

## Indiana University, Bloomington, IN

D16-00587 (Legacy: A4094-01)

### Animal Welfare Assurance for Domestic Institutions

I, Fred H. Cate as named Institutional Official for animal care and use at Indiana University-Bloomington, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

#### I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS, HHS, NSF, and/or NASA. This Assurance covers only those facilities and components listed below.

- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:
  - 1. All components (Colleges, Schools, Centers, Departments, etc.) that are physically located on the University's main campus in Bloomington, Indiana.
  - 2. The Kent Farm Aviary, which is owned and managed by the university, and is located in rural Monroe County approximately 10 miles from campus.
  - 3. There are no other off-campus satellite facilities and/or other covered components.
  - 4. There are no other branches or components over which this Institution has legal authority.
- B. The following are other institution(s), or branches and components of another institution:

Not applicable.

#### II. Institutional Commitment

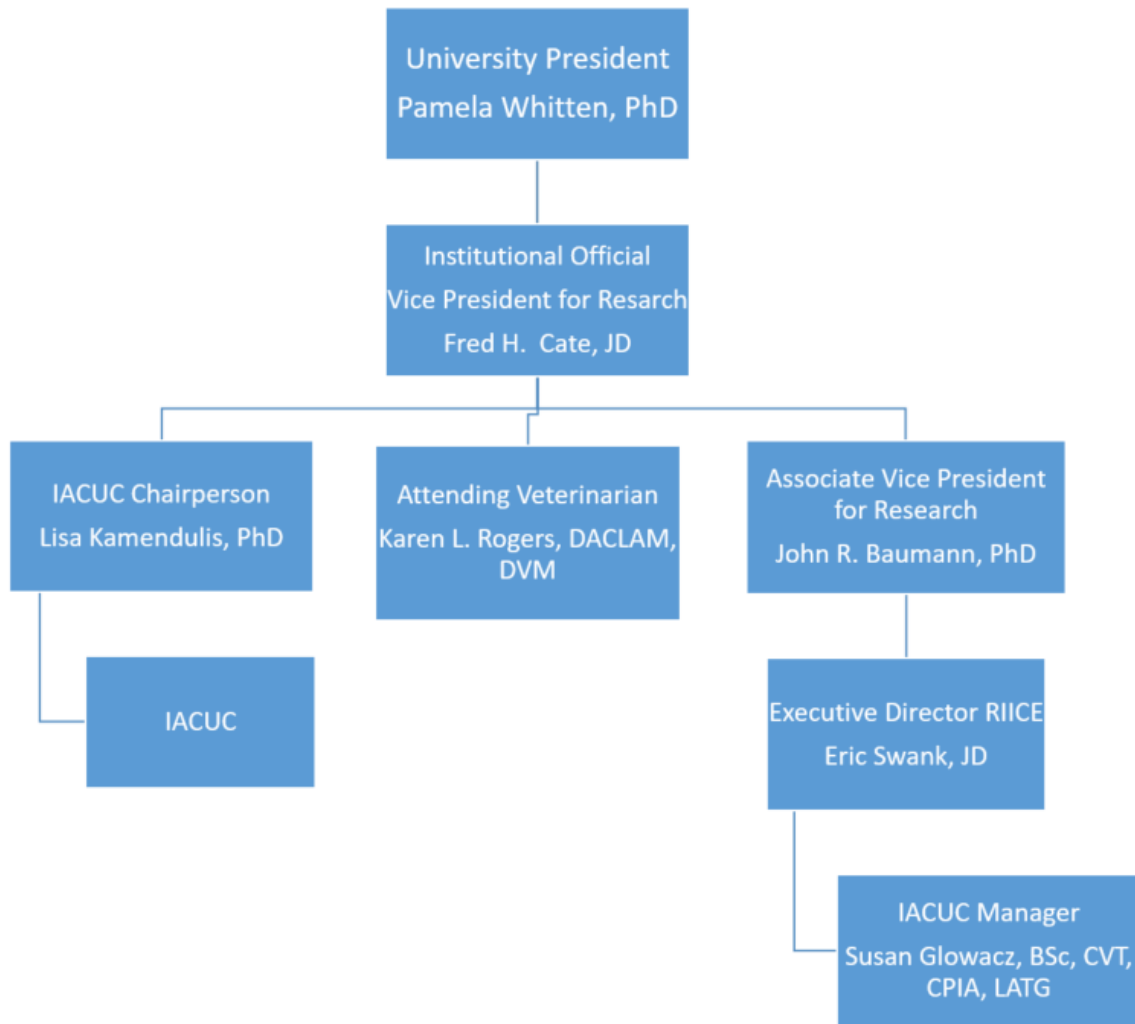
- A. This Institution will comply with all applicable provisions of the *Animal Welfare Act* and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, 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 most recent edition of the *Guide for the Care and Use of Laboratory Animals (Guide)*.
- E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

### **III. Institutional Program for Animal Care and Use**

- A. The lines of authority and responsibility for administering the program and ensuring compliance with the PHS Policy, which maintain an open and direct line between IACUC members and the IO, are as follows:



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

1) Name: Karen L. Rogers

Qualifications

- Degrees: BS – Chemistry – John Carroll University, DVM – The Ohio State University
- Board certification in Laboratory Animal Medicine by ACLAM since 1999.
- Training or experience in laboratory animal medicine or in the use of the species at the Institution. Postdoctoral Training Laboratory Animal Medicine – University of Michigan, ~30 years’ experience in laboratory animal medicine at University of Michigan, Warner-Lambert Parke-Davis Research, Pfizer Inc., Princetoni Children’s Hospital Medical Center, Indiana University and several CRO’s.

Authority: Dr. Rogers 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. Rogers is a full-time employee of Indiana University - Bloomington. Approximately 100 percent of her time is contributed to the animal care and use program.

2) Name: J. Randalyn Shepherd

Qualifications

- Degrees: DVM – Purdue University
- Training or experience in laboratory animal medicine or in the use of the species at the Institution: Twelve years' experience in laboratory animal medicine at Indiana University.

Responsibilities: Clinical Veterinarian, responsible for the clinical program.

Time contributed to program: Dr. Shepherd is a full-time employee of Indiana University-Bloomington. Approximately 100 percent of her time is contributed to the animal care and use program.

- C. The IACUC at this Institution (known as the Bloomington IACUC or BIACUC) is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

See membership table in Part VIII.

D. The IACUC will:

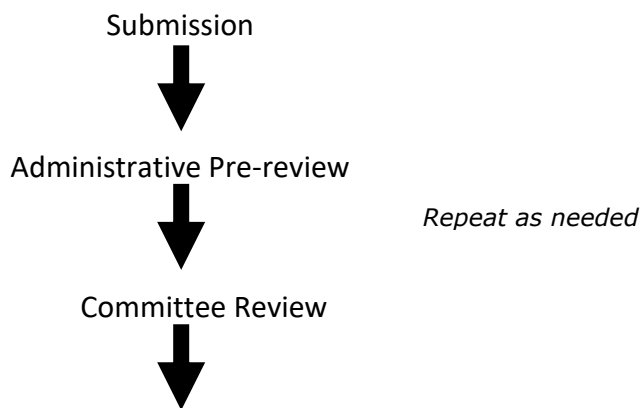
- 1) Review every 6 months the Institution's Animal Care and Use Program, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:
  - The Committee will use the *Guide* and other pertinent resources (e.g., the PHS Policy, the Code of Federal Regulations for Animal Welfare) as a basis for the review.
  - To facilitate the evaluation, the Committee will use a checklist based on the Sample OLAW Program Checklist provided on the IACUC's website.
  - The review typically occurs at a fully convened IACUC meeting. The Committee retains the opportunity to assign a portion or all of the Program review to a subcommittee of the IACUC.
  - The evaluation will include, but not necessarily be limited to, a review of the following institutional policies and responsibilities:
    - *The animal care and use program*

- *Disaster planning and emergency preparedness*
  - *The IACUC*
  - *Protocol review – special considerations*
  - *IACUC membership and functions*
  - *IACUC training*
  - *IACUC records and reporting requirements*
  - *Veterinary care*
  - *Personnel qualifications and training*
  - *Occupational health and safety of personnel*
  - *Investigating and reporting animal welfare concerns*
- In addition, the following veterinary care responsibilities may be reviewed:
    - *Clinical care and management*
    - *Animal procurement, transportation, and preventative medicine*
    - *Surgery*
    - *Pain, distress, anesthesia, and analgesia*
    - *Euthanasia*
    - *Drug storage and control*
  - 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. A minor deficiency is one that does not present a threat to the health and safety of the animals or personnel, and does not result in an increase in distress, discomfort, and/or pain in the animals.
  - No member shall be excluded from participating in any portion of the review.
- 2) Review every 6 months the Institution's research 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:
- BIACUC members or subject matter expert (SME) delegated by BIACUC will inspect (virtually or in-person) all of the Institution's facilities where animals are housed and animal procedures are conducted, as well as feed storage areas, holding areas, animal care support areas, and animal surgery areas. Two voting members will inspect (virtually or in-person) any housing or procedural areas where USDA-regulated species are used.
  - In response to the 2020 pandemic, the BIACUC may conduct semiannual inspections virtually and in accordance with NIH/OLAW COVID FAQs VIII.8 and VIII.9 as well as NOT-OD-20-088.

- Laboratory Animal Resources vehicles and personal vehicles approved by the IACUC are inspected.
  - The Committee uses the *Guide* and other pertinent resources (e.g., the PHS Policy, the Code of Federal Regulations for 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.
  - 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 shall be 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:
- BIACUC members will convey their observations to either the BIACUC Chairperson, the Chair's designee, or the IACUC Manager, who will then draft reports to the Institutional Official.
  - The reports will contain a description of the nature and extent of the Institution's adherence to the *Guide* and the PHS Policy, 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, this will be stated as such.
  - *Guide* departures will be documented and reviewed by the Committee in animal use protocols on a case-by-case basis. The IACUC identifies *Guide* departures through various mechanisms, including protocol review, amendment review, post-approval monitoring, veterinary consult, and semiannual facilities inspections.
  - Departures from the *Guide* that are not IACUC-approved are considered noncompliant and deficient, and will be addressed by the IACUC. For example, the Committee will develop a reasonable plan for either discontinuing the departure or for its review and approval. If federal funds support the relevant IACUC protocol, then a report will be made to the respective federal agency and OLAW, as required, through the IO. Relevant animal care and use programmatic concerns would be reported to the respective federal agency and OLAW as well, through the IO.

- 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.
  - Animal facilities accredited by AAALAC International will be identified as such on related reports.
  - Copies of the draft reports will be reviewed, revised as appropriate, and approved by the Committee.
  - The final reports will be signed by a majority of the BIACUC members and, if applicable, will include any minority opinions.
  - Following completion of each evaluation, the report will be submitted to the Institutional Official in a timely manner.
  - Deficiencies will be tracked by BIACUC office 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 BIACUC Office, the Laboratory Animal Resources Office, or the Office of Research Compliance.
  - Concerns may be reported verbally, in writing, or by email to the IACUC Chair, the IACUC Committee Members, the veterinary staff, or the IACUC Manager.
  - Reports can also be submitted anonymously through the University's Whistleblower Hotline. Whistleblowers are protected from discrimination by an Institutional policy.
  - Notices are located in the animal facilities advising individuals of 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.
  - All reported concerns will be brought to the attention of the full Committee.
  - If necessary, the BIACUC Chair will convene a meeting to discuss, investigate, and address any reported concern(s).

- Reported concerns and all associated BIAUC actions will be recorded in the BIAUC meeting minutes. The Committee will report such actions to the IO and, as warranted, to OLAW via the IO.
- 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:
- Issues regarding any aspect of the program, facilities, or training will be discussed at a convened BIAUC meeting.
  - As appropriate, the Committee will discuss and vote upon a recommendation to be made to the IO.
  - Committee recommendations may also be included in the BIAUC's semiannual reports (e.g., program reviews and facility inspections).
- 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:
- New protocols, three-year renewals and major amendments will be submitted by email to the BIAUC office on a Committee-approved protocol form.
  - An administrative pre-review will be conducted by the IACUC Manager and sent to the PI. Following the completion of the pre-review, the protocol or major amendment will be reviewed by the Committee by either Designated Member review (DMR) or by Full Committee Review (FCR).





Formal BIAUCUC:  
Designated Member  
Review (DMR) or Full-  
Committee Review (FCR)

### **Pre-review Process**

- New protocols, three-year renewals, and major amendments are submitted via email to the IACUC office.
- The administrative pre-review evaluates protocol submissions for completeness, grammar, and organizational flow. PIs are invited to consider this feedback for incorporation.

### **Designated Member Review (DMR) Process**

- The IACUC Chair and Manager work together in assigning IACUC reviewers.
- Protocol and major amendment submissions are posted for a prescribed amount of time on a weekly Call for Comment email, giving Committee Members the opportunity to move a submission to FCR.
- If the protocol or amendment is not called to FCR, then the assigned review is categorized as DMR. The DMR reviewers are asked to provide feedback within 7 business days of assignment for the PI to consider. The DMR reviewers receive the identical version of the protocol or amendment.
- If revisions are suggested by the DMR reviewers, the IACUC Manager compiles the comments into one document and sends the requested revisions via email to the PI. All reviewers are made aware of each other's modification requests and agree to have them issued to the PI for consideration.
- When the PI responds and either submits a revised document or provides an explanation for not incorporating suggested revisions, this information is sent via email to the DMR reviewers. The DMR reviewers receive the identical revised document.
- If no additional revisions are requested, approval is issued for the protocol or major amendment. The PI is notified via email. If additional revisions are requested, these are

compiled and sent to the PIs as outlined above.

- The DMR reviewers can move to approve, require modifications, or move to FCR. DMR reviewers must reach consensus when approving; if consensus is not reached, the protocol will move to FCR.

### **Full Committee Review (FCR) Process**

- If a Member requests that a protocol or major amendment submission be reviewed using the FCR process, then the PI is notified of this procedure via email.
- Committee Members are selected to review the protocol or major amendment prior to the Full Committee Meeting. The Chair confirms the reviewer selection.
- The reviewers provide feedback at a fully convened IACUC meeting. The Committee can vote to approve the protocol or amendment with no revisions, move to DMR with pending modifications, table the discussion, or withhold approval. A discussion may be tabled in order to obtain additional information from the PI. A modification request can be routed back through FCR or through DMR. Decisions are made by a majority vote of the quorum present.
- The Committee reserves the opportunity to process a modification request subsequent to FCR through the DMR process. The Committee has an IACUC SOP for this process. Members review the SOP at regular intervals and then vote to retain the SOP. This is recorded in the IACUC minutes.

If all members of the IACUC are present at a meeting, the committee may vote to require modifications to secure approval and have the revised research protocol reviewed and approved by designated member review (DMR), or returned for FCR at a convened meeting.

If all members of the IACUC are not present at a meeting, the committee may use DMR subsequent to FCR according to the following stipulations: All IACUC members agree in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote 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.

- The IACUC Manager notifies the PI of the review outcome and the reasons for this decision via email.
- In accordance with the NIH Guidance on the *Use of Telecommunications for IACUC*

*Meetings* NOT-OD-06-052, BIACUC meetings may be conducted virtually, with IACUC Members contributing to quorum via telephone or a video-styled communication platform. Members will be provided with relevant documentation in advance of the meeting.

### **Administrative Review Process**

- Administrative modifications to ongoing research projects are also submitted on an amendment form via email to the IACUC office.
- Administrative modifications are delegated to and processed by the IACUC Manager and involve a change in or addition to the protocol title, the addition of a grant resource, the addition of new research personnel - other than the PI - and a request for additional animals (less than 10%).

### **Administrative Veterinary Review Process**

- In accordance with NIH-OD-14-0126, the IACUC supports the administrative veterinary amendment review process, also known as VVC, in consultation with an IUB veterinarian authorized by the IACUC.

### **All BIACUC Reviews (FCR & DMR)**

- No Member may participate in the BIACUC review or approval of a protocol in which the Member has a conflicting interest (e.g., personal involvement with a study) except to provide information as requested by the BIACUC, nor may a Member who has a conflicting interest contribute to the constitution of a quorum.
- The BIACUC may invite consultants to assist in reviewing complex issues. Consultants may not vote with the BIACUC unless they are also members of the BIACUC.
- In order to approve proposed protocols or proposed significant changes in ongoing protocols, the BIACUC will conduct a review by DMR or FCR 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 BIACUC 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 BIACUC shall determine that the protocol conforms to the Institution's PHS Assurance and meets the

following requirements:

- Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals and are consistent with sound research design.
  - 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 withholding these is justified for scientific reasons in writing by the Investigator.
  - Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be euthanized at the end of the procedure or, if appropriate, during the procedure.
  - 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, senior animal care staff, or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.
  - Medical care for animals will be available and provided as necessary by qualified veterinary staff.
  - Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
  - 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.
- 7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities according to PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:
- Significant changes to ongoing research projects (e.g., major amendments) are submitted in writing to the BIACUC office.
  - Review and approval of significant changes are handled in the same manner as new protocols.
  - Examples of changes considered to be significant include, but are not limited to,

changes:

- in the scope of a study;
  - from nonsurvival to survival surgery;
  - resulting in greater discomfort or in a greater degree of invasiveness;
  - in the species or in approximate number of animals used, equal to or greater than 10%;
  - in Principal Investigator;
  - in anesthetic agent(s) or the use or withholding of analgesics;
  - in the method of euthanasia; and
  - in the duration, frequency, or number of procedures performed on an animal.
- The IACUC maintains a policy in support of the administrative veterinary amendment review process, also known as VVC. The policy and related drug formulary are reviewed annually at a fully convened IACUC meeting. Veterinarians using the administrative veterinary review process have been authorized by the IACUC to do so. The review process is as follows:
    - Veterinary staff review the proposed amendment with the PI and communicate in-person, by phone call, or email.
    - Changes to a protocol that may be processed by administrative veterinary amendment include:
      - In purpose-bred mice:
        - ❖ Addition of veterinary-approved vendor.
        - ❖ Refinement of technique description (depilatory application, von Frey, etc.) of currently approved study activities.
        - ❖ Transfer of animals between IUB IACUC approved protocols.
        - ❖ Add option of using nonpharmaceutical grade substance (analgesics, neuromuscular blockers) in terminal procedures.
        - ❖ Addition of inhalation anesthesia as an option for anesthesia.
        - ❖ Addition of non-invasive sample collection.
        - ❖ Decrease in frequency of sample collection.
        - ❖ A change in bedding or feed, which does not include feed or water restriction.
        - ❖ Extension of feed shelf-life in accordance with manufacturer's specifications.
        - ❖ Addition of testing a compound of similar drug class as previously approved.
        - ❖ Change in antibiotics or analgesics, in accordance with IACUC-approved LAR formulary.
        - ❖ Change in dose range of injectable agent for anesthesia/sedation.

- ❖ Addition of identification methods (toe clipping, tattooing, microchipping, nonpermanent marker, and ear punch), as described in IACUC policy.
- In purpose-bred rats:
  - ❖ Addition of veterinary-approved vendor.
  - ❖ Refinement of technique description (depilatory application, von Frey, etc.) of currently approved study activities.
  - ❖ Transfer of animals between IUB IACUC approved protocols.
  - ❖ Add option of using nonpharmaceutical grade substance (analgesics, neuromuscular blockers) in terminal procedures.
  - ❖ Addition of inhalation anesthesia as an option for anesthesia.
  - ❖ Addition of non-invasive sample collection.
  - ❖ Decrease in frequency of sample collection.
  - ❖ A change in bedding or feed, which does not include feed or water restriction.
  - ❖ Extension of feed shelf-life in accordance with manufacturer's specifications.
  - ❖ Addition of testing a compound of similar drug class as previously approved.
  - ❖ Change in antibiotics or analgesics, in accordance with IACUC-approved LAR formulary.
  - ❖ Change in dose range of injectable agent for anesthesia/sedation.
  - ❖ Addition of identification methods (toe clipping, tattooing, microchipping, nonpermanent marker, and ear punch), as described in IACUC policy.
- In hamsters:
  - ❖ Clarification of currently approved study activity.
  - ❖ Transfer of animals between IUB IACUC approved protocols.
  - ❖ Add option of using nonpharmaceutical grade substance (analgesics, neuromuscular blockers) in terminal procedures.
  - ❖ Addition of non-invasive sample collection.
  - ❖ Decrease in frequency of sample collection.
  - ❖ A change in bedding or feed, which does not include feed or water restriction.
  - ❖ Extension of feed shelf-life in accordance with manufacturer's specifications.
  - ❖ Change in antibiotics or analgesics, in accordance with IACUC-approved LAR formulary.
  - ❖ Change in dose range of injectable agent for anesthesia/sedation.
- In fish:
  - ❖ Addition of external vendor after careful background check by compliance manager or veterinary staff. Results of background check are shared with the PI, compliance manager and veterinary staff.

- ❖ Refinement of technique description (rapid cooling, etc.) of currently approved study activities.
  - ❖ Transfer of animals between IUB IACUC approved protocols.
  - ❖ Decrease in frequency of sample collection.
- In wildlife research:
    - ❖ Refinement of technique description of currently approved study activities.
    - ❖ Addition of non-invasive sample collection.
    - ❖ Decrease in frequency of sample collection.
    - ❖ For captive studies, transfer of animals between IUB IACUC approved protocols.
    - ❖ For captive studies, change in antibiotics, anthelmintics, parasiticide, or analgesics, in accordance with IACUC-approved LAR formulary.
- After the veterinarian and PI agree on the amendment content and have established that the content is in accordance with the related IACUC policy and relevant references, the veterinarian may choose to verify the change requested if:
    - It is consistent with eligible significant changes in the IACUC approved Administrative Veterinary Review Amendment (VVC) Policy;
    - There is an appropriate reference for the veterinarian to verify against the change being requested; and
    - The change is appropriate for animals in the context of the protocol.
    - Or, the veterinarian may choose to send the protocol back to the IACUC for DMR or FCR.
  - If the administrative veterinary amendment is authorized for approval, then this is processed and documented by the IACUC Manager. Approval is communicated to the PI by email.
- 8) Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval according to PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:
- The BIACUC has delegated to the IACUC Manager the task of notifying the Investigators of Committee decisions regarding protocol and major amendment review.
  - The IACUC Manager notifies Investigators of decisions regarding protocol and major amendment review by email.
  - If protocol approval is withheld, the decision is communicated to the PI by email. The PI is provided with an opportunity to respond by email to this decision, for further consideration by the BIACUC.

- If the BIACUC's decision is to require modifications to secure approval, the required modifications are sent to the PI by email.
  - The Institutional Official is notified by receiving a copy of the BIACUC 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 IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:
- Protocols are approved for a maximum of 36 months. That is, all protocols expire no later than three years from the initial BIACUC approval date. If activities will continue beyond the expiration date, a new protocol must be submitted, reviewed, and approved prior to expiration of the original or preceding protocol.
  - The IACUC Manager visits active labs at least once every three years, either in-person or virtually. The results of post-approval monitoring (PAM) visits are to be reported to the IACUC Chair or the full committee.
- 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 BIACUC may suspend a previously approved protocol if it is determined that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the *Guide*, the Institution's Assurance, IV.C.1.a.-g. of the PHS Policy, and/or the approved protocol.
  - The BIACUC may suspend an activity after reviewing the matter at a convened quorum of the BIACUC and with a majority suspension vote of a majority of the quorum present.
  - The Committee may require that all animals be moved from an Investigator's protocol to the LAR holding protocol until the necessary corrections have been made. The Committee may ensure the health, safety, and welfare of animals by having LAR maintain the animal colonies until all matters are resolved.
  - If the BIACUC suspends an activity involving animals, or if any other Institutional intervention results in the temporary or permanent suspension of an activity due to noncompliance with the approved protocol, Policy, Animal Welfare Act, the *Guide*, or the Institution's Assurance, the Institutional Official in consultation with the BIACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW in writing. Preliminary reports may be made verbally.



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 Environmental Health and Safety (IUEHS; occupational safety, chemical safety, biosafety, radiation safety, hazardous waste, public health, and emergency response) is responsible for the overall management of Indiana University's occupational safety and health programs. Members of this team review all animal use protocols and major amendments for safety and provide the Committee with an assessment of hazards and risks associated with the study.
- These functions provide comprehensive occupational safety and health programs and the necessary oversight and training to ensure the safety of personnel and compliance with all applicable Institutional, federal, state, and local regulations.

**2. Scope**

- The Occupational Health and Safety for Animal Users Program covers all personnel involved in laboratory animal care and/or use, including Principal Investigators, research staff, veterinarians, animal care staff, animal technicians, students conducting animal research for academic projects, and facilities/custodial staff who may have indirect with animals or animal facilities.
- Personnel enroll in the program by completing a confidential online medical questionnaire and risk assessment that are retained on the Occupational Health and Safety for Animals Users secure server. An IU Health physician and/or licensed nurse practitioner reviews the questionnaire and risk assessment. All personnel working with research animals are required to submit these forms.

**3. Health Histories and Evaluations**

- Medical evaluation and preventive medicine for personnel: Medical care and evaluations are provided by the IU Health physician and/or licensed nurse practitioner or medical personnel at the Campus Health or in association with Campus Health, prior to working with research animals, then on a yearly or as-needed basis. All medical records are maintained by Campus Health and are kept confidential in accordance with federal, state, and local HIPAA regulations.
- Medical histories and evaluations are for the physician's or licensed nurse practitioner's use to determine if there are any medical conditions that would require certain PPE, work restrictions or preclude an individual from working with animals.

- Medical surveillance is provided:
  - Prior to initial assignment of LAR and facilities staff with indirect animal contact;
  - Annually for animal care workers and animal research personnel;
  - As part of the approval process for an individual to be included on an IACUC animal use protocol (new or renewal protocol);
  - On a frequency as indicated by a medical services provider; or
  - When an individual undergoes a change in medical status.
  
- Medical history includes:
  - Animal allergy background;
  - Baseline health history; and
  - Applicable vaccination history.
  
- Medical evaluation includes:
  - A review of the online medical questionnaire for animal users;
  - Physical examination, if indicated;
  - Communication of risk factors associated with animal contact, including potential zoonotic agents, wound care, and potential hazards of field studies, when necessary;
  - Communication of health risks associated with illness, pregnancy, or compromised immune system (e.g., cancer, chemotherapy, radiation, steroid use, immunosuppressive drugs after organ transplant), when necessary; and
  - Updating of tetanus-diphtheria immunization, as needed.
  
- Visiting faculty and students are required to enroll in the Occupational Health program, prior to beginning work with live research animals. If visiting faculty and students are expected to enter core animal facilities, then they will be required to participate in training provided by animal facilities or veterinary staff.
  
- Individuals unwilling to participate in the Occupational Health program are not permitted to work with live research animals. Participation in this program is mandatory for research animal personnel.

#### **4. Hazard Identification and Risk Assessment**

- Inherent animal hazards, such as exposure to allergens and potential bites, are currently identified by supervisors, PI's, and IUEHS Staff. IUB utilizes four methods to evaluate and identify potential hazards and risks: 1) All protocols and major amendments are routed electronically to the IUEHS Division of Research Safety for hazard assessment, 2)

Periodic inspections and audits of animal research areas includes a risk/hazards review, 3) All animal handlers are required to complete and submit an online risk assessment, and 4) A risk/hazard assessment form associated with animal care and use that was developed by IUEHS.

- Inexperienced personnel are supervised until they are competent at the skills necessary to perform their duties.

## **5. Procedures in Place to Alleviate Hazards and Minimize Risks**

- Personnel in contact with animals receive job-specific training that clearly defines duties. Personnel are instructed by biosafety officers to identify hazards (chemical, physical, biological, and radiological), and by their supervisor/PI to implement the necessary hazard controls (administrative and personal protective equipment) for performing their duties safely.
- Each individual also receives applicable training for specific duties, including chemical safety, hazardous waste, biological waste, and emergency response. The training is conducted by the Chemical Hygiene Officer, Biosafety Officer, and Radiation Safety Officer. Training records are maintained by the IUEHS office.
- Personal hygiene – Laboratory safety training, required by all lab personnel, includes instruction in good personal hygiene practices to protect the health of the individual and the health of the animals. Hand washing stations are provided near all animal research and holding facilities.
- Suitable work attire is provided to animal care staff and laundered by a commercial service. Whenever necessary, disposable gloves, masks, face shields/eye protection, coveralls, and head covers are provided.
- Eating, drinking, using cosmetics, and using tobacco are strictly forbidden in all laboratories and animal holding facilities. Human food used for animals is clearly labeled (e.g., *For Animal Use Only*) and not allowed for human consumption.
- Facilities, procedures, and monitoring: Animal holding facilities are equipped with cage washing facilities that allow for the safe movement and washing of heavy materials.
- Dirty bedding is emptied in HEPA-filtered dump stations designed for that purpose. Bedding changes for transgenic mice are conducted in HEPA-filtered change stations. In addition, staff industrial hygienists are available to conduct exposure monitoring as necessary.

- All equipment, facilities and surfaces are disinfected regularly. All waste (chemical, biological, radiological, and bedding) is collected and disposed of properly.
- Potentially infectious or biohazardous waste (as identified by the Institutional Biosafety Committee (IBC) and the biosafety office) is sterilized in autoclaves and disposed of as sanitary waste or shipped as medical waste for incineration.
- Deceased animals are frozen and shipped for proper disposal. Liquid biological waste is chemically disinfected and disposed of as sanitary waste.
- **Animal experimentation involving hazards:** Animal experimentation with hazardous materials including drugs, chemicals, and biological agents are carefully considered during protocol review. The use of biological agents is reviewed by the biosafety officers. Chemical use and waste disposal including chemical, biological, and animal waste are reviewed by the chemical hygiene officer and biosafety officers.
- Safety equipment is provided in each facility to ensure the safety of the public, the staff, and other occupants of the building.
- **Personal protective equipment:** All necessary personal protective equipment (PPE) is provided to animal care staff including eyewear, clothing, and gloves. Disposable PPE is used as necessary. Equipment (e.g., protective eyewear, gloves, clothing, hearing, respiratory protection, etc.) may be necessary based upon the conditions and hazards indicated within the protocol and are subsequently noted on the safety review form by IU-EHS.
- If respirator use becomes necessary, all respiratory protection is provided and conducted in accordance with the Indiana University Respiratory Protection Program. All personnel receive a medical evaluation, a respirator fit test, and are provided with appropriately fitted respirators for the exposure conditions present.

## 6. Immunizations

- Updating of tetanus-diphtheria immunization is required and provided during the medical evaluation and preventive medicine program.

## 7. Precautions for 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 the authorized medical provider and if necessary, 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/their health care professional, and human resources.

## **8. Provisions for Personnel Not Involved in Animal Care/Use and Enter Animal Areas**

- Custodial staff with indirect animal contact with research animal facilities are included in the medical surveillance program.
- Custodial personnel are also trained to recognize and protect themselves against chemical, biological, and radiological hazards.
- In situations where non-IU maintenance/or other non-animal care and use personnel must access the animal rooms, they are briefed on appropriate precautions and provided with the necessary PPE. A member of the animal care staff will be available for escort if needed. For extensive or prolonged maintenance projects, animals may be removed prior to granting room access.

## **9. Procedures for Treatment of Bites, Scratches, Illness or Injury**

- Per written IUEHS procedure, the following steps shall be taken for an injury that breaks the skin while working with any animal used in research:
  - Massage the wound immediately to expose the possible contaminant.
  - Wash and irrigate the wound and surrounding area thoroughly with water and soap, antibacterial if possible. It is recommended to scrub vigorously for 3-5 minutes, rinse, and repeat two more times.
  - Inform the supervisor or Principal Investigator of the incident.
- Employees may seek medical attention from the designated medical services provider for the respective campus. Non-paid individuals or students who are injured may seek medical treatment from Student Health or their primary care physician.

## **10. Procedures/program for reporting and tracking injuries and illnesses**

- All individuals shall notify their Supervisor or Principal Investigator of an injury or illness, and a report of the injury must be sent to IUEHS. A list of all injuries involving research animals will be maintained by IU OHS.
- For employees, an occupational injury/illness report must also be completed and sent to University Human Resources by the supervisor.
- Follow up regarding hazard mitigation is provided by the supervisor or PI, and IUEHS, if warranted.

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

See part X.

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

### 1. BIACUC Members

- Each BIACUC Member will be provided with a copy of or the electronic link to the following:
  - The *PHS Policy for the Humane Care and Use of Laboratory Animals*;
  - *Animal Welfare Act/Regulations*;
  - The National Research Council (NRC) *Guide for the Care and Use of Laboratory Animals* (2011);
  - The *ARENA/OLAW IACUC Guidebook*;
  - The *AVMA Guidelines on Euthanasia*; and
  - A copy of this Assurance.
- Prior to their first full Committee meeting, all Members receive an orientation to Committee procedures.
- All Members of the BIACUC will complete the *Essentials for IACUC Members* curriculum located at the Collaborative Institutional Training Initiative website, <https://research.iu.edu/training/citi/index.html>.
- BIACUC Members will review throughout their appointments the pertinent regulatory updates, NIH Notices, policies and laws, and other resources.
- Members are encouraged to attend IACUC-related conferences (e.g., PRIM&R, IACUC 101/201, SCAW, NABR, ICARE).

### 2. Research and Animal Care Personnel

- All personnel performing procedures using animals must be identified in the animal care and use protocol. A description of each individual's qualifications, experiences, and/or training with the specific animal species and procedures must be available for IACUC review.
- Any person needing additional protocol-specific training will be identified during the review process. Additional training is provided by veterinary personnel, the PI, external,

qualified research personnel, or senior research personnel.

Required Training for all Personnel:

- Online training with the Collaborative Institutional Training Initiative (CITI) is provided to all personnel involved with animal care and use.
- The training includes instruction on research or testing methods that minimize the number of animals required to obtain valid results and limit the animal pain or distress as well as other requirements delineated in 9 CFR, Part 2, Subpart C, Section 2.32(c). It also covers the laws and regulations governing laboratory animal care and use with an emphasis on the contents of the *NRC Guide* and the 3Rs; and the following:
  - Humane methods of animal maintenance and experimentation;
  - The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress;
  - 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;
  - Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information:
    - On appropriate methods of animal care and use;
    - On alternatives to the use of live animals in research;
    - That could prevent unintended and unnecessary duplication of research involving animals; and
    - Regarding the intent and requirements of the *Animal Welfare Act* and USDA-APHIS Regulations;
  - Instruction in basic Occupational Health and Safety for working with animals;
  - Proper handling and care for the various species of animals used by the facility; and
  - The basic needs of each animal species.

Specialized Training: Experimental Methods

- Training in experimental methods (e.g., specific animal manipulations/techniques, the care of new and nontraditional laboratory animal species) will be conducted in accordance with the type of research conducted and the species used at the Institution.

- Investigators who transfer from other institutions with similar training credentials may receive credit for this training at the IACUC's discretion. These credentials will be verified.

Specialized Training: Surgery and Anesthesia

- In addition, individualized instruction is provided, as indicated by study, to lab personnel by the veterinary and animal care staff in the following:
  - Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility;
  - Aseptic surgical methods and procedures surgery;
  - Proper pre-procedural and post-procedural care of animals; and
  - Euthanasia and medical issues.
- Further compliance training is provided by the IACUC Manager.
- Educational materials and revisions in policy and/or procedures are periodically provided to the campus research community via an electronic BIACUC communication, which is distributed through a closed (membership is limited and confidential) listserv.
- BIACUC procedures and policies are also available to the research community on the IU Bloomington IACUC's website.

**IV. Institutional Program Evaluation and Accreditation**

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past 6 months and will be reevaluated by the IACUC at least once every 6 months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the PHS Policy and the *Guide*. Any departures from the *Guide* will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

A. This Institution is Category 1 — accredited by AAALAC International. As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request.

B. Category 2 is not applicable.

**V. Recordkeeping Requirements**




- A. This Institution will maintain for at least three years:
  - 1. A copy of this Assurance and any modifications made to it, as approved by the PHS.
  - 2. Minutes of IACUC meetings, including records of attendance, activities of the Committee, and Committee deliberations.
  - 3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was granted or withheld.
  - 4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, the Vice President for Research.
  - 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 the completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

## **VI. Reporting Requirements**

- A. The Institutional reporting period is the federal fiscal year (October 1 through September 30). The IACUC, through the Institutional Official, will submit an annual report to OLAW after September 30, but on or before December 1 of each year. The annual report will include:
  - 1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or if 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, the Vice President for Research.
  - 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 deviation from the provisions of the *Guide*; and
  - 3. Any suspension of an activity by the IACUC.
- C. Reports filed under VI.A. and VI.B. above should include any minority views filed by Members of the IACUC.

**VII. Institutional Endorsement and PHS Approval**

<b>A. Authorized Institutional Official</b>	
Name: Fred H. Cate, J.D.	
Title: Vice President for Research	
Name of Institution: Indiana University-Bloomington	
Address: <i>(street, city, state, country, postal code)</i>  Bryan Hall 300 107 S. Indiana Ave. Bloomington, IN 47405	
Phone: (812)856-2096	Fax: (812)855-9943
E-mail: <a href="mailto:VPR@iu.edu">VPR@iu.edu</a>	
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: 02/22/2022

<b>B. PHS Approving Official</b> <i>(to be completed by OLAW)</i>	
Name/Title: Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6705 Rockledge Drive RKL1, Suite 360, MSC 7982 Bethesda, MD USA 20892-7982 (FedEx Zip Code 20817) Phone: +1 (301) 496-7163 Fax: +1 (301) 451-5672	
Signature:	Date:
Assurance Number:	
Effective Date:	Expiration Date:

### VIII. Membership of the IACUC

Date: August 1, 2021			
Name of Institution: Indiana University-Bloomington			
Assurance Number: D16-00587 (Legacy: A4094-01)			
<b>IACUC Chairperson</b>			
Name*: Lisa Kamendulis			
Title*: Associate Professor		Degree/Credentials*: PhD	
Address*: (street, city, state, zip code)			
<p style="text-align: center;">Innovation Center 2719 E. 10<sup>th</sup> Street Bloomington, IN 47408</p>			
E-mail*: lkamendu@iu.edu			
Phone*: (812)856-3098		Fax*: --	
<b>IACUC Roster</b>			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
Karen Rogers/1	DVM, DACLAM	Attending Veterinarian	Veterinarian
9	DVM	Clinical Veterinarian	Veterinarian (Alt. AV)
3	PhD	Associate Professor	Scientist (Alt.)
12	BSc	Graduate Student Representative	Scientist
26	MA	Retired Teacher	Nonscientist; Nonaffiliated
28	PhD	Professor	Scientist (Alt.)
Lisa Kamendulis/29	PhD	Associate Professor/ IACUC Chairperson	Scientist
31	PhD	Professor	Scientist
34	PhD	Professor	Scientist (Alt.)
39	PhD	Assistant Dean	Scientist
42	PhD	Professor	Scientist
57	PhD	Associate Professor	Scientist
17	PhD	Associate Professor	Scientist

\* This information is mandatory.

\*\* Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

\*\*\* List specific position titles for all members, including nonaffiliated (e.g., banker, teacher, volunteer fireman; not "community member" or "retired").

\*\*\*\* [PHS Policy](#) Membership Requirements:

*Veterinarian*      veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals at the institution.

*Scientist*            practicing scientist experienced in research involving animals.

*Nonscientist*      member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).

*Nonaffiliated*      individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

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

## IX. Other Key Contacts (optional)

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

<b>Contact #1</b>	
Name:	
Title: IACUC Manager	
Phone:	E-mail: BIACUC@iu.edu
<b>Contact #2</b>	
Name:	
Title: Executive Director	
Phone: (812)856-1229	E-mail:

## X. Facility and Species Inventory

Date: August 1, 2021			
Name of Institution: Indiana University-Bloomington			
Assurance Number: D16-00587 (Legacy: A4094-01)			
Laboratory, Unit, or Building*	Gross Square Feet [ <i>include service areas</i> ]	Species Housed [ <i>use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog</i> ]	Approximate Average Daily Inventory
RSB	3627	Mouse	2
MSB II	10,769	Mouse	876
		Rat	79
PSY	3525	Mouse	46
		Rat	26
OPT	1260	Mouse	281
BiO	5588	Mouse	82
		Hamster	154
		Frog	32
		Fish	900
		Bird	12
MH	126	Frog	40
		Tadpoles	350
KFA	4025	Bird	300
MESH	8852	Fish	5000
ABL	2302	Rodent Swing Space	0

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