LEHIGH UNIVERSITY
Animal Welfare Assurance 3877-01

Animal Welfare Assurance for Domestic Institutions

I, Alan J. Snyder, as named Institutional Official for animal care and use at Lehigh University, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS and NSF. This Assurance covers only those facilities and components listed below.

A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:

   Lehigh University – Bethlehem, PA

B. The following are other institution(s), or branches and components of another institution:

   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, and 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 according to the Guide for the Care and Use of Laboratory Animals (Guide).

E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.
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 as follows:

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

1) Name: [redacted]

Qualifications: Veterinarian
Degrees:
B.S. – Animal Bioscience
VMD – School of Veterinary Medicine
Training and experience in laboratory animal medicine: The attending veterinarian has been a general practitioner for 23 years. The attending veterinarian has worked with the species housed at the Institution since October 1995

Authority: The attending veterinarian has been delegated program authority and responsibility for the Institution’s animal care and use program. The attending veterinarian has access to all animals in the facility and provides guidance and oversees all aspects of animal care and use. In addition, the attending veterinarian provides guidance/oversight on handling, immobilization, sedation, analgesia, anesthesia, euthanasia, surgery programs and postsurgical care. The attending veterinarian also 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 the Institution.
Part-time employee: The attending veterinarian is present at the Institution approximately 1-2 hours per month on average during which 100% of the attending veterinarians efforts are focused on the animal care and use program.

In the event that the attending veterinarian is unavailable, the following veterinarian is available to provide back-up veterinary support to ensure adequate veterinary care of research animals: [redacted].

C. The IACUC at this Institution is properly appointed according to 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 5 members, and its membership meets the composition requirements of PHS Policy 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 6 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:

   All IACUC members are invited to meet together at the Institution 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 by a majority vote of the IACUC and forwarded to the Institutional Official for review and approval. For any change in animal laboratory practices, communication to the Institutional Official will indicate endorsement of the Central Animal Facility Director.

   The Institutional Official is made aware of the issues and recommended resolutions in the Report to the Institutional Official. The report is reviewed and signed by a majority of the IACUC members and includes minority views. Office of Animal Welfare's Sample Semi-Annual Program Review Checklist for the "Guide" Eighth Edition has been adapted for use in the review process and supplements our current form.

2) Inspect at least once every 6 months all of the Institution's animal facilities, including satellite facilities and animal surgical sites, using the "Guide" as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

   The six-month review includes inspection of the Central Animal Facility and each of the satellite facilities listed in the attached Facilities and Species Inventory report. All members of the IACUC are invited to participate. At least one member of the IACUC, or a person designated by the IACUC, will perform inspections for non-USDA regulated species. At least two voting members of the IACUC will perform inspections for USDA-regulated species. Each inspection includes a complete review of the overall facility including food supply rooms, cage washing areas, records, each animal suite, surgery suites, all housing, patient records, and any individual investigator laboratories and classrooms that are utilized for animal research. Investigators are permitted to take animals to their laboratories or classrooms 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, and a "correct by" date is assigned. This information is also included in the formal Report to the Institutional Official. The report is reviewed and signed by a majority of the IACUC members and includes minority views.

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

3) Prepare reports of the IACUC evaluations according to PHS Policy IV.B.3. and submit the reports to
the Institutional Official. The IACUC procedures for developing reports and submitting them to the
Institutional Official are as follows:

Prepare reports of the IACUC evaluations as set forth in the “Guide” and submit the reports to the
Institutional Official.

Upon completion of the semi-annual program review and facility inspection, the Executive
Secretary promptly prepares a draft report using the Office of Laboratory Animal Welfare sample
format letter for reporting to the Institutional Official. The report summarizes the Committee’s
findings at the semiannual meeting including any minority views.

For each deficiency, the report will note whether the IACUC views the deficiency as involving
significant or continuing deficiency from the requirements of the Guide or Public Health Service
policy. For each deficiency, the IACUC Chair and Executive Secretary draft a corrective action
plan including personnel responsible and a timeline for completion, for inclusion with the report.
The Executive Secretary circulates the draft report for IACUC member review, correction and/or
approval.

In the case of any departures from the Guide or Public Health Service policy, the report includes
a description of each departure including the reasons for the departure.

The final report and recommended corrective action plans and timelines are submitted to the
Institutional Official after being signed by a quorum of the IACUC members.

The Executive Secretary, along with the Central Animal Facility Director and Manager are
charged with ensuring timely correction of any deficiencies noted. The Executive Secretary and
the Institutional Official are charged with reporting any significant deficiencies not resolved within
15 days of the timetable for correction of deficiencies to the Animal and Plant Health Inspection
Service (APHIS) and to any Federal agency funding affected activity. Any deficiency classified by
the IACUC or the Institutional Official as involving significant or continuing departure from
requirements of the Guide or Public Health Service policy will be reported promptly to OLAW.

Signatures of the IACUC voting members indicating their approval of the report are retained on file by
the Executive Secretary. The report 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 each facility listed in the attached Facilities and Species Inventory report with
steps to follow should anyone have concerns involving animal care and use. Conditions that
reportedly jeopardize the health or well-being of animals are evaluated immediately. The
Institution has selected EthicsPoint to provide a simple, anonymous way for employees to
confidentially report activities that may involve alleged misconduct or alleged violation the
Institution's or government policies and regulations. The University Ethics Hotline is provided on
this site: http://www.lehigh.edu/%7Einiao/hotline.html. Any person who reports a legitimate
concern to the IACUC is guaranteed the right to do so without reprisal.

The Director of the Central Animal Facility is authorized to temporarily halt activities which he/she
believes to be noncompliant 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. Whenever possible, the source of the report must be identified to the IACUC as an aid
to discerning the degree to which the concern comes from a knowledgeable source. The identity of the person reporting the concern is kept confidential within the IACUC upon request.

Upon receipt of a concern, the IACUC Chair convenes a meeting of a quorum of the IACUC. After initial review of the concern the IACUC determines 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 determines which individuals or other institutional or non-institutional offices require timely notification. The notification is in written form and distributed via campus mail, and/or US Mail or other major carrier or courier.

The Institutional Official is apprised of all concerns through internal written and oral discussion and participates in resolution.

If immediate action is deemed by the IACUC to be warranted because animal or human welfare may be compromised, the IACUC proceeds accordingly and notifies the Institutional Official. 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 as required to Animal and Plant Health Inspection Service and any Federal agency funding that activity. If the activity is supported in any way by the Public Health Service, the IACUC, through the Institutional Official, must promptly notify Office of Laboratory Animal Welfare (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 Central Animal Facility Report and by a Report to the Institutional Official and at any other time as necessary. All recommendations are in written form and distributed via email.

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

In accordance with the Public Health Service Policy Section IV.C.1-3, the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of activities related to the humane care and use of vertebrate animals.

In order to submit a protocol or protocol modification for review, protocol forms must be completed and signed by the Principal Investigator and the Chair of the Principal Investigator’s academic department and sent to the Executive Secretary of the IACUC. In the case of a Principal Investigator who is a department chair or who does not have an appointment in an academic department, the Dean of the college in which the Principal Investigator holds an appointment or the Vice President to whom the Principal Investigator’s unit reports shall sign in lieu of the department Chair.

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

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

The review procedure provides for Full Committee Review at the request of any IACUC member, while also supporting timely designated member review, as follows: The Executive Secretary reviews the protocol for completeness, resolves open questions and has the completed identical
protocol forms distributed via campus, U.S. mail, or email to all members of the IACUC for review with opportunity to call for Full Committee Review. The distribution documentation provides the due date for response (generally five business days) by which members should respond by if they believe that the protocol or modification should be reviewed by Full Committee Review. The IACUC Chair, or the Vice Chair if the IACUC Chair is the Principal Investigator or is absent from campus, advises the Executive Secretary of the selection of Designated Member Reviewer(s). If no member calls for Full Committee Review by the end of the response due date, then the Executive Secretary will notify the designated reviewers that the protocol is to be reviewed by Designated Member Review. This communication is done through e-mail. The Executive Secretary incorporates all comments and questions raised by any Committee members into the materials provided for Designated Member Review. The Designated Member Review process may result in approval, request for modifications in order to secure approval, or return for Full Committee Review 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 Full Committee Review is implemented, protocols are reviewed only at a convened meeting of the IACUC with a quorum present. In order to approve a protocol a majority of the quorum present must be in agreement. The available outcomes of Full Committee Review are (1) approval, (2) modifications required to secure approval, or (3) disapproval. In the event that the quorum of members present at the convened meeting decide that modifications are necessary to secure approval, the Principal Investigator is asked to resubmit the protocol. The protocol is then reviewed as a new submission and follows the process as defined from the beginning in this Section 6.

Principal Investigators are notified that they may not order any animals or begin procedures until the protocol describing the work has received final approval.

No member of the IACUC may participate in the review and or approval of any research project in which they may have a conflicting interest. All participants in the proposed research effort are provided in the protocol form. Any member of the IACUC would not be permitted to participate in the review process except to provide information requested by the IACUC.

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

Upon IACUC approval, the Executive Secretary sends the approval notice to the Principal Investigator via both email and hard copy. The Manager of the Central Animal Facility is also sent the approval notice for posting.

Upon IACUC withholding of approval or a decision that modification is required to secure approval, the Executive Secretary provides notice to the Principal Investigator via both 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 Institutional Official 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 at least once every 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

Postapproval monitoring is overseen by the Director and Manager of the Central Animal Facility, the Executive Secretary of the IACUC, and Principal Investigators for individual protocols. The Executive Secretary makes both unannounced and regularly scheduled visits to do a general review each facility and documentation associated with the research (e.g. patient record forms) to verify that procedures and personnel correspond to what was proposed in the protocol. Animal misuse, mistreatment, neglect, and discrepancies that result in animal welfare concerns (deliberate animal misuse, mistreatment, or neglect, or those that involve willful disregard of appropriate animal care) are immediately reported at the IACUC in accordance with institutional policy and the PHS Policy. Any significant deficiencies not resolved within 15 days of the timetable for correction of deficiencies to the Animal and Plant Health Inspection Service (APHIS) and to any Federal agency funding that activity. The IACUC receives and evaluates reports of PAM activity, identifies corrective actions, and determines outcomes. As necessary, the IACUC evaluates PAM reports to determine instances of noncompliance and make the appropriate corrective action and reporting recommendations to the IO. The IO receives and evaluates reports of PAM activity. In consideration of the IACUC’s determinations, the IO provides guidance, resources, and support for systemic and policy changes, updates, and improvements to address issues identified through PAM activity.

Renewals of existing protocols are required annually. A renewal form must be completed and signed by the Principal Investigator and the Chair of the Principal Investigator’s academic department and provided to the Executive Secretary of the IACUC. In the case of a Principal Investigator who is a department chair or who does not have an appointment in an academic department, the Dean of the college in which the Principal Investigator holds an appointment or the Vice President to whom the Principal Investigator’s unit reports shall sign in lieu of the department Chair.

The protocol is then reviewed and signed off on by the Director of the Central Animal Facility and then sent to the Executive Secretary of the IACUC.

The Executive Secretary then emails an acknowledgement of receipt of the renewal packet to the Principal Investigator, reminding 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 Full Committee Review or Designated Member Review as described in Section III.D.6.

Annual Renewals where the “Research is continuing as defined in the original protocol” or “Renewals with Modifications with Changes in Personnel Only” do not go for Full Committee Review. The Chair or the Vice Chair of the IACUC, in the absence of the Chair, are Designated Member Reviewers in these two situations and the renewals otherwise processed by DMR as described in Section III.D.6.

Triennial reviews require the submission of a full new protocol by the Principal Investigator. The protocol is then reviewed as a new submission and follows the process as described in Section III.D.6.

3) Be authorized to suspend an activity involving animals according to PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:

Aside from temporary halts of procedures as described in Section 4 above, the IACUC may suspend an activity only after review of the matter at a convened meeting of the IACUC, by a majority vote of the quorum present.
The Executive Secretary provides written notification to the Principal Investigator that the IACUC has determined the need to suspend an activity involving animals in accordance with specifications set forth in the “Guide”, Section IV.C.6. The Executive Secretary, IACUC Chair, or Director of the Central Animal Facility may in addition provide verbal notification.

The IACUC, through the Institutional Official, promptly provides OLAW with a full explanation of the circumstances and actions taken with respect to

   a) any serious or continuing noncompliance with this Policy;

   b) any serious deviation from the provisions of the Guide; or

   c) any suspension of an activity by the IACUC.

IACUC suspensions of activities require a convened meeting of a quorum of the IACUC and the vote of a majority of the quorum present. The Institutional Official must review the reasons for suspension in consultation with the IACUC, take appropriate corrective action and report that action with full explanation to OLAW.

All institutions with Animal Welfare Assurances are required to comply with the provisions of IV.F.3. The Institutional Official signing the Assurance, in concert with the IACUC, is responsible for this reporting.

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

   The risk-based occupational health and safety program is overseen by the Director of the university Office of Environmental Health and Safety (EHS). The Director reports directly to the Institutional Official, with secondary reporting to the Associate Vice President for Campus Planning and Facilities. EHS has front line responsibility for promotion of a safe and healthful environment across the Institution, and does so through development and implementation of health, safety and regulatory compliance programs and procedures including inspections, training programs, emergency response actions and accident investigations. The program for risk assessment, hazard identification and hazard mitigation is based on a combination of institutional standards for laboratory facilities and the specific requirements of the Guide.

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

   The Institution utilizes St. Luke’s Occupational Medicine for care of workplace injuries, physical exams, and any special medical testing requirements that are dictated by specific workplace risks. Health screenings for all personnel working in animal facilities and for all personnel working under animal protocols, and care of students with minor injuries and illnesses, is provided by the Institution’s Health and Wellness Center.

   Tetanus vaccination is among the immunization requirements for all students as a condition of attendance at the Institution. The Health and Wellness Center will provide vaccination as needed. Faculty and staff obtain required immunizations from their own providers.

   The IACUC will not maintain or have access to any personal medical records. Individuals working in animal facilities or listed on protocols are required to complete a Qualification Form which requires them to provide the month and year of their last tetanus vaccination, provides them with the General Zoonotic Training document and requires that they certify the accuracy and understanding of potential health issues. This form is renewed annually for students. Students not up-to-date on their Tetanus
inoculations are not permitted to work with animals until that is resolved. Research faculty are also monitored through the Qualification form for their Tetanus inoculation dates.

All new and current employees who work in animal facilities or have contact with animals in the course of their work are encouraged to participate in baseline and annual health screenings. All students who work in animal facilities or have contact with animals in the course of their work are required to participate in baseline and annual health screenings. Screenings are administered by the Health and Wellness Center. The Qualification Form requires personnel to either certify the date of completion of the screening or note that screening has been declined. Annual review of the form utilized in the health screening procedure is part of the annual renewal process for the protocols.

The Qualification Form is also used to capture a history of the individual and their experience with working with animals, including training in biohazards in the workplace. The on-line form can be found at this site: http://research.cc.lehigh.edu/content/iauc-qualifications-form

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, the supervisor must notify Risk Management 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 Institution's 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, and as appropriate provide transportation, or summon an ambulance for transport, to Institution’s Health and Wellness 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.

It is the policy of the University to maintain, insofar as it is reasonably within its control to do so, a Campus environment for faculty, staff, students, and the public that will not adversely affect their health and safety nor subject them to avoidable risks of accidental injury or illness. No student or employee will be required to perform any task which is determined to be unsafe or unreasonably hazardous.

To accomplish this, the University, its Departments, Centers, and Institutes will provide facilities and equipment that meet Federal, State, and Local health, safety, and environmental laws and regulations, and will promulgate appropriate policies, standards, and procedures for governing Campus health and safety programs.

While the overall responsibility for Campus health and safety rests with the President of the University, the immediate responsibility for workplace health and safety belongs to each Campus employee who performs a supervisory role. At Lehigh University, faculty members are regarded as supervisory personnel for their laboratories as well as students. In addition, individual employees are responsible for preventing Campus accidents. Accordingly, all faculty and staff are to ensure that safe and healthful conditions and practices are provided and followed within the areas under their control, and all members of the Campus community are to cooperate fully with all aspects of the various Campus health and safety programs.
On-line training programs are in place through CITI (Collaborative Institutional Training Initiative) for animal users working in campus animal facilities. Training on personal protective equipment, safety, eyewash usage, injuries, bite wounds, disaster planning, zoonosis, allergies to laboratory animals, hazards and other safety topics are also available and are required.

All individuals using the animal facilities must complete the CITI training and a Qualifications Form which documents, among other elements, the month and year of their last tetanus inoculation and requires them to certify that they have read and understand the General Zoonotic Training document. Access to the Central Animal Facility training is provided by the Manager of the Central Animal Facility.

The Executive Secretary is responsible for notifying Environmental Health and Safety requesting training for all new individuals who will work with animals.

Nonhuman primates are not utilized in our facility.

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

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<th>On-Line Quizzes</th>
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<td>Lockout/Tagout</td>
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<td>Cryogenic Gases</td>
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Environmental Health and Safety has developed training programs designed to meet general safe work practice requirements. These programs are elements of larger programs which service broad campus needs and are as follows:

- 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
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 there and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table.

[Complete the Facility and Species Inventory table provided (see Part X.).
Note: list common names for animal species, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog.
Note: animal areas (buildings/rooms) may be represented by a number or symbol in this submission to OLAW.]

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 Principal Investigators, 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 per Public Health Service 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, students 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.

In addition, the Institution’s IACUC has adopted a common training pathway as a way to ensure consistent and thorough training for all animal users and handlers: The Collaborative Institutional Training Initiative (CITI) Animal Care and Use Course, an online course that was originally developed by the VA for the research community. This online course meets the federal (USDA, OLAW) requirements for basic training in the humane care and use of animals in research and teaching. The online course was developed by a team of veterinarians, IACUC members, IACUC chairs and IACUC coordinators, ethicists and laboratory animal users.

Every animal user (student, faculty, staff, paid or unpaid) will be required to have passed the basic CITI module Working with the IACUC. The sub-section titled Alternatives, specifically discusses the concept of the “Three R's” and the various alternative and database search resources. In addition, for users that work with species for which CITI has a module are required to have passed the CITI specialty modules for the species.

All Principal Investigators are required to use experimental designs that minimize the numbers of animals required and to use and train their own laboratory personnel in procedures that limit pain and/or distress in laboratory animals.

All animal caretakers also receive project-specific training by the Principal Investigator. The Principal Investigator assures that caretakers understand necessary details of their projects as well as the importance of the proper care of the animals for which they are responsible.

IACUC members are provided on-line and hard copy background materials and resources including the most recent versions of the "Guide", PHS Policy, the Animal Welfare Act and Regulations, the OLAW/ARENA IACUC Guidebook, and a copy of the approved Animal Welfare Assurance.

https://research.cc.lehigh.edu/animals Training and opportunities for update training are agenda items.
at each regular IACUC meeting as well as webinar programs sponsored by organizations such as OLA, An IACUC Member's Guide to Animal Facility Inspections the Public Health Service Policy on Humane Care and Use of Laboratory Animals Tutorial.

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 also available for the Manager of the Central Animal Facility.

In addition, the Institution has chosen to utilize the CITI Lab Animal Welfare Course provided by the CITI Lab Animal Welfare Working Group. The Group, consisting of veterinarians, IACUC members, IACUC chairs and IACUC coordinators, ethicists and lab animal users, meet semiannually to review the Institution's Animal Care and Use Program and develop new materials. This training is required for all individuals involved in animal care and use and all members of the IACUC Committee.

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 6 months and will be reevaluated by the IACUC at least once every 6 months according to PHS Policy IV.B.1-.2. Reports have been and will continue to be prepared according to 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 PHS Policy and 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 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 3 years:
1. A copy of this Assurance and any modifications made to it, 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 granted or withheld
4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Alan J. Snyder.
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 3 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. The Institutional reporting period is the calendar year (January 1 – December 31). The IACUC, through the Institutional Official, will submit an annual report to OLAW by January 31 of each year. The annual 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)
   2. Any change in the description of the Institution's program for animal care and use as described in this Assurance
   3. Any change in the IACUC membership
   4. 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.
   5. Any minority views filed by members of the IACUC

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 VI.A. and VI.B. above should include any minority views filed by members of the IACUC.