

LEHIGH UNIVERSITY

Animal Welfare Assurance

#D16-00505 (A3877-01)

Animal Welfare Assurance for Domestic Institutions

I, Anand Jagota, 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, teaching, 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

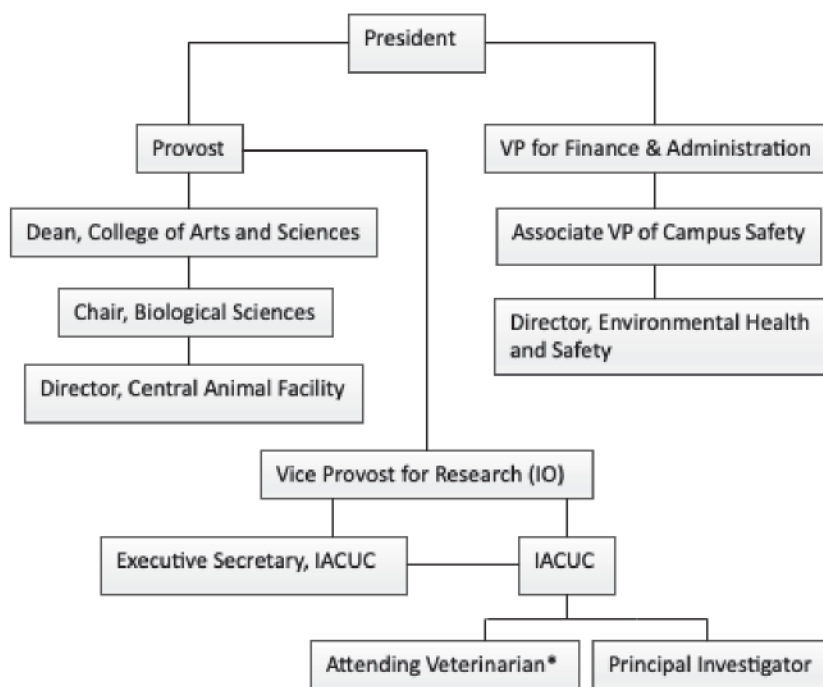
- B. The following are other institution(s), or branches and components of another institution: None.

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. [REDACTED] 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 [REDACTED] 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], V.M.D.

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.

The oversight of daily care and animal facility management is handled by the facility animal care manager, [REDACTED]. [REDACTED] works directly with Principal Investigators and their lab-specific personnel to ensure continuity of care and management of the facilities.

- 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. 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 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 its findings and recommendations in a 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.

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 assess departures as well as the scientific justification provided. IACUC approval of departures from the Guide are based on scientific, veterinary medical, or animal welfare issues. The report includes a description of each departure and the reasons for the departure.

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 current AAALAC accreditation status of the program and facilities are noted in the report to the Institutional Official.

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 as a secure, online form for anonymous and confidential reporting of activities that may involve misconduct or violations 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 written notification is 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. The Institutional Official will report any action that the IACUC has determined must be taken immediately to protect animal or human welfare as required to APHIS and any Federal agency funding the activity. This could include veterinary medical intervention, suspension of a research activity, and/or notification of the appropriate safety, occupational health, or other officials. 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).

Aside from temporary halts of procedures as described 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, as described in Part III.D.10.

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. Matters requiring the immediate attention or involvement of the Institutional Official are promptly communicated by the IACUC Executive Secretary directly in person or via phone call.

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 through the institution's web-based compliance committee submission system, IRBNet.

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. Application materials are distributed to all committee members 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 unavailable. If no member calls for Full Committee Review by the response due date, the application is reviewed by 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. Designated members each review identical copies of the protocol as shared in the IRBNet platform. 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 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 reviews the revised materials during a Full Committee Review at a convened meeting of the IACUC with a quorum present.

Convened IACUC meetings are typically held in person; in the event that a meeting will be held via video conference, all members are given advance notice of the virtual meeting and provided with copies of all relevant documents used in a traditionally convened physical meeting. The virtual meeting commences only once all attending members are able to communicate with one another directly, and there is a quorum of voting members. All voting takes place verbally during the virtual meeting and is appropriately documented in the written meeting minutes. Members who are absent or otherwise unable to attend the virtual meeting are welcome to submit opinions but are not counted as part of the quorum or as voting members of the IACUC for the virtual meeting.

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. In the event that recusal affects the ability to maintain quorum, alternate members of the IACUC will participate in the review and approval of the protocol.

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 and 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 in writing.

In the event that protocol approval is withheld, the Executive Secretary sends notice to the Principal Investigator. The notice includes the reasons for the IACUC's decision and gives the investigator an opportunity to respond in writing.

The Institutional Official is notified semiannually 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:

Post approval 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.

As necessary, the IACUC evaluates post approval monitoring reports to

determine instances of noncompliance and make the appropriate corrective action and reporting recommendations to the IO. If post approval 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 post approval 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 post approval 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 through the institution's web-based compliance committee submission system, IRBNet.

Protocol renewals 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. This full protocol review is conducted and approved prior to the expiration date as set under the previous Full Committee or Designated Member Review.

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.

- 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 Environmental Health and Safety (EHS). The Director reports directly to the Associate Vice President for Campus Safety. 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 university implements a comprehensive, ongoing risk assessment process administered by Environmental Health and Safety (EH&S). EH&S conducts regular laboratory and facility inspections, reviews standard operating procedures (SOPs), and evaluates equipment, facility design, and work practices to identify and mitigate hazards.

SciShield, the university's research safety and compliance platform, is used to document EH&S inspections, track findings, and ensure timely corrective actions. Inspection data from SciShield is reviewed regularly by EH&S to identify trends, support hazard mitigation, and inform training needs.

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. Information on who to contact in the event of an after-hours or holiday injury / illness is posted in a central location in the animal facility, as well as within lab spaces located in the Central Animal Facility.

The Institution partners with designated area physicians and regional health networks for care of workplace injuries, physical exams, and any special medical testing requirements

that are dictated by specific workplace risks. All students working in animal facilities must submit a Health Screening Form to the Institution's Health and Wellness Center. All staff working in animal facilities must certify that they will receive a health screening from their 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. Personnel working in animal facilities must receive a tetanus vaccination every 10 years unless they have been granted a vaccination exemption by the institution.

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 their understanding of potential health issues. This form is renewed triennially for students.

The Qualification Form requires students to certify the date they submitted their health screening form to the Institution's Health and Wellness Center, requires current employees, volunteers, intern or external researchers to certify that they will receive a health screening from their own provider, or requires personnel to certify that they are not in frequent or substantial contact with animals and have opted out of the screening. Individuals who opt-out of the annual health screening requirement are screened for eligibility by the IACUC Executive Secretary.

The Health and Wellness Center will contact the IACUC Executive Secretary when a potential health concern is identified for a specific individual, revealing only information consistent with HIPAA requirements. Those who receive a screening from their own provider, external to the Health and Wellness Center, are required to inform the IACUC if they are not cleared to work with animals. Providers will use the Health Questionnaire form to guide their assessment to evaluate the susceptibility of the individual. In the Health Questionnaire form, individuals must report health issues relevant to contact with vertebrate animals.

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.

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 to their supervisor immediately. In the event of employee injury, the supervisor must notify Environmental Health and Safety 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 and pregnancy. Environmental Health and Safety will assist in evaluating risks presented by exposure, pregnancy, 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 on Lehigh property.

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 and students. 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.

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; Compressed Gas Safety; Construction Site Safety; COVID-19 Respirator/Face Mask Use; Cryogenic Gas; Drones and Other Remote Control Aircraft; Electrical Safety; Fall Protection; Field Safety; Forklift Safety; Graduate Lab Safety; Hazardous Waste; Hearing Conservation; Hydrogen Gas Use; Lab Biosafety; Lab Fire Safety; Laser Safety; LiPo Battery Safety; Lockout Tagout Training; Nanotechnology; Radiation Safety; Respirator Training; Responding to Chemical Spills in Laboratories; Right to Know; Water Reactive Chemicals; Working Safely with Hydrofluoric Acid (HF)

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: Confined Space Entry; Contractor Safety; Fall Protection; Forklift Safety; Hazardous Waste Disposal; Hearing Conservation; Hydrogen Gas Use and Storage in Laboratories; Laser Safety; OSHA Chemical Hygiene Plan; Respiratory Protection

Lehigh University does not use nonhuman primates.

- 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. 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%. 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. The CITI course includes training on research and testing methods that minimize the number of animals required to obtain valid results and minimize distress. 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 and the minimization of distress of the animals for which they are responsible.

The IACUC evaluates the effectiveness of the overall training program by documenting proficiency in the CITI Training. Trainees must receive a score of 80% or higher in embedded quizzes. Principal Investigators must also document how in-person training will be delivered within all IACUC protocols. Effectiveness of training is also observed in post approval monitoring activities including unannounced and scheduled inspections. As necessary, the IACUC evaluates post approval monitoring reports to determine the appropriateness of training, and to make appropriate corrective actions.

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 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 and reviewed.

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, Anand Jagota.
 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

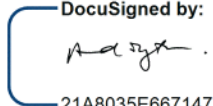
The Institutional reporting period is the federal fiscal year (October 1 – September 30). The IACUC, through the Institutional Official, will submit an annual report to OLAW after September 30, but on or before December 1 of each year. The annual report will include:


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, Anand Jagota.
 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: Anand Jagota	
Title: Vice Provost for Research	
Name of Institution: Lehigh University	
Address: 27 Memorial Drive West, Bethlehem, PA 18015	
Phone: 610-758-5212	Fax: 610-758-5810
E-mail: anj6@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:  DocuSigned by: 21A8035E667147D...	Date: 8/5/2025

B. PHS Approving Official <i>(to be completed by OLAW)</i>	
Name/Title: Temeri Wilder, DVM, MPH, DACLAM, DACVPM Animal Welfare Program Specialist Office of Laboratory Animal Welfare (OLAW) National Institutes of Health Bethesda, Maryland Phone: (301) 496-7163	
Signature: TEMERI D. WILDER-KOFIE -S 	Date: August 6, 2025
Assurance Number: D16-00505 (A3877-01)	
Effective Date: August 6, 2025	Expiration Date: August 31, 2029

VIII. Membership of the IACUC

Date: 5-Aug-2025			
Name of Institution: Lehigh University			
Assurance Number: D16-00505 (A3877-01)			
IACUC Chairperson			
Name*: [REDACTED]			
Title*: [REDACTED] / Chair, IACUC			Degree/Credentials*: Ph.D.
PHS Policy Membership Role*: Scientist			
Address*: [REDACTED]			
E-mail*: [REDACTED]			
Phone*: [REDACTED]		Fax*: [REDACTED]	
IACUC Vice Chairperson			
Name: [REDACTED]			
Title*: [REDACTED] / Vice Chair, IACUC			Degree/Credentials*: Ph.D.
PHS Policy Membership Role*: Scientist			
Address*: [REDACTED]			
E-mail*: [REDACTED]			
Phone*: [REDACTED]			
IACUC Roster			
Name of Member/ Code **	Degree/ Credentials	Position Title ***	PHS Policy Membership Requirements ****
[REDACTED]	V.M.D.	Attending Veterinarian	Veterinarian
S1	Ph.D.	Research Assistant Professor, Biological Sciences	Scientist
NS1	J.D.	Assistant General Counsel, Attorney	Nonscientist
NA1	Ph.D. (Psychology)	Faculty, Moravian University	Nonaffiliated
NS2	Ph.D. (Religious Studies)	Clergy	Nonscientist (alternate)
NS3	Ph.D. (Psychology)	Assistant Director, Research Integrity / Executive Secretary, IACUC	Nonscientist (alternate)

M1	M.P.H.	Director of Research Policy and Compliance	Member (alternate)
S4	V.M.D.	Veterinarian	Veterinarian (alternate)
NA2	B.A.	Engineer	Nonaffiliated (alternate)

- * This information is mandatory.
- ** Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.
- *** List specific position titles for all members, including nonaffiliated (e.g., banker, teacher, volunteer fireman; not “community member” or “retired”).
- **** PHS Policy Membership Requirements:

- Veterinarian* veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals at the institution.
- Scientist* practicing scientist experienced in research involving animals.
- Nonscientist* member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).
- Nonaffiliated* individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

[Note: all members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Non-voting members and alternate members must be so identified.]

IX. Other Key Contacts (optional)

If there are other individuals within the institution who may be contacted regarding this Assurance, please provide information below.

Contact #1
Name: <div></div>
Title: <div></div>

Phone: [REDACTED]	E-mail: [REDACTED]
Contact #2	
Name: [REDACTED]	
Title: [REDACTED] IACUC Executive Secretary	
Phone: [REDACTED]	E-mail: [REDACTED]

X. Facility and Species Inventory

Date: 5-Aug-2025			
Name of Institution: Lehigh University			
Assurance Number: D16-00505 (A3877-01)			
Laboratory, Unit, or Building*	Gross Square Feet [<i>include service areas</i>]	Species Housed [<i>use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog</i>]	Approximate Average Daily Inventory
1	[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]
2	[REDACTED]	[REDACTED]	[REDACTED]
3	[REDACTED]	[REDACTED]	[REDACTED]

*Institutions may identify animal areas (buildings/rooms) by a number or symbol in this submission to OLAW. However, the name and location must be provided to OLAW upon request.