notification would be in written form and distributed via campus mail.

The Institutional Official would be apprised of all concerns through internal written and oral discussion and would participate in resolution.

If immediate action appears warranted because animal or human welfare may be compromised, the IACUC will notify the Institutional Official and proceed accordingly.

Veterinary medical intervention, suspension of a research activity, and/or notification of appropriate safety, occupational health, or other officials, are examples of actions that may be taken immediately to protect animal or human welfare.

The Institutional Official shall report that action to APHIS and any federal agency funding that activity. If the activity is supported in any way by the PHS, the IACUC, through the Institutional Official, must promptly notify OLAW.

5. Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

The IACUC makes recommendations to the Institutional Official through the Semiannual Animal Care Program Evaluation and Tour Report and the Report to the Institutional Official and at any other time as necessary. All would be in written form and distributed via campus mail.

In addition, the IACUC also sends follow-up letters on all issues to the Institutional Official. The Institutional Official also receives copies of all IACUC correspondence, meeting agendas and minutes including protocol actions taken.

6. In accord with the PHS Policy IV.C.1-3, the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals. The IACUC procedures for protocol review are as follows:

In order to submit a protocol for review, protocol forms must be completed and signed by the principal investigator (PI), the Chair of the Department of Biological Sciences and sent to the Executive Secretary of the IACUC committee. If the protocol's PI is the Chair of the Department of Biological Science, then the protocol is reviewed and signed off on by the Director of the Central Animal Facility and then sent to the Executive Secretary of the IACUC committee.

Qualification forms for all individuals listed in the protocol are required as part of the submission.

An acknowledgement of receipt of the modification packet is sent via email to the PI reaffirming that no animals may be purchased or any protocol activity can move forward until the PI receives the IACUC Approval Notice.

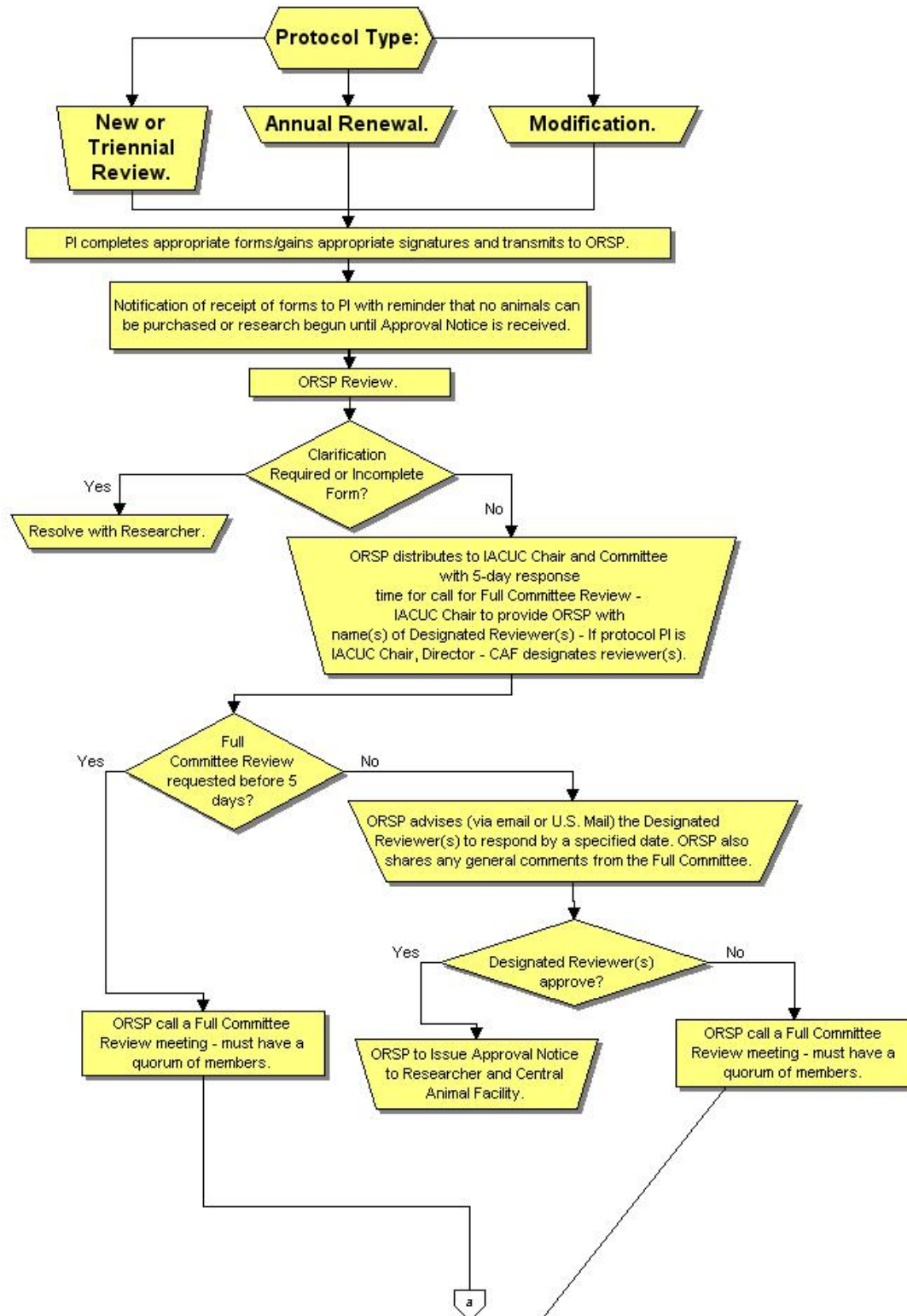
The Executive Secretary reviews the protocol for completeness, resolves open questions and has the completed protocol forms distributed via campus, U.S. mail and email to all members of the IACUC for review/opportunity to call for Full Committee Review (FCR). A cover sheet checklist also provides the due date for response (generally 5 business days) for members to respond by if they feel that the protocol should be reviewed by FCR. The IACUC Chair advises the Executive Secretary

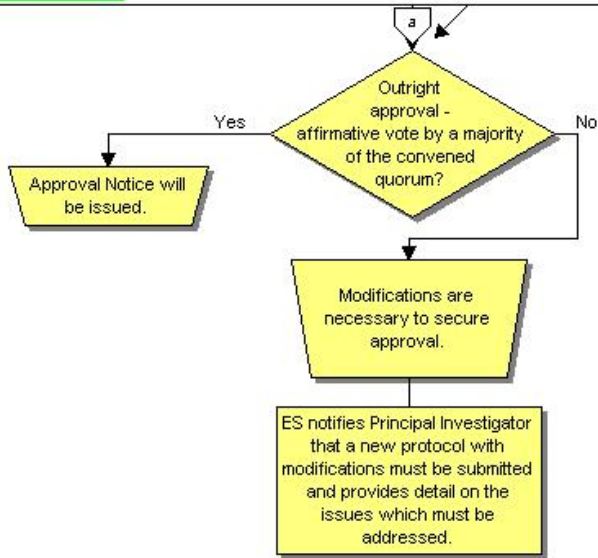
(ES) of his selection for who will be the Designated Reviewers(s). If the IACUC Chair is the PI on the protocol, the Director of the Central Animal Facility advises the ES of the Designated Reviewers(s). If no member calls for FCR by the end of the 5 day period, then the ES will notify the designated reviewers that the protocol is to be reviewed by DMR. This communication is done through e-mail. Additionally, the ES will forward any comments provided by other IACUC members during the initial 5 day period after the notification was sent. The designated members will consider these comments during their review. The DMR process may result in approval, request for modifications in order to secure approval, or return to FCR if the designated reviewers cannot agree upon the outcome. All designated reviewers must be unanimous in their response; if they cannot agree, then the protocol is returned to the full committee for review.

In the event that FCR is implemented, protocols are reviewed only at a convened meeting with a quorum present. In order to approve a protocol a majority of the quorum present must be in agreement. The outcomes of FCR are approval, modifications required to secure approval or disapproval. In the event that the quorum of members present at the convened meeting decide that modifications are necessary to secure approval, the PI is asked to resubmit the application. The protocol is then reviewed as a new submission and follows the process as defined from the beginning in this Section 6.

PIs are notified that they may not order any animals or begin procedures until the protocol describing the work has received final approval by either FCR or DMR.

PROTOCOL REVIEW: DESIGNATED MEMBER REVIEW





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 IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

Proposed significant changes are reviewed using the same procedures described in Part III. D. 6. above.

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 IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

Approvals: After committee approval, the ES sends the approval notice to investigators both via email and in hard copy. The Manager of the Central Animal Facility is also sent the approval notice for posting.

Withhold approval and Requests for Modifications: The investigator is notified of committee decisions to withhold approval related to the care and use of animals, or of modifications required to secure IACUC approval via email and hard copy. The correspondence includes the reasons for its decision and gives the investigator an opportunity to respond in person or in writing.

The IO is notified quarterly of IACUC decisions regarding protocol review in a summary report.

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 IV.C.1-4 at least once every three years. The IACUC procedures for conducting continuing reviews are as follows:

Renewals of existing protocols are required annually. A two-page renewal form must be completed and signed by the Principal Investigator (PI) and the Chair of the Department of Biological Sciences. If the protocol's PI is the Chair of the Department of Biological Sciences, then the protocol is reviewed and signed off on by the Director of the Central Animal Facility and then sent to the Executive Secretary of the IACUC committee.

The ES then emails an acknowledgement of receipt of the renewal packet to the PI informing him/her that no animals may be purchased or any protocol activity can proceed until the IACUC approves the annual renewal document, which is done using either FCR or DMR.

Triennial reviews require the submission of a full new protocol by the investigator. The protocol is then reviewed as a new submission and follows the process as defined in Section 6.

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

The Principal Investigator (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.

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 those present.

If the IACUC suspends an activity involving animals, the Institutional Official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to the Office of Laboratory Animal Welfare (OLAW).

E. The occupational health and safety program for personnel working in laboratory animal facilities or have frequent contact with animals is as follows:

Environmental Health and Safety oversees the Occupational Health and Safety Program which is based on risk assessment and hazard identification.

The mission of Environmental Health and Safety is to promote a safe and healthful environment for the University through the development and implementation of health, safety, and regulatory compliance programs and procedures, which include hazardous waste management, NRC License administration, inspections, training sessions, and emergency response actions.

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

All individuals handling animals or animal tissues are provided with an Environmental Health & Safety Program brochure. Students in classes of instruction or individuals observing animals only will receive a training hand-out or it will be the class syllabus directing them to review the Environmental Health & Safety information <http://www.lehigh.edu/~inehs/index.html>. The program brochures contain general information and discuss the overall program.

Individuals are advised by the Manager of the Central Animal Facility during their training to see their personal physician or the University Health Center with any concerns regarding allergies, pregnancy, illness or decreased immunocompetence. The animal care program will not maintain or have access to any personal medical records. Tetanus vaccinations are required. Individuals working in the Central Animal Facility are required to complete a Qualification Form which requires the month and year of inoculation. This form is renewed annually for students. Research faculty (PIs) do not have to renew this form annually.

First aid kits and disinfectant soaps are readily available to the animal users in the facility along with the instructions for reporting injuries. All incidents involving chemical spills, bodily injury, and significant property damage must be reported on the **Lehigh University Accident Investigation Report**. All accidents and "near misses" must be investigated. Employees are required to report all accidents or "near miss" accidents to their supervisor immediately. In the event of employee injury, Risk Management must be notified within 24 hours of the injury. Supervisors are responsible for investigating all accidents, determining the cause of the accident, implementing corrective measures, and following up to ensure corrective measures are adequate. Environmental Health and Safety will assist in evaluating the accident and the accident investigation process.

The Lehigh University Health and Wellness Center provides acute and on-going care. Treatment is provided at this facility for any individual who has been injured on the job to include bites, scratches, illness, or other injury.

All police officers are trained in first aid and cardiopulmonary resuscitation. In the event of a medical emergency, all officers respond to the scene and assess the situation, provide transportation, or summon an ambulance to transport the patient to our medical center or to St. Luke's Hospital for treatment.

In addition, the Lehigh University Emergency Medical Services Response Team (L.U.E.M.S.), under the direction of the University Police, provides medical first response for all emergencies on campus.

Consumption of food and beverages is prohibited in all animal facilities. Smoking is prohibited in all University buildings.

On-line programs are in place for animal users working in campus animal facilities that includes training on PPE, safety eyewash usage, injuries, bite wounds, disaster planning, zoonoses, allergies to laboratory animals and hazards and other safety topics.

All individuals using the animal facilities must complete this training. Access to the Central Animal Facility training is provided by the Manager, Central Animal Facility.

Supervisors are responsible for notifying Environmental Health and Safety to request training for all new employees who will work with animals. A New Employee Training Checklist Form is utilized and sent directly to EH&S by the supervisor to facilitate training.

Environmental Health and Safety has developed on-line training topics for the Lehigh Community mandated by federal, state, and local requirements. EH&S maintains the training records for these on-line programs.

Tutorial

[Bloodborne Pathogens](#)

[Confined Space](#)

[Compressed Gas](#)

[Fall Protection](#)

[Lab Fire Safety](#)

[Hearing Conservation](#)

[Lockout/Tagout](#)

[Laser Safety](#)

[Cryogenic Gases](#)

On-Line Quizzes

[Bloodborne Pathogens On-Line Quiz](#)

[Confined Space On-Line Quiz](#)

[Compressed Gas On-Line Quiz](#)

[Fall Protection On-Line Quiz](#)

[Lab Fire Safety On-Line Quiz](#)

[Hearing Conservation On-Line Quiz](#)

[Lockout/Tagout On-Line Quiz](#)

[Laser Safety On-Line Quiz](#)

[Cryogenic Gases On-Line Quiz](#)

Environmental Health and Safety has developed numerous training programs designed to meet general safe work practice requirements. These programs are elements of larger programs which service broad campus needs and are listed below:

[Asbestos](#)
[Biosafety Bloodborne Pathogen Exposure Plan](#)
[Chemical Hygiene](#)
[Cylinder Handling](#)
[Confined Space Entry](#)
[Department of Transportation \(DOT\) Training](#)
[EPPC](#)
[Fire Safety](#)
[Forklift](#)
[Hearing Conservation](#)
[Laboratory Fume Hoods](#)
[Laser Safety](#)
[Lockout/Tagout](#)
[Overhead Crane Operation](#)
[Personal Protective Equipment](#)
[Radiation](#)
[Respirator](#)
[Right-To-Know](#)
[Waste Generation](#)

Programs such as Right –To-Know, Radiation Safety and Bio Safety are presented in live sessions.

F. 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 Facility and Species Inventory table.

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

All new Central Animal Facility Users, including PI's, students, technicians, and work study students report to the Manager of the Central Animal Facility for an initial 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. Facilities training also encompasses safety procedures, equipment operation, animal handling, zoonosis, allergies and hazards. 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 an exam, with a score of 100%. The exam covers all of the rules and guidelines for the animal facility. Every third year, all users must pass a renewal exam 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, methods to include research methods that minimize the number of animals required and that limit pain and/or distress in laboratory animals.

IACUC members are continually provided on-line and hard copy background materials and resources as well as training / update training opportunities.

All animal caretakers also receive project-specific training by the Principal Investigators who discuss the details of their projects to ensure that the caretakers understand the importance of the animals for which they responsible.

The IACUC members and any animal users are sent pertinent information about alternatives to animal use and any other relevant material from professional publications, professional meetings, and at times presented by the USDA inspector.

Continued educational opportunities are available for the Manager of the Central Animal Facility.

In addition, the University has chosen to utilize the [CITI Lab Animal Welfare Working Group](#) provides direction and oversight for the the CITI Lab Animal Welfare Course. The Group, consisting of veterinarians, IACUC members, IACUC chairs and IACUC coordinators, ethicists and lab animal users, meet semiannually to review the Program and develop new materials. This is available now and will required for all individuals involved in animal care and use and the IACUC Committee by January 2010.

IV. INSTITUTIONAL PROGRAM EVALUATION AND ACCREDITATION

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past six months and will be re-evaluated by the IACUC at least once every six months thereafter, in accord with the PHS Policy IV.B.1-2. Reports have been and will continue to be prepared in accord with the PHS Policy IV.B.3. 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's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

This Institution is Category Two (2)—not accredited by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request. The report of the most recent evaluations (program review and facility inspection) is attached.

V. RECORDKEEPING REQUIREMENTS

- A. This Institution will maintain for at least three years:
1. A copy of this Assurance and any modifications thereto, as approved by the 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 the Institutional Official, Bruce E. Koel.
 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. This Institution's reporting period is January 1 – December 31. The IACUC, through the Institutional Official, will submit an annual report to OLAW by January 31st of each year. The report will include:
1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation 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 change in the IACUC membership. If there are no changes to report, this Institution will provide 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 the Institutional Official, Bruce E. Koel.
- B. The IACUC, through the Institutional Official, will promptly provide OLAW 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 sections VI.A. and VI.B. of this document shall include any minority views filed by members of the IACUC.