

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, HHS, NSF, and/or NASA. 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."

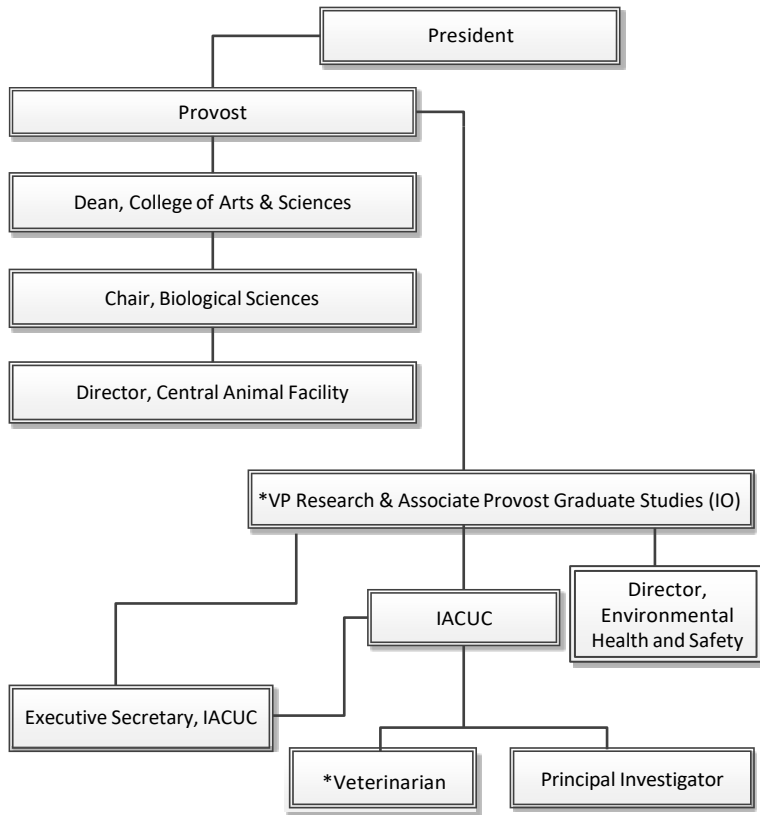
C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand 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:



*As required by PHS policy, there are open lines of communication between the Attending Veterinarian and the Institutional Official. Each may contact the other directly whenever needed.

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

Name: [REDACTED]

Qualifications: Veterinarian [REDACTED]

Degrees:

B.S. – Animal Bioscience [REDACTED]

V.M.D. – School of Veterinary Medicine [REDACTED]

Training and experience in laboratory animal medicine: [REDACTED] has been a general practitioner since 1986 and has worked with the species housed at the Institution since October 1995.

Authority: [REDACTED] has been delegated program authority and responsibility for the Institution’s animal care and use program. [REDACTED] has access to all animals in the facility and provides guidance and oversees all aspects of animal care and use. In addition, [REDACTED] provides guidance and oversight on handling, immobilization, sedation, analgesia, anesthesia, euthanasia, surgery programs and postsurgical care. She also liaises with the Director of the Central Animal Facility, the IACUC Executive Secretary, and the Institutional Official on all matters relating to animal care and use at the Institution.

Part-time employee: [REDACTED] is present at the Institution 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 [REDACTED] is unavailable, the following veterinarian is available to provide back-up veterinary support to ensure adequate veterinary care of research animals:

[REDACTED]

Qualifications: Veterinarian [REDACTED]

Degrees:

B.S. – Biology [REDACTED]

V.M.D. – School of Veterinary Medicine [REDACTED]

Training and experience in laboratory animal medicine: [REDACTED] has been a general practitioner and has worked with the species housed at the Institution since 2016.

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 review the Institution's program for humane care and use of animals at least every six months, using the Guide as the basis for evaluation, and reporting its findings and recommendations to the Institutional Official. The Office of Animal Welfare's Sample Semiannual Program Review Checklist has been adapted for use in the review process. The key aspects of the program that are reviewed during the semiannual review process include all institutional policies and responsibilities regarding the animal care and use program; disaster planning and emergency preparedness; the IACUC; special considerations in IACUC protocol review; IACUC membership and functions; IACUC training; IACUC records and reporting requirements; veterinary care; personnel qualifications and training; occupational health and safety of personnel; personnel security; investigating and reporting animal welfare concerns; veterinary clinical care and management; animal procurement and transportation/preventative medicine; surgery; pain, distress, anesthesia, and analgesia; euthanasia; and drug storage and control. The review is completed by sub-committees of IACUC members. All IACUC members are invited to participate in the semiannual program review. Issues identified by sub-committees are brought to the full committee for discussion in the semiannual meeting.

Issues or challenges are discussed by the full committee. Policies and procedures are developed or amended by a majority vote of the IACUC, and forwarded to the Institutional Official for review or approval as part of its Report (as described in Section III, D.3). For any change in animal laboratory practices, communication to the Institutional Official indicates the endorsement of the Central Animal Facility Director.

The IACUC informs the Institutional Official of the issues and recommended resolutions in the Report to the Institutional Official. The report is reviewed and approved by a majority of the IACUC members and includes any minority views. The Institutional Official reviews all identified issues and recommended resolutions and may require additional clarification or changes prior to issuing final approval by the IACUC.

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 semiannual review includes inspection of the Central Animal Facility and each satellite facility 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, performs inspections for non-USDA regulated species. At least two voting members of the IACUC perform inspections for USDA-regulated species. Each inspection includes a complete review of the facility, including food supply rooms, cage washing areas, records, each animal experimentation suite, surgery suites, housing areas, patient records, and individual investigator

laboratories or 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 used to note any deficiencies that are identified during the facility inspection. Deficiencies are reported to the Central Animal Facility Director and Manager immediately following the inspection, and a due date for corrections is assigned. The checklist is also included in the Report (as described in Section III, D.3) to the Institutional Official. The report is reviewed and approved by a majority of IACUC members and includes minority views.

The IACUC Executive Secretary, the Central Animal Facility Director, and the Central Animal Facility Manager are responsible for ensuring timely correction of deficiencies. Failures to adhere to the plan and schedule that result in a significant deficiency remaining uncorrected are reported in writing within fifteen days by the IACUC, through the Institutional Official, to APHIS and any federal agency funding the associated project.

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:

The IACUC Executive Secretary prepares reports of the IACUC evaluations as set forth in the Guide and submits the reports to the Institutional Official.

Upon completion of the semiannual program review and facility inspection, the IACUC Executive Secretary promptly prepares a draft report using the Office of Laboratory Animal Welfare sample letter for reporting to the Institutional Official as a template. The report summarizes the IACUC's findings and includes any minority views.

The report notes if the IACUC identified deficiencies, and distinguishes significant deficiencies from minor deficiencies. A significant deficiency is one which, with reference to the requirements of PHS Policy and the Guide, and, in the judgement of the IACUC and the Institutional Official, is or may be a threat to the health or safety of animals and/or research personnel. A minor deficiency is an issue that does not represent an immediate or ongoing threat to the health or safety of animals and/or research personnel. A reasonable and specific corrective action plan, including responsible personnel and a timeline for completion, is included for each deficiency noted. The IACUC Executive Secretary circulates the draft report for review, correction, and approval by the IACUC.

Departures from the Guide and PHS Policy are first identified by the Principal Investigator within the protocol. Principal investigators must provide a detailed scientific justification for the departure. Prior to approval of protocols, IACUC reviewers are asked to assess departures as well as the scientific justification provided. When departures from PHS Policy and the Guide are included in protocols approved by the IACUC, the report includes a description of each departure and the reasons for the departure. IACUC approval of departures from the Guide are based on scientific, veterinary medical, or animal welfare issues.

The final report is approved by a majority of the IACUC members and submitted to the Institutional Official. Approvals are provided in writing by email and retained with IACUC records.

The IACUC Executive Secretary, together with the Central Animal Facility Director and Manager, is responsible for ensuring timely correction of any deficiencies noted. Failures to adhere to the plan and schedule that result in a significant deficiency remaining uncorrected are reported in writing within fifteen days by the IACUC, through the Institutional Official, to APHIS and any federal agency funding the associated project. 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.

Documentation of IACUC members' approval of reports is retained by the IACUC 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:

Each facility posts signs 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 uses the University Ethics Hotline (<http://lehigh.edu/internalaudit/hotline>) as a secure, online form for anonymous and confidential reporting of activities that may involve misconduct or violations of the Institution's or government policies and regulations. Any person who reports a legitimate concern to the IACUC is guaranteed the right to do so without reprisal. Furthermore, Lehigh University's Policy on Harassment and Discrimination specifically prohibits discrimination against anyone who has reported or is believed to have made a report concerning such behavior.

The Director of the Central Animal Facility is authorized to temporarily halt activities that 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 is identified to the IACUC to assist in 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. Next, the IACUC determines which individuals or other Institutional or non-Institutional offices require timely notification. The notification is in written form and distributed via email, and if necessary, via US Mail or other major carrier or courier.

The IACUC informs the Institutional Official of all concerns through internal written and verbal discussion. The Institutional Official participates in resolution of reports of concerns.

If the IACUC deems that immediate action is 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 the 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 will report that action as required to Animal and Plant Health Inspection Service and any Federal agency funding the activity. If the activity is supported in any way by the Public Health Service, the IACUC, through the Institutional Official, promptly notifies the 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 reviews and approves, requires modifications in (to secure approval), or withholds approval of activities related to the humane care and use of vertebrate animals.

Protocol application forms are completed and signed by the Principal Investigator and signed by the Chair of the Principal Investigator's academic department. 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 signs in lieu of the department Chair. Applications for new protocols involving use of the Central Animal Facility must also be signed by the Central Animal Facility Director. Completed and signed protocol application forms are accepted via email, hard copy, or through the institution's web-based compliance committee submission system, IRBNet.

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

An acknowledgement of receipt is sent to the Principal Investigator via email or IRBNet confirming that no animals may be purchased and no protocol activity can be conducted until the Principal Investigator receives the IACUC approval notice.

The review procedure allows for Full Committee Review at the request of any IACUC member, while also supporting timely Designated Member Review. The Executive Secretary completes a pre-review for completeness and resolves any open questions. Application materials are distributed to all committee members via email or through IRBNet. All members have the opportunity to call for Full Committee Review. Responses to call for Full Committee Review are generally due within five business days. The IACUC Chair advises the Executive Secretary of the assigned Designated Member Reviewer(s). The Vice Chair serves as Chair if the IACUC Chair is the Principal Investigator or is absent from campus. If no member calls for Full Committee Review by the response due date, the application is reviewed by Designated Member Review. The Executive Secretary incorporates all comments and questions raised by any committee member into the application materials provided for Designated Member Review. The Designated Member Review process may result in approval, requests for modifications required in order to secure approval, or return for Full Committee Review if the Designated Members Reviewers are unable to agree on an outcome. All Designated Member Reviewers must be unanimous in their response; if they do not agree, the protocol is sent for Full Committee Review. This review process is completed through either email or IRBNet.

Applications are reviewed by Full Committee Review only at a convened meeting of the IACUC with a quorum present. A majority of the quorum present must be in agreement in order to approve an application. The Full Committee Review process may result in approval, modifications required in order to secure approval, or disapproval. When the Full Committee Review results in modifications required to secure approval, the IACUC requests that the Principal Investigator resubmit the protocol. The protocol is then reviewed as a new submission, and follows the process as defined from the beginning of Section 6 above.

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 activity are listed in the protocol application form. Any member of the IACUC with a conflicting interest may only provide information regarding the research activity proposed at the request of 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 as described in Section III, D. 6. Significant changes are changes that have, or have the potential to have, a negative impact on animal welfare. Examples of significant changes include changes from nonsurvival to survival surgery; changes resulting in greater pain, distress, or degree of invasiveness; changes in housing and or the use of animals in a location that is not part of the animal program overseen by the IACUC; changes in species; changes in study objectives; changes in the Principal Investigator; changes that impact personnel safety; changes in anesthesia, analgesia, sedation, or experimental substances; euthanasia method; duration, frequency, type, or number of procedures performed on an animal, and; increases in previously-approved animal numbers.

Proposed changes determined not to be significant are administratively approved by the IACUC Executive Secretary. Non-significant changes include the correction of typographical errors; correction of grammar; contact information updates; changes in funding source; changes in personnel other than the PI, and; reductions in previously-approved animal numbers.

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:

The Executive Secretary sends an approval notice to the Principal Investigator upon IACUC approval. The notice is sent via email or through IRBNet. The Manager of the Central Animal Facility is copied on all approval notices.

The Executive Secretary sends notice via email or IRBNet when IACUC review results in modifications required to secure approval. The notice includes the reasons for the IACUC's decision and gives the investigator an opportunity to respond.

The Institutional Official is notified quarterly of IACUC protocol review decisions 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 may make both unannounced and regularly scheduled visits to do a general review of each facility and documentation associated with the research (e.g. patient record forms) to verify that procedures and personnel correspond to what is described in the approved protocol. Animal misuse, mistreatment, neglect, and discrepancies that result in animal welfare concerns (e.g. deliberate animal misuse, mistreatment, or neglect, or those that involve willful disregard of appropriate animal care) are immediately reported to the IACUC in accordance with Institutional policy and the PHS Policy.

The IACUC receives and evaluates reports of postapproval monitoring activity, identifies corrective actions, and determines outcomes. As necessary, the IACUC evaluates postapproval monitoring reports to determine instances of noncompliance and make the appropriate corrective action and reporting recommendations to the IO. If postapproval monitoring identifies significant deficiencies, any failure to adhere to the subsequent corrective action plan and schedule that result in a significant deficiency remaining uncorrected are reported in writing within fifteen days by the IACUC, through the Institutional Official, to APHIS and any federal agency funding the associated project. The IO receives and evaluates reports of postapproval monitoring 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 postapproval monitoring activity.

Protocol renewal forms are completed and signed by the Principal Investigator and signed by the Chair of the Principal Investigator's academic department. 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 signs in lieu of the department Chair. Completed and signed protocol renewal forms are accepted via email, hard copy, or through the institution's web-based compliance committee submission system, IRBNet.

An acknowledgement is sent to the Principal Investigator via email or IRBNet confirming receipt of the submission, and if modifications are proposed, that the work described in the modification may not be conducted until the Principal Investigator receives the IACUC approval notice. The IACUC conducts annual reviews by using either Full Committee Review or Designated Member Review, as described in Section III.D.6. above.

Annual renewals where the research is continuing as defined in the original protocol or renewals with modifications only to the protocol personnel 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 renewal is otherwise processed by DMR as described in Section III.D.6. above.

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

10) 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 III, D. 6 above, the IACUC may suspend an activity pursuant to 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 there is a 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 provide additional 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:

Occupational health and safety at Lehigh University is overseen by the Director of the university Office of Environmental Health and Safety (EHS). The Director reports directly 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 risk-based health, safety and regulatory compliance programs and procedures including inspections, training programs, emergency lab 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.

The Office of Risk Management provides leadership and facilitates collaboration in preparing the University for emergencies and recovery from emergencies, administers the University's Disaster and Emergency Preparedness Plan (DEPP), guides campus leaders in emergency response and the creation of integrated risk based mitigation and continuity plans. Risk mitigations and contingency plans address natural disasters as well as threats that criminal activities such as personnel harassment and assault, facility trespassing, arson, and vandalism pose to laboratory animals, research personnel, equipment and facilities. Additional institutional preventative measures include pre-employment screening and physical and IT security.

All individuals handling animals or animal tissues are provided information about Lehigh's Environmental Health and Safety Program as part of required training to be completed prior to animal research work. Students in classes of instruction or individuals observing animals only, receive a training hand-out or this information is included in the class syllabus directing them to review the Environmental Health and Safety information (<https://facilities.lehigh.edu/environmental-health-safety>).

The Institution partners with Lehigh Valley Health Network HealthWorks 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 and/or by the individual's personal medical provider.

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 vaccinations for students as needed. Faculty and staff must 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.

Individuals in frequent or substantial contact with animals are required to complete a baseline health screening. Individuals who are not in frequent or substantial contact with animals have the option to complete a baseline health screening. The individual risk assessment will consider the species of animal and amount of exposure. Health screenings are administered by the Health and Wellness Center or by the individual's personal medical provider. To facilitate the assessment of risk, individuals being screened by their personal medical provider are encouraged to share their specific responses to the health screening questionnaire with their personal medical provider. The Qualification Form requires personnel to either certify the date of completion of the screening or certify that they are not in frequent or substantial contact with animals and have opted out of the screening. Annual review of the form utilized in the health screening procedure is part of the annual renewal process for the protocols. Individuals who opt-out of the annual health screening requirement are screened for eligibility by the IACUC Executive Secretary. Those individuals who are determined to be in frequent or substantial contact with animals and thus ineligible to opt-out are directed to complete the required health screening and resubmit the form once the screening has been completed.

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 form is available through the following link: <http://research.cc.lehigh.edu/content/iacuc-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.

Personnel are instructed to notify their supervisor of potential, suspected, or known exposures to health hazards or illnesses, including decreased immunocompetence. Environmental Health and Safety will assist in evaluating risks presented by exposure or illness and coordinate an appropriate response, including any additional precautions that must be taken.

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, 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. Visiting faculty and summer students must meet the same requirements as regular, full-time faculty and students, including the completion of the Qualification Form and baseline health screening. Maintenance, police and safety, security, and housekeeping personnel access the animal facility on a limited basis and are escorted by animal facility personnel at all times.

All personnel are required to comply with the EHS policy on Personal Protective Equipment (PPE), which protects employees and students from the hazards of processes or environment, chemical hazards, radiological hazards, or mechanical irritants by providing protective equipment for eyes, face, head, and extremities and to ensure protective clothing, respiratory devices, and protective shields, and barriers are used and maintained in a sanitary and reliable condition. All personnel are required to comply with EHS policies related to handling hazardous agents, including the Occupational Exposure to Hazardous Chemicals in Laboratories Policy, the Shipping of Hazardous Materials Policy, the Use of Biohazardous Materials in Research and Instruction Policy, and the Waste Disposal Policy. All policies related to PPE and handling hazardous agents are established and regularly reviewed and updated by EHS.

Animal users working in campus animal facilities and with frequent and substantial animal contact are required to complete training through CITI as described in section III.G. below. 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 and with frequent and substantial animal contact must complete 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.

Environmental Health and Safety has developed online training topics for the Lehigh community mandated by federal, state, and local requirements. Environmental Health and Safety maintains the training records for these online programs. The tutorials and corresponding quizzes cover the following topics: Bloodborne Pathogens; Bloodborne Pathogens for Emergency Responders; Confined Spaces; Compressed Gas; Construction Site Safety; Electrical Safety; Field Safety; Forklift Safety; Hazardous Waste; Lab Biosafety; Written Requirements for BSL1/BSL2; Nanotechnology; Right-to-Know; Working in the Lab While Pregnant; Fall Protection; Lab Fire Safety; Hearing Conservation; Lockout/Tagout; Laser Safety; Cryogenic Gasses.

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 Safety; Right-To-Know; Waste Generation.

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

Nonhuman primates are not used in the facility.

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.

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

All new Central Animal Facility users, including Principal Investigators, students, and technicians, are required to complete training on working in the animal facility. 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. Training on safety procedures, equipment operation, animal handling, zoonosis, and hazards is included. New users are required to review the Central Animal Facility Rules and Procedures and must pass an exam with a score of 100%. The exam covers all of the rules and guidelines for the animal facility. Training and testing is documented by the Manager of the Central Animal Facility and the IACUC Executive Secretary.

The institution uses the Collaborative Institutional Training Initiative (CITI) online program for a portion of the required training. CITI meets the federal (USDA, OLAW) requirements for basic training in the humane care and use of animals in research and teaching. All personnel involved in animal care, treatment or use are required to pass the "Working with the IACUC" CITI training module. The sub-section titled "Alternatives", specifically discusses the concept of the "Three R's" and the various alternative and database search resources. All users are also required to pass the CITI module specific to the species with which they are working.

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. Specific training on research and testing methods of minimizing animal numbers required to obtain valid results and limit pain and distress is also provided as part of the required CITI training completed by all personnel involved in animal care, treatment, or use.

Every animal user also receives in-person project-specific training by the Principal Investigator. The Principal Investigator assures that animal users understand necessary details of their projects as well as the importance of the proper care of the animals for which they are responsible.

All IACUC members receive background materials and training/orientation resources including the most recent versions of the Guide, PHS Policy, the Animal Welfare Act and Regulations, the OLAW/ARENA IACUC Guidebook, the PHS Policy on Humane Care and Use of Laboratory Animals tutorial, An IACUC Member's Guide to Animal Facility Inspections, and a copy of the approved Animal Welfare Assurance. IACUC members are required to complete the CITI training module for IACUC committee members. Opportunities for ongoing training and education are provided at IACUC meetings and through access to organizations such as Public Responsibility in Medicine and Research (PRIMR) and OLAW. Continuing education opportunities are also available to the Central Animal Facility Director and Manager.

The Attending Veterinarian providing clinical and program oversight and support has the experience, training, and expertise, including training and experience in laboratory animal science and medicine, necessary to appropriately evaluate the health and well-being of the species used in the context of the animal use at the institution.

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) was submitted.

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

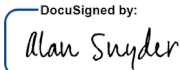
- A. The Institutional reporting period is the federal fiscal year (October 1 – September 30). The IACUC, through the Institutional Official, will submit an annual report to OLAW after September 30, but on or before December 1 of each year. The annual report will include:
 - 1. Any change in the accreditation 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, Alan J. Snyder.
 - 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 include any minority views filed by members of the IACUC.

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official
Name: Alan J. Snyder
Title: Vice President and Associate Provost for Research and Graduate Studies
Name of Institution: Lehigh University
Address: 27 Memorial Drive West, Bethlehem, PA 18015

Phone: 610-758-6964	Fax: 610-758-5810
E-mail: ajs410@lehigh.edu	
Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.	
Signature:  <small>28E287BF07D3401...</small>	Date: 8/10/2021

B. PHS Approving Official *(to be completed by OLAW)*

Jacquelyn Tubbs, DVM, DAACLAM
Animal Welfare Program Specialist
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive
Suite 2500, MSC 6910
Bethesda, MD USA 20892-6910 (FedEx Zip Code
20817) Phone: +1 (301) 496-7163

Signature:	Date:
Assurance Number: D16-00505 (A3877-01)	
Effective Date: 08-10-2021	Expiration Date: 08-31-2025