

**SOUTHERN ILLINOIS UNIVERSITY
EDWARDSVILLE
D16-00304 (A3486-01)
Animal Welfare Assurance for Domestic Institutions**

I, Jerry B. Weinberg, Associate Provost for Research and Graduate Dean, as named Institutional Official for animal care and use at Southern Illinois University Edwardsville (SIUE), 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**, 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:
 - a. SIUE Main Campus, Edwardsville (Includes Sci Lab West, Sci Lab East and Vadalabene Ctr.)
 - b. SIUE School of Pharmacy, Edwardsville, IL
 - c. SIUE School of Dental Medicine, Alton, IL (It is a 30 minute drive from the Edwardsville campus to the Dental School campus in Alton, IL.)

- B. The following are other institution(s), or branches and components of another institution:
Does not apply.

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."

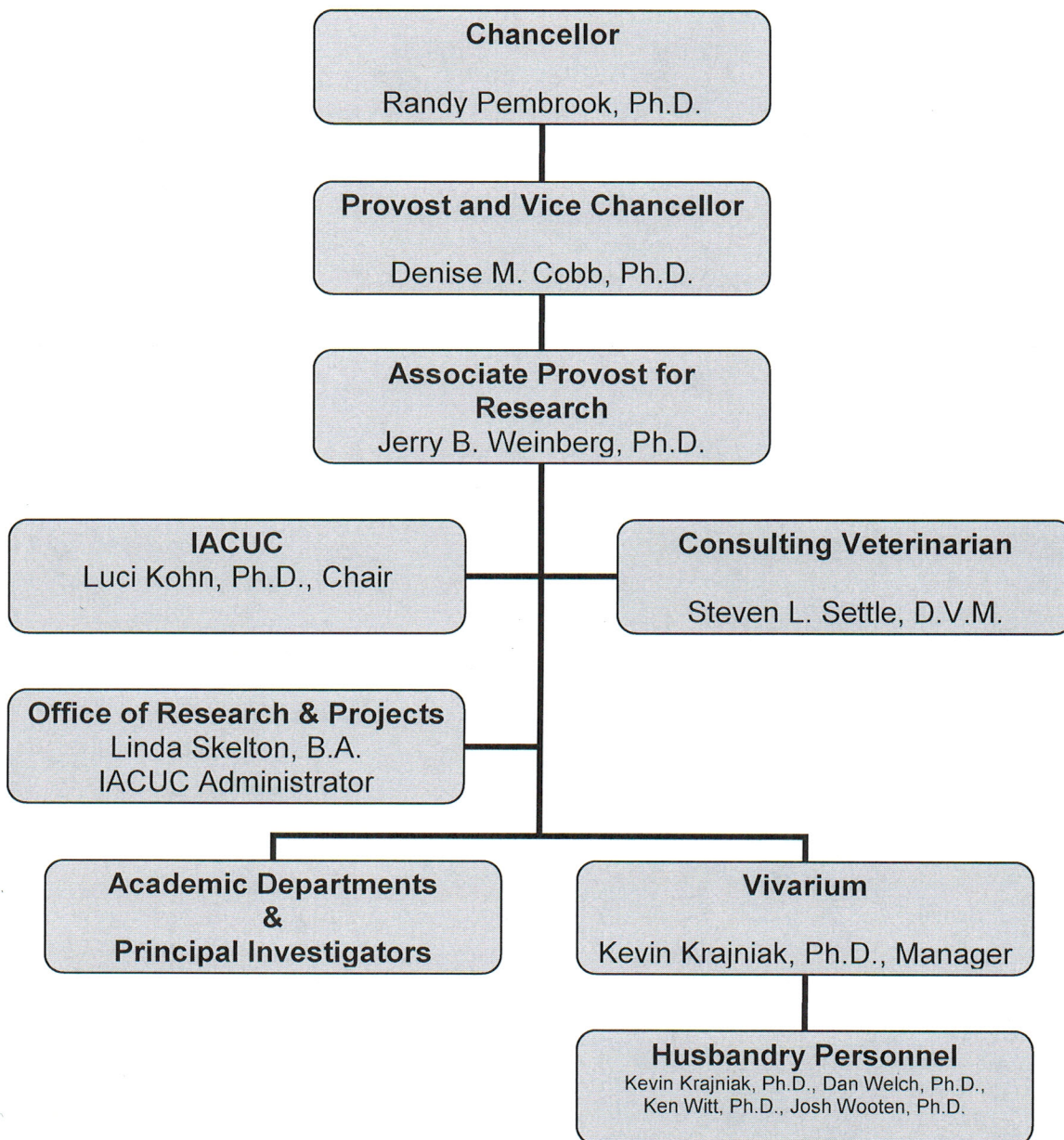
- C. This institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand 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 (sub award) 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 PHS Policy are as follows:



Note: As indicated above, there are direct and open lines of communication between the IACUC and the Institutional Official (IO) and between the Veterinarian and the IO.

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

- Name: Steven L. Settle

Qualifications:

- Degrees: D.V.M., University of Missouri-College of Veterinary Medicine; BA, Biology from William Jewell College.
- Professional Licenses and Memberships: Missouri State Veterinary License, Illinois State Veterinary License, member of American Society of Laboratory Animal Practitioners.

Dr. Settle is a Doctor of Veterinarian Medicine who has graduated with his D.V.M degree from the University of Missouri-College of Veterinary Medicine which is a veterinary school accredited by the AVMA Council on Education. Training or experience in laboratory animal medicine or in the use of the species at the institution: Dr. Settle's experience with laboratory animal medicine stretches over many years beginning in 1987 – 1990 when he was the Senior Research Medical Technologist in the Pharmacology Department at Washington University School of Medicine in St. Louis, Missouri and from 1991 through 2010 as a Research Biologist in Molecular Pharmacology, employed by the Monsanto Corporate Research Office at Monsanto Company/Pfizer Inc., in St. Louis, Missouri and from 2010-2013, surgical veterinarian with the St. Louis County Animal Care and Control and from 2013-present, Mallinckrodt Pharmaceuticals as Principal Research Pharmacologist. Dr. Settle has been this institutions consulting veterinarian for the IACUC for since 1989.

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

Time Contributed to Program: Dr. Settle is present at the Institution an average of approximately three hours per month. One-hundred percent of this time is contributed to the animal care and use program. In addition, Dr. Settle contributes on average approximately five hours per month to the program while off-site reviewing protocols and providing consultation on various program related topics.

- Provisions for Back-up Veterinary Care : To ensure adequate veterinary care of research animals should Dr. Settle not be available, we have in place a backup veterinarian:

- Name: John Patrick Long DVM, DACLAM

Qualifications:

Dr. Long is Doctor of Veterinarian Medicine and Professor and Chairman in the Department of Comparative Medicine at Saint Louis University School of Medicine, St. Louis, MO. Dr. Long possesses experience in laboratory animal science and medicine and satisfies the requirement of the definition of attending veterinarian as described by the USDA Animal Welfare Regulations as he has graduated with his doctorate from

Louisiana State University which is a veterinary school accredited by the AVMA Council on Education.

His degrees include:

- Laboratory Animal Medicine Fellowship, Washington University 06/97-05/00
- Doctor of Veterinary Medicine, Louisiana State University 04/93-04/97
(AVMA Accredited veterinary school)
- BS, Biology, Southern Illinois University 08/87-05/91

Dr. Long's Board Certifications and Licensures include the following:

- Diplomate, American College of Laboratory Animal Medicine 09/03- Present
- Veterinary licensure, State of Illinois 05/97-Present
- Veterinary licensure, State of Missouri 05/00-Present
- DEA licensure, Federal Schedule 1-5 10/00-Present
- BNDD licensure, State of Missouri 10/00-Present

Responsibilities:

Dr. Long has delegated program authority and responsibility for the Institution's animal care and use program including access to all animals in the event that Dr. Settle is unavailable.

Time contributed to program:

Dr. Long provides backup veterinarian care as needed if Dr. Settle is unavailable. He is not an employee of the institution so he is neither full- or part-time, however he is on call at all times when Dr. Settle is unavailable.

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 Chancellor, as Chief Executive Officer (C.E.O.), has delegated to the Institutional Official the authority to appoint the members of the IACUC. In accordance with the Health Research Extension Act of 1985, this delegation of authority is specific and is in writing. The IACUC consists of at least five members, and its membership meets the composition requirements of PHS Policy, Section IV.A.3.b. Part VIII is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties and institutional affiliations (see attached).

D. The IACUC will:

1. **Review at least once every six 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:**

- The IACUC will meet at a convened meeting at least once every six months to review the Institutional Program for Humane Care and Use of Animals.
- The Committee uses the *Guide* and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review.
- To facilitate the evaluation, the Committee will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website.

- The evaluation will include, but not necessarily be limited to, a review of the following:
 - a. Institutional and Individual Responsibilities
 - b. IACUC Membership and Functions;
 - c. IACUC Member Experience and Training
 - d. IACUC Records and Reporting Requirements;
 - e. Husbandry and Veterinary Care (all aspects);
 - f. Personnel Qualifications (Experience and Training);
 - g. Occupational Health and Safety;
 - h. Emergency and Disaster Planning.
 - i. Security (personal and facility)

 - If program deficiencies are noted during the review, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel.

 - No member will be involuntarily excluded from participating in any portion of the reviews.
2. **Inspect at least once every six 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 six months all or most (no less than two voting) members of the IACUC will visit the institute's facilities where animals are housed or used, i.e., holding areas, animal care support areas, storage areas, procedure areas, and laboratories where animal manipulations are conducted. Equipment used for transporting of the animals is also inspected.

 - The Committee uses the *Guide* and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review.

 - To facilitate the evaluation, the Committee uses a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website.

 - If deficiencies are noted during the inspection, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel.

 - No member will be involuntarily excluded from participating in any portion of the inspections.

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:

- Individual IACUC members will convey their observations to the IACUC Chairperson, or his or her designee, who, in turn, will draft the reports using the sample OLAW Semiannual Report to the Institutional Official format from the OLAW website.
- The reports will contain a description of the nature and extent of the institution's adherence to the *Guide* and the PHS Policy.
- The reports will identify specifically any departures from the provisions of the *Guide* and the PHS Policy, and state the reasons for each departure. If there are no departures the reports will so state.
- Approved departures must be approved as part of a protocol, protocol amendment, or other written document, using either FCR or DMR as delineated below in Section III.D.6.
- Departures from the provisions of the *Guide* that are not approved by the IACUC prior to implementation are considered non-compliant with PHS Policy. Those departures will be promptly reported to OLAW and will subsequently be included in the semiannual report to the Institutional Official (IO). Also, the IACUC will develop a reasonable plan for discontinuing the departure or for having the departure properly reviewed and approved.
- The reports will distinguish significant deficiencies from minor deficiencies. If program or facility deficiencies are noted, the reports will contain a reasonable and specific plan and schedule for correcting each deficiency.
- If some or all of the institution's facilities are accredited by AAALAC International the report will identify those facilities as such.
- Copies of the draft reports will be reviewed, revised as appropriate, and approved by the Committee.
- The final reports that will be submitted to the IO will be signed by a majority of the IACUC members and will include any minority opinions. If there are no minority opinions, the reports will so state.
- Following completion of each evaluation, the completed report will be submitted to the Institutional Official in a timely manner.
- Deficiencies will be tracked by the facilities manager, the IACUC Chair, and the IACUC Administrator to ensure that they are appropriately resolved.

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

- Any individual may report concerns to the IO, IACUC Chair, Institutional Veterinarian, or any member of the IACUC.
- Concerns can be reported verbally either by phone or in person, or in writing either electronically or hard copy.
- Notices are located in the animal facilities advising individuals how and where to report animal welfare concerns and stating that any individual who, in good faith, reports an animal welfare concern will be protected against reprisals.
- The IACUC Administrator provides information to individuals regarding their ability to contact the IACUC of any concerns regarding the care and use of animals in research by providing articles in the ORP's publication, The Researcher, and via the ORP website.
- Contact information, including phone numbers and email addresses, for the IACUC Chair, Administrator, Institutional Official and all IACUC members, is listed on the ORP website and printed in ORP and campus directories which are distributed campus wide.
- All reported concerns will be brought to the attention of the full Committee.
- If necessary the IACUC Chair will convene a meeting to discuss, investigate, and address any reported concern.
- Reported concerns and all associated IACUC actions will be recorded in the IACUC meeting minutes.
- The Committee will report such actions in writing to the IO and, as warranted, to OLAW. Reports to the IO may be either via meeting minutes, semiannual report of IACUC evaluations, or separate document. Reports to OLAW will be in writing and through the IO. Preliminary reports to both the IO and OLAW may be made verbally.
- SIUE protects confidentiality of those who report concerns as well as anyone against whom allegations are directed, while allegations are under investigation. As required under the Animal Welfare Act, any individual reporting concerns to the SIUE IACUC will be protected from reprisal.

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:

- Recommendations regarding any aspects of the institution's animal program or facilities are discussed and developed by the Committee.

- The Committee's recommendations are included in the IACUC Meeting Minutes or a report of the IACUC's evaluations or a separate letter. Such documents are reviewed and approved by the Committee and then submitted to the IO.

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:

- Protocols are received by the Ethical Compliance Officer (ECO) in the Graduate School's Office of Research and Project via the KualI electronic protocol system. The KualI system applies a protocol number to the protocol and the ECO does a preliminary screening to make sure all necessary documents are included.
- Members are notified via KualI communication by assigning the protocol to each member and applying it to a monthly meeting Agenda for the next regularly scheduled monthly meeting. This is done one week prior to the meeting to give members a chance to read the protocols in preparation for the convened meeting.
- No member may participate in the IACUC review or approval of a protocol in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.
- The IACUC may invite consultants to assist in reviewing complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also members of the IACUC.
- Any use of telecommunications will be in accordance with NIH Notice NOT-OD-06-052 of March 24th, 2006, entitled Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals.
- In order to approve proposed protocols or proposed significant changes in ongoing protocols, the IACUC will conduct a review of those components related to the care and use of animals and determine that the proposed protocols are in accordance with the PHS Policy. In making this determination, the IACUC will confirm that the protocol will be conducted in accordance with the Animal Welfare Act insofar as it applies to the activity, and that the protocol is consistent with the *Guide* unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the protocol conforms to the institution's PHS Assurance and meets the following requirements:
 - a. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
 - b. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.

- c. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
- d. The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.
- e. Medical care for animals will be available and provided as necessary by a qualified veterinarian.
- f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
- g. Methods of euthanasia used will be consistent with the current recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.

Full- Committee Review (FCR)

- The IACUC reviews protocols at full convened committee meetings unless they decide to use the designated member method (DMR).
- Meetings are conducted using Robert's Rules in person at a convened meeting and may combine the use of teleconferencing if necessary. There must be a quorum in order to conduct meetings. The IACUC Chairperson leads the meetings.
- The IACUC's voting process consists of a member making a motion to the Chair, another member seconds the motion, the Chair then asks the committee to vote by stating yes, no, or abstain. The Chair will then announce the result of the members vote.
- The possible outcomes of a FCR are as follows:
 - a. Approval
 - b. Require Modifications (to secure approval)
 - c. Approval Withheld
- Review of Required Modifications subsequent to FCR. When the IACUC requires modifications (to secure approval), of a protocol, such modifications are reviewed as follows:
 - a. FCR or DMR following all applicable procedures as delineated in the PHS Policy and elsewhere in Part III.D.6 of this Assurance.

OR

- b. DMR if approved unanimously by all members at the meeting at which the required modifications are developed/delineated AND if all IACUC members have previously agreed in writing (e.g., documented a policy) that the quorum of members present at a convened meeting may decide by unanimous decision to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.

Minor modifications of an administrative nature, i.e., typographical or grammatical errors, required signatures, etc. may be confirmed by IACUC administrative/support personnel.

Designated Member Review (DMR)

- Generally, the FCR method will be used. However, should a situation warrant it, the institution or the IACUC may want to use the designated-member review (DMR) method. In such instances, the protocol will be distributed to all IACUC members to allow all members the opportunity to call for FCR; records of polling of members to obtain concurrence to use the DMR method, and approval of protocols via DMR are maintained and recorded in the minutes of the next convened IACUC meeting.
- If FCR is requested, approval of those protocols may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present.
- If FCR is not requested at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, may be assigned to review those protocols and have the authority to approve, require modifications in (to secure approval) or request full committee review of those protocols.
- Other IACUC members may provide the designated reviewer with comments and/or suggestions for the reviewer's consideration only. That is, concurrence to use the DMR method may not be conditioned.
- After all required modifications are made, a final revised protocol, i.e., an identical document with all required modifications included, is submitted to all designated reviewers for review and approval (i.e. to secure approval, each DMR review will include identical copies of the protocol).
- If multiple designated reviewers are used, their decisions must be unanimous; if not, the protocol will be referred for FCR.
- The possible outcomes of a DMR are as follows:
 - a. approval of the protocol
 - b. Require modifications to the protocol (to secure approval)
 - c. Referral for a FCR.

DMRs are not authorized to withhold approval.

- There are no alternate processes or procedures for expedited reviews.
- 7. Review and approve, required modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities according to PHS Policy at IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:**
- Review and approval of significant changes are handled in the same manner as new protocols. See Paragraph III.D.6. above.
 - Significant changes described in 1.a.-g., below, must be approved by one of the valid IACUC approval methods described in the PHS Policy IV.C.2., that is FCR or DMR, including changes:
 - a. from nonsurvival to survival surgery;
 - b. resulting in greater pain, distress, or degree of invasiveness;
 - c. in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
 - d. in species;
 - e. in study objectives;
 - f. in Principal Investigator (PI); and
 - g. that impact personnel safety.
 - A significant change that may be handled administratively according to an existing IACUC-reviewed and -approved policy without additional consultation or notification is up to 10% increase in previously approved animal numbers (PHS Policy IV.D.1.a.).
- 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 at IV.C.4. The IACUC procedure to notify investigators and the institution of its decisions regarding protocol review are as follows:**
- Principal Investigators are notified by the Quali electronic protocol system with an e-mail notification which includes a scanned copy of a letter from the IACUC Chairperson.
 - If the IACUC's decision is to require modifications to secure approval, those modifications will be requested in writing to the investigator electronically via the Quali electronic system and/or by use of an email.
 - 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

- The Institutional Official is notified by receiving a copy of the PI's notification letter and/or a copy of the IACUC meeting minutes.

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 at IV.C. 1-5. The IACUC procedures for conducting continuing review are as follows:

- Post-approval Monitoring at SIUE is conducted as follows:
All ongoing activities are monitored by the animal care and use staff on a continual basis. We have an animal facilities manager for each animal facility. This manager is required to be a SIUE faculty member who has taken the appropriate animal care and use training, and who has met the Occupational Health requirements for health records and vaccination histories. In most cases, although, not required, the facility manager also serves on our IACUC. This manager monitors daily the activities of the animal facilities at SIUE and is in charge of reporting any deficiencies to the ORP. Our Semi-annual Inspections and Program Review also serve as another oversight mechanism of our animal facilities and post approval monitoring of protocols. In addition, each Principal Investigator (PI) on a current animal care and use protocol is required to submit annually a continuing review report to the IACUC for review. In addition to the semi-annual inspection, the IACUC will, either by full committee or by a sub-committee, visit the animal facility more often than twice a year as needed. Our Veterinarian is always on call to visit or consult with the PIs or the facilities manager. Our Veterinarian is available to provide consultation or physically assist PIs with any procedure, including surgical procedures, that may be requested by the PI or that may be determined by the IACUC.
- USDA Regulated Species – Protocols are (would be*) reviewed by a member or members of the IACUC at least annually. *Currently, there are no USDA covered species at SIUE.
- Non-USDA Regulated Species – Non-USDA regulated species protocols are reviewed by a member or members of the IACUC at least annually.
- Annual protocol reviews are recorded in the IACUC meeting minutes. The IACUC meeting minutes are reviewed and approved by the Committee. Reviews are conducted in either the month prior to or including the month of initial approval but before the date of initial approval. All IACUC members are given the opportunity to participate in the reviews and all reviews are documented in writing and made available to the IACUC members via the electronic Quali protocol system.
- Protocols are approved for a maximum of 36 months. That is, all protocols expire no later than the three-year anniversary of the initial IACUC review.
- If activities will continue beyond the expiration date, prior to expiration of the original or preceding protocol a new protocol must be submitted, reviewed, and approved as described in Part III.D.6. above.

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

- The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the *Guide*, the institution's Assurance, or IV.C.1.a.-g. of the PHS Policy.
- Only the IACUC has the authority to suspend an animal activity after review of the matter at a convened meeting of a quorum of the IACUC and the suspension vote of a majority of the quorum present.
- If the IACUC suspends an activity involving animals they will take appropriate corrective action, and report that action with a full explanation in writing to OLAW.

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

1. Administration/management.

- The Office of Research and Projects is responsible for the overall management (ensuring development, implementation, monitoring, etc) of the Occupational Health and Safety Program for Personnel involved in the care and/or use of laboratory animals. The Office of Research and Projects, the IACUC Chairperson, and the IACUC Facilities Manager all contribute to the program. SIUE Health Services will perform all medical services.

2. Scope.

- The program covers all personnel involved in laboratory animal care and/or use at SIUE. Participation in the program is required. However, individuals who wish to decline to provide their health history must do so in writing and that individual will not be allowed to participate in any activities of the project that involve animals including access to the animal facility. In those cases where they do provide their health history but decline to receive the required vaccinations (e.g. religious reasons, cost, etc.), they shall sign the SIUE Vaccination Declination form prepared by the SIUE legal office. Signing this form will allow them to participate in activities that include animals, but they will do so without the University's legal support.

3. Hazard Identification and Risk Assessment.

- The program is based on hazard identification, risk assessment, and developing and implementing measures to minimize identified hazards and risks.
- Potential hazards such as chemical cleaning agents, allergens, and zoonosis will be monitored on a continuing basis by the IACUC Facilities Manager.

- The IACUC includes hazard identification in its semi-annual facility inspections. Also, the Office of Emergency Management and Safety conducts inspections.

4. Health Histories and Evaluations.

- It is the policy of SIUE that all individuals who will have significant contact with live vertebrate animals used for scholarly or instructional activities are required to have a current medical history, physical examination, and appropriate vaccinations/testing prior to any exposure to the animals.
- As part of Occupational Health and Safety (OH&S) program, these individuals must have on file with a health care professional, e.g., a physician or nurse, a completed health history that meets the federal, state, and local HIPAA regulations.
- The individual's health histories are reviewed and maintained by their own personal health care professional, or if they are a student, they can be maintained by a SIUE Student Health Services health care professional. The Medical History form includes personal health history and record of immunizations for known infectious agents (i.e. tetanus for all and rabies for certain wildlife species). Individuals may formally refuse receipt of immunization(s) by completing a declination form.
- The Individual will provide the health care professional with the health history form and a cover letter listing the risks related to working with and/or caring for animals used for research and instruction at SIUE, which will allow the health care professional to make a meaningful risk assessment. These documents are made available on the SIUE IACUC website. The health care professional will review the individual's personal health history and conduct a physical examination. Based on the animals used by the individual, as specified on the health history form, appropriate vaccinations and testing will be offered. The health care professional will record all vaccinations or testing administered on the health history form. If the individual declines the vaccination(s), they are then required to complete the Vaccination Declination form, also provided on the IACUC website. The health care professional will check the appropriate box on the form that states whether or not the individual's medical status will put the individual at risk, based on the animals specified, provide any necessary comments, sign, and date the form. The individual will read, sign, and date his/her section of the form. The health care professional will notify the ORP that the individual is cleared to work with animals by making a copy of only Part A of the Medical History Form and the Declination Form (if it was needed), giving the copies to the patient, who will then return Part A to the ORP. Part B of the form will not be copied. The original will be kept by the individual. The Medical History form was developed in collaboration with the Director of the SIUE Student Health Services who plays a continuing role in providing support and services for SIUE's OH&S program.
- All personnel who handle animals are required to complete a web-based training course on animal care which includes training on OH&S rules including, but not limited to, lab safety, personal hygiene, equipment monitoring, reporting requirements for injury, bites,

scratches, and allergies. This training requirement must be completed prior to engaging in any work on the approved animal care and use protocol.

- In the event of an injury occurring in the lab, Student Health Services will provide appropriate care for students. Faculty and staff may seek health care from either the Urgent Care facility which is less than 5 miles from campus or from Anderson Hospital which is less than 15 minutes from campus. Faculty and staff may also seek health care from their personal health care provider.

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5. Common Identified Hazards and Risks

- Allergic reactions are among the most common conditions that adversely affect the health of personnel working with laboratory animals.
- Major sources of allergens include rodent urine and saliva.
- Other potential hazards include chemical cleaning agents, slips, trips, and falls, bites and scratches, and zoonotic agents.

6. Procedures in Place to Alleviate Hazards and Minimize Risks.

- Measures taken to minimize exposure include the following: education, protective clothing, gloves, and hand washing.
- To reduce aerosol exposure, the use of bedding dump stations, appropriate hoods or laminar flow benches/cabinets, and/or other respiratory protection, e.g., N95 masks, are worn when performing cage changing and/or handling dirty bedding.
- Training - The Office of Research & Projects, the IACUC Chair, and the Facilities Manager are responsible for assuring that all personnel (faculty, staff, and students) working with animals and/or providing animal care are properly trained in: (1) animal husbandry, (2) occupational hazards, and (3) personal hygiene associated with animal care.
- Online training for animal care entitled Collaborative Institutional Training Initiative (CITI) Program, developed by the University of Miami, is provided via a link on the ORP website. Certificates of Completion for completing the training are required to be submitted with the protocol for each person associated with the research project. Certification is good for three years and is kept electronically in the ORP office. Training will include instruction in proper animal care (handling, feeding, sanitation and cleaning, animal requirements, etc.). Instruction includes information concerning: zoonosis, hazards such as bites, allergic reactions, dealing with contaminated materials, etc., and emergency procedures.
- The principal investigators, along with the departmental safety officer, the Office of Research & Projects, the IACUC Chair, and the Facilities Manager are required to

assure that all personnel participating on their projects receive training in animal husbandry, personal hygiene, and occupational health.

- Personal Hygiene - Personal cleanliness is essential in order to maintain a healthy environment for laboratory animals and for animal care facility workers (professional and custodial). It is the responsibility of the Facilities Manager (or as officially delegated by that person) to assure that these personal hygiene guidelines are followed. Personnel shall wash regularly before and after handling laboratory animals, animal feed, animal cages, or any other material that might come into contact with the animals. SIUE shall provide appropriate protective clothing including gloves, masks, head covers, coats, coveralls, and shoe covers for all workers to wear while in the animal care facility. Animal facility garments shall be laundered or disposed of by the University. Commercial laundering services are permissible unless the garments have been exposed to infectious or otherwise potentially injurious microbic agents or toxic substances. In such cases, the University must decontaminate the garments.

7. Immunizations.

- Vaccination against tetanus is required.
- Individuals who decline vaccination must do so in writing. To date, no covered personnel have declined vaccination. University Health Services will provide the vaccination upon request.

8. Precautions taken during pregnancy, illness or decreased immunocompetence.

- Personnel are advised during training that if they are planning to become pregnant, are pregnant, are ill, or have impaired immunocompetence that they should consult a health care professional/physician regarding such conditions and how they might pertain to their working with laboratory animals. If warranted, any work restrictions and/or accommodations are coordinated among the individual, his/her health care professional, human resources, etc.

9. Provisions for personnel who are not involved in animal care and/or use but nevertheless need to enter areas when animals are housed or used.

- The housekeeping staff and the university facilities staff is not routinely allowed access to the animal facilities.
- In situations where housekeeping, maintenance, or other non-animal care and use personnel must access the animal rooms, they are briefed on appropriate precautions and provided any appropriate PPE and are then are permitted in for a limited amount of time. A member of the animal care staff will be available for escort if needed. If there is extensive or prolonged work to be done the animals are removed prior to the individuals being allowed into the room.

10. Availability and procedures for treatment in the event of bites, scratches, illness or injury.

- All Staff and students have free access to the health center in the event of an animal related injury, or bite. Treatment is free in most cases or subject to a small fee (i.e. \$10.00) and records are maintained by the Health Center.
- If required, treatment is also available at the local hospital – Anderson Hospital, Maryville IL (approx. 10 minutes from campus).

11. Procedures/program for reporting and tracking injuries and illnesses.

- The Facilities Manager is responsible for zoonosis surveillance.
 - The Facilities Manager must also maintain records of any bite wounds and unusual illnesses and communicate that information to the University Health Services Office. Occupational injuries are monitored by the Environmental Health and Safety Office (through the Human Resources Department).
 - Report of all work-related illness and/or injury is mandatory. This requirement is covered and during OH&S training and Animal Care & Use Training.
 - Bite wounds or unusual illnesses must be reported to the IACUC Facilities Manager and to the Health Services office. The IACUC Facilities Manager is responsible for notifying the IACUC of any and all of these situations immediately as they occur.
- 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 Part X, the Facilities and Species Inventory table.
- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

1. IACUC Training

- The orientation process for new IACUC members at SIUE will consist of a meet and greet of current members, a tour of the animal facilities on campus, an overview of the Inspection and Program Review checklists and distribution of the following resources: Each new IACUC member will be provided with a copy of the following:
 1. The PHS Policy for the Humane Care and Use of Laboratory Animals;
 2. The National Research Council (NRC) *Guide for the Care and Use of Laboratory Animals*;
 3. The ARENA/OLAW IACUC Guidebook;
 4. The AVMA Guidelines on Euthanasia;
 5. A copy of this Assurance.
- All members of the IACUC will complete the Essentials for IACUC Members Curriculum located at the American Association for Laboratory Animal Science website,

www.aalaslearninglibrary.org or the Collaborative Institutional Training Initiative website, www.citiprogram.org

- All IACUC members will visit the OLAW website at least semi-annually and will complete the IACUC tutorial module (initial visit) and will familiarize themselves with the other pertinent modules and information, e.g., OLAW FAQs, Policies and Laws, Guidance, Educational and other Resources.
- Attendance at an IACUC 101, IACUC 102, IACUC Advanced, PRIM&R/ARENA IACUC meeting, or similar course may be substituted for any required IACUC training session.

2. Animal Care and Use Personnel

- All personnel performing procedures using animals must be identified in the Institutional Animal Care and Use Protocol.
- A description of each individual's qualifications, experience and/or training with the specific animal species, model and procedures must be available for IACUC review.
- Any person needing additional protocol-specific training will be identified during the review process and such required training will be a condition of approval of the protocol.
- All persons involved in animal care and use will be required to attend an orientation seminar given by the IACUC Chair, Consulting Veterinarian, or other qualified individual(s), which covers the laws and regulations covering laboratory animal care and use with an emphasis on the contents of the NRC Guide and the 3R's. The training includes training or instruction on research or testing methods that minimize the numbers of animals required to obtain valid results and limit animal pain or distress as well as other requirements delineated in 9 CFR, Part 2, Subpart C, Section 2.32(c).
- Specifically, as applicable, training and instruction of personnel must include guidance in at least the following areas:
 1. Humane methods of animal maintenance and experimentation, including:
 - a. The basic needs of each species of animal;
 - b. Proper handling and care for the various species of animals used by the facility;
 - c. Proper pre-procedural and post-procedural care of animals; and
 - d. Aseptic surgical methods and procedures;
 2. The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress;
 3. Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility;
 4. Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of

the facility. No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act;

5. Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information:
 - a. On appropriate methods of animal care and use;
 - b. On alternatives to the use of live animals in research;
 - c. That could prevent unintended and unnecessary duplication of research involving animals; and
 - d. Regarding the intent and requirements of the Animal Welfare Act and USDA-APHIS Regulations

- On-line training may be used and accepted in lieu in-house training. Any use of on-line training to fulfill training requirements must be approved by the IACUC. Approval and completion of on-line training will be documented.
- Specialized Training: Training in experimental methods, i.e., specific animal manipulations and techniques and in the care of new and nontraditional laboratory animal species, will be conducted based on the types of research being conducted and the species being used at the institution.
- For investigators transferring from other facilities at which they have received similar training, verification of previous training may be accepted in lieu some Institutional required training. Acceptance of previous training in lieu of the Institution's training is solely at the IACUC's discretion.
- Once the training has been completed by personnel involved in animal care, treatment, or use, an electronic copy of the Certificate of Completion of Training, sent by the CITI Program, is sent to the IACUC Administrator who stores the certificates in an email file. The IACUC Administrator also attached a hard copy to the protocol.

IV. INSTITUTIONAL PROGRAM EVALUATION AND ACCREDITATION

- A. All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past six months and will be reevaluated by the IACUC at least once every six 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.

- B. This Institution is Category 2 — not accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request. The report of the most recent evaluations (program review and facility inspection) is attached.

V. RECORDKEEPING REQUIREMENTS

- A. This institution will maintain for at least three years:
1. A copy of this Assurance and any modifications thereto, as approved by PHS.
 2. Minutes of IACUC meetings, including records of attendance, activities of the committee, 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, Associate Provost for Research and Graduate Dean.
 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 and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. REPORTING REQUIREMENTS

- A. This institution's reporting period is January 1 – December 31st. The IACUC, through the Institutional Official, will submit an annual report to OLAW on January 31st of each year. The 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 IACUC membership. If there are no changes to report this institution will provide OLAW with written notification that there are no changes.
 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, Associate Provost for Research and Graduate Dean.
 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. of this document shall include any minority views filed by members of the IACUC.

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official

Name: Jerry B. Weinberg

Title: Associate Provost for Research and Graduate Dean

Name of Institution: Southern Illinois University Edwardsville

Address: *(street, city, state, country, postal code)*

Graduate Studies and Research
Southern Illinois University Edwardsville,
Campus Box 1046
Edwardsville, IL 62025

Phone: 618/650-3010

Fax: 618/650-3523

E-mail: jweinbe@siue.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: 

Date: 10/12/18

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

Name/Title:

Neera Gopee, D.V.M., Ph.D., DACLAM, DABT
Veterinary Medical Officer
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700 B Rockledge Drive
Suite 2500, MSC 6910
Bethesda, Maryland 20892
gopeenv@od.nih.gov

Signature: 

Date: 11-02-2018

Assurance Number: 016-00304 (A3486-01)

Effective Date: 11-02-2018

Expiration Date: 11-30-2022

VIII. Membership of the IACUC

| Date: October 9, 2018 | | | |
|-----------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|--------------------------------------------------------------|----------------------------------------------|
| Name of Institution: Southern Illinois University Edwardsville | | | |
| Assurance Number: D16-00304 (A3486-01) | | | |
| IACUC Chairperson | | | |
| Name*: Luci Kohn | | | |
| Title*: Associate Professor | | Degree/Credentials*: Ph.D., Biology | |
| Address*: (<i>street, city, state, zip code</i>) SIUE, Biology Department Campus Box 1651 Edwardsville, IL 62026 | | | |
| E-mail*: lkohn@siue.edu | | | |
| Phone*: *: 618-650-2394 | | Fax*: 618-650-3174 | |
| IACUC Roster | | | |
| Name of Member/ Code** | Degree/ Credentials | Position Title *** | PHS Policy Membership Requirements**** |
| M1. Kevin Krajniak | Ph.D., Biology | Professor | Scientist (voting) |
| M2. Guim Kwon | Ph.D., Pharmacy | Professor | Scientist (voting) |
| M3. Lisa McCormick | High School Diploma | Founder of Partners for Pets rescue and rehab facility | Nonscientist & Non-affiliated (voting) |
| M4. Vance McCracken | Ph.D., Biology | Associate Professor | Scientist (voting) |
| M5. Megan Robb | MA, ATR-BC, LPC, NCC., Art Therapy Counselor | Associate Professor | Nonscientist (voting) |
| M6. Steve Settle | D.V.M | Consulting Veterinarian | Veterinarian (voting) |
| M7. Richard Essner | Ph.D., Biology | Professor | Scientist (voting) |
| M8. Dan Welch | Ph.D., Dental Medicine | Associate Professor | Scientist (voting) |
| M9. Josh Wooten | Ph.D., Applied Health | Associate Professor | Scientist (voting) |
| NV1. Susan Morgan | Ph.D | Associate Dean | <i>Ex-Officio (non- voting)</i> |
| NV2. Linda Skelton | B.A. | IACUC Administrator | <i>(non-voting)</i> |
| | | | |

* 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). |
| <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. |

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

IX. Other Key Contacts (optional)

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

| | |
|---------------------------------------------------------|--------------------------|
| Contact #1 | |
| Name: Linda Skelton | |
| Title: IACUC Administrator | |
| Phone: 618-350-2958 | E-mail: lskelto@siue.edu |
| Contact #2 | |
| Name: Susan Morgan | |
| Title: Associate Dean for Research and Graduate Studies | |
| Phone: 618-650-2171 | E-mail: smorgan@siue.edu |

X. Facility and Species Inventory

| Date: 7/24/18 | | | |
|-----------------------------------------------------------------------------------|----------------------------------------------|-----------------------------------------------------------------------------------------------------|-------------------------------------|
| Name of Institution: Southern Illinois University Edwardsville | | | |
| Assurance Number: D16-00304 (A3486-01) | | | |
| 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 |
| Science Lab West, main campus facility including aquarium room. | 1794 total sq ft including Aquaria | | |
| | Room 0270 | | |
| | Room 0275 | Tailed frogs | 29 |
| | | Leopard frogs | 5 |
| | | Pacific Giant Salamanders | 2 |
| | | Fire belly toads | 2 |
| | | | |
| | | | |
| School of Education, Health and Human Behavior Dept. of Applied Health | | | |
| Vadalabene Center, Main Campus | Room 2305F, 225 sq ft | mice | 120 |
| | | | |
| Pharmacy School | | | |
| Pharmacy Building, University Park | Room 1044, 400 sq ft | Rats | 16 |
| | Room 1051, 100 sq ft | Mice | 60 |
| Dental School | Room 16A, 400 sq ft | rats | 0 |
| Bldg. 279, Alton Campus | | | |
| | | | |

Unless otherwise indicated, mice and rats means mice of the genus mus and rats of the genus rattus that are purposely bred for research.

Revised 7.24.18_LS