

ANIMAL WELFARE ASSURANCE
in accordance with the PHS Policy for
Humane Care and Use of Laboratory Animals

UNIVERSITY OF PENNSYLVANIA
D16-00045 (A3079-01)

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

I. APPLICABILITY OF ASSURANCE

This Assurance 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, 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:

- Perelman School of Medicine (PSOM)
- School of Veterinary Medicine (SVM)
- School of Arts and Sciences (SAS)
- School of Engineering and Applied Sciences (SEAS)
- School of Dental Medicine (SDM)
- School of Nursing (SN)

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 this Policy are as follows (see Attached Organizational Chart:

The Vice Provost of Research (VPR) at the University of Pennsylvania has delegated authority from the President/CEO to serve as the Institutional Official (IO) responsible for oversight of the animal care and use program. The IO appoints the IACUC Chair, all IACUC members, and authorizes a scientist “vice chair” to be “Acting Chair” if the appointed IACUC Chair is unavailable. The Executive Director of University Laboratory Animal Resources (ULAR) serves as the Institution's Attending Veterinarian. The Executive Director of ULAR directly reports to the VPR/IO and is responsible for all Penn-owned animals, including their husbandry, welfare and veterinary care provided by personnel within University Laboratory Animal Resources. The Attending Veterinarian meets at least monthly with the IO. The Director of Animal Welfare (AW) directly reports to the VPR/IO and is responsible for animal welfare for the university and its animal welfare program and the Director Office of Animal Welfare (OAW) is responsible for the Office of Animal Welfare, which includes an Animal Welfare Compliance Team and IACUC Administration Team. The IACUC Chair, Director of AW, Director of the Animal Welfare Office, and AV meet periodically with the IO. General IACUC members are encouraged to communicate with the IO with any questions or concerns.

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

| | |
|-------------|---|
| Name: | F. Claire Hankenson (Attending Veterinarian/Institutional Veterinarian; Executive Director, University Laboratory Animal Resources) |
| Degrees: | D.V.M., M.S., ACLAM Diplomate |
| Experience: | Dr. Hankenson serves as the Associate Vice Provost for Research and Executive Director, ULAR. She is the Attending Veterinarian and is a Professor of Laboratory Animal Medicine, Department of Pathobiology, SVM. Dr. Hankenson is a Diplomate of the American College of Laboratory Animal Medicine (ACLAM) and has 25 years of experience as a laboratory animal veterinarian. Her credentials include residency training and graduate work at the University of Washington, Seattle, WA; 4 years at the University of Michigan, Ann Arbor, MI as a clinical veterinarian and Assistant Professor; 8 years at the University of Pennsylvania as Senior Associate Director of University Laboratory Animal Resources and Associate Professor. From 2014-2021, Dr. Hankenson served as the Director for Campus Animal Resources and Attending Veterinarian at Michigan State University, with a Professor appointment. Dr. Hankenson currently serves on the Executive Board for PRIM&R and is an ad-hoc specialist to AAALAC, |

Authority:

International. Dr. Hankenson received the Pravin Bhatt Young Investigator award in 2009 and the Joseph J. Garvey Management award in 2017, both presented by AALAS. Dr. Hankenson, as Attending/Institutional Veterinarian, has *direct* program authority and ultimate responsibility for the clinical care of all the animals in the Institution's animal care and use program and has access to all animals. Dr. Hankenson is the official university contact to and correspondent with AAALAC, International.

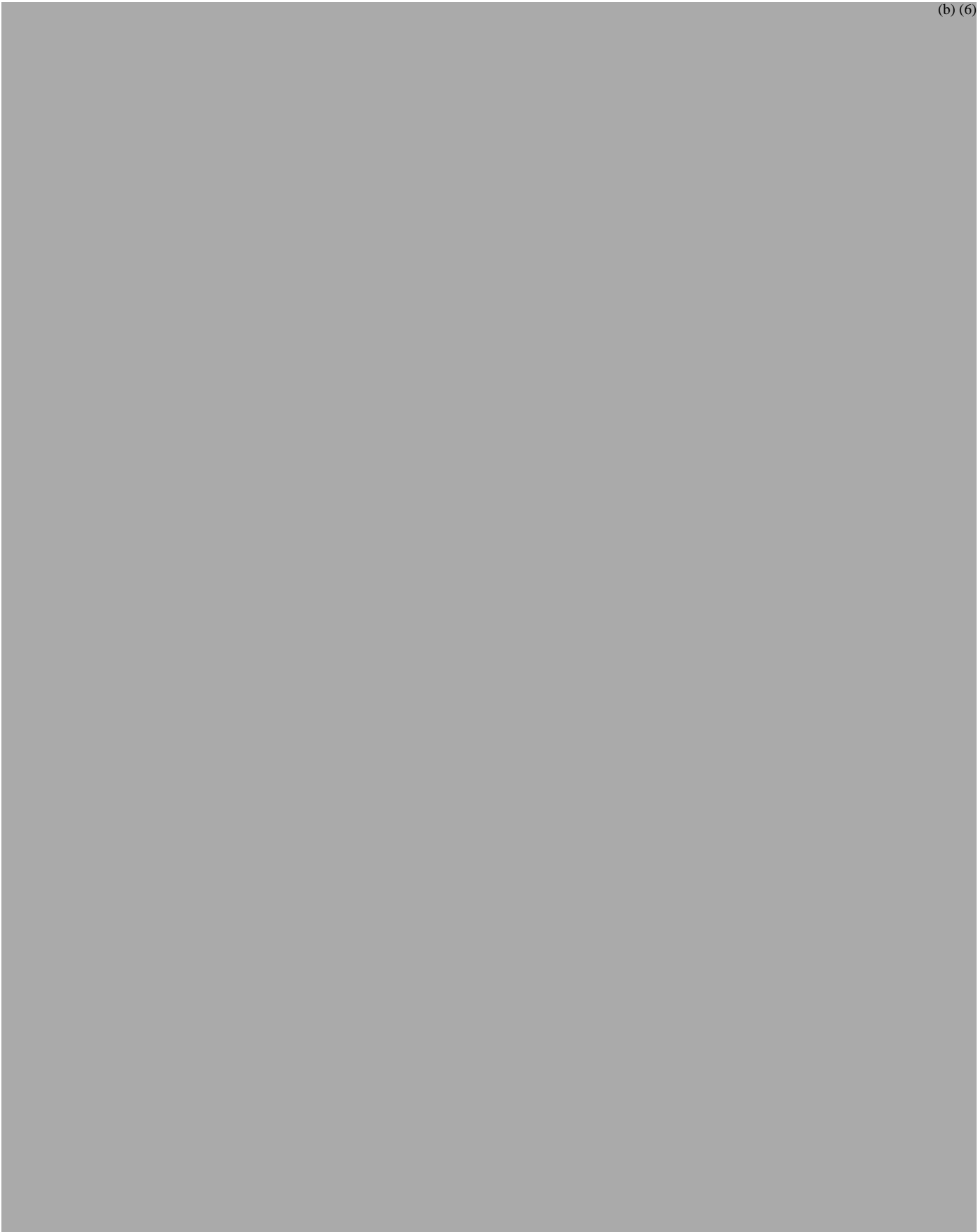
Time:

Full-time employee and contributes 100% of her time to the animal care and use program.

(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. See Attached IACUC list for the attached list of the Chairperson, Attending Veterinarian, and members of the IACUC and their degrees, profession, titles or specialties, and institutional affiliations. The Office of Animal Welfare maintains a coded list of members' names. (see the list of IACUC members at the end of the document.)

D. The IACUC will:

1. Review at least once every six months the Institution's program for humane care and use of animals, at a minimum, using the "Guide" as a basis for evaluation. All IACUC members are invited to participate in the semiannual program review and inspection. The IACUC procedures for conducting semiannual program reviews are as follows:

The Institution conducts semiannual program reviews for the periods of November to April and May to October of each calendar year. Routinely, in May and November of each year, the animal care and use program is reviewed during an IACUC meeting. An OLAW checklist of specific topics are provided to all members prior to the meeting and is used as guidance at the meeting to assure that all aspects of the program are reviewed. Discussion comments are compiled and a report reflecting the IACUC's review is written by the staff of the Office of Animal Welfare.

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

The Institution conducts approximately 50 scheduled semiannual inspection tours for each semiannual review period (i.e., April and October). An IACUC subcommittee of at least 2 IACUC members performs each inspection for USDA regulated species and one IACUC member for Non-USDA species. Participation from other components of the Institution usually in attendance and this includes Clinical Veterinarians, facility supervisors, maintenance supervisor, EHRS staff and a member of the Compliance team from the Office of Animal Welfare). No IACUC member is excluded from any inspection in which they wish to participate.

In order to conduct thorough standardized inspections, we use paper or electronic documents, which provides IACUC members with a list of the areas to be inspected, a semi-annual site visit checklist list, and a list of previous findings for that area. Inspection reports are generated using an electronic database. Any deficiencies that are identified in the report are categorized as either "minor" or "significant" and an appropriate time frame and a specific date for correction is also included in the report. Depending on the severity of the deficiency and the complexity of the resolution, the IACUC determines the appropriate time to require corrective plans from the responsible party. All non-compliance items are tracked by the IACUC compliance group to resolution. Additionally, during the IACUC meeting immediately prior to the semi-annual inspection the Compliance Group provide training on performing inspections and key items to review.

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

After the Program Review is complete and Semi-annual inspections are completed, a summary document (Semi-Annual Program Review and Inspection Report) is prepared for the IO. The summary documents include sections on the Program reviewed, IACUC membership, Guidelines and Policies updates, IACUC subcommittees, Semi-Annual Inspection summary, OAW IACUC administrative support, OAW Compliance report, recommendations or concerns regarding the animal care and use program, AAALAC status and Minority Views. Attachments to the summary include Exemptions (e.g. reasons for departures from the provisions of the Guide and the PHS Policy, AWA or Penn Policies or Guidelines), IACUC-approved satellite housing locations, and detail list of all inspection findings, the category (minor or significant) and correction status/plan as well as breakdown of the inspections in general categories which helps to identify categories that may need additional attention. At a convened IACUC meeting of a quorum of the committee membership present, the documents are reviewed and approved. Any minority reports are included in the report. A majority of the IACUC members sign the semiannual review prior to submitting it to the IO. The semiannual inspection reports are also provided to the IACUC for their review and included as part of the semiannual program review. Deficiencies are distinguished as "minor" or "significant" and include a reasonable plan and schedule for correction as described in section III.D.2. The semi-annual documents are sent to the IO and at the next scheduled meeting between the IO and an IACUC representative, usually the Director of Animal Welfare, the semi-annual documents are discussed. Additionally, significant deficiencies identified that are defined as non-compliances noted during the semiannual program review and inspection that are funded by PHS, NSF and/or NASA funded with be reported to OLAW.

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

The Institution and IACUC encourages the rapid reporting of concerns related to animal welfare and has established procedures to review and investigate any allegation of violations of Public Health Service Policy or Animal Welfare Act and Regulations, University of Pennsylvania IACUC guidelines and policies, and University Laboratory Animal Resources Standard Operating Procedures. Information delineating how to report animal welfare concerns is posted in each animal facility. Animal welfare concerns from any source can be conveyed in writing/email, by telephone, or in person. The Office of Animal Welfare/IACUC website includes a link to start the process of reporting animal-welfare concerns. The Institution also has a contract with an independent third party to manage concerns by email or by telephone via a “hotline”. This third-party reports to the Office of Audit which in turn sends any animal related concerns to the OAW. The caller/reporter can be kept anonymous if he/she requests it. The Institute’s policy on whistleblowing and IACUC policy on reporting animal welfare concerns prohibits retaliation against those making the report. Allegations should be detailed and specific, to allow for a thorough investigation. All concerns are reviewed regardless as to how they are received. Reports may also be communicated anonymously, if requested. The IACUC has policy “Investigation Animal Welfare Concerns and Noncompliant Activities which provides guidance on the subject:

A major deterrent to reporting is the fear that the person or persons against whom the report is made will retaliate against the person making the report. Because of this, the University prohibits retaliation as well as nondiscrimination against those (individuals or parties) who make bona fide reports of possible noncompliance, also referred to as ‘whistleblowers’ (Human Resources Policy 718 “Policy Against Retaliation”). If requested by the whistleblower, their identity will be limited to the IACUC Chair and/or Director of Animal Welfare. If the whistleblower wishes to remain fully anonymous, then reports should be filed with Penn’s Confidential Reporting and Help Line by telephone “Third party managed hotline or the OAW telephone” or online or via the OAW-IACUC website. If requested by the whistleblower, OAW may communicate general findings to the concerned employee(s) (Guide, p. 23-24).

Reports may be filed with the IACUC by telephone or email (IACUC Chair, Director of Animal Welfare, and/or OAW Compliance staff). Reports may also be filed in-person by submitting a report to the OAW, the IACUC Chair, the Director of Animal Welfare or any IACUC member. The Institution is committed to protecting the rights of any individual (whistleblower) reporting concerns of animal welfare and anonymity of reporter is offered upon request.

An investigation, if warranted, proceeds immediately. The IACUC Chair is informed and may also assign members of the IACUC Compliance Subcommittee or an IACUC member. The IACUC Compliance Subcommittee is chartered by IACUC and includes the IACUC Chair, additional IACUC members, AV or designee, the Director of Animal Welfare and is supported by the compliance group of the OAW. A member of the Office of Animal Welfare Compliance staff typically collects the initial information. If there is an ongoing animal well-being concern, the AV or AV Designee is immediately contacted, and they will address the immediate health concern of the animal. The IACUC Chair is kept informed during the investigation, usually at the IACUC Compliance Subcommittee meeting. Other individuals are notified and are involved as required (e.g., AV or designee for animal husbandry or veterinary care for urgent animal welfare concerns, and EHRS officers for hazardous material concerns involving animals). The process for conducting investigations varies depending on the nature of the report. A typical investigation includes the inspection of the animal facility area and/or laboratory and questioning of individuals allegedly involved in the incident, meeting with animal care or veterinary staff as well as review of protocols and records. The Compliance Subcommittee meets approximately weekly to review investigation findings and formulates recommendations for immediate actions if needed. If the Chair recommends immediate actions regarding staff that report to the AV (e.g. training staff, veterinarians), the AV is informed at that time. The Director of Animal Welfare and OAW Compliance staff implements those immediate actions approved by the IACUC Compliance Subcommittee (which includes the IACUC Chair). The

Chair, if warranted, may call a special IACUC meeting. Otherwise, the immediate actions taken by the Compliance Subcommittee are summarized for the IACUC at a regularly scheduled meeting. The IACUC may accept or modify the recommendations and actions or require additional information or actions. Through the IO, the Institution reports findings of the investigation that constitute a reportable incident as required by external regulatory and accrediting agencies. This includes prompt reporting based upon NOT-OD-05-034 of PHS, as well as NSF, CDC or NASA-funded activities to OLAW and actions required to be reported to the USDA per the Animal Welfare Act and Regulations. Reporting to AAALAC follows their requirements for the AAALAC-accredited facilities. The IACUC Chair and the AV are copied on resolutions to all reported incidents to external regulatory and accrediting agencies.

Animal welfare concerns are reported to the IO by a variety of mechanisms that depend on the severity of the issue. The IACUC Chair/Director of Animal Welfare determines how to report to the IO. For relatively minor incidents not directly impacting animal welfare, the IACUC Chair/Director of Animal Welfare or designee may communicate with the IO via telephone, email, or at person-to-person meetings, summarizing the incident and the finding. For scenarios that directly impact animal welfare or chronic issues, the Chair/Director of Animal Welfare or designee may meet with the IO personally, summarizing the incident, findings, and the decision by the IACUC.

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 IO receives written reports from the IACUC at least semiannually. The IO supports the animal care and use program and has given the IACUC the authority to oversee the animal care and use program and to use appropriate judgment as to when the IO should become directly involved in specific matters relating to the program. The IACUC Chair and the Director of Animal Welfare (together or separately) then meet with the IO to discuss the details of the semiannual program review and inspection report. Corrective actions and, if warranted, plans to avoid recurrence of the deficiencies submitted by the responsible parties are also included with the inspection report. The reports are updated each semiannual period upon completion of the required semiannual evaluations and shall be maintained by the Institution.

The IACUC develops guidance documents and policies to assure animal welfare and institutional compliance with federal regulations. If the guidance may impact other components of the Institution (outside the animal program), and/or significant interpretation of the regulations is necessary, or the IACUC Chair requests counsel from the IO, then the IO is directly involved in the approval process.

The IACUC and the Training Subcommittee, in conjunction with the Training Division (ULAR), develop training requirements for participants of the animal program to assure animal welfare and institutional compliance with federal regulations. If the training program is directly associated with the federal regulations, the IACUC approves of such training without the direct involvement of the IO. If the training program may impact other components of the Institution (beyond the animal program), and/or significant interpretation of the regulations is necessary, the IACUC Chair may request counsel from the IO when formulating a plan to be presented to the IACUC to review and approve. The administrative management and the functional execution of the institutional training program reside in ULAR, under the immediate direction of the AV and designee.

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

The research and teaching faculty of the Institution submits IACUC protocols, amendments, and other documents via an in-house designed animal research information and electronic submissions application (ARIES). The

Institution does not differentiate between PHS-supported and other supported activities - the review, approval and post approval process for any IACUC submission is identical, regardless of support.

Pre-Review

- i. Penn has single IACUC for the entire institution and uses an internally developed computer-based Protocol system named “ARIES”
- ii. The PI uses the ARIES system to create a protocol based on template. The system provides instructions and guidance to help the PI.
- iii. Prior to being submitted to the IACUC, a protocol is routed to the protocol PI’s Department Chair for certification and approval. If there are any comments regarding performing the research project in the Department, the Department Chair may return it to the PI.
- iv. Principal Investigators consult with ULAR veterinarians (AV-designees) or for non-USDA regulated species (mostly rodents), the aforementioned OAW veterinarians prior to protocol approval for all animal activities requiring more than momentary or slight pain or distress.
- v. Upon submission, OAW protocol specialists conduct an administrative pre-review for all protocols and amendments. The pre-review includes an evaluation of the content relative to institutional guidelines and policies, completion of training records, and various other checks to assure that the protocol is complete.
- vi. Any necessary “secondary” reviewers (e.g. Diagnostic Services, Environmental Health and Radiation Safety (EHRS) or compliance) are assigned during the pre-review. Institutional guidelines for the assignment of “secondary” reviews are as follows:
 - All surgical protocols or amendments, those using neuromuscular blocking agents, or those with any other procedures that may cause more than momentary pain or distress are reviewed by a veterinarian, either an OAW veterinarian or an AV-designee.
 - Environmental Health and Radiation Safety review all protocols or amendments using hazardous/infectious materials or radiation in animals.
 - ULAR Diagnostic Services and Rodent Quality Assurance review all protocols or amendments involving potential biosecurity issues, include transportation, for rodents.
 - OAW Compliance staff reviews all protocols and amendments involving survival surgery performed outside ULAR-managed vivaria, as well as all exemptions from the *Guide* or the Animal Welfare Regulations, and satellite housing requests.
 - The IACUC Chair or support staff has discretion whether to assign secondary reviewers to a protocol or amendment based in the protocol’s content. (Protocols with a USDA pain category E are assigned two IACUC members if they are reviewed DMR.)
- vii. Every business day, each IACUC member is emailed an agenda that consists of a list of protocols and amendments to be reviewed. This email includes at least the PI’s name, protocol number, the highest procedure-related pain/distress category, and a short-written description of the research project and species in the protocol. The IACUC member have full access to entire protocol as well as all comments from the reviewers. The IACUC has determined that a waiting period of 2 days for significant amendments and annual reviews and 5 days for protocols is an appropriate amount of time for any member to request full committee review (FCR) prior to final review and approval. Any IACUC member may request FCR for a specific protocol or amendment at any time (during the review process or after approval). All protocols/significant amendments are assigned at least one IACUC member qualified to conduct the review, designated by the IACUC Chair (or determined from a list of members approved by the IACUC Chair) for Designated Member Review (DMR). The IACUC member is notified by email and has the protocol added to their “action” list in the ARIES system. The DMR reviewer may not have a conflict of interest with the protocol. On rare occasions the OAW staff may need to change DMR reviews to avoid review delays due to illnesses or vacations.

Review & Decision

- viii. All submissions requiring IACUC review will undergo DMR, unless any member of the IACUC requests FCR of any protocols and/or amendments. The IACUC does not have a special expedited protocol review process, new protocols require a 5-day waiting period for approval and significant amendments require 2 days unless the amendment fulfills the requirements of the IACUC approved Veterinary Verification and Consultant amendment requirements or Administrative change.
- ix. All IACUC reviewers have the opportunity to submit comments for both DMR and FCR (to be reviewed by a convened quorum of the members of the IACUC) protocols and amendments. Outcomes of a DMR may be “approval”, “modifications required to secure approval”, or “request FCR”. Outcomes of a FCR may be “approval”, “modifications required to secure approval”, “tabled”, or “withhold approval”.
- x. The Aries system allows each individual IACUC member see list of protocols that require their attention. The system allows the IACUC member to all comments written about the protocol as well as all changes to the protocol (deletions highlighted in blue and additions highlighted in yellow)
- xi. DMR approval may be granted as early as 5 days after the email agenda (action “v” above) for protocols or 2 days for significant amendments, which are the IACUC-approved time periods allowing for the opportunity for members to call for a FCR.
- xii. The IACUC will notify PIs in writing (by email or within ARIES) of its decision to approve, require modifications (by DMR or tabled for FCR) or withhold approval of those activities related to the care and use of animals. Comments from all review entities, including the reasons for the decision, are combined into an email, electronically within ARIES, or in a letter that is sent to the PI. If the IACUC decides to withhold approval of an activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
- xiii. A quorum of the IACUC may decide to “table” further discussion of a submission until the next scheduled meeting for any reason; i.e., if information is lacking for a FCR approval or to withhold approval of a research protocol.

Revisions & Approval

- xiv. The PI revises the submission, addressing the IACUC’s concerns, and then resubmits the protocol or amendment.
- xv. The designated member reviewer(s), who decided “modifications were required to secure approval”, re-review the resubmission with the PI’s revisions and make another review decision. The DMR is notified when the revisions have been submitted for re-review. For FCRs, please see “Full Committee Review & Voting” below.
- xvi. A review cycle (between actions “viii” and “xii”) continues until all animal care and use concerns of any and all designated member reviewers are resolved. The PI may meet with the IACUC Chair, IACUC member(s), the full Committee, or OAW protocol specialists to discuss how to respond appropriately to the review. All IACUC-designated member reviewers assigned to review a protocol/amendment review the latest versions with highlighted changes in the ARIES system, and the protocol/amendment is not be approved until a unanimous decision for approval has been submitted.
- xvii. Upon making its final decision, the IACUC notifies the PI by email. Additionally, an approval email/letter (or “withhold approval” email/letter) may be generated and be made available to the PI.

The above procedures describe the actions taken for research protocols and significant amendments. There are slight modifications to this general procedure for other IACUC submissions – for minor changes (e.g. funding source associated with the protocol, personnel amendments, spelling error correction, etc.). These administrative modifications may be processed by an IACUC administrator (or the OAW staff member).

There are also slight modifications for reviews to document IACUC review and approval (or foreign equivalent) for collaborations and subcontracted activities for which Penn is the primary grant awardee. These submissions undergo a purely administrative pre-review by OAW protocol specialists followed by IACUC review as described

above for protocols and significant amendments. Review of this “offsite” work follows the waiting period described above (v.) to allow the IACUC an opportunity to re-review the IACUC-approved protocol from the offsite institution.

Full Committee Review & Voting

Any member of the IACUC may request FCR of any protocols and/or amendments. All IACUC members have the opportunity to submit comments for both DMR and FCR. FCRs are assigned at least two IACUC members as “primary” reviewers.

At a convened meeting with a quorum of members, the assigned primary reviewers present a summary of any protocol or amendment brought to the full Committee. A quorum is considered 50% the number of voting members plus one. The IACUC has a full committee meeting scheduled once a month. A complete agenda is sent to all IACUC members prior to the meeting. For FCR any IACUC member with conflict of interest is excused from the FCR. Since March 2020, they IACUC had the ability of live-video conference meeting or hybrid (in-person and video conference) meeting. In a live-video conference IACUC meeting all members have access to all IACUC documents the meeting allows for real time verbal interaction equivalent to that occurring in a physically convened meeting. The meetings are conducted in adherence to the NIH Guidance on Use of Telecommunications for IACUC meeting NOT-OD-06-052. Penn defines conflict of interest as being on the protocol or consulting for the PI on the projects in the protocol or is a relation of the PI. Protocols undergoing FCR is assigned to at least two IACUC members as “primary” reviewers. Any protocol that is to have FCR is added to protocol action list of all IACUC members. They present the FCR submission to the Committee, including any outstanding comments or questions sent to the PI. During the discussion of the FCR protocol, comments and questions from the full Committee are recorded and sent to the PI after the meeting. Following each discussion, a recommendation is made, the votes are counted, and a decision recorded based upon the majority vote of the quorum. The PI is notified, in writing, of the decision—approval, modifications required to secure approval, tabled, or withhold approval.

In January 2009, the IACUC unanimously approved using the DMR process subsequent to full committee review of a protocol or amendment with a unanimous vote of “modifications required to secure IACUC approval”. All IACUC members have also signed a memo indicating their agreement with Notice NOT-OD-09-035. New IACUC members also sign this memo during their IACUC member training, indicating their agreement with this decision and maintaining unanimous consent of the full Committee. DMR is used to approve a protocol originally reviewed by FCR if a unanimous decision of the quorum present at the IACUC meeting elects to use DMR as the re-review mechanism. The DMRs are assigned as described above, unless any committee member requests FCR, in which case the revised protocol is forwarded for FCR.

For tracking animal numbers used the protocol, ARIES system communicates the approved numbers, the protocol number and the species to Penn’s animal order system which monitors and prevents PIs from ordering in excess of their protocol approved numbers.

7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

- Amendments are categorized as administrative/minor or significant. Please refer to III.D.6. for a complete description of the actions taken to review and approve significant amendments to animal use protocols; the process of protocol review is very similar to the process for amendment review. Administrative/minor amendments may include:
- Change in the protocol title

- Addition or removal of personnel in the protocol (not including the PI or a USDA regulated species surgeon— this is considered a significant change) or specific procedures, or updates to their qualifications — the IACUC has approved the administrative review and training requirements based upon the personnel role in procedures.
- Change in the funding source(s) associated with a protocol.
- Decrease in requested animal numbers to be used.
- Update to the dates of the literature search.
- Update to the IBC registration numbers
- Update of the qualifications of existing personnel (training added)
- Correction of grammar or typographical errors.

Significant Changes

All other changes to a protocol are considered significant changes that must be reviewed by the IACUC through DMR or FCR. Some common examples are given below.

- Change in PI
- Addition of animal numbers, including addition of breeding activity
- Change in the study objectives (Experimental Design)
- Addition of species
- Changes in hazardous materials that impact personnel safety
- Addition of procedures or changes to existing procedures, including those that result in greater pain, distress, or degree of invasiveness (USDA C -> D -> E; Penn A -> B -> C)
- Non-survival to survival surgery)
- In housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;

The decrease in number of animals is considered an administrative change but an increase request for additional animals is a significant change and is reviewed by the IACUC through the amendment process.

Administrative amendments may be approved on the same day they are submitted. All changes other than those described above will be considered “significant.” Significant amendments, which may be approved in 2 days (see IV.D.6.v. above), are reviewed by DMR or by FCR at a convened meeting of a quorum of the IACUC.

Veterinary Verification and Consultation “VVC”

The specific significant changes described below, may be handled administratively according to IACUC reviewed and approved policies in consultation with a veterinarian authorized by the IACUC. The list of names of the IACUC authorized veterinarians as well as approved references will be kept as an appendix to IACUC Policy-*Review of Protocols and Related Submissions*. The IACUC approved Policies and Guidelines are located on the IACUC Website. The veterinarian is not conducting DMR but is serving as a subject matter expert to verify that compliance with the IACUC reviewed and approved policy/guideline or reference is appropriate for the animals in this circumstance. The consultation by the veterinarian will be documented in the protocol system. The veterinarian cannot approve a VVC change that increases adverse outcomes, pain category, or increases hazards to the staff. The veterinarian may refer any request to the IACUC for review for any reason and must refer any request that does not meet the parameters of the IACUC reviewed and approved policies.

This includes changes in:

- Anesthesia, analgesia, and sedation or FDA-approved medical drugs previously listed in the protocol noted in the IACUC policies/guidelines as well as in select references approved the IACUC;

- Euthanasia to any AVMA approved method including those approved with conditions as long as the conditions are met for that species. The reference will be AVMA Guidelines for the Euthanasia of Animals;
- Duration, frequency, type, or number of procedures performed on an animal within acceptable veterinary parameters as prescribed in IACUC approved guidelines, policies and professional references and will not have significantly negative affect on the wellbeing or pain/distress status of the animal and based on IACUC reviewed and approved policies.

A significant change that may be handled administratively according to an existing IACUC reviewed and approved policy without additional consultation or notification. The changes are effective upon the Office of Animal Welfare/IACUC receiving writing documentation from a VVC approved veterinarian regarding the VVC eligible protocol change.

All amendments are reviewed as described above.

8. Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

The IACUC notifies a PI electronically and/or in writing of its decision to approve, require modification to secure approval, or withhold approval of those activities related to the care and use of animals. Comments from all review entities, including the reasons for the decision, are combined into the letter or email that is sent to the PI. The decision and review comments are also available to the PI via the ARIES electronic database. If a protocol has a “withhold approval decision, the PI is notified in writing. The PI is required to respond in writing via the ARIES protocol system, additionally the IACUC will work with PI to address concerns regarding the protocol, and this may include attending an IACUC meeting to discuss the project/protocol. All protocol final actions and the IACUC meeting minutes are shared with the Institutional Official. Upon approval, the IACUC notifies the Ps by an email from the ARIES system of its decision to approve. Additionally, an approval letter may be generated and be made available to the PI via the database. At list of all approved protocols is part of the IACUC meeting minutes. The minutes are reviewed and approved at the next IACUC meeting and then they are shared with the IO.

9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy IV.C.1-4 at least once every three years. The IACUC procedures for conducting continuing reviews are as follows:

Three-year protocol renewals are required to be updated to include any modifications or new scope of the project and resubmitted at appropriate intervals, but not less than every 3 years. This resubmission undergoes a *de novo* review as described in III.D.6. A protocol that is does not have *de novo* by its third years anniversary is inactivated.

Pre- and Post-Approval Monitoring (PAM)

Pre-approval Compliance:

Investigators proposing to conduct survival surgical procedures in a newly submitted protocol or amendment are required to contact the OAW office for an initial inspection of the surgical area. At least two IACUC members, which may include one veterinarian, visit all areas where survival surgical procedures will be performed. These areas include both USDA covered species and non-USDA covered species, regardless of funding source.

Investigators are required to contact the OAW office for an initial inspection of any area for which they are proposing to conduct housing greater than 12 hours outside of an ULAR-managed vivarium. These areas include both USDA covered species and non-USDA covered species, regardless of funding source and investigators are required to submit a request for satellite housing. The IACUC Satellite Housing Subcommittee reviews active and proposed satellite facilities, including the justification for housing outside of a vivarium. This review includes the suitability of the site, the infrastructure of the site, and the satellites' SOPs and disaster management plan. Satellite locations are inspected by two IACUC members before approval.

Follow-up on deficiency findings during semi-annual inspections (responsibility of the IACUC Compliance Staff):

The OAW Compliance staff follow-ups on all facility sites that were given a deficiency notice during the IACUC semiannual inspections. They review whether the corrections have been completed in a timely fashion as required and follow-up with the responsible parties as required. The IACUC is notified when corrections to minor deficiencies have not occurred within the designated time frame. If there is not an adequate response following the second notice, the IACUC Compliance Subcommittee (CSC) is informed and decides on the proper course of action which may include notifying the Chair of the Department and/or the Institutional Official. If a semiannual significant deficiency is not corrected in the IACUC assigned period, then OLAW and the USDA will be notified as required in their guidance.

Post-Approval Monitoring:

Animal activity areas (facilities, laboratories, etc.) are monitored for compliance with approved protocols, regulations, policies, and other guidance. The OAW Compliance staff visits research laboratories to completely review practices, ensure protocol compliance, and educate research staff. Protocols are also evaluated randomly or based on risk for a post-approval audit. The Compliance staff assists the research staff with any necessary corrective action plans and ensures implementation in a manner that meets the expectations of the IACUC. Non-compliance issues are reported to the IACUC CSC and then subsequently to the IACUC at the next regularly scheduled full-committee meeting. A special meeting, if warranted, may be called by the Chair.

Actions taken for non-compliance issues

- All potential compliance issues are discussed with the IACUC CSC.
- The CSC determines the severity of a compliance issue on a case-by-case basis, considering animal involvement, chronicity, and whether welfare was compromised.
- Minor non-compliance issues are recorded, and an email is sent to the Principal Investigator that explains, in detail, the concerns and recommendations for improvements. The Compliance staff generally works with the PI to resolve the issue and then report the resolution back to the CSC.
- Significant non-compliance issues are coordinated through the CSC and include communication between the CSC and the PI. This communication includes the recommended course of corrective action, a request for a written response from the PI, and a specific time frame for the response.
- The non-compliance issues are summarized for the IACUC at its scheduled meeting as required. The IACUC may accept the recommendations and actions taken or may require additional information or actions.
- On a case-by-case basis, the Department Chair or the Dean of the School may be notified as well.
- If the non-compliance is a reportable incident or involves immediate action to assure animal welfare, all of the above procedures are followed (e.g. IACUC deliberation and consultation with IO and AV), and the proper regulatory agencies are notified as required.

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

The IACUC may suspend any or all animal-related activities associated with an approved protocol, if the Committee determines that the activities present an animal welfare, safety concern, or chronic issues (through noncompliance with established policies, procedures, or protocols or by unacceptable management of an animal). The IACUC may suspend an activity only after review at a convened meeting of the IACUC, and a majority vote of the quorum in favor of a suspension. If the IACUC suspends an activity involving animals, the IO, in consultation with the IACUC Chair, and the Director of Animal Welfare reviews the reasons for the suspension, takes appropriate action, and reports the activity as deemed appropriate to the USDA and OLAW, as well as any related funding or accreditation agencies, in accordance with their specific policies.

Regarding any IACUC decision (e.g. protocol or amendment review, investigation and resolution of a noncompliance, suspension), any IACUC member with a real or perceived conflict of interest may provide information requested by the IACUC but will not contribute to the quorum for any vote. The individual(s) with a conflict may be asked to leave the room during any discussion. Real or perceived conflict has been defined as an individual being listed as personnel or consults for the PI on the submission under review or is a direct family member (e.g. spouse) of the PI of a submission under review, but other conflicts are considered on a case-by-case basis

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

Hazard and Risk Assessment

The Office of Environmental Health and Radiation Safety (EHRS) supports the University Institutional Biosafety Committee and the University Radiation Safety Committee. These committees are responsible for approving the use of hazardous chemicals and physical hazards, infectious agents, recombinant DNA and radioactive materials in research at the University. Biohazard protocols involving animal work are reviewed by biological safety professionals, industrial hygienists review protocol using hazardous chemicals and lasers and health physicists review the use of ionizing radiation. Safety criteria for the use and handling of these materials within the animal research setting are established by these reviews. EHRS defines what materials are “hazardous” and reviews the IACUC protocols proposing the use of hazardous materials in animals. Investigators must comply with the requirements stipulated by EHRS.

Prior to protocol approval, completion of an online orientation outlining the Occupational Health and Safety Program is required for all people having contact with animals. This module focuses on topics such as facilities, species exposed to (including wild animals), special hazards (biological, chemical, or radiation), and zoonoses. See “Personnel Training” below for a summary of the training component of the module. The module includes explicit instructions explaining how to schedule appointments with Occupational Medicine professionals. This module must be completed at least every 3 years for all animal users. A similar module including the general information previously described plus additional information on non-human primates must be completed at least annually by nonhuman primate users.

Additionally, all personnel must complete Penn Profiler, an Institution-required online survey used to assign job-specific training for all University employees, not just animal users. Completion of Penn Profiler is required annually. Penn Profiler includes a series of health and animal exposure related questions (online risk assessment), which will, depending on the answers, assign a required visit to Occupation Medicine for collection of a health history. These questions were written by the Director of Occupation Medicine in the University of Pennsylvania Health System, whom is a medical doctor specializing in occupational health. IACUC approval of each submission (a protocol or an amendment to add personnel) is contingent on the completion of Penn Profiler within the previous year.

In addition to those individuals identified as being “at risk” by EHRS (based on being listed on an IACUC protocol and substantial animal contact) or by the online risk assessment (Penn Profiler), there are several

categories of personnel that may be required to attend an in-person interview with a medical professional in Occupational Medicine and collection of a clinical history, prior to working with animals or with specific compounds or agents. These include:

- All ULAR employees working with animals (e.g. husbandry and veterinary staff)
- Personnel working with non-human primates (e.g. animal husbandry staff)
- Research personnel working with other agents (risk determined by EHRS)
- Personnel using agents for which vaccines are available
- Any employee working under ABSL3 conditions
- Maintenance personnel working in the vivaria.
- Undergraduate students working with animals
- Visiting faculty with substantial animal contact have their home institution's occupational health program reviewed and any gaps in the program is addressed by Penn.

Employees "at risk" or exposed to a risk assessment is required and there is an affirmative obligation to consult with Occupational Medicine.

Facilities, Equipment and Monitoring

Facilities, equipment, and procedures are designed, selected, and developed to reduce the potential of physical injury or health risk to personnel. EHRS is involved in the design of all animal facilities and related laboratories. Safety equipment is properly maintained and validated. An EHRS professional attends semi-annual inspection visits of vivaria and satellite housing locations. The EHRS has visit all laboratories annual for EHRS policy compliance. The EHRS also performs risk-based hazard assessments on all job roles and works with PIs to create a safe lab environment and using engineering controls whenever possible in addressing risks.

Personnel Training

Completion of at least one occupational health online module (for general animal users or nonhuman primate users) is required for every individual working with animals on an IACUC protocol. These training modules describe the Occupational Health and Safety Program for those persons having contact with animals. These modules also warn about the risks during pregnancy and general illness, as well as potentially severe health problems associated with working with animals. Special attention to laboratory-animal allergies, preventive control measures, proper techniques for working with animals (e.g. sharps and ergonomic issues), chemical- and biosafety hazards potential exposure outside of work, and decreased immunocompetence are also covered. Species-specific fact sheets are part of these modules and cover all species used at the institution. These fact sheets address the risks associated with working with specific species and zoonosis. Additionally, occupational health concerns are discussed in instructor-led species-specific hands-on training, which is also required prior to the individual working with animals on an IACUC protocol.

EHRS oversees the safety program that involves hazard assessments, evaluating safeguards, developing training programs and ensuring personnel are adequately trained, and participating in the design and evaluation of facilities for the safe conduct of research. Safety training provides hazard awareness instruction allowing personnel to assess workplace hazards in order to take steps to reduce risks.

Personnel Hygiene

Lockers, showers, and restrooms are either immediately within or in close proximity to all animal facilities and are available to all animal-husbandry staff. Animal-husbandry technicians are provided with uniforms that are laundered either by an outside service or within the facility. Outer garments (e.g. scrubs or uniforms) worn in the animal rooms are not worn outside the animal facility unless covered (e.g. lab coat). Additional protective clothing is provided as necessary for all animal-housing areas. Protective clothing typically consists of shoe covers, gloves, and a protective gown, but may include other equipment as necessary. PPE is provided, but different levels are required, based on the risks involved, i.e. based on species or hazards. Personnel are expected to wash and/or disinfect their hands and change clothing as often as necessary to maintain good personal hygiene.

Personnel are not permitted to eat, drink, use tobacco products, apply cosmetics, or handle or apply contact lenses in housing rooms and laboratories where animals are used.

Animal Experimentation Involving Hazards

When hazardous materials are proposed for use in animals, investigators are required to work under the appropriate containment conditions for the specific agent. The proper containment conditions are determined by EHRS, based on a risk assessment. Risks associated with the agent and the activity to be conducted are taken into consideration. Infectious agents are classified according to risk by EHRS professional staff using written institutional policies and procedures governing experimentation with hazardous biologic, chemical, and physical agents and these institutional policies are compliant with CDC/NIH guidelines. Airborne exposures to potential hazards are minimized through the use of engineering controls such as downdraft tables, fume hoods, or biosafety cabinets when using hazardous agents, necropsies on contaminated animals, and/or working with chemical hazards. Waste anesthetic gases must be appropriately scavenged.

Through ARIES (Penn's online IACUC submission application) a protocol using hazardous materials is automatically routed to EHRS for review and approval. A professional member of EHRS staff reviews the protocol. The protocol may be reviewed by up to four different disciplines in EHRS as determined by the potentially hazardous agents intended for use in the protocol (e.g. biosafety, radiation safety, industrial hygiene, laser, and chemical safety). EHRS staff considers the established PPE Program, ULAR husbandry practices and procedures, and the potential hazards of the material(s) when reviewing the protocol. In some instances, a protocol may be approved with special handling requirements that place additional protective measures to be implemented by research and husbandry staff. Prior to initiating an experiment, principal investigators work with animal facility managers to ensure that proper housing is available, and all required safeguards and animal husbandry procedures are in place. Prior to using a hazard in animal experimentation, the research staff informs the facility manager and provides training for husbandry personnel focusing on the hazards of the material(s) and the procedures necessary to minimize exposure. The signs and symptoms of exposure are also discussed.

Personal Protection

Risk assessments are used to establish the requirements for occupational medicine services and personal protective equipment (PPE) in University of Pennsylvania animal facilities. These risk assessments are a cooperative effort among the schools with animal research, EHRS and ULAR. The PPE program is maintained at a level to provide adequate protection to all personnel, regardless of individual risk. Additionally, ULAR established husbandry practices and procedures minimize husbandry and research staff exposure to animal waste and bedding. All facilities have appropriate PPE available to staff, with differing requirements based on the species and hazards used in the facilities. These PPE requirements and other facility operations are outlined in SOPs. Protective clothing and equipment are not worn beyond the hazardous-agent work area or the animal facility. Protective clothing generally consists of shoe covers, gloves, and a protective gown.

Additionally, each at-work injury or illness of a Penn student, faculty, post-doc or staff member is reported to EHRS. EHRS investigates each illness or injury and makes recommendations for remedial actions. Through its investigation, EHRS evaluates the effectiveness of the current Occupational Health and Safety Program as it applies to animal research and makes recommendations to correct any potential deficiencies identified through its reviews.

Medical Evaluation and Preventative Medicine for Personnel

A health-history evaluation is required for those personnel deemed to be "at risk", following completion of Penn Profiler or risk assessment by EHRS. Continuing periodic medical evaluations are encouraged for personnel in specific risk categories—either through Occupational Medicine or by an individual primary care physician.

If necessary, based on an individual's risk, EHRS specifies the type and model of respirator needed and will provide the special training and fit testing to assure the worker can safely wear a respirator. Occupational Medicine also conducts the medical evaluation to assure the worker has no health condition that would prohibit wearing a respirator. As part of the Hearing Conservation Program, EHRS assesses work areas within facilities where noise levels have the potential to equal or exceed 85 dB, posts clear signage at the entrance to any of these work areas, and requires anyone entering or working in the area to wear proper hearing protection. Personnel that work in these areas are provided hearing protection, instructed in its proper use, and are required to wear this equipment when in these identified/posted areas. Occupational Medicine has the responsibility for administering the audiometric testing as part of the Hearing Conservation Program. Staff members working in high noise areas are routinely evaluated as part of the Occupational Medicine program. Immunization is a key component of the Occupational Medicine program. Based on an in-person individual risk assessment, immunization is offered and strongly encouraged as medically indicated. For example, animal husbandry personnel are routinely vaccinated against tetanus, and those with a risk of exposure to specific agents such as rabies virus (e.g., if working with species at risk for infection) or hepatitis B virus (e.g., if working with human materials) are counseled and offered the appropriate vaccines to minimize their occupational risks.

Personnel are instructed to notify their supervisors of potential or known at-work exposures (injuries and accidents) and of suspected health hazards and illnesses. Procedures have been established for personnel to report all injuries, accidents, bites, scratches, and allergic reactions to Occupational Medicine, regardless of the species involved. The faculty, staff, students and contractors have received training on how and where to address medical accidents/emergencies and emergency contact information is posted near the entrances of all animal facilities. Animal technicians, veterinary staff, students, research staff, and maintenance workers who have contact with non-human primates or who have duties in nonhuman primate housing areas are screened for tuberculosis at least annually. These individuals also have access to, and have been instructed in the use of bite and scratch kits and give Herpes B Medical Alert Information cards. Personnel are required to notify their supervisors of all injuries associated with macaques, their tissues or body fluids, or caging and equipment with which the animals have had direct contact and visit the Occupational Health Office, located at 3600 Civic Center Blvd, Philadelphia (After hours emergencies are managed by Emergency Medicine department in the University of Pennsylvania hospital.) All other types of injuries on main campus are also managed at the Occupational Health Office or for after-hours at the Hospital of the University of Pennsylvania Emergency Service. Injuries at the New Bolton Center in Kennett Square can be managed at three local medical facilities, two of which have after-hours emergency medical services and are part of the University of Pennsylvania health network. Occupational Medicine doctors are trained on Herpes B exposure, and they have an SOP to follow. Occupational Medicine confirms that the ULAR attending veterinarian or designee has been informed of the incident. Occupational health evaluates these exposed individuals and provides appropriate post-exposure treatment, test sampling, and follow-up care. The ULAR veterinary staff, follow their Herpes B exposure SOP "Individuals Sustaining Macaque Bite/Scratch Wounds and Exposure" and evaluate the macaque involved with the incident and take samples for analysis. Samples are taken and shipped as per SOP "Macaque Exposure Specimen Processing, Handling and Shipping SOP to the National B Virus Resource Center, Georgia State University. The ULAR staff share the NHP test results with occupational health physician.

F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table.

See "Facilities and Species Inventory Chart" (pages 36-42).

G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment or use. In the ULAR department there is professional training group of six people that help create and implement training for the Animal Care staff as well as the research staff. The IACUC has subcommittee that

is comprised of members of the ULAR, OAW, the Training group and IACUC members that oversee and evaluate the researcher training programs.

Animal care and use training is provided by either web-based module(s) only, instructor-led sessions, or a combination of web-based modules followed by an instructor-led session.

Animal Care Technician Training: The Animal care staff join ULAR with a diverse background of education and experience. Animal care staff members are provided continuing education opportunities appropriate to their positions. Director of Husbandry Operations, has a dedicated budget specific for training opportunities for the ULAR animal care staff. Selected animal husbandry staff

members attend the National AALAS meeting every year. ULAR supports numerous animal care staff members to attend the regional Tri-Branch AALAS meeting each year (with daily transportation from campus) and we provide local AALAS memberships and transportation to Delaware Valley Branch (regional AALAS) meetings for ULAR staff members.

ULAR's Animal Care/Husbandry Trainers that provide New Employee Orientation (NEO) for all new animal caretakers; NEO includes two weeks of SOP, procedural and hands-on training. In addition, these Animal Care Trainers design and provide annual refreshers and additional training for animal caretakers based on current SOPs. Additional training opportunities are available for AALAS certifications (at the ALAT level), career ladder classes, team building skills, cultural competency & sensitivity, resume writing, and basic computer skills. The ULAR Scientist Training Division provides assistance for animal caretakers to take the LAT and LATg AALAS examinations. Staff members are selected by their supervisors, based on attendance and job performance, for work-time participation in AALAS training sessions. ULAR awards pins for passing AALAS examinations at dept-wide General Staff Meetings. Penn Human Resources provides in-house courses "Transition to Management" and "Essentials of Management" and these courses are utilized for individuals who desire to move into supervision. Animal care staff with the potential and desire to manage others, as well as staff new to supervision, are granted opportunities to take these courses. Educational topics appropriate for animal care staff are presented at each the ULAR General Staff Meetings. Attendance at General Staff meetings is required.

Training required for scientists prior to working on IACUC protocols and offered to animal technicians and other personnel involved in animal care, treatment or use includes:

- **Regulations and the IACUC.** This web-based training provides a basic understanding the roles of the IACUC and presents the federal policies, guidelines, and laws that regulate animal research. It discusses the basic parts of the protocol form as well as policies regarding specific animal use procedures that are commonly performed at Penn. It includes the humane practice of animal care and use, instruction in research or testing methods that minimize the number of animals and minimize animal pain/distress required to obtain valid results. This training must be completed by all personnel listed on an IACUC protocol prior to approval and must be updated every three years. A modified version of this online module is presented in an instructor-led course to animal technicians and other personnel involved in animal care, treatment or use. The IACUC orientation training discusses importance of the 3Rs in research and minimizing pain and distress as well as good scientific design of their studies. The IACUC has generated website with helpful information on animal research. This includes updates on new analgesics, regulation and large collection of Policies and Guidelines to help guide the PI. These documents range from IACUC operations to study design aids such as Humane Endpoints, Oncology Tumor studies, Anesthesia/Analgesic, Vaporizer and Gas Sampling, Reporting Animal Concerns, Antibody Production, Euthanasia, EAE Models, Food and Fluid Regulation, Literature Searching for Alternatives, Social Housing, Environmental Enrichment, Survival Surgery, and many others.
- **Species-Specific Training.** These trainings (an online module and an instructor-led laboratory) provide a basic understanding of handling and common bi methodologies related to particular species, as well as

general procedures (e.g. injections, euthanasia). Depending on the role(s) the individual plays on the protocol, personnel may be required to take all or some of the species-specific curriculum prior to being approved to work on the IACUC protocols.

- Occupational Health and Safety Animal Users Orientation. This web-based course reviews occupational health and safety requirements and practices, as they relate to faculty, staff, and students working with animals intended for research, teaching, or testing. Topics include: occupational medicine contact information, zoonotic considerations, laboratory animal allergies, ergonomic concerns, chemical safety, sharps safety, and best practices when working in animal facilities. Each animal user receives specific instruction on communication with Occupational Medicine or Student Health, as applicable. This training must be updated every 3 years. Radiation Safety training is required annually for the people that work with radiological hazards. A module that is specific for non-human primates emphasizes zoonotic diseases and provides a reminder for tuberculosis screening, and must be completed each year. Tuberculosis screening must also be done annually.
- Aseptic Technique Training. This is a web-based training that provides an overview of the requirements to perform surgical procedures on either USDA (e.g. sheep, dogs, pigs, cats) and non-USDA regulated animals (e.g. mice and rats). This training includes video demonstrations of proper aseptic technique. This course is required for all individuals performing survival surgical procedures.
- Physical Methods of Euthanasia (Acceptable with Conditions) Training. This is an instructor-led training, which provides an overview of the techniques and issues surrounding physical methods of euthanasia, as described by the AVMA, e.g. cervical dislocation and decapitation without anesthesia. If re-training is needed because of updates to the AVMA Guidelines, the retraining may be performed via completion of a web-based module (and requirement to pass an on-line quiz) or instructor-led training as determined by the IACUC. This is required for any individuals performing these special procedures.
- CO₂ Euthanasia in Rodents. Principles and Procedures. This is a web-based training that provides an overview of the requirements to perform euthanasia of rodents by carbon dioxide. It clarifies the needs and goals for euthanasia, reviews the new AVMA Guidelines for euthanasia by carbon dioxide, and outlines procedures that scientific and animal care staff must follow in vivaria and laboratory spaces.
- Animal Facility Orientation. Before gaining key access to an animal facility, new personnel must complete an Animal Facility Orientation for each of the facilities to which they need access. This orientation includes a facility tour by ULAR staff. During the tour, they are shown different functional areas of the facility and learn the general policies for working in animal facilities and any specific policies for that particular facility.
- ULAR Rodent Breeding Training Module. This web-based training was developed by ULAR in accordance with the IACUC policies on mouse and rat breeding and cage management, which can be found on the IACUC website. This training is required for all personnel involved in rodent breeding. The module covers important aspects of colony management, including breeding schemes and basics, overcrowding, recordkeeping, factors to consider when breeding, and troubleshooting.
- Procedures for Non-Animal Users Entering ULAR Facilities. This course is for faculty, staff, and students who do not work directly with animals or for ULAR but may need to enter animal facilities (e.g., Physical Plant employees, outside contractors, and compliance or safety staff). This course may be online or instructor-led, includes an overview of animal research and occupational health and safety, and describes procedures for entering an animal facility.

Other training opportunities may be suggested or required by the IACUC, ULAR veterinary and training staff, as well as OAW for refinement opportunities or compliance-related issues. Customized training can be provided by Penn's Training Group, Veterinary or Veterinary Technician Staff or by the OAW.

All new IACUC members complete the online IACUC curriculum that is completed by researchers and receive additional training during a 1-2 hour in-person IACUC training session with OAW staff as well as 1-2 hours on working with the ARIES IACUC Protocol Software. New members work closely with IACUC Administrative

staff during the early period of being on the IACUC. The IACUC webpage is also going to feature articles on key aspects of animal research and it will include 3Rs, Statistics, Reproducibility and Culture of Care,

This initial training includes key aspects of:

- Animal welfare regulations, history and Animal Welfare Policies,
- PHS Policy on Humane Care and Use of Laboratory Animals, US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, and the IACUC's role with NIH, HHS, and NSF funded studies,
- AAALAC history and Accreditation
- The responsibilities of an IACUC member including conflict of interest, Semi-annual program review, Semi-annual facility inspection, investigation of animal concerns, recommendations to the IO and protocol and amendment review as well as the IACUC's authority to suspend an activity involving animals.
- The protocol review training includes information on:
 - The IACUC Review process included full committee review and designated member review;
 - Define committee quorum and majority vote and other IACUC processes;
 - Special supportive protocol reviews by a veterinarian, EHRS, and Bio-security office;
 - Specific topics of the IACUC protocol form
 - Summary statement and goals
 - Animal numbers and justification
 - Alternative searches
 - Peri-operative and surgical management
 - Euthanasia and AVMA Guidelines (IACUC Guideline)
 - Endpoints and monitoring (IACUC Guideline)
 - Hazardous agents
 - Researcher Qualifications and training
 - Special considerations for protocol review as outlined in the guide
 - Penn IACUC's policies and guidelines
 - The principles of the 3Rs (Refinement, Reduction and Replacement) in animal research
- Post Approval monitoring and adverse event reporting
- The roles and responsibilities of the IO and Attending Veterinarian, New members are provided with a copy (hard copy or link to online PDF versions) of the AWA and Regulations, the PHS Policy, the *Guide for the Care and Use of Laboratory Animals*, and AVMA Euthanasia guidelines and other relevant AAALAC FAQs, position statements, or guidelines, as well as the approved Animal Welfare Assurance. Members of the animal program with specific areas of expertise also provide continuing training for IACUC members during convened meetings. Topics include the review of research procedures, statistics, 3Rs, regulatory and sponsor requirement updates, special husbandry techniques, how to conduct semiannual and other inspections, and discussions of protocol review. Additional IACUC member training may include presentations by USDA representatives and OLAW, NABR, SCAW, or PRIM&R webinars. Occasionally, consultants not directly associated with the program are invited to provide focused training (e.g. USDA, AWIC, statisticians, etc.).

IV. INSTITUTIONAL PROGRAM EVALUATION AND ACCREDITATION

The Institution's program and facilities (including satellite facilities) for activities involving animals are evaluated by the IACUC at least once every six months in accordance with the PHS Policy IV.B.1-2. Reports have been and will continue to be prepared in accordance with the PHS Policy IV.B.3. All IACUC semiannual reports include a description of the nature and extent of this Institution's adherence to the Animal Welfare Act and Regulations, PHS Policy, and the *Guide*. Any departures from the federal regulations, policies, or guidance 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 and other regulatory agencies, upon request.

The University of Pennsylvania is Category 1 — accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). All 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 three years:

1. A copy of this Assurance and any modifications thereto, as approved by the PHS.
2. Minutes of IACUC meetings, including records of attendance, activities of the Committee, and Committee deliberations.
3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.
4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Dr. Dawn A. Bonnell.
5. Records of accrediting body determinations.

B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity.

C. All records shall be accessible for inspection by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. REPORTING REQUIREMENTS

A. The Institutional reporting period is now October 1 – September 30 of each year or prescribed by OLAW. The IACUC, through the Institutional Official, will submit an annual report to OLAW by December 1st 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, Dr. Dawn A. Bonnell.
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 sections VI.A. and VI.B. of this document shall include any minority views filed by members of the IACUC.

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institutional Official

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Title: Senior Vice Provost for Research
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Signature: _____

Date: September 30, 2022

B. PHS Approving Official Name: Nicole

Lukovsky Akhsanov

Title: Senior Animal Welfare Program Specialist

Address: 6700B Rockledge Dr, Suite 2500,

Bethesda,

MD 20892-6910

Phone: 301-480-8196

Nicole L. Lukovsky-
akhsanov -S

Digitally signed by Nicole L.
Lukovsky-akhsanov -S

Date: 2022.10.03 14:44:16
-04'00'

Signature: _____

Date: 10/3/2022 - Assurance updated section III.B. only- no other changes to document approved on 7/25/2022

C. Assurance Number: D16-00045 (A3079-01)

D. Effective Date of Assurance: July 27, 2022

E. Expiration Date of Assurance: July 31, 2026

MEMBERSHIP OF THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

DATE: March 29, 2022
NAME OF INSTITUTION: University of Pennsylvania
ASSURANCE NUMBER: A3079-01

| Chairperson Name, Title, and Degree/Credentials | Bart De Jonghe PhD IACUC Chairperson PhD, Pennsylvania State University, 2006 BS, Pennsylvania State University, 2001 Served on the IACUC since 2014 and Vice Chair since 2015 Professor of Nutrition Science Associate Director, Nutrition Undergraduate Programs Department of Biobehavioral Health Sciences, School of Nursing Department of Psychiatry, Perelman School of Medicine University of Pennsylvania Translational Research Laboratory 125 S. 31st St., Room 2209 Philadelphia, Pennsylvania 19104 | | |
|---|--|---|--------------------------|
| (b) (6) | | | |
| Title*: Professor of Nutrition Science Associate Director, Nutrition Undergraduate Programs Department of Biobehavioral Health Sciences, School of Nursing Department of Psychiatry, Perelman School of Medicine | | | |
| Name of Member/Code # | Degree | Position / Specialty | PHS Policy Affiliation |
| 1 – Bart De Jonghe | PhD | Professor of Nutrition Science Associate Director, Nutrition Undergraduate Programs Department of Biobehavioral Health Sciences, School of Nursing Department of Psychiatry, Perelman School of Medicine | Scientist IACUC Chair |
| 2 – F. Claire Hankenson* (new) | DVM, MS, DACLA M | ULAR Executive Director | Attending Veterinarian |

(b) (6)

Veterinarian

Scientist

Scientist

Scientist

Veterinarian

Scientist

Nonaffiliated
Non-scientist

Veterinarian

Scientist

Scientist
(Veterinarian)

Scientist

Scientist

Scientist

Scientist- Veterinarian

| | |
|---------|--------------------------------|
| (b) (6) | Veterinarian |
| | Scientist |
| | Nonaffiliated Non-scientist |
| | Scientist |
| | Alternate- Veterinarian |
| | |

IX KEY CONTACTS (OPTIONAL)

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

Name: Dr. Dawn Bonnell
 Title: Senior Vice Provost of Research
 Institutional Official
 Address: 1 College Hall, (b) (4) Philadelphia, PA 19104
 Phone: (b) (6)
 E-mail: vpr@upenn.edu

Name: F. Claire Hankenson
 Title: Executive Director ULAR, Institutional/Attending Veterinarian
 Address: 177E OVQ ULAR 3800 Spruce Street Philadelphia PA 19104
 Phone: (b) (6)
 E-mail: Fclaire@upenn.edu

FACILITY AND SPECIES INVENTORY

DATE: March 1, 2022
NAME OF INSTITUTION: University of Pennsylvania
ASSURANCE NUMBER: A3079-01

| Location (building, site, farm name, etc. ^a) | Approx. ft ² , m ² , or acreage for animal housing | Approx. ft ² , m ² , or acreage for support or procedures | Species housed | Approx. Daily Animal Census by species |
|--|--|--|----------------|--|
| | | | | (b) (6) Mice-966 Rats-14 |
| | | | | Mice-992 Rats-45 Tree Shrews- 14 Cowbirds 65 Finches 107 |

| Location (building, site, farm name, etc. ^a) | Approx. ft ² , or acreage for animal housing | Approx. ft ² , or acreage for support or procedures | Species housed | Approx. Daily Animal Census by species |
|--|---|---|----------------|---|
| | | | | (b) (6) Mice-7,855 Swine-4 Rhesus- 24 Cynos-3 |
| | | | | Mice-6,238 Rats-13 |
| | | | | Mice-500 Rats-0 Rhesus-53 African |

| | |
|--------------------|-----------------------|
| <div>(b) (6)</div> | Green-2 Cynos-97 |
| | Mice-1,841 Rats-90 |
| | Zebrafish- 250,000 |

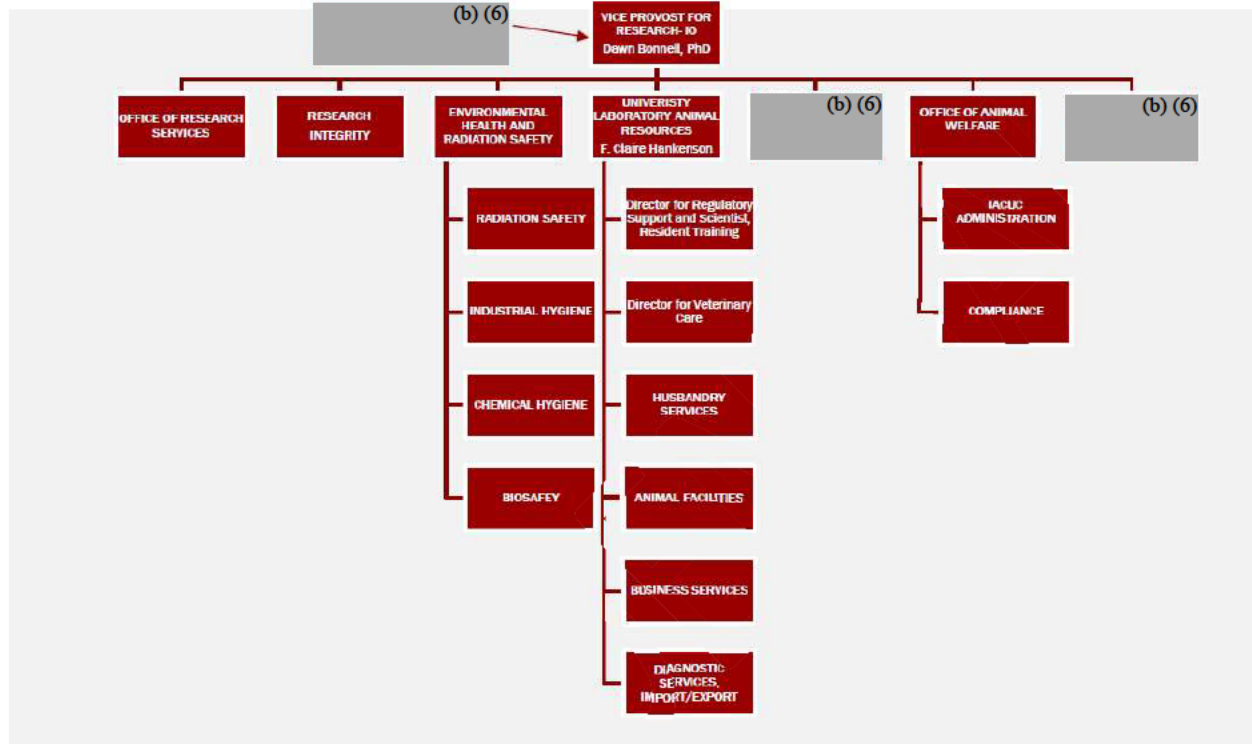
| Location (building, site, farm name, etc. ^a) | Approx. ft ² , ,or acreage for animal housing | Approx. ft ² , or acreage for support or procedures | Species housed | Approx. Daily Animal Census by species |
|--|--|---|--|---|
| (b) (4) | | | | |
| | 18,013 | 37,997 | Mice, Rats, Xenopus, Rabbits, Guinea Pigs, Swine, Sheep, Primates | Mice-13,837 Rats- 23 Guinea Pigs- 25 Rabbits-9 Xenopus-20 Sheep-5 Pigs- 29 |
| | 5,055 | 13,221 | Mice, Rats, Primates | Mice-782 Rats-204 Rhesus- 42 |
| | 4,841 | 7,591 | Mice, Rats, Musk Shrews | Mice- 3, 115 Rats-144 Hamsters- 26 Musk Shrews-72 Rhesus 10 Cyno 6 |
| | 6,940 | 9,935 | Mice, Rats, Gerbils, Marmosets | Mice-7,409 Rats-6 Gerbils-8 |

| Location (building, site, farm name, etc. ^a) | Approx. ft ² , or acreage for animal housing | Approx., or acreage for support or procedures | Species housed | Approx. Daily Animal Census by species |
|--|---|--|--|--|
| (b) (4) | | | | |
| | 6,222 | 7,632 | Cats, Dogs | Cats-54 Dogs-62 |
| | 4,018 | 2,384 | Mice, Rats, Dogs | Mice-231 Rats-37 Dogs-9 |
| | 2,060 | 1,622 | Mice, Rats | Mice -563 Rats-27 |
| | 124,517 | 69,359 | Horses, ponies, cattle, swine, sheep, goats, dogs, rabbits and potentially rats and mice | Dog- 120 |
| | N/A | N/A | Cattle | 60 |

| Satellite Facilities: Laboratory, Unit, or Building | Gross Square Feet | Species | Average Daily Inventory |
|--|-------------------------|---------------------|-------------------------------|
| (b) (4) | 415 | Mice, rats | 22 m, 15 r |
| | 50 | Mice | 75 m |
| | 300 | Swine | 2 sew |
| | 20 | Mice | 0-5 m |
| | Hood | Xenopus tadpoles | 10 x |
| | 102 | Mice | 0-5 m |
| | 2860 | Zebra Fish | 100,000 f |
| | 20 | Birds | 15 F |
| | 1500 | Mice, Rats | 820 m, 53 R |
| | 15, 35 | Birds | 43 b |
| | 45 | Mice, Rats | 10 m |
| | 1200 | NHP | 42 nhp |
| | 190 | Mice | 0-8 m |
| | 58 | Mice | 0-8 m |
| | 180 | Rats | 25 r |
| | 10,000 | Mice, Rats | 2399 m, 88 r |
| | 1200 | Rats, Mice | 262 r 21 m |
| | 61 | Tree Shrews | 26 ts |
| | 150 | Mice, Rats | 35 m |

| Satellite Facilities: Laboratory, Unit, or Building | Gross Square Feet | Species | Average Daily Inventory |
|--|-------------------------|------------|-------------------------------|
| (b) (4) | 100 | Rats, Mice | 75 m |
| | 150 | Mice | 10 m |
| | 300 | Rat | 110 R |
| | 100 | Mice | 30m |
| | 600 | Mice | 100m |
| | 5 | Zebrafish | Incubator |
| | 5 | Zebrafish | Incubator |
| | | | |
| | | | |

UNIVERSITY OF PENNSYLVANIA ANIMAL CARE AND USE MANAGEMENT



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