

**Eastern Michigan University  
Assurance Number A3899-01**

**Animal Welfare Assurance  
In accordance with the PHS Policy for  
Humane Care and Use of Laboratory Animals**

I, Wade Tornquist, as named Institutional Official for animal care and use at Eastern Michigan University, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

**I. Applicability of Assurance**

This assurance applies whenever Eastern Michigan University (EMU), or its faculty, staff, or students, conducts the following activities: all research, teaching, 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.

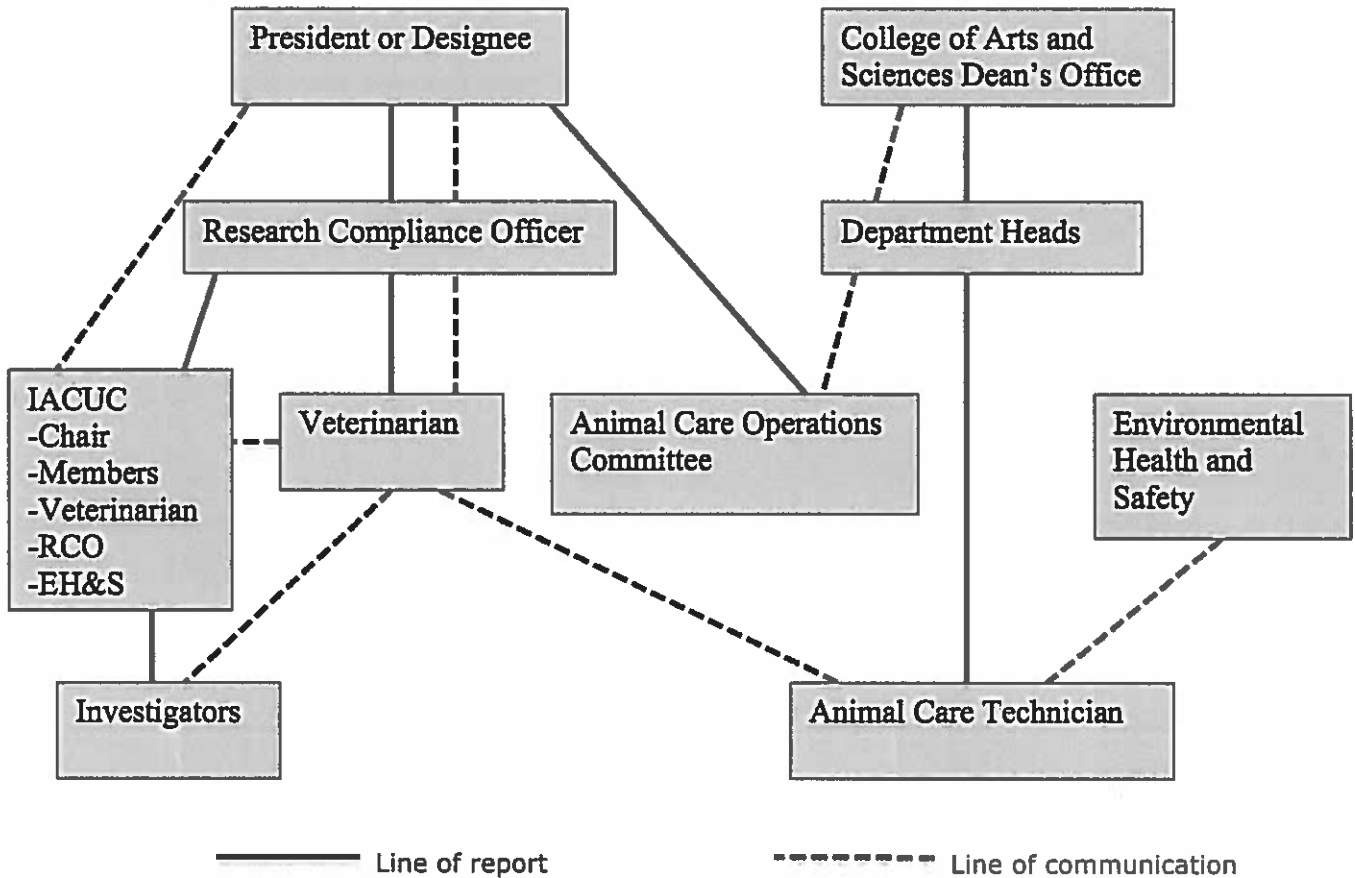
- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name: Eastern Michigan University main campus vivarium and any field locations identified in animal use protocols.
- B. The following are other institution(s), or branches and components of another institution:
  - None -

**II. Institutional Commitment**

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

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

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



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

1) Name: Howard G. Rush, DVM, MS

Qualifications

- Degrees: DVM, MS, DACLAM

The consulting veterinarian is **qualified** through training and experience to advise on the animal care and use program. He is a retired Associate Professor of Laboratory Animal Medicine at the University of Michigan, Ann Arbor. He is a Diplomate of the American College of Laboratory Animal Medicine and has more than 37 years of experience in laboratory animal care and medicine.

Authority: Dr. Rush has delegated program authority and responsibility for the Institution’s animal care and use program including access to all animals.

Time contributed to program: The consulting veterinarian devotes approximately 90 hours per year of his time to the EMU facility and IACUC. This includes facility inspections, animal health and welfare, and compliance related activities. The Division of Academic Affairs pays the consulting veterinarian a retainer for these services, and as a consultant 100% of this effort is devoted to the IACUC and EMU animal facility.

Dr. Rush provides the name of a back-up veterinarian to the IACUC in case he should be unavailable. Patrick Lester, DVM, MS, DACLAM, Assistant Professor, University of Michigan Unit

for Laboratory Animal Medicine. Dr. Rush notifies the Research Compliance Officer when he is unavailable. All investigators will be provided with the name of the back-up veterinarian and will be immediately notified of the name and telephone number of the back-up veterinarian, should that be necessary, by IACUC.

Responsibilities. The consulting veterinarian is responsible for:

- a) Directing the animal care program to assure that animals are observed daily in order to assess their health and welfare.
  - b) Providing direct veterinary services as required and assuring that appropriate methods are used to prevent, control, diagnose, and treat diseases and injuries.
  - c) Providing guidance to users regarding handling, immobilization, anesthesia, analgesia, and euthanasia.
  - d) Monitoring surgery programs and post-surgical care.
  - e) Meeting with the IACUC to advise on compliance with animal care standards and regulations and on operation of the animal care facilities and program.
  - f) Reviewing protocols with respect to adequate veterinary care and animal welfare.
- C. The IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least five 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 (Section VIII).

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 semi-annual program evaluations are conducted following the semi-annual inspection (2. below) during the months of April/May and October/November. The consulting veterinarian presents the results of the inspection to a full meeting of the IACUC. The IACUC conducts its review by completing a program evaluation checklist (Attachment A), following discussion of the inspection report. The key elements covered during the program evaluation are as follows: animal care and use program; disaster planning and emergency preparedness; IACUC, special considerations about IACUC program review; IACUC membership and functions; IACUC training; IACUC records and reporting requirements; veterinary care; personnel qualifications and training; occupational health and safety of personnel; personnel security; investigating and reporting animal welfare concerns; clinical care and management of animals; animal procurement and transportation/preventative medicine; surgery, pain, distress, anesthesia, and analgesia; euthanasia; drug storage and control; inspection of terrestrial housing and support areas (location, construction, room/cage, primary enclosure, enrichment, behavioral and social management, sheltered or outdoor housing, naturalistic environments, food, water, bedding and nesting materials, sanitation, waste disposal, pest control, emergency/weekend/holiday animal care, identification, recordkeeping, storage, and personnel); inspection of aquatic housing and support areas (location, construction, room, primary enclosure, enrichment, behavioral and social management, sheltered or outdoor housing, naturalistic environments, food, water, sanitation, waste disposal, pest control, emergency/weekend/holiday animal care, identification, recordkeeping, storage, and personnel); procedure areas including non-survival surgeries, laboratories, rodent surgeries, imaging, whole body irradiation, hazardous agent containment, and behavioral studies; and inspection of aseptic surgery facilities (general considerations, operating room, surgical support, animal preparation, surgical scrub, postoperative recovery, and dressing area).
- 2) Inspect at least once every 6 months all of the Institution's animal facilities, including satellite facilities and animal surgical sites, using the *Guide* as a basis for evaluation. A group consisting of the consulting veterinarian and at least one regular member of the IACUC will tour the facilities during the months of April/May and October/November. The Research Compliance Officer notifies the IACUC members and invites the members to participate. The consulting veterinarian performs the inspection. Key areas inspected are as follows:

terrestrial housing and support areas (location, construction, room/cage, primary enclosure, enrichment, behavioral and social management, sheltered or outdoor housing, naturalistic environments, food, water, bedding and nesting materials, sanitation, waste disposal, pest control, emergency/weekend/holiday animal care, identification, recordkeeping, storage, and personnel); aquatic housing and support areas (location, construction, room, primary enclosure, enrichment, behavioral and social management, sheltered or outdoor housing, naturalistic environments, food, water, sanitation, waste disposal, pest control, emergency/weekend/holiday animal care, identification, recordkeeping, storage, and personnel); procedure areas including non-survival surgeries, laboratories, rodent surgeries, imaging, whole body irradiation, hazardous agent containment, and behavioral studies; and inspection of aseptic surgery facilities (general considerations, operating room, surgical support, animal preparation, surgical scrub, postoperative recovery, and dressing area).

- 3) Following inspection the consulting veterinarian prepares an inspection report that is reviewed and signed by the members of the inspection group. This inspection report is submitted to the chairperson of the IACUC for consideration during the semi-annual program evaluation (see 1. above).

Prepare semiannual reports of the IACUC evaluations according to PHS Policy IV.B.3. and submit the reports to the Institutional Official (IO), the Associate Provost and Associate Vice President for Graduate Studies and Research. The Semiannual Report will include a description of the nature and extent of this Institution's adherence to the *Guide for the Care and Use of Laboratory Animals*. Any departures from the *Guide* will be identified specifically and the reasons for each departure will be stated and reported to the IO. Deficiencies noted will be distinguished as minor or significant with a reasonable plan and schedule for correcting each deficiency. Any minority views will be included with the report. The Report will be signed by a majority of the IACUC members.

- 4) Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows: The names, departments, telephone numbers and email addresses of the members of the IACUC are made available through the Office of Research Compliance. The public website of EMU – Office of Research Compliance contains information regarding institutional compliance and lists contact information for the Research Compliance Officer and IACUC Chair. The availability of the list is also prominently displayed in the Animal Facility. Individuals with concerns about the care and use of animals at the institution are invited to voice their concerns either by requesting a meeting with members of the IACUC or submitting their concerns either by letter, telephone call, or email message to the IACUC, its Chair, or the Research Compliance Officer, which has responsibility for federal compliance with PHS research guidelines. This may be done anonymously. Alternatively, individuals may express their concerns to the academic department heads or to specific union officer who may then bring the concerns to the IACUC. Concerns brought to the attention of the IACUC will be investigated and the results of the investigation reported to the Institutional Official by formal letter. Any individual raising concerns about the care and use of animals shall be protected from any reprisal from EMU staff, faculty, officials, or students if the issue of concern is investigated and found to be valid.
- 5) Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. Any recommendations to the Institutional Official are included in the semi-annual program review evaluation. A recommendation may also be made directly at any time the IACUC decides an issue requires attention, or alternatively, the IACUC may request to meet with the Institutional Official or a staff member of their office.
- 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.
  - a) IACUC review of "Application to Use Vertebrate Animals" ("Application") submitted by an investigator begins with the investigator securing a blank application form or electronic copy,

completing the form and filing it with the Office of Research Compliance. The Research Compliance Officer assigns an application number to the proposed project, does a preliminary check of the application for completion of all required fields, and then sends it in PDF via email to the IACUC chair. The IACUC chair is responsible for designating the Committee members who would conduct the Designated Member Review, and so informs the Research Compliance Officer. In turn, the Research Compliance Officer circulates to all members of the IACUC the application and the names of the designated reviewers, giving all members one week (seven calendar days) to call for review by the full committee. Full Committee review is described below.

If no one calls for a full committee review, the Research Compliance Officer informs the designated reviewers and the consulting veterinarian, who then perform the review. If any of the designated reviewers or veterinarian requests supplemental clarification from the investigator, the Research Compliance Officer forwards the request and supplemental information supplied to the other reviewers and the veterinarian so that all reviewers are basing their decisions on the same information. In order for an application to be approved, the designated reviewers must be unanimous in their decision. The possible outcomes of the designated member review process are: Approved, Require Modifications of the Protocol, or Request Full Committee Review. Full Committee review may result in Approval, Requirement for Modification, or Disapproval.

Normally the IACUC will review applications within 30 days of receipt. If approved the application number will be designated as an "approval number" which must accompany all requisitions for procurement of animals for the project.

b) Approval must also be obtained for projects where animals are not directly purchased, e.g., wild trapping, donated, "in-house breeding," received from other laboratories, or obtained from other non-commercial sources. Only those species and quantities that are listed in the approved application may be procured (the Purchasing Department monitors this).

c) If full IACUC review is requested, approval 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. A member may not participate in the IACUC review of an application or proposal in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC. No member who has a conflicting interest may contribute to the constitution of a quorum.

If the Full Committee determines that additional substantive clarifications are required prior to approval, the full Committee will reconvene at a subsequent meeting when the information has been provided. If the Full Committee determines that a protocol is approvable, contingent on receipt of a very specific administrative modification or clarification, (e.g., a contact telephone number), the Committee may elect to handle the issue as an administrative detail that the IACUC Chair or Research Compliance Officer may verify prior to approval.

d) The IACUC may invite consultants to assist in the review of complex issues. Consultants may not approve or withhold approval of an application or proposal and do not vote with the IACUC.

e) Applications and proposals that have been approved by the IACUC may be subject to further appropriate review and approval by University officials. Those officials, however, may not approve those sections of an application or proposal related to the care and use of animals if they have not been approved by the IACUC.

f) If the IACUC suspends an activity involving animals, as described in section III.D.10 of this Assurance, the Institutional Official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with full explanation to OLAW.

g) The EMU IACUC does not permit expedited protocol reviews.

- 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. Significant changes include changes from non-survival to survival surgery; changes resulting in greater pain, distress, or degree of invasiveness; changes in housing and/or the use of animals in a location that is not a part of the original, approved IACUC protocol; changes in species; changes in study objectives; changes in principal investigator; changes that affect personnel safety; changes in anesthesia, analgesia, sedation, or experimental substances; and changes in the duration, frequency, type, or number of procedures performed on an animal. Significant changes can also include changes, not listed above, that substantively change the research activities or risks as outlined in the originally approved IACUC protocol. The IACUC procedures for reviewing proposed significant changes in ongoing research projects require that the investigator submit either a new application, with the proposed protocol changes highlighted, or a memo describing in detail the proposed changes, with appropriate references to the portion of the original application that changes apply to, along with the original application. From this point the process of Part III.D.6 (above, Designated Member Review) of this procedures statement is followed. Non-significant changes are reviewed either by the IACUC Chair or the Attending Veterinarian.
- 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 shall notify the Institutional Official and the investigator in writing of its decision to approve or withhold approval of those sections of application or proposal related to the care and use of animals, or of modifications required to secure IACUC approval. If the IACUC decides to withhold approval of an application, written notification to the investigator must include a statement of the reasons for its decision and give the investigator an opportunity to respond in person and in writing.
- 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 *de novo* review at least once every 3 years according to PHS Policy IV.C.1-5. Each protocol shall be approved for not more than three years. The IACUC shall conduct continuing review of application and proposals covered by these procedures at appropriate intervals as determined by the IACUC but not less than once every three years. The list of active protocols is reviewed by the Office of Research Compliance at the beginning each month to determine whether any annual reviews are due or any approvals will expire the following month. If an annual review is due the following month the investigator will be contacted, usually via email (with copies to IACUC Chair), and the investigator will provide a report of the study progress to the IACUC Chair and Research Compliance Officer. If a protocol is due to expire the following month the Office of Research Compliance will inform the investigator via email (with copies to IACUC Chair) of the obligation to either terminate the research at the expiration date or submit a new protocol for review in a timely manner, including that, should the protocol expiration date be reached, the research must be halted until a new application has been reviewed and approved by the IACUC in the manner of Designated Member Review or Full Committee Review of all new applications described in III.D.6. above.

In the rare circumstance that a protocol expires and protocol-covered animals remain in the facility, no PHS funds will be used for the care of those animals.

- 10) Be authorized to suspend an activity involving animals according to PHS Policy IV.C.6. If the IACUC suspends an ongoing activity involving animals, the Institutional Official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action and report that action with a full explanation to OLAW. The IACUC may suspend an activity that it previously approved if the IACUC determines that the activity is not being conducted in accordance with the applicable provisions of the Animal Welfare Act, the *Guide*, the institution's Assurance, or University Policy. The IACUC may suspend an

activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.

- E. Investigators are required to submit an IACUC Application to Use Vertebrate Animals and obtain IACUC approval prior to initiating research involving animals. In addition, investigators are required to notify the IACUC Chair and the consulting veterinarian prior to bringing a new species into the facility. The IACUC Chair and/or consulting veterinarian will inform the investigator of record keeping requirements for animal husbandry.

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: By institutional policy, EMU has an Environmental Health and Safety program administered through the University's Environmental Health and Safety Director and a Workers' Compensation program administered through the Office of Risk Management and Workers' Compensation. All University employees, including but not limited to faculty, visiting faculty, animal care staff, IACUC members, plant staff, maintenance staff, police and safety, security, and housekeeping, are covered by these University programs and are enrolled at the time of hire by virtue of their employment status. Students, including visiting students, are covered by the Environmental Health and Safety program by virtue of their student status. The Environmental Health and Safety staff conducts campus-wide risk assessments, hazard identification and risk reduction in compliance with university policy and requirements of OSHA, MIOSHA and DEQ. The Environmental Health and Safety staff conducts periodic evaluations of university facilities, including the vivarium and any satellite facilities. There are institutional policies and procedures for personal hygiene, handling hazardous agents, and personnel protection in accord with OSHA and MIOSHA regulations. For the vivarium, these include providing protective gloves, facemasks and protective coverings for individuals while exposed in the facility. Signs are posted regarding hazardous materials and safety precautions. The program includes a procedure for reporting injuries or accidents through Risk Management, and a workers' compensation facility (Washtenaw Urgent Care) for treating bites, scratches, illness; employees with more serious injuries will be taken to nearby St. Joseph Mercy Hospital Emergency Room. Any necessary immunizations and vaccinations, including tetanus vaccinations or prophylaxis, are handled at the main campus University Health Service facility or Washtenaw Urgent Care.

The specific program for the vivarium is a specialized component of the institutional program. With respect to animal users, the University has established a screening program for all faculty and staff who handle animals. This program is administered through Environmental Health and Safety and the health care providers for the University, University Health Services and Washtenaw Urgent Care. Prior to exposure to animals or potential health and safety risks, and thereafter, once a year or at intervals deemed appropriate by Environmental Health and Safety, each faculty or staff member is required to complete a Risk Assessment Form for health evaluation. This form both surveys and informs the animal user of potential health and safety risks with respect to the use of laboratory animals in specific procedures. The physician screens the forms and those individuals deemed to be at significant risk are selected for physical examinations and inoculations, as appropriate. The Research Compliance Officer is responsible for arranging for training regarding potential zoonoses in laboratory animals, allergies to laboratory animals, and hazards associated with working with laboratory animals and in an animal facility. The Environmental Health and Safety staff, the Research Compliance Officer, the chair of IACUC or the veterinarian, as appropriate, provide the training for typical hazards as well as for identification of any precautions to be taken during special circumstances such as pregnancy, illness, or decreased immunocompetence. All individuals with exposure to animals will be offered protective gloves and approved facemasks while they are exposed in the facility.

Eastern Michigan University has in place various safety protocols and guidelines in place to address personal hygiene and handling of hazardous agents. The following is a brief summary of these protocols and guidelines:

- 1) The University has in place a Safety Policy and Procedures Program, which addresses overall compliance with MIOSHA, EPA, DEQ, NRC, etc., requirements.

- 2) The Chemical Hygiene Plan, Bloodborne Pathogen programs, and Research Facility Safety Plan address specific issues of personal hygiene and handling of hazardous agents. PPE hazard assessments should be conducted for all areas with potential hazards, see attached assessment sheet. The EMU vivarium requires that individuals working with animals in any capacity use appropriate PPE (e.g., nitrile gloves, lab coats, masks, etc.). Lab coats are not worn outside of the animal facility and are laundered by a commercial laundry service after use. Hand washing stations are in the vivarium hallway and in each room in which animals are housed and in which animal procedures occur. Eating, drinking, and tobacco use are prohibited in the vivarium, with the notable exception of the office, where eating and drinking can occur. The office is separated by a fire door from the areas in which animals are used. There are signs posted around the vivarium, on the door to the facility and on the doors to each lab and housing room within the facility, indicating that food and drink are prohibited. EMU's campus is tobacco free, so tobacco use is not permitted anywhere in or around the vivarium building. Cosmetic and contact lens application is prohibited in areas in which animals are used or housed. The IACUC application contains a section in which the principal investigator is required to list hazardous agents used. The use is reviewed by the IACUC, including the consulting veterinarian. Before any hazardous agents are purchased or obtained for use, the Laboratory Compliance Manager discusses use, storage, and disposal requirements with the principal investigator. All EMU faculty, staff, and students who work in a laboratory are required to complete laboratory safety training. The Laboratory Compliance Manager, who conducts the training, sits on the IACUC ex-officio, and informs the IACUC on training status. For specific hazards, the principal investigator is responsible for ensuring that they and their research staff are trained and for documenting training. The IACUC protocol application requires that principal investigators provide an explanation of such training and their method for documentation.
  - 3) For animal handlers, the health and safety questionnaire for Working with Animals is to be completed by all faculty, staff and students entering into the animal facility. Specific training is provided to the Physical Plant and Custodial staff.
  - 4) The Laboratory Compliance Manager routinely conducts inspections of the animal care facility and laboratories, addressing safety concerns or issues of non-compliance.
- F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed there and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table.
- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows.

EMU implements the Collaborative Institutional Training Initiative (CITI) Animal Care Training modules offered by the University of Miami. EMU requires CITI training for all IACUC members, the Institutional Official, all investigators on IACUC protocols, student vivarium employees, and students who handle animals as a part of their coursework. There are specialized CITI courses for people working with different species of vertebrates as well. In addition, the investigators or instructors for each project or course will offer specific training sessions for the activities included in their projects. The CITI course includes material about research or testing methods that minimize the number of animals required to obtain valid results and minimizing distress. In addition, principal investigators must demonstrate this knowledge in their application to use animals in research or teaching.

There are additional training sessions for specific issues such as: anesthesia, surgical interventions, aseptic and surgical technique, anesthesia, surgery, and post-surgical care for rodents or non-rodent mammals, maintaining rodent breeding colonies, orientation for teaching assistants using animals in instructional project, or handling of uncommon species (e.g., snakes). Training and supervision is provided by either PowerPoint-based tutorial (e.g., injection or surgical techniques), or in-person demonstrations (e.g., snake handling) from the consulting



veterinarian or a qualified designee. If the need cannot be satisfied internally, arrangements are in place for attending training sessions held at the University of Michigan Unit for Laboratory Animal Medicine (ULAM).

Investigators provide hands-on demonstration and training for research assistants and students as individuals or small groups on common methodology such as retrieval from the cage, handling, restraint, injections, euthanasia, and aseptic surgical technique, and health hazards for both animal and handler. If a specialized need is identified for a species or technique, the investigator together with the IACUC Chair and the consulting veterinarian will locate a qualified individual to provide proper training.

Indirect training is provided for investigators by the design of the protocol application. The Animal Use Application has been designed to convey information to researchers as they complete the application through the instructions in each section, in particular there are sections on rationale, use and justification reduction of animal use, reductions of pain, discomfort and distress, as well as a section on identification of the availability of non-animal based methods and a justification of the animal-based model. Periodic updates are provided to IACUC and the investigators by the consulting veterinarian at the semi-annual reviews together with references to changes in standard operating procedures, guidelines, and other informational documents pertinent to research projects. During the application review process, communication between researchers and reviewers provides many opportunities to educate researchers on current regulations and standards, as well as appropriate agents, methods, models, and other refinements.

IACUC member training is provided by an orientation to animal care at EMU, PHS Policy, *The Guide for the Care and Use of Laboratory Animals*, the *Animal Welfare Act and Animal Welfare Regulations*, the OLAW/ARENA IACUC Guidebook, and the approved EMU Animal Welfare Assurance, by distributing electronic (PDF) copies of each of these documents to the new members. Websites, training sessions, and the previously listed reference documents are also made available to standing members. The consulting veterinarian provides training and updates to the longstanding members of IACUC at the semi-annual meetings. IACUC members and investigators are provided information about and encouragement to attend professional conferences regarding the human care and use of animals.

Additional training or instruction of scientists, animal technicians, students and other personnel involved in animal care, treatment, or use is provided in training sessions developed by the University of Michigan Unit Laboratory Animal Medicine faculty and staff. Sessions and materials provided to us by the consulting veterinarian are available to investigators and animal users for their own use and to use in their classes. Additional training sessions devoted rodent care, our major need, are available to instructors for use with their students and assistants. For instances where individuals cannot use these materials or where more specific needs occur, EMU has an independent contracting arrangement with an experienced trainer at the University of Michigan. The trainer at the University of Michigan provides additional training in minimizing distress.

#### **IV. Institutional Program Evaluation and Accreditation**

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

This Institution is Category 2 — not accredited by the [Association for Assessment and Accreditation of Laboratory Animal Care International \(AAALAC\)](#) <sup>®</sup>. 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) from November 2017 is attached.

## **V. Recordkeeping Requirements**

All records of the IACUC and the operation of the Animal Facility at this institution will be maintained in the Office of Research Compliance. Health records of animal handlers are maintained by the individual employee's Health Care Provider and HIPAA compliant information is provided to the University. Environmental Health and Safety maintains these records.

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

## **VI. Reporting Requirements**

- A. This Institution's reporting period is the calendar year (January 1 – December 31). The IACUC, through the Institutional Official, will submit an annual report to OLAW by January 31 of each year. The annual report will include:
  - 1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked)
  - 2. Any change in the description of the Institution's program for animal care and use as described in this Assurance
  - 3. Any change in the IACUC membership
  - 4. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, the Associate Provost and Associate Vice President for Graduate Studies and 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 deviations from the provisions of the *Guide*
  - 3. Any suspension of an activity by the IACUC
- C. Reports filed under VI.A. and VI.B. above should include any minority views filed by members of the IACUC.