

Animal Welfare Assurance for Domestic Institutions

I, Mark E. Lowe, MD, PhD, as named Institutional Official for animal care and use at Washington University in St. Louis (WUSTL), 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, NASA, and/or NSF. This Assurance covers only those facilities and components listed below.

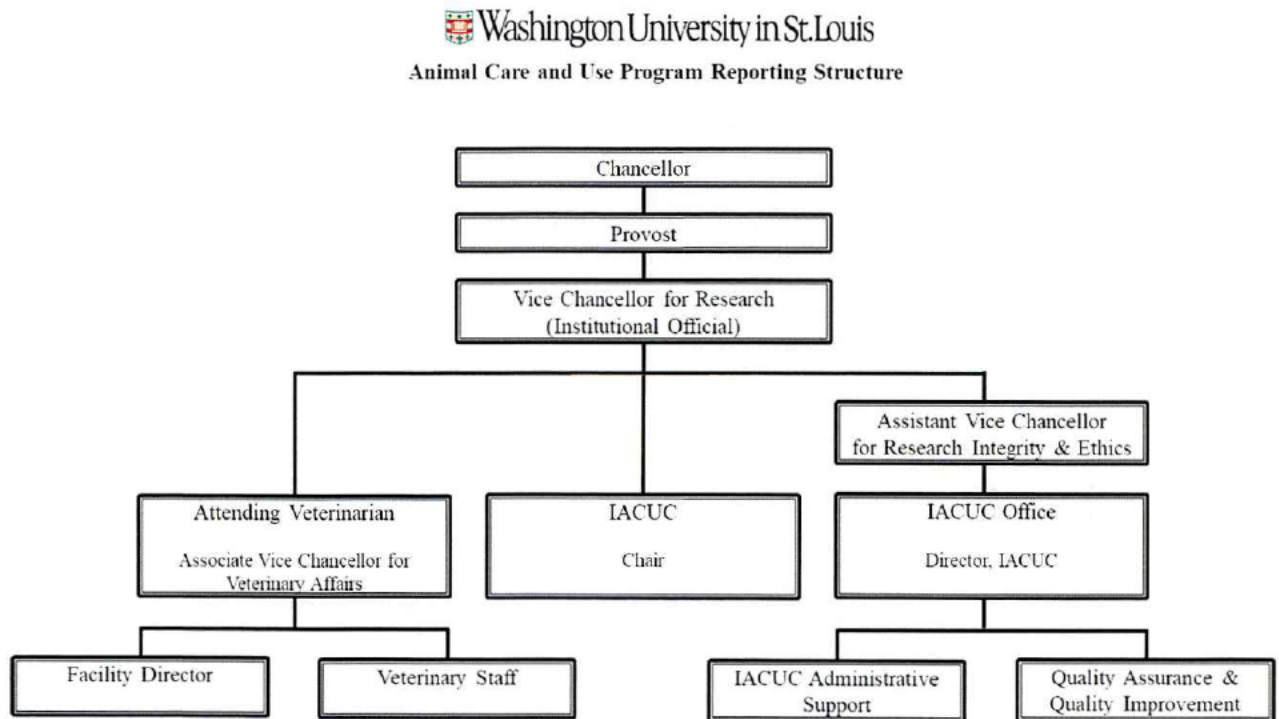
- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:
 - Washington University - Danforth Campus
 - Washington University School of Medicine (WUSM)
 - Barnes-Jewish Hospital
 - Central Institute for the Deaf (CID)
 - Center of Research, Technology and Entrepreneurial Exchange (CORTEX)
- B. The following are other institution(s), or branches and components of another institution where Washington University in St. Louis provides IACUC oversight according to a signed MOU:
 - University of Health Sciences and Pharmacy in St. Louis (UHSP)

II. Institutional Commitment

- A. This Institution will comply with all applicable provisions of the [Animal Welfare Act](#) and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "[U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training](#)."
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use.
- D. This Institution has established and will maintain a program for activities involving animals according to the *Guide for the Care and Use of Laboratory Animals* ([Guide](#)).
- E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

III. Institutional Program for Animal Care and Use

- A. The lines of authority and responsibility for administering the program and ensuring compliance with the PHS Policy are as follows:



- B. The qualifications, authority and percent of time contributed by the veterinarians who will participate in the program include the following individuals, all of whom are employed in the Division of Comparative Medicine (DCM) at WUSTL:

1. Nirah Shomer, DVM, PhD, DAACLAM, CMAR serves as the Attending Veterinarian; is the Associate Vice Chancellor for Veterinary Affairs and the Director of the Division of Comparative Medicine (DCM).

Qualifications: Dr. Shomer received her veterinary degree from the fully accredited University of Minnesota and has 26 years of experience in laboratory animal medicine. She is a federally accredited veterinarian, former AAALAC ad hoc consultant, and a member of AALAS, ACLAM, and AVMA. Additional degrees and certifications listed above.

Authority: Dr. Shomer has primary program authority and responsibility for the Institution's animal care and use program including access to all animals.

Time contributed to the animal care and use program: 100%; full time employee

(b) (6)

- 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.

See Part VIII. Membership of the IACUC

- 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:

At least once every 6 months, the IACUC reviews the institution's program for the humane care and use of animals. While the program review may be conducted on a rolling schedule over a 6-month period or over a relatively short timeframe (e.g. days or weeks) within a given 6-month period, no program component is reviewed less than every 6 months. Program reviews may be conducted at a convened meeting of a quorum of the IACUC or outside of a convened meeting by no less than two IACUC (voting) members. A quorum is defined as 50% of the IACUC membership plus one additional member not including any member with a conflict of interest. While no IACUC member is required to participate in program review, no member can be denied participation. Consultants may be invited to participate in the program review to provide information to the committee. The IACUC completes the evaluation and generates the report and recommendations to the IO.

The IACUC evaluates the program using the following standards: The Guide for the Care and Use of Laboratory Animals (Guide), Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), Animal Welfare Act (AWA), USDA Animal Welfare Regulations (AWR), the WUSTL PHS Animal Welfare Assurance (Assurance), as well as other relevant resources as necessary. To facilitate Program Review, the IACUC uses the Sample Semiannual Program Review Checklist (OLAW NIH) based on the 8th edition of the Guide, customized as necessary to address the unique aspects of the WUSTL program and the facilities. The program review includes all plans, mechanisms, or systems that the IACUC considers part of the Institutional Animal Care and Use Program, and their associated outcomes, including, but not necessarily limited to all the corresponding program components addressed in the Guide, PHS Policy, AWA, and the AWR.

The results of program reviews are presented for consideration, deliberation, and action as needed at convened meetings of a quorum of 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:

At least once every 6 months, the IACUC inspects any and all buildings, rooms, areas, enclosures, or vehicles, used for animal confinement, transport, maintenance, breeding, or research, teaching and testing, including animal study areas or satellite facilities and all areas where surgery (minor, major, survival or non-survival) is conducted.

While inspections may be conducted on a rolling schedule over a 6-month period, no area is inspected less than every 6 months. Inspection teams include at a minimum at least one voting member of the IACUC and may include representatives from the IACUC office, the veterinary staff, or Environmental Health and Safety. Inspection teams visiting areas that house and/or support USDA-regulated animals will consist of at least two voting members of the IACUC. No IACUC member wishing to participate is excluded from inspections. Consultants may be invited to participate in facility inspections and provide information and advice to the IACUC.

The IACUC evaluates its facilities using the following standards: The Guide, PHS Policy, AWA, AWR, the Assurance, as well as other relevant resources as necessary. To facilitate the inspection, the IACUC uses the Sample Semiannual Facility Checklist (OLAW NIH) based on the 8th edition of the Guide, and customized as necessary to address the unique aspects of the WUSTL program and the facilities.

Results of the animal facility inspections are presented for consideration, deliberation, and action as needed at convened meetings of a quorum of the IACUC.

- 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 utilizes the OLAW's Semiannual Report to the Institutional Official template as a guide to prepare the reports of its evaluations of the program and facilities. The report consists of several sections including a description of the nature and extent of the program's adherence to the PHS Policy, the Guide, and the AWA and presents any program recommendations regarding any aspect of the institution's animal program, facilities, or personnel training that the IACUC believes will help enhance the current program. It also includes AAALAC accreditation status by facility and a description of program changes that occurred since the previous semi-annual report and a list of all IACUC-approved departures and the reasons for each. Departures are defined as deviations from "should" statements in the Guide or the standards set forth in the PHS Policy unless those deviations are supported by performance standards or allowed by a "specifically described Guide exception". Departures also include IACUC-approved exceptions from the standards or regulations under the AWA and IACUC-approved exemptions from the requirements set forth in the institution's own policies or Standard Operating Procedures (SOP). Departures, exceptions and exemptions are most often identified and tracked during protocol/amendment review and approval, however they may also be tracked during the conduct of other official business at convened meetings if and when the IACUC approves a departure or exemption from an established program process, policy or SOP (e.g. protocol review, veterinary care, animal husbandry or housing, training programs, etc.).

The report also includes any and all programmatic or facility deficiencies, categorized as minor or significant, designated as repeat, if and when applicable, and the corresponding plans and timetables for corrections. The IACUC defines a significant deficiency as any situation, which in the judgment of the IACUC and the IO is or may be a threat to the health or safety of the animals or humans. Deficiencies associated with activities covered under this Assurance, which represent serious or continuing noncompliance with PHS policy or any serious deviation from the provisions of the Guide, are promptly reported to OLAW.

The IACUC delegates the task of monitoring the correction of deficiencies to specified program personnel. The timeliness of correcting deficiencies is reported as a standing agenda item at IACUC meetings. In the event a program or facility significant deficiency is not corrected within the IACUC-established timeframe, it is promptly reported to OLAW; if it involves USDA regulated species and remains uncorrected, it is reported within 15 business days to the USDA.

Finally, the report includes any minority views voiced during the conduct of program review and facility inspections or during the conduct of any other official IACUC business (e.g.

minority recommendations addressing any aspect of the institution's animal program, facilities, or personnel training voiced during IACUC meetings). Minority views do not include dissenting votes associated with protocol approval or suspension of animal activities unless an IACUC member specifically requests that his/her minority view be presented in the semiannual report to the IO.

Semi-annual reports are presented, reviewed and approved at a convened meeting of a quorum of the IACUC, signed by a majority of all IACUC members, and submitted to the IO. The IACUC Chair and the Attending Veterinarian (at a minimum) meet with the IO to discuss the report and the IACUC's evaluation and recommendations.

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

It is the responsibility of the IACUC to review, and if warranted, investigate all animal welfare concerns including those not directly received by the IACUC. In keeping with this charge, the IACUC has established a Reporting Animal Welfare Concerns (Whistleblower Policy); a process whereby IACUC members, laboratory and research facility employees, other employees, students, visitors, and the public can voice animal welfare concerns or alleged violations to federal, state or local animal welfare regulations, internal SOPs or IACUC policies. In addition, WUSTL has a broad based Whistleblower Protection Policy for reporting actual or suspected violations along with protections for whistleblowers. Animal welfare concerns may be conveyed via phone, written communication or in person to the IO, IACUC Chair, IACUC Office staff, Attending Veterinarian, or via the anonymous University Compliance Office "hotline". The University Compliance Office hotline ensures anonymity by collecting only the details of the animal welfare concern and does not collect any data on the reporting individual.

All personnel listed on an animal use protocol must complete a web-based training module that includes details regarding the IACUC's Whistleblower Policy and WU's Whistleblower Protection Policy outlining the methods of reporting concerns about animal care and treatment without fear of recrimination. The IACUC's whistleblower policy is posted on an intranet website to which all approved protocol personnel have access. In addition, all employees annually review WUSTL's Code of Conduct, which includes the University's Whistle Blower Protection Policy. Contact information for reporting allegations to the IACUC is posted in animal care and use locations and includes an anonymous reporting option (compliance hotline).

Upon receipt of an animal welfare concern or an alleged animal welfare violation or deficiencies in animal care or use, the recipient of the concern notifies the IACUC Chair or Office. If the concern alleges sick or injured animals, the appropriate veterinary personnel are notified immediately and directed to the area where the animal(s) is housed.

Regardless of the origin of the concern, all individuals voicing concerns are assured that they will not be discriminated against or be subject to reprisal for making a report. Individuals who voice concerns are encouraged to provide a specified minimum amount of information to enable the IACUC to make a reasonable evaluation of the concern.

The IACUC Chair or Director, in consultation with the AV and IO as appropriate, reviews the concern and initiates an investigation as necessary. The IACUC Chair appoints a subcommittee or an IACUC member(s) to investigate the concern. Interviews of relevant personnel may be conducted, which are compiled into an investigative report along with relevant evidence. The report of the investigation is provided to the IACUC. The IACUC by a majority vote (with a quorum present at a convened meeting, not including any member with a conflict of interest) will determine appropriate action. The nature of the concern and the steps taken to investigate and resolve the concern are documented in IACUC meeting minutes. If IACUC action includes suspending an animal activity and/or the investigation reveals a significant deviation or serious non-compliance, the IO in consultation with the IACUC will take immediate corrective actions and report the incident with a full explanation

and a description of the actions taken to minimize a future occurrence to the appropriate regulatory agencies, if and when applicable.

- 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 semi-annual program and facility review report submitted to the IO includes IACUC recommendations regarding any aspect of the animal care and use program, including, but not limited to, animal facilities, occupational health and safety program, animal facility emergency/disaster plan, animal care program, veterinary care program, and personnel training. While recommendations to the IO may point to actions necessary to correct identified minor or significant deficiencies, recommendations are not always indicative of program deficiencies. Instead, recommendations may be intended to improve or enhance an already adequate aspect of the program or to thwart an anticipated future deficiency.

The senior leadership of the animal welfare program components participate in monthly meetings with the IO as part of an Animal Advisory Group (AAG). This provides an opportunity to present and discuss recommendations with the IO. The IACUC Chair, AV, IACUC Office Director and/or other members of the IACUC are encouraged to contact the IO directly or may present recommendations during IACUC meetings when the IO is present. Other venues for making program recommendations to the IO are through the provision of IACUC meeting minutes.

- 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:

Prior to the use of any animals in research, teaching, and testing, the IACUC reviews and approves the activity. The IACUC-approval date dictates when research can be initiated as well as the required deadlines for all subsequent continuing reviews and "de novo" reviews and approvals. Proposed animal use activities are evaluated to ensure compliance with all applicable federal laws, regulations, policies, the Guide, and all IACUC and institutional guidelines, unless satisfactory scientific justification for a departure is presented and approved. No animal use activity can be initiated unless it has been reviewed and approved by the IACUC.

Protocol Submission Process

Both new and 3-year resubmission protocols are submitted to the IACUC office via an electronic protocol management system. Simultaneously, a DCM veterinarian and IACUC office staff conduct a pre-review. If significant gaps are identified, the protocol may be returned to the investigator for revision. In addition, during this pre-review, the veterinarian may request Full Committee Review (FCR). If the veterinarian does not recommend FCR, protocols are distributed to all IACUC members who are given a minimum of two (2) business days to request FCR. Protocols are available in the protocol management system and members receive system notifications as well as an email with the list of protocols for review. If a member does not respond within the allotted time-period, it is assumed the member does not request FCR and the submission is reviewed by Designated Member Review (DMR).

Full-Committee Review Method (FCR)

If any IACUC member requests FCR of a protocol, the submission is presented and reviewed at a convened meeting of a quorum of the IACUC. A quorum of the committee does not include the vote of any member who may have a conflict of interest (e.g., the principal investigator). In order to facilitate committee review, the PI may be asked to attend a portion of the scheduled convened meeting to respond to committee questions or concerns. Following discussion, the IACUC will vote and the numbers voting for, opposed and abstaining will be recorded. Possible outcomes of an IACUC vote include: approval, requires modifications to secure approval, or withhold approval.

If additional modifications are requested subsequent to FCR by unanimous vote of the quorum present, the protocol is assigned by the Chair or their designee to a qualified voting member for designated member review. DMR is conducted according to the IACUC policy "Designated Member Review (DMR) subsequent to Full Committee Review". Requests for revisions are sent to the investigator and responses are reviewed by the DMR. Protocols are available to all committee members in the protocol management system and any member may request FCR at any time. Designated member reviewers are authorized to "Approve", "Require modifications in order to secure approval", or request FCR. Designated members are not authorized to withhold approval. A decision to withhold approval can only be made at a convened meeting of a quorum of the IACUC with a majority vote in favor of withholding approval. In the event that more than one designated member reviewer is assigned, their decision must be unanimous. If multiple designated member reviewers are unable to reach a unanimous decision, the protocol is assigned to FCR.

Designated Member Review Method (DMR)

DMR is initiated after the IACUC members are sent the protocols and given a minimum of two (2) business days to request FCR. If no voting member requests FCR during the review period, the Committee's comments and any subsequent PI revisions are reviewed by the assigned Designated Member Reviewer. In the event of a conflict of interest, the Chair may reassign a new DMR. Designated reviewers are authorized to "Approve", "Require modifications in order to secure approval", or request FCR. Designated members are not authorized to withhold approval. A decision to withhold approval can only be made at a convened meeting of a quorum of the IACUC with a majority vote in favor of withholding approval. In the event that more than one designated member reviewers are assigned, their decision must be unanimous. If multiple designated member reviewers are unable to reach a unanimous decision, the protocol is assigned to FCR.

Any member may call for FCR of any submission at any time. IACUC meetings may be in person or conducted electronically via teleconference. Any meetings held electronically allow for real-time discussion and adhere to the requirements outlined in NOT-OD-06-052: Guidance on Use of Telecommunications for IACUC Meetings.

- 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:

The process and procedures for the review and approval of modifications is the same as those described for protocol review and approval. Significant modifications must be reviewed and approved by either the Full Committee Review (FCR), Designated Member Review (DMR), or Veterinary Verification and Consultation (VVC) method. Minor modifications can be reviewed and approved by the Administrative review method.

In most cases, significant modifications to IACUC-approved animal use activities do not require completion of a new animal protocol application. However, if the nature and/or extent of the proposed significant modification(s) alters the original IACUC-approved activities substantially, and at the discretion of the IACUC, the IACUC may require the investigator to submit a new animal protocol application.

Amendment Submission Process

Requests to modify previously approved protocols are submitted via an electronic protocol management system. IACUC office staff review the amendment summary and based on the requested change(s) assign it to either the DMR, VVC, or Administrative review. Assignment to VVC review is determined by the criteria defined in the IACUC policy *Review Processes for Protocol Amendments* (VVC section). The IACUC has designated all DCM veterinarians as eligible to perform VVC review according to the criteria defined in the IACUC amendment review policy VVC section.

Designated Member Review Method (DMR) and Full Committee Review (FCR)

DMR and FCR procedures for amendments are identical to the procedures described for protocols above. Examples of significant changes reviewed by DMR or FCR include: changes in PI, addition of new procedures, addition of new substances to be administered, increases to animal numbers greater than 30%, activation of a new use location.

Veterinary Verification and Consultation (VVC) Review Method

Amendments eligible for VVC are assigned to a DCM veterinarian and an IACUC office staff member. During this pre-review, the veterinarian may recommend the amendment be reviewed by DMR or FCR. If the veterinarian does not recommend DMR or FCR, the veterinarian verifies that the proposed change meets the requirements of the VVC policy, the veterinary consultation is documented, and amendments are approved by the administrative staff.

The veterinarian is not conducting DMR, but is serving as a subject matter expert to verify that the proposed change is consistent with all applicable IACUC approved policies and is appropriate for the species. The IACUC policy *Review Processes for Protocol Amendments* includes a list of the IACUC approved reference books, documents, SOPs, and allowed parameters for items listed below. Examples of significant changes eligible for VVC include:

- Personnel changes for individuals handling USDA covered species
- Change of anesthesia or sedation agent
- Change of analgesia agent when adequate pain relief is provided
- Change of any euthanasia method approved in the current version of the AVMA Guidelines for the Euthanasia of Animals. If methods are approved with conditions, the veterinarian confirms conditions are met. If methods require additional or specialized training, personnel have sufficient experience or have completed the necessary training.
- Change in the duration of an approved procedure or experimental timeline by up to 100%. If the extension of the procedure or experiment would increase the adverse clinical consequences, the modification must be reviewed by DMR or FCR.
- Change in the frequency or number of an approved procedure by up to 100%. The veterinarian will verify that the increase in frequency is not expected to increase the clinical consequences to the animal.
- Increase of 10% animal numbers for USDA covered species, no new experiments. The 10% eligible number is calculated from the current total number approved and must be consistent with the requirements and parameters outlined in the IACUC reviewed and approved *Review Processes for Protocol Amendments Policy*.
- Change to post-procedure monitoring program (drugs and/or non-pharmaceutical interventions for medical treatment) if the following conditions are met:
 - Drugs and dosages must be selected from current veterinary formularies and not used for experimental or research purposes.
 - Non-pharmaceutical interventions may include supplemental warmth, fluids, phototherapy, physical therapy, or dietary supplements.
 - Surgical interventions are not eligible for approval via VVC
- Experimental substances
 - Changes in the dose, route, frequency, or volume of approved substances administered to animals may be approved via VVC
 - This includes administration via special diets or modified water
 - The veterinarian will verify that the proposed changes are appropriate for the species, substance, and route selected
 - New experimental substances to be administered will be reviewed by DMR or FCR

Administrative Review Method

IACUC office staff review the submission and may request revisions from the PI. After all comments are addressed, the IACUC staff may approve the amendment or recommend the amendment be reviewed by VVC or DMR.

The following changes may be managed administratively as they do not require review and approval by FCR or DMR.

- Funding changes
- Personnel addition or modification for use of non-USDA covered species or controlled substances
- Correction of typographical errors
- Correction of grammar
- Updates to personnel information or training
- Change/addition of DCM housing location
- Change/addition of previously approved animal use location
- Increase of 30% animal numbers in non-USDA covered species, no new experiments. The 30% eligible number is calculated from the current total number approved and must be consistent with the requirements and parameters outlined in the IACUC reviewed and approved *Review Processes for Protocol Amendments Policy*.

IACUC Approval Period

IACUC approval of modifications does not change the IACUC-approval period for the approved protocol.

- 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 IACUC notifies the principal investigator by email regarding IACUC actions related to proposed animal activities and significant modifications to approved animal activities. Investigators are notified of approaching expiration dates, results of IACUC reviews, requests for modifications required to secure approval, and approval. If the IACUC votes to withhold approval, the PI will be notified in writing of the reasons for withholding approval and provided the opportunity to discuss the IACUC's concerns at a subsequent convened meeting and/or the opportunity revise the protocol.

All IACUC actions on all new protocols and significant modifications, continuing reviews (conducted at least annually), triennial renewals, are documented in the electronic protocol tracking system. IACUC actions taken during convened meetings are documented in the meeting minutes. The institution, represented by the IO, is notified of actions related to the IACUC's decisions to approve or withhold approval of proposed animal use through the provision of the IACUC minutes to the IO as well as electronic system access.

- 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:

The IACUC performs continuing review of protocols utilizing USDA covered species or when required by a funding agency no less than annually and "de novo" review at least every 3 years for all animal species. "De novo" review is defined as the review and approval of the complete protocol by either Full Committee Review (FCR) or Designated Member Review (DMR) as described in paragraph 6. Protocols undergoing "de novo" review are reviewed as if it is a first time review. The IACUC-approval date is defined as the date that the protocol is fully and unequivocally approved by either FCR or DMR.

The purpose of continuing review is to inform the IACUC of the current status of approved animal activities; to ensure the activities continue to be conducted in compliance with all applicable federal laws and regulations, IACUC and Institutional policies; to determine if future modifications are needed; and to identify those protocols that are no longer active and for which IACUC approval can be terminated. The IACUC also reviews the status of personnel working with USDA covered species to ensure that all annual training requirements are met.

A continuing review is completed during or prior to the anniversary month of the protocol's IACUC-approval date. Investigators submit the Continuing Review form through the electronic protocol management system. The IACUC office coordinates committee review via FCR or DMR.

Approved protocols may also be periodically reviewed as part of the semi-annual inspections, QA/QI post-approval monitoring visits, the Site Initiation Visit program, amendment review, in response to non-compliant or adverse events, and in response to external inspections or assessments (USDA, DOD, and AAALAC).

Site Initiation Visits New labs with recently approved protocols, or any lab by request, can participate in the Site Initiation Visit program administered through the IACUC Office by the QA/QI staff. The visit includes a review of the approved protocol, applicable policies, and allows investigators to ask questions and establish best practices in partnership with the IACUC office.

In response to non-compliant events, the IACUC may request additional monitoring of procedures be performed by the DCM veterinary or veterinary technician staff. DCM staff may participate or observe procedures on behalf of the IACUC and will typically present a summary of the activity to the IACUC during the next scheduled meeting.

IACUC staff regularly review University publications, including The Record, for articles related to animal use on campus. Parallel review of the protocol provides a check for research compliance.

The QA/QI staff is notified by DCM the first time controlled substances are purchased by new research teams. The QA/QI staff meets with the lab to review the expectations surrounding the use of controlled substances (e.g., storage, access, use, monitoring expiration dates, documentation, and record retention). Existing labs may request refresher training as well.

Quarterly newsletters and brown bag seminars present best practices, regulatory updates, and other suggestions for labs to avoid non-compliance. Each year, the IACUC office presents the non-compliance trends to the research community with tips for avoiding these missteps. Outreach efforts also include help with the electronic protocol system to encourage staff to access the protocol and make the amendment process easier.

Our program is also subject to external inspections and assessments (i.e., USDA inspections, DOD study reviews, sponsor evaluations) that serve as additional checks on protocol compliance.

- 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:

The IACUC is authorized to suspend any and all animal activities due to noncompliance, report suspensions to the IO, and through the IO, promptly notify OLAW, USDA and any corresponding funding agency, if and when applicable. The IACUC suspends an animal activity, only after review of the activity and the alleged noncompliance at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. If the IACUC suspends an animal activity, the IO, in consultation with the IACUC, will review the grounds for suspension; develop and implement corrective and preventative action plans; promptly report the suspension and the action taken with a full explanation to OLAW, USDA and any federal agency funding the activity, if and when applicable.

In the event of any serious or continuing noncompliance with PHS Policy; any serious deviation from the provisions of the Guide; any failure to adhere to an IACUC plan and schedule to correct a significant deficiency; or any suspension of an activity by the IACUC, the IACUC through the IO notifies the appropriate agencies (e.g. OLAW, USDA, funding agency).

In the event of any other institutional intervention resulting in the temporary or permanent interruption of an activity due to noncompliance with the Policy, the Guide, the AWA, the Assurance, or Institutional policy, the IO, in consultation with the IACUC, will review the grounds for interruption, develop and implement corrective/preventative action plans, and promptly report the suspension and action with a full explanation to OLAW and any federal agency funding the activity, if and when applicable.

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

The Occupational Health and Safety Program (OHSP) is administered through the Division of Comparative Medicine (DCM) in conjunction with Occupational Health Services (OHS) on the Medical School campus and the Environmental Health and Safety Office (EHS). The OHSP is designed for the safety of personnel who work in laboratory animal facilities and/or have direct contact with animals (living or dead), animal tissues, body fluids, cages, bedding, or waste products. The focus of the OHSP is a safe and healthy workplace for Washington University faculty, staff, students, and volunteers. The OHSP is fully supported by the IO, the IACUC, the AV, EHS, Human Resources, and the university administration and is consistent with federal, state, and local regulations. There are multiple components to the OHSP including an initial and annual health surveillance medical evaluation form, health check review of the form by an OHS professional, and a medical evaluation (may include required or recommended immunizations) as determined by the OHS professional. Individuals do not have the option to decline participation into the program and must complete the initial health surveillance medical evaluation form with health check review by OHS. Occupational health professional staff may request additional evaluations or medical visits in response to the submitted health surveillance form. OHS professional staff will also determine if the exposure levels require annual resubmission of the health surveillance form and health check (example: DCM husbandry staff) or resubmission in response to changes in health status, as needed and according to the criteria provided in occupational health training.

All new medical school employees, non-appointees, and volunteers are required to participate in the OHSP. All employees, regardless of job duties, have 10 business days after hire to complete a new employee evaluation from the Occupational Health Service (OHS) and initiate employee testing/immunization requirements. Visitors, contractors, and individuals with security access only, are required to submit paperwork corresponding to their anticipated duties. DCM animal caretakers are required to complete a fit-for-duty physical at Barnes Care (Occupational Health provider) specific for the physical demands of the job. Danforth employees and students are evaluated by the medical school occupational health program using the same forms and procedures. Non-employees on campus are notified of the risks of working with animals, advised to consult with their employer, and sign a waiver accepting these risks.

PIs are responsible for the safety of personnel in their laboratories and are required to maintain a separate work space for animal use. PIs are responsible for notifying non-animal users that the area around them may have animal allergens or biological hazards if applicable.

Components of the OHSP

1) Control and Prevention Strategies—All WUSTL animal facilities are designed, selected, developed and operated with SOPs intended to minimize or avoid any physical injury or health risk to personnel using the facilities. Appropriate personal protective equipment (PPE) is provided to all animal handlers based on the risk assessment for assigned duties. Online training is required for all individuals handling animals. The training module addresses working safely with animals, chemical agents, and biohazard agents in the facilities. Training includes information on how changes in health status (i.e., ill, immunocompetent, and/or pregnant) can impact the risks associated with animal handling and instructs personnel to discuss risks with their Occupational Health specialist and their own physician to determine if additional precautions or PPE are necessary. The Institutional Biological & Chemical Safety Committee (IBC) reviews all proposed animal activities that involve the use of hazardous

agents and DCM and the IACUC implement the recommendations. Individuals are instructed in the proper way to report injuries and obtain medical treatment by OHS and through a web-based training module and documentation posted in facilities. Minor injuries (requiring first aid) can be treated by the OHS or the Protective Services paramedic division for medical school campus employees or Barnes Care for main/Danforth campus employees. Student injuries are addressed by Student Health Services at both campuses. If students are "employed" (or volunteer) in a lab on the medical school campus, OHS provides services.

2) Hazard Identification and Risk Assessment—Risks associated with the use of animals are identified, managed, and mitigated to help ensure the safety of personnel. A DCM safety committee meets regularly to discuss workplace injuries and determine appropriate strategies to safeguard all personnel and minimize reoccurrences. EHS professionals monitor workplace accidents on campus and engage in discussions with DCM staff and offer recommendations to improve safety procedures. EHS and the IBC review IACUC protocols to identify biological or chemical risks associated with the agents used and recommend personal protective equipment, containment equipment, disinfection methods, emergency response protocols, and disposal methods to mitigate any risks identified.

3) Facilities, Equipment, and Monitoring—All biohazard areas within the facilities and animal housing systems are designed and operated to fully contain biohazard agents based upon CDC recommendations as described in the 5th edition of the Biosafety in Microbiological and Biomedical Laboratories publication. Facilities and investigator laboratories are monitored by EHS according to federal and state regulations and University policies. Only authorized personnel with appropriate training have access to these areas. Biohazard areas are clearly identified with door signs that include the animal biosafety level, occupational health requirements, personal protective equipment requirements, names of individuals responsible for the research, and emergency contact information. Online training modules have specific instructions for personnel authorized to enter these areas including traffic pattern, personal hygiene, and disposal of biohazard materials.

4) Personnel Training— A prerequisite for IACUC protocol approval and facility access is mandatory online training modules and didactic training for all individuals working in animal facilities and/or who have contact with animals. Annual training is required for all large animal users. Training is provided through individual facility tours and instruction, SOPs written by knowledgeable specialists and access to guidelines on the IACUC, DCM, and EHS websites are available. All individuals entering an animal facility receive training and PPE appropriate to the hazards they might encounter. Specific training is provided based on the target audience and includes modules and materials designed for physical plant staff, IACUC, contractors, security, etc. All visitors schedule access with knowledgeable personnel who verify training and understand the workplace hazards and biosafety concerns.

5) Personal Hygiene/Personal Protection— Use of good personal hygiene is emphasized to reduce the possibility of occupational injury and cross contamination. Policies regarding the use of PPE are strictly enforced and all PPE is provided at no extra cost to the user. In addition, DCM employees including veterinarians, veterinary technicians, animal caretakers and cage wash personnel are issued uniforms, which are laundered by an outsourced company. Uniforms from biohazard areas are autoclaved prior to being sent out for cleaning. DCM employees are trained to use gloves, wash their hands, and change clothing when leaving an animal facility. Showers are available in the main animal facilities for use by anyone with access to the facility. No one is permitted to eat, drink, smoke, or apply contact lenses or cosmetics in rooms and laboratories where animals are housed.

6) Animal Experimentation Involving Hazards—The Institutional Biological and Chemical Safety Committee (IBC) is responsible for ensuring that research carried out at WUSTL is conducted in a safe and responsible manner. A DCM veterinarian serves as a member of the IBC. The IBC oversees research involving recombinant or synthetic nucleic acids, infectious or potentially infectious agents, and/or hazardous chemicals. The IBC will determine the appropriate biosafety level, PPE, containment equipment, medical surveillance, emergency response, and disposal methods for proposed experiments based on the biological and

chemical risks presented by the agents used. Facilities are furnished with the proper equipment (i.e. biological safety cabinets, chemical fume hoods, HEPA filters, and HVAC) as necessary to fulfill the IBC requirements for animal care and experimentation. Biological safety cabinets and exhaust HEPA filters are certified annually by an outside vendor. Chemical fume hoods are tested by EHS personnel annually to ensure adequate airflow. All equipment is maintained according to federal, state, and local regulations. For individuals working with animals that are exposed to radioactive, chemical, and/or biological hazards, additional health monitoring and immunizations may be required. Employees are referred to their supervisor or laboratory director for further information. The handling of laboratory animals may pose special risks for individuals who are immunosuppressed for any reason, including long-term administration of oral corticosteroids, chemotherapy, or IV/Acquired Immunodeficiency Syndrome. Individuals that are immunosuppressed or pregnant or could become pregnant are instructed to discuss this risk with the OHS and with their personal physician. This is re-enforced in the web based OSHP training module.

7) Medical Evaluation and Preventive Medicine for Personnel—Individuals working in animal facilities participate in the OHSP and access to animal facilities is contingent upon this participation. An initial health surveillance medical evaluation form is submitted to OHS to identify individuals with conditions that could place them at risk when working with animals, with an emphasis on the potential for allergy development or the escalation of pre-existing allergies. Occupational health professional staff may request additional evaluations or medical visits if there is an increased risk of zoonosis from using biohazardous agents in rodents, when non-human primates or large animals are used, or when the medical history would indicate the necessity of an office visit. OHS professional staff will also determine if the exposure levels require annual resubmission of the health surveillance form and health check or resubmission in response to changes in health status, as needed and according to the criteria provided in occupational health training.

All DCM employees, who also have the highest exposure to animals, are required to complete the health surveillance medical evaluation form on an annual basis along with their annual health check and TB test.

Additional safeguards are in place for individuals working with feral animals from populations known to be potential carriers of rabies. Based on a risk assessment conducted by the OHS doctor, individuals may receive a prophylactic rabies immunization series with human diploid cell vaccine (HDCV). Individuals who choose not to receive prophylactic rabies immunization will be asked to sign a waiver annually and may not be permitted to work with animals in this category. Pre-exposure vaccination does not eliminate the need for additional medical evaluation after a rabies exposure; it simplifies management by eliminating the need for Rabies Immunoglobulin and decreasing the number of doses of vaccine needed.

8) Additional precautions for all individuals working with nonhuman primates (NHPs): Annual Interferon Gamma Release Assay for Tuberculosis (TB) screening is required for anyone without prior history of a reactive test. Those who test positive for TB will be evaluated annually to determine if they may work with NHPs. Individuals must provide written official documentation of Measles, Rubella immunity. Individuals who are nonimmune will be offered the vaccine; those who choose not to receive the vaccine will not be allowed to work with NHPs. A serum sample will be taken at the time of the initial physical examination to be stored and used as a baseline sample, and additional samples will be taken every five years thereafter. Additional samples may be taken after a bite or scratch injury or at the discretion of a physician when an illness that may be animal-related is suspected. All individuals working with macaques must schedule an appointment with OHS to discuss the exposure protocol. Potential exposures to Macacine herpesvirus-1 or accidental exposures to biohazards are handled by OHS. Bite/scratch kits and eyewash kits are in every animal suite, lab, and procedure rooms. Individuals receive training on how to use the kits, prior to obtaining access to the facilities, when they complete a tour of the facility and through the mandatory web-based training courses.

Web-based training, one-on-one training, specialized PPE, and additional oversight are

required of all macaque handlers to prevent exposure to Macacine Herpesvirus-1. Specialized web-based training courses are required to be completed by all macaque users on an annual basis. This training addresses all aspects of Macacine Herpesvirus-1 including prevention, transmission, pathophysiology, reporting of potential exposures, treatments, and possible outcomes.

- 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.

See Part X. Facility and Species Inventory

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

IACUC Member Training

New IACUC members receive an in person orientation/education that includes a variety of relevant materials and resources either in hard copy or via electronic links including, but are not necessarily limited to, the following:

- Guide for the Care and Use of Laboratory Animals
- Public Health Service Policy on Humane Care and Use of Laboratory Animals
- Animal Welfare Act and Animal Welfare Regulations
- AVMA Guidelines for the Euthanasia of Animals
- Overview of the IACUC program and responsibilities - provided by IACUC Chair and/or IACUC office staff.
 - Review new member materials, IACUC charge, IACUC policies, regulations, processes, protocol review, etc.
 - Reviewer training on how to evaluate submissions based on the requirements covered in the species-specific training modules, which include instruction on basic needs and behaviors, appropriate care and handling/restraint methods, anesthesia/analgesics, testing methods that minimize the number of animals required to obtain valid results and minimize distress, and the approved methods of euthanasia.
 - Overview of Member Roles and Responsibilities
- Electronic protocol management system one-on-one tutorial - provided by IACUC office staff
 - Initial basic session using sample data
 - Advanced session using the member's first protocol review Web Based Training
- Washington University's Introduction to Animal Care and Use online module (required)
- Additional animal care and welfare online training modules offered through Washington University (voluntary)

Members are expected to participate in continuing education on a regular basis. Continuing education is a standing agenda item at the IACUC meeting each month. Presentations may include scientific articles about commonly used species, IACUC case study discussions, or new research models/topics.

Additional educational opportunities are available to members (e.g., professional meetings, webinars, etc.), which will be communicated by the IACUC office and/or the Division of Comparative Medicine.

Training for personnel who use live animals in research, testing, or teaching

Training and qualifications for all personnel on an IACUC protocol are documented in a list of completed Learn@Work courses and for those handling animals an additional narrative section is populated in the IACUC protocol. Learn@Work courses are added to the protocol through an integration with the electronic protocol system. The training and qualifications narrative includes a summary statement of training, years of experience, and identifies the protocol procedures the

individual will perform. If an individual does not have sufficient experience, the narrative will also include the training plan with the name of the experienced trainer responsible (PI, lab staff, collaborator, or DCM veterinary staff). The IACUC may request initial procedures to be observed by DCM staff to verify successful training and skill.

Required courses for research personnel are determined by location, species, and assigned protocol activities. Requirements are detailed in the Training and Training Documentation Policy. Animal users can access courses using the Compliance Profile questionnaire, selecting the courses directly in Learn@Work, or through the IACUC Education and Training website. Anyone listed on the protocol is required to complete the "Introduction to Animal Care and Use" module and those handling animals are also required to complete an Occupational Health and Safety course as well as species-specific orientation module(s). The species-specific training modules include instruction on basic needs and behaviors, appropriate care and handling/restraint methods, anesthesia/analgesics, testing methods that minimize the number of animals required to obtain valid results and minimize distress, and the approved methods of euthanasia.

Individuals must complete specialized web-based training modules on an annual basis, when appropriate; such as personnel working with NHPs or with other large animals must complete species-specific modules. In addition, personnel using biohazards or the irradiator must receive training from EHS and/or the Radiation Safety Office and DCM before security access is granted.

In addition to the web-based training, DCM is equipped with a modern rodent training and education facility and offer hands-on training programs for research staff members. Examples of ongoing wet labs include a rodent handling lab and an aseptic procedures lab (i.e. to demonstrate rodent handling, restraint injections, blood collection, oral gavage, identification, anesthesia, and euthanasia). The veterinary staff also provides individual instruction in numerous small animal techniques as needed when requested by an investigator. Investigators may request veterinary staff to perform animal procedures on their behalf or request the necessary training to ensure proficiency.

The QA/QI staff regularly visits animal research satellite facilities and laboratories. They discuss opportunities for additional training to address concerns or gaps identified by the PI or laboratory staff. They may observe procedures performed during the visit and will verify training in post-operative care procedures through document review.

The IACUC office conducts quarterly Newsletters and Brown Bag seminars to provide continuing education on various topics. These outreach efforts include information on policy changes, compliance trends, resource links, and helpful hints. When permitted, conferences on various topics are offered on campus several times a year by lab animal vendors (e.g., Animal Care Training Services, Charles River Labs, Jackson Laboratory, Taconic, Transnetyx) and these meetings are advertised to the researchers for continuing education. Webinars have been available directly from the vendors for all research personnel.

Training for personnel involved in animal care

Individuals performing animal care duties are required to complete all relevant training modules to help ensure proficiency. In the facilities, new sanitation technicians, cagewash technicians, and laboratory animal technicians (LAT) assigned to work in a rodent facility must attend Rodent Boot Camp prior to reporting to their assigned building. Individuals are expected to also complete the Purina Laboratory Animal Care Course within the first six months of employment. This course covers a wide variety of information on the fundamentals of laboratory animal management and welfare. Rodent Boot Camp training falls into four categories: administrative, regulatory, husbandry, and safety. Training includes completing HR and OHS appointments, completing assigned online training courses in Learn@Work, becoming knowledgeable in animal use regulations and Washington University and DCM policies and procedures, and learning safety in the workplace. After the first two days of rodent boot camp, sanitation technicians and cage wash technicians will report to their assigned building and receive additional training provided by lead techs and supervisors until the new employee can work independently. Refresher safety training for cage wash personnel is completed monthly. Cage wash technicians are enrolled in

the Hearing Conservation program upon hire, which include training and audiograms are done annually.

LATs continue Rodent Boot Camp for two weeks. The remaining training includes presentations by the husbandry trainers and subject matter experts. Hands-on training in a rodent barrier room occurs during the second week of Boot Camp. LATs start by watching a video to learn the proper way to change a rodent cage followed by a live demonstration of cage changing techniques and safe handling of equipment. Finally, the trainers provide direct supervision of the trainees as they learn how to maintain a rodent barrier room and practice changing cages. At the end of the second week, the LATs are proficiency-tested. Trainers will continue to work with the LATs until they are awarded a certificate of completion of rodent boot camp. Additional training is provided by lead techs and supervisors at the work site until the new employee can work independently. LATs receive refresher species training if a species has not been housed in a facility for more than three months.

Veterinary Technicians are all certified and registered/licensed to work in Missouri. New hires are required to attend the first two days of rodent boot camp. All new veterinary technicians work closely with skilled veterinary technicians during the probationary period. Veterinary technicians are required to complete all of the DCM courses in Learn@Work, attend the rodent handling wet lab and the rodent aseptic techniques wet lab, learn to access animal protocols and understand policies related to working at Washington University. Veterinarians directly supervise the new veterinary technician in collaboration with the training coordinator until proficiency is gained. A training checklist must be completed before the veterinary technician is considered "trained" and ready to work independently.

DCM offers free AALAS certification classes to all employees and AALAS certification exams are paid for by DCM. Continuing education opportunities including conferences and webinars are available for veterinary staff. Veterinarians typically attend one conference per year. Veterinary technicians are able to attend the national AALAS meeting on a rotating basis or whenever a poster or seminar session is accepted.

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.

(1) This Institution is Category 1 — 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.

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, Jennifer Lodge, PhD, Vice Chancellor for Research, Associate Dean for Research for the School of Medicine, Professor, Molecular Microbiology.
 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, Jennifer Lodge, PhD, Vice Chancellor for Research, Associate Dean for Research for the School of Medicine, Professor, Molecular Microbiology.
 5. Any minority views filed by members of the IACUC
- B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
 1. Any serious or continuing noncompliance with the PHS Policy
 2. Any serious deviations from the provisions of the *Guide*
 3. Any suspension of an activity by the IACUC
- C. Reports filed under VI.A. and VI.B. above should include any minority views filed by members of the IACUC.

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official	
Name: Mark E. Lowe, MD, PhD	
Title: Interim Vice Chancellor for Research, Interim Associate Dean for Research for the School of Medicine, Professor, Pediatric Science	
Name of Institution: Washington University in St. Louis	
Address: (street, city, state, country, postal code) 660 South Euclid Avenue Campus Box 8106 St. Louis, MO 63110	
Phone: (b) (6)	Fax: (b) (6)
E-mail: lowe@wustl.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: (b) (6)	Date: 01/04/2022

B. PHS Approving Official (to be completed by OLAW)	
<div>Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6700B Rockledge Drive Suit 2500 Bethesda, MD USA 20892-7982 (FedEx Zip Code 20817) Phone: +1 (301) 496-7163 Fax: +1 (301) 451-5672</div> <div>Nicole L. Lukovsky-akhsanov - S Digitally signed by Nicole L. Lukovsky-akhsanov -S Date: 2022.03.02 16:44:12 -05'00'</div>	
Signature:	Date: 3/2/2022
Assurance Number:	
Effective Date: 3/2/2022	Expiration Date: 10/31/2025

VIII. Membership of the IACUC

Date: November 5, 2021			
Name of Institution: Washington University in St. Louis			
Assurance Number: D16-00245			
IACUC Chairperson			
Name*: John Cirrito			
Title*: Associate Professor, Neurology		Degree/Credentials*: PhD	
Address*: (street, city, state, zip code) 660 South Euclid Avenue Box 8031 St. Louis, MO 63110			
E-mail*: IACUC@wustl.edu			
Phone*: (b) (6)		Fax*: (b) (6)	
IACUC Roster			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
Nirah Shomer	PhD, DVM, DACLAM	Associate Vice Chancellor for Research, Director/Department Comparative Medicine	Veterinarian
(b) (6)			Vice Chair/Scientist
			Scientist
			Scientist
			Scientist
			Scientist
			Scientist
			Scientist
			Scientist
			Scientist
			Scientist
			Scientist
			Scientist

(b) (6)	Scientist
	Scientist
	Scientist
	Member
	Member
	Member
	Nonaffiliated
	Nonaffiliated
	Nonaffiliated/Nonscientist
	Veterinarian
	Member/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:

<i>Veterinarian</i>	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.
<i>Scientist</i>	practicing scientist experienced in research involving animals.
<i>Nonscientist</i>	member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy). Any individual classified as nonscientist meets this requirement.
<i>Nonaffiliated</i>	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. Any individual classified as nonaffiliated meets these requirements.

[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

(b) (6)

Contact #2

(b) (6)

X. Facility and Species Inventory

Date: June 25, 2021			
Name of Institution: Washington University in St. Louis			
Assurance Number: D16-00245			
Laboratory, Unit, or Building*	Gross Square Feet [include service areas]	Species Housed [use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog]	Approximate Average Daily Inventory
(b) (4)	673.75	Mouse	29
	58,450	Mouse	12,819
	6,460	Mouse	13
	11,880	Frog	2
		Mouse	1,122
		Hamster	11
		Rat	6
		Guinea Pig	22
	139,370	Mouse	19,572
		Fat-tailed dunnart	16
		Gerbil	31
		Hamster	10
		Rat	1,325
		Ferret	0
		Rabbit	15
		Dog	4
		Sheep	30
		Pig	11
		Cow	0
	626	Mouse	49
		Rat	0
		Rabbit	0
	3,047	Mouse	182
	619	Mouse	22
	86,503	Mouse	15,391
		Macaque	54
	4,070	Zebrafish	100,000
		Mouse	745
		Rat	56
	12,427	Mouse	1,170
		Rat	13
		Horseshoe crab	9
		Pigeons	15
		Poultry	12
	54,740	Mouse	11,209
		Rat	83
	13,236	Mouse	360
		Rat	10
	14,635	Locusts	Swarm
		Frog	22
		Mouse	557
		Rat	21
	2,436	Mouse	135

*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.

December 29, 2021

Nicole Lukovsky-Akhsanov
Veterinary Medical Officer
Office of Laboratory Animal Welfare, NIH
6700B Rockledge Drive, Suite 2500, MSC-6910
Bethesda, MD 20892-6910

Dear Dr. Lukovsky-Akhsanov,
The University of Health Sciences and Pharmacy in St. Louis agrees to be added as a covered component under the WUSTL Assurance. We further acknowledge that UHSP agrees to the terms as stated in the Assurance document and that UHSP complies with and follows guidance of the WUSTL animal welfare committee and authorized institutional official. We will also comply with the Public Health Service Policy, the provisions of the Guide for the Care and Use of Laboratory Animals, the AVMA Guidelines for the Euthanasia of Animals, and the conditions of the Washington University-St. Louis's Assurance.

Regards,

 (b) (6)

Brandi Clements, MPA
Assistant Vice President-Research & Technology Transfer