

**Cleveland State University**  
**D16-00338 (Legacy A3554-01)**  
**ANIMAL WELFARE ASSURANCE**  
**in accordance with the PHS Policy for**  
**Humane Care and Use of Laboratory Animals**

## **Animal Welfare Assurance for Domestic Institutions**

I, Dr. Jerzy T. Sawicki, Vice President for Research, as named Institutional Official for animal care and use at Cleveland State University (CSU), hereinafter referred to as Institution, by means of this document, provide assurance that this Institution will comply with the Public Health Service Policy (PHS) on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

### **I. Applicability of Assurance**

This Assurance is applicable to all research, research training, experimentation, biological testing, and related activities, hereinafter referred to as activities, involving live, vertebrate animals supported by the Public Health Service (PHS), Health and Human Services (HHS) and National Science Foundation (NSF) conducted at Cleveland State University (CSU), or at another Institution as a consequence of the sub-granting or subcontracting of a PHS conducted or supported activity by this Institution. There are no branches or components of this Institution.

### **II. Institutional Commitment**

- A. CSU will comply with all applicable provisions of the [Animal Welfare Act](#) and other Federal statutes and regulations relating to animals.
- B. CSU is guided by the "[U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training.](#)"
- C. CSU 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. CSU 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. CSU 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.

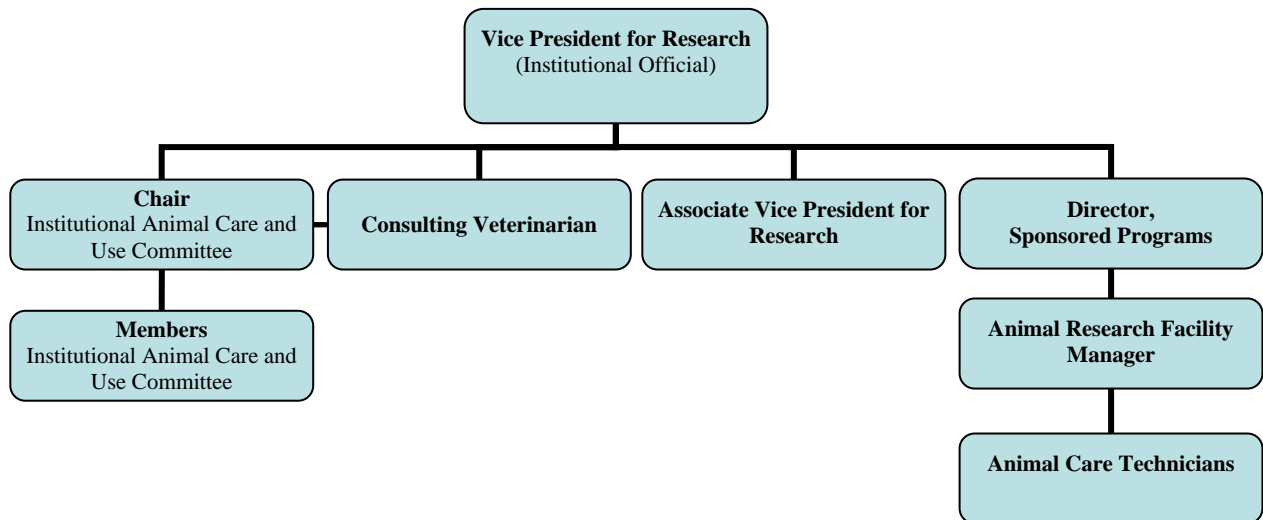
### **III. Institutional Program for Animal Care and Use**

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

The chairperson and members of the Institutional Animal Care and Use Committee (IACUC) are appointed directly by the Vice President for Research. At CSU, the Vice President for Research is the Institutional Official (IO). The IACUC is supported by staff under the supervision of the Associate Vice President of Research. Animal facilities at the University are under the direction of

the Vice President for Research. The Consulting Veterinarian reports both to the Vice President for Research in matters related to the day-to-day veterinary care of animals and to the Chairperson of the Animal Care and Use Committee for policy matters related to the University's compliance with applicable federal regulations. The Animal Research Facility Manager reports directly to the Director of Sponsored Programs who in turn reports directly to the Vice President for Research. In addition to communication amongst the IACUC Chair, Attending Veterinarian, and Institutional Official, there are also open lines of communication between the IACUC members and the designated IO as required by PHS Policy. These lines of communication include the ability of IACUC members to contact the IO directly by visiting the IO office, by telephone communication, and/or by e-mail communications.

## Organizational Chart Lines of Authority Cleveland State University



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

1) Name: Dr. Stanley Dannemiller

- **Qualifications**

Degrees:

M.S., Comparative Medicine/Toxicology, University of Pennsylvania, Philadelphia, PA, 1995

D.V.M., Veterinary Medicine, The Ohio State University, Columbus, OH, 1988

M.S., Zoology, (Comparative Physiology), The Ohio State University, Columbus, OH, 1984

Board certified, American College of Laboratory Animal Medicine (ACLAM), 1996

- **Training or experience in laboratory animal medicine or in the use of the species at the institution:**

Dr. Dannemiller is licensed to practice veterinary medicine, and is USDA accredited, in the State of Ohio. He maintains his license and board-certification by participation in local, regional, and national meetings presented by AALAS, ACLAM, Ohio Scientific Education & Research Association (OSERA) and USDA, and participation in OLAW and other scientific organization webinars. He is an active member of the American Veterinary Medical Association, the American Society of Laboratory Animal Practitioners, The American College of Laboratory Animal Medicine, the American Association for Laboratory Animal Science, and the Association of Primate Veterinarians.

Dr. Stanley Dannemiller, our consulting veterinarian, has established and supervises programs of disease control and prevention, pest and parasite control, technical and animal husbandry, pre-procedural care, nutrition, euthanasia, and adequate veterinary care for all animals housed within the University's animal facilities. Dr. Dannemiller has experience caring for a diverse animal population from transgenic mice to agricultural species. The University has employed Dr. Dannemiller since May 15, 2006 and he oversees our University's Program of Veterinary Care, which is administered by the Animal Research Facility Manager who is responsible for the daily operations of the animal facilities.

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

Time contributed to program:

Dr. Dannemiller performs site visits as needed, but at least 6 times per year (approximately every other month) and he attends the Institutional Animal Care and Use Committee meetings as scheduled. Dr. Dannemiller partakes in the semi-annual facility inspections performed by the IACUC and he is readily available for training purposes or for additional consultations. Dr. Dannemiller contributes 5% of his time to the animal care and use program.

## 2) **Backup Veterinarian**

Name: Dr. Nannette Kleinman

Qualifications

- Degrees:  
D.V.M. The Ohio State University, 1980  
Board certified by the American College of Laboratory Animal Medicine (ACLAM), 1995
- Training or experience in laboratory animal medicine or in the use of the species at the institution:

Dr. Kleinman was employed by Case Western Reserve University as Associate Director for Veterinary Services from 1983-2001 and as Associate Director, Animal Resource Center and Head of Veterinary Services from 2001-2012.

Responsibilities:

Serves as backup veterinarian when consulting veterinarian is unavailable.

Time contributed to program:

Serves as backup veterinarian when consulting veterinarian is unavailable.

- C. The IACUC at CSU 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 in section VIII page **12** is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

D. The IACUC will:

- 1) Review at least once every 6 months the Institution's program for humane care and use of animals, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

During a convened IACUC meeting the committee Chair designates a subcommittee to conduct the semiannual program review. The subcommittee uses the semiannual program review checklist to help facilitate the program review and ensure compliance with this Policy (*attached Appendix A*). The subcommittee uses professionally accepted standards for the care, treatment and use of animals, considers alternatives to painful protocols; ensures facilities adhere to USDA Regulations; and sets standards and regulations to be followed by investigators and researchers.

It is the policy of Cleveland State University to review the institution's program for humane care and use of animals and inspect all of the institution's animal facilities at least once every 6 months using the *Guide for the Care and Use of Laboratory Animals: Eighth Edition* as a basis for evaluation. Toward this goal, the IACUC uses the Inspection Checklist (see attached) to evaluate each major program for animal use and care. These include Occupational Health and Safety, Veterinary Care Program, PHS Policy/Animal Welfare Assurance, Training Program, and Terrestrial Animal Housing and Support Areas including Aquatic Animal Housing and Support Areas, Cagewash, and Special Facilities used for Aseptic Surgery, Non-survival Surgeries, Laboratories, Rodent Surgeries, Hazardous Agent Containment, and Behavioral Studies. Please note that the checklist covers the major topics of the *Guide* and the requirements of the PHS Policy. However, the checklist does not replace the *Guide*, but is utilized in conjunction with the *Guide*.

- 2) Inspect at least once every 6 months all of the Institution's animal facilities, including satellite facilities and animal surgical sites, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:
  - a. All IACUC members are invited to participate in semiannual facility and satellite facilities inspections, but at least two members of the IACUC and the Animal Research Facility Manager (or designee) must attend these inspections. The IACUC performs a walk-through of the facility and satellite facilities. Each room in the animal facility and satellite facilities are examined and the results of the inspection are documented in a report. A checklist indicating room number, condition of room, condition of animals housed within that room, and any deficiencies noted are reported. Deficiencies are listed in a report to the proper Investigator and he\she has two weeks to make corrections. All inspection reports are disseminated to the IACUC for feedback.
  - b. Even though a formal, semi-annual review is undertaken, the attending veterinarian also provides the Animal Research Facility Manager, and members of the IACUC with, at minimum, written reports on the state of the animals and the facility as needed, but at least 6 times per year (approximately every other month). Topics covered include use of space, animal care needs, health of animals, and maintenance/staffing of the facility. Any items of concern brought forward by the attending veterinarian are further discussed at the next regularly scheduled IACUC meeting.

- 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:
  - a. Note deficiencies in the Animal Care and Use program using the semiannual program review checklist. Identify departures from the PHS Policy and USDA Regulations, state possible reasons for the departures, and list any major\minor deficiencies that are found. The deficiencies in the program are listed on the program review checklist which is distributed to the IACUC members and discussed\resolved at the next convened IACUC meeting.
  - b. Note deficiencies in the animal facility or satellite facilities using an inspection report. The deficiencies in the animal facility are noted in the report and sent to the Animal Research Facility Manager for corrective action. Deficiencies in satellite facilities are sent to the appropriate Investigator. Corrections should be made within two weeks of receiving the inspection deficiency report. After modifications are made the areas are re-inspected by the IACUC and the forms are sent to the committee for review and feedback. These forms are approved by the IACUC.
  - c. The IO report lists the findings of the evaluations, any changes of personnel to the IACUC or staff at the animal facility; and includes minority views, if applicable. The report is sent to the IACUC for review and approval. The IO Report is signed by a majority of the IACUC members. Once signed, it is forwarded to the Vice President of Research. After the IO receives the report, an IACUC leadership meeting is scheduled to discuss deficiencies found with the program.
  
- 4) Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:
  - a. Promote CSU policies that encourage and support high levels of animal care and welfare.
  - b. Establish guidelines for the investigation of complaints, including reporting lines, authority to impose sanctions, assurances of due process, appeal procedures, confidentiality and nondiscrimination against the reporting party.
  - c. Provide multiple channels for personnel to bring complaints or comments to the IACUC. Personnel should receive instruction on methods of raising concerns and on whistle-blower protection against reprisals as required by law.
  - d. Determine if a complaint has sufficient substance to be investigated further and appoints an Investigative Committee.
  - e. Investigative Committee of the IACUC informs alleged violator of nature of complaint and investigative procedures that will be followed.
  - f. Investigative Committee examines pertinent documents, animals, procedures, personnel, etc.
  - g. Investigative Committee presents findings to IACUC for endorsement with appropriate recommendations to Institutional Official.
  - h. Institutional response dictated by nature of findings, legal requirements and Institutional policies.

The Institution has an Animal Care and Use Investigative Concerns Policy which specifies the courses of action that can be taken to report concerns. All calls and reports may be made anonymously. Any individual identifying any animal care and/or use concern(s) or possible protocol violation(s) should (1) contact the IACUC Chair or IO or (2) fill out an "*Animal Care and Use Reporting Form*" and submit the document to the IACUC Secretary. Animal Care

and Use Reporting Forms are located on the bulletin board in the animal facility and in each satellite facility. This information is discussed with individuals during Facility Orientation.

- 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:
  - a. Prepare reports of IACUC evaluations and submit the reports to the Vice President of Research.
  - b. Make recommendations to the Vice President of Research regarding any aspect of the research facility's animal program, facilities, or personnel training.
  - c. At a scheduled IACUC meeting mention recommendations to the program, facilities, or training and send the meeting minutes to the Institutional Official.
  - d. Contact the Institutional Official via phone or email to make recommendations to the program or facilities.
  
- 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:
  - a. A new protocol submission is submitted to the IACUC secretary in person or via email. The IACUC secretary sends a receipt of submission to the investigator and the proposed protocol is sent to the consulting veterinarian to preview. The consulting veterinarian sends his comments to the investigator. The needed corrections/clarifications are made and the document is sent back to the IACUC Secretary. Prior to the review, each IACUC member is provided with a full copy of the protocol outlining the list of proposed research projects to be reviewed. Written descriptions of research projects that involve the care and use of animals shall be available to all IACUC members at least ten (10) business days prior to a scheduled IACUC meeting. Full committee review is required of all proposals submitted to the IACUC.

Approval of research projects may be granted only after review at a convened meeting of a quorum of the IACUC with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of a research project in which the member has a conflicting interest (e.g., is personally involved in the project), except to provide information requested by the IACUC, nor may a member who has a conflicting interest contribute to the constitution of a quorum.
  - b. The IACUC shall notify investigators and the Institution in writing of its decision to approve, require modifications in (to secure approval), or withhold approval of those activities related to the care and use of animals. If modifications are required to secure approval, following full committee review by the IACUC, the IACUC votes to approve protocol by designated member review (DMR). If any member requests full committee review (FCR) then that method must be used. In addition, all members, (including members who might not have been present at the meeting in which the application was reviewed) receive a revised research protocol via e-mail and have an opportunity to call for FCR if it is deemed necessary. DMR may be conducted only if all members of the committee have had the opportunity to request FCR and none have done so. A designated member review (DMR) group is appointed by the IACUC Chair. This group works with the investigator to ensure that the needed modifications are made. Once changes to the document are completed the DMR may approve the protocol. DMR may result in approval, a requirement for

modifications (to secure approval), or referral to the full committee for review. If more than one DMR, all DMRs will review identical copies of the protocol and the reviewers will be unanimous in their decision. If the IACUC decides to withhold approval of an activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond to the committee in writing. Special and/or expedited reviews may be scheduled for a full committee review on an emergency basis.

- c. The IACUC shall determine that the research project conforms to the Institution's Assurance and meets the following requirements:
  - 1). Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
  - 2). Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
  - 3). 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.
  - 4). Living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and non-medical care of the animals will be directed by a veterinarian, or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.
  - 5). Medical care for animals will be available and provided as necessary by a qualified veterinarian, by the Animal Research Facility Manager, or by trained staff.
  - 6). Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures. Training records will be kept by the Investigator providing the training
  - 7). Methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.
- d. If the researcher is out of compliance with any of the above, the IACUC will request a modification to the protocol, e.g., the number of animals used is greater than the IACUC determines is needed, the researcher must submit a justification for the number of animals. If a significant modification is requested by the researcher, the IACUC will request a new protocol for review. The IACUC will withhold approval of the protocol if it is determined that the experiment(s) planned can be done without animals (computer simulations), or if the procedures proposed are not scientifically sound.

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:

- a. Proposed significant changes are reviewed using the process described in Part III.D.6.

Significant changes are considered to be:

- from nonsurvival to survival surgery;
- resulting in greater pain, distress, or degree of invasiveness;
- in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
- in species;

- in study objectives;
- in Principal Investigator (PI); and
- that impact personnel safety

Amendments with changes determined not be significant are reviewed by the IACUC Chair. The IACUC Chair will review amendment and grant approval or contact researcher for additional information.

- b. Approval of research projects may be granted only after review at a convened meeting of a quorum of the IACUC with the approval vote of a majority of the quorum present. Work can begin after training and facility orientation is completed by the person(s) listed in the protocol.

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

The IACUC shall notify investigators and the Institution in writing of its decision to approve, require modifications to (to secure approval), or withhold approval of those activities related to the care and use of animals. If the IACUC decides to withhold approval of an activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

The Institutional Official is notified of the decisions to approve, withhold, or require modifications to secure IACUC approval by receipt of the minutes of IACUC meetings which provides extensive details regarding the IACUC's decisions on all applications (renewals and new) and amendments to existing protocols.

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:

- a. The IACUC shall conduct continuing review of each previously approved, ongoing activity covered by this Policy at least annually, including a complete review in accordance with IV.C.1-4. once every three years (please refer to process described in Part III.D.6). After three years, if the animal work is to continue, the investigator must write and submit a new protocol to the IACUC for review and approval prior to the expiration date of the protocol the animals are currently listed under.

The IACUC monitors ongoing activities through a variety of different methods. The primary method is through open lines of communication with the Attending Veterinarian. In particular, the Attending Veterinarian provides the IACUC with reports from bimonthly inspections performed by the Attending Veterinarian. In addition, the IACUC maintains open lines of communication with the Manager of the ARF, and the IACUC Chair and Manager routinely communicate (~once a week) to discuss details regarding the operational status of the ARF which includes, but not limited to, post-approval monitoring. Likewise, there is a "whistle-blower" policy that allows ARF staff and animal researchers to directly report any incident involving post-approval monitoring to the IACUC Chair.

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:

- a. The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the *Guide*, the Institution's Assurance, or section IV a. - h. of this Policy.



- b. 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. If the IACUC suspends an activity involving animals, the Institutional Official in consultation with the IACUC reviews the reasons for the suspension, takes appropriate corrective action, and reports the action with a full explanation to OLAW and the federal granting agency. If regulated species are involved in the research, then the USDA must also be notified.
  - c. All animals housed under a suspended protocol will be transferred to a holding protocol which is held by the manager of the Animal Research Facility and that has been approved by the IACUC; the investigator will NOT be allowed to continue the research with these animals during the period of the suspension.
- E. The risk-based occupational health and safety program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals is as follows:

The IACUC at Cleveland State University is aware that the development and implementation of a program of medical evaluation and preventive medicine should involve input from trained health care professionals. As such, all animal users must undergo a health evaluation before work assignment is advisable to assess potential risks for individual employees. These examinations are provided at St. Vincent's Charity Hospital. In addition, periodic medical evaluations are advised for personnel in specific risk categories such as those that may be at risk for allergic reactions. Appropriate immunization schedules are recommended as the IACUC recognizes the importance to immunize animal care personnel against tetanus and other agents such as rabies virus and hepatitis B virus.

The Occupational Health and Safety Program was written to increase awareness of the hazards involved in the use of animals for teaching and research, to suggest some courses of action, which may be taken to reduce these hazards and to prevent accidents. The program covers personal hygiene, handling hazardous agents, and personnel protection.

Policies are established and enforced with respect to the proper maintenance of personal hygiene while entering and working within the Animal Research Facility (ARF). In particular, the ARF supplies suitable attire and PPE including gloves, masks, head covers, coats, coveralls, and shoe covers for use in the animal facility and laboratories in which animals are used. It is the policy that all soiled attire be disposed of and/or decontaminated by the institution as appropriate. Personnel are expected to wash and/or disinfect their hands and change clothing as often as necessary to maintain good personal hygiene. Outer garments worn in the animal rooms should not be worn outside the animal facility unless covered. Finally, personnel are not allowed to eat, drink, use tobacco products, apply cosmetics, or handle or apply contact lenses in rooms and laboratories where animals are housed or used.

In some instances, researchers perform experiments that may use hazardous agents such as selected anti-cancer, anti-microbial, or anti-viral agents. In cases where hazardous agents are used, it is the policy of the IACUC to ensure that careful attention be given to procedures for animal care and housing, storage and distribution of the agents, dose preparation and administration, body fluid and tissue handling, waste and carcass disposal, items that might be used temporarily and removed from the site. Specific examples include that researchers provide written records, experimental devices, and protective sample vials in addition to the use of personal protection as described above for Personal Hygiene (vide supra). In addition, the IACUC communicates with the institution's Office of Environmental Health and Safety that is responsible for evaluating the safe use of hazardous materials and/or procedures involving hazardous materials. Together, the IACUC and Office of Environmental Health and Safety review the procedures and facilities to be used to evaluate and assess specific safety concerns. Formal safety programs are established by the Office of Environmental Health and Safety to assess hazards, determine the safeguards needed for their control, and ensure that staff have

the necessary training and skills and that facilities are adequate for the safe conduct of the research.

As indicated above, all animal users must undergo a health evaluation before work assignment is advisable to assess potential risks for individual employees. During this initial health evaluation process, all employees are trained on precautions to be taken during personnel pregnancy, illness, or decreased immunocompetence. In addition, the Animal Research Facility, under the direction of the IACUC, has posted messages highlighting the importance of precautions to be used during personnel pregnancy, illness, or decreased immunocompetence.

The program is in accordance with the Risk Assessment and Hazard Identification as described in the *Guide for the Care and Use of Laboratory Animals*. One IACUC member currently serves as an Environmental Health & Safety Officer at Cleveland State University and is involved in planning and monitoring the program. Every participant of a research project involving animals undergoes training on safe and humane handling of the animals, recognition of the sign of animal aggression, safe performance of the sampling techniques and the like. In order to prevent injuries and illnesses, the individuals are required to wear various personal protective equipment (PPE). Additional safety items are provided as feasible upon an individual request. Appropriate warning signage is posted, on an as needed basis, to prevent exposure to potentially hazardous chemicals, allergens or work conditions. To assure safe work environment, ARF is continuously monitored for maintenance of the appropriate levels of clean air, temperature, lighting, noise and vibration.

1. Employees of the Cleveland State University's Animal Research Facility are required to participate in the Occupational Health Program. A pre-employment physical examination including a medical history and tuberculosis test are required for employee's protection. It is also required that a tetanus vaccination be given if it has been greater than seven years since the employee's last vaccination. This is conducted prior to beginning work. Arrangements are made with St. Vincent Charity Hospital, located at 2322 East 22<sup>nd</sup> Street, Suite 101, Cleveland, Ohio 44115 for the pre-employment physical examination and vaccination.
2. Employees are made aware of zoonotic diseases, allergies to laboratory animals, and the inherent hazards associated with handling laboratory animals, as well as working in an animal facility through required CITI Online Training Modules. Investigators and their personnel are also required to participate in the established online training. In addition, each investigator is responsible for familiarizing themselves and their personnel with the contents of the Occupational Health and Safety program and with the aforementioned Public Health Service publication. The investigator should be aware of and is responsible for all potential hazards created by their work. The PI should devise and implement suitable safeguards for the prevention of accidents. The investigator is to motivate, inform, and instruct all personnel to use animals and equipment in a correct and safe manner. The IACUC oversees the training of individuals who are involved with laboratory animal research projects.

Other personnel such as maintenance, police and safety, security, housekeeping, summer students or visiting faculty must receive prior approval to enter the ARF. All personnel working in ARF must receive health clearance by St. Vincent's Medical Hospital. General training is provided during the ARF orientation

Techniques in handling of animals to minimize risk of receiving bites are taught by the veterinarian, manager, or investigator. Every feasible effort is made to prevent injuries or illnesses. First Aid kits and Eye Wash stations are available at multiple locations throughout ARF to address minor incidences. Should more serious injuries or illnesses occur, the affected individuals may utilize professional medical care services provided by the CSU

Wellness Clinic or St. Vincent Charity Medical Center (24-hr emergency service). During normal business hours, injuries occurring at ARF are reported to the ARF Manager and addressed as appropriate. At all other times, the affected individuals are instructed to contact CSU Police (24-hr service) for a prompt assistance.

3. The Manager must be notified if a person is bit or scratched by an animal. The Procedures for bites and scratches are:
  - a. Immediately following a bite/scratch, thoroughly cleanse and irrigate the full depth of the wound with soap and water. Allow at least five minutes direct contact of solution with wound.
  - b. Report the injury to your supervisor and, if needed, go to St. Vincent Charity Hospital, located at 2322 East 22<sup>nd</sup> Street, Suite 101, for treatment. If the injury is severe, call University Police for transportation to the appropriate emergency facility.
  - c. When Injuries are reported to the Supervisor, an "Accident\Incident Report" form is filled out by the employee and signed by the supervisor.
  - d. The form is sent to Environmental Health and Safety and the Human Resources Departments. If medical attention was needed, Care Works should be contacted
  
- 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 in Section X Facility and Species Inventory Table, Page 13.
  
- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:
  1. In accordance with the *GUIDE*, Cleveland State University ensures that the Animal Technicians caring for the animals are qualified to do so. The Institution also provides for on-the-job training to facilitate implementation of the humane care and use of animals. The staff consists of a full-time Animal Research Facility Manager, and two part-time employees who work up to 20+ hours each per week. Personnel using or caring for animals are encouraged to participate in continuing education activities relevant to their responsibilities. The consulting Veterinarian conducts briefings with the staff from time-to-time.
  2. Cleveland State University ensures the qualifications of those performing animal research are adequate. High standards of professional conduct are expected of all faculty researchers. CSU faculty members train technicians and students, both graduate and undergraduate, in proper methods of animal anesthesia, surgery, or other experimental manipulations. For more specialized training involving hazardous, biological, or chemical agents, researchers may take special training at other universities or government laboratories.
  3. A series of Online Training Modules are required for researchers, lab personnel and the IACUC through Collaborative Institutional Training Initiative (CITI). The IACUC and anyone who has direct contact with animals are required to complete at least three of the available modules. A completion report is emailed, by CITI, to the IACUC Secretary. The "Working with Animals in Biomedical Research" module is used as a refresher course every 5 years thereafter. The options for Online Training Modules are as follows:

Working with IACUC  
Essentials for IACUC Members  
Reducing Pain and Distress in Laboratory Mice and Rats  
Aseptic Surgery

Working with Amphibians in a Research Setting  
Working with Mice in Research Settings  
Working with Rats in Research Settings  
Post Approval Monitoring (PAM)  
Working with Animals in Biomedical Research (refresher course)

As part of the orientation, IACUC members are provided a link to the PHS Policy, the *Guide*, the *Animal Welfare Act and Animal Welfare Regulations*, the IACUC Handbook, a copy of the approved Animal Welfare Assurance, Cleveland State Universities' Policies and Guidelines Training Intranet Website and information regarding required CITI training.

#### **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 \(AAALAC\)](#). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request. The report of the most recent evaluations (program review and facility inspection) is attached.

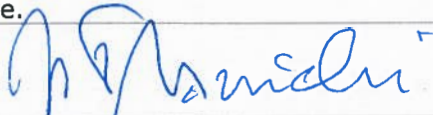
#### **V. Recordkeeping Requirements**

- A. This Institution will maintain for at least 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, Dr. Jerzy T. Sawicki, Vice President of Research
  - 5. Records of accrediting body determinations
- B. CSU will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional 3 years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

## **VI. Reporting Requirements**

- A. The Institutional reporting period is the 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, Dr. Jerzy T. Sawicki, Vice President of 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.

## VII. Institutional Endorsement and PHS Approval

<b>A. Authorized Institutional Official</b>	
Name: Jerzy T. Sawicki, Ph.D.	
Title: Vice President for Research	
Name of Institution: Cleveland State University	
Address: <i>(street, city, state, country, postal code)</i> 2121 Euclid Avenue Parker Hannifin Hall, 2 <sup>nd</sup> Floor Cleveland, OH 44115-2405	
Phone: 216-687-9364	Fax: 216-687-9280
E-mail: sprs@csuohio.edu	
Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.	
Signature: 	Date: 12/19/18

<b>B. PHS Approving Official</b> <i>(to be completed by OLAW)</i>	
<p>Doreen H. Bartlett          Senior Assurance Officer, Division of Assurances          Office of Laboratory Animal Welfare (OLAW)          National Institutes of Health          6700B Rockledge Drive Suite 2500 MSC 6910          Bethesda, MD 20892          bartletd@od.nih.gov          301-496-7163</p>	
Signature:	Date: December 26, 2018
Assurance Number: D16-00338 (A3554-01)	
Effective Date: December 19, 2018	Expiration Date: December 31, 2022

## VIII. Membership of the IACUC

Date: September 26, 2018			
Name of Institution: Cleveland State University			
Assurance Number: D16-00338 (Legacy A3554-01)			
<b>IACUC Chairperson</b>			
Name*: Anthony Berdis			
Title*: Associate Professor		Degree/Credentials*: Ph.D.	
Address*: ( <i>street, city, state, zip code</i> ) 2351 Euclid Avenue, SR 363 Cleveland, OH 44115			
E-mail*: a.berdis@csuohio.edu			
Phone*: 216-687-2454		Fax*: 216-687-9298	
<b>IACUC Roster</b>			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
Stanley Dannemiller	D.V.M.	Consultant	Veterinarian
1	Ph.D.	Associate Professor	Scientist
2	Masters (Art), RSO, AHES, CHMM	Environmental Health & Safety Officer	Member
3	Ph.D.	Professor	Scientist
4	Ph.D.	Professor	Scientist
5	BSB	Executive Director	Non-Scientist/Non-affiliate
6	Ph.D.	Associate Professor	Scientist
7	Ph.D.	Professor	Scientist
8	Ph.D.	Professor	Scientist
<b>Non-Voting Members</b>			
9	D.V.M	ARF Manager	N/A
10		IACUC Secretary	N/A

## 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: Lyubomyr Turchyn	
Title: Animal Research Facility Manager	
Phone: 216-687-2071	E-mail: <a href="mailto:l.turchyn14@csuohio.edu">l.turchyn14@csuohio.edu</a>
<b>Contact #2</b>	
Name: Mary Jane Karpinski	
Title: IACUC Secretary	
Phone: 216-687-3630	E-mail: <a href="mailto:m.karpinski2@csuohio.edu">m.karpinski2@csuohio.edu</a>

## X. Facility and Species Inventory

Date: September 26, 2018			
Name of Institution: Cleveland State University			
Assurance Number: D16-00338 (Legacy A3554-01)			
Laboratory, Unit, or Building*	Gross Square Feet [include service areas]	Species Housed [ <i>use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog</i> ]	Approximate Average Daily Inventory
Science Research Building A	4,600	Mice	625
Science Research Building B	1,100	African Clawed Frogs ( <i>Xenopus spp.</i> )	200
Science Research Building C	936	n/a	n/a
Science Building D	258	n/a	n/a

\*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.



## APPENDIX A

**CLEVELAND STATE UNIVERSITY  
Institutional Officer and  
Semiannual Program Review Checklist  
Review conducted on April 18, 2018**



### MEMORANDUM

**To:** Jerzy T. Sawicki, Ph.D.  
Vice President for Research & Institutional Officer

**From:** Institutional Animal Care & Use Committee

**Subject:** Semiannual Report of the Program Review and Facility Inspections

**Date:** June 1, 2018

This report summarized the IACUC's results of its most recent program review and facility inspections, as required by the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), Section IV.B.1.-3., the *Guide for the Care and Use of Laboratory Animals* (Guide), and the Animal Welfare Act (AWA) regulations, as applicable. Submission of semiannual reports to the Institutional Official is a condition of this institution's Animal Welfare Assurance with the NIH Office of Laboratory Animal Welfare (OLAW).

I.

#### II. Evaluation of the Animal Care and Use Program

The IACUC conducted its Semiannual Program Review evaluation of the institution's animal care and use program on April 11, 2018 using the *Guide for the Care and Use of Laboratory Animals, Eighth Edition* as the basis for the evaluation. Attached are the results of the Semiannual Program Review and Facility Inspection Checklist.

#### Meetings

The IACUC met on February 21, 2018 and April 11, 2018. Minutes for these meetings are attached. A student organization at Cleveland State University called Student Advocates for Vegan Ethics (S.A.V.E) contacted the IACUC Chair with a request to attend an IACUC meeting. Per their request, members of S. A. V. E. attended an IACUC meeting on February 21, 2018. In addition, on March 8, 2018, Dr. Anthony Berdis (IACUC Chair), Dr. Stanley Dannemiller (Veterinarian), Lyubomyr Turchyn (Animal Research Facility Manager) and Dr. Meredith Bond (Dean of the College of Sciences and Health Professions) met with members of S.A.V.E to educate them and answer questions regarding animal research being done at Cleveland State University.

### **IACUC Membership/Personnel Issues**

The Chair and six IACUC members are currently serving a two year term, 7/1/2017 to 6/30/2019. Two members were re-appointed to a two year term 7/1/2018 to 6/30/2020. One member completed the two year appointment term. A search for a non-affiliated member has been started. One animal technician was hired and started on May 14, 2018.

### **Training Sessions**

The CITI online training module requirement for anyone who works with live vertebrate animals at Cleveland State University is on-going. The IACUC approved requiring the CITI renewal training for IACUC members, researchers and students to every 5 years. In addition, the IACUC held one training session during this reporting period. On April 11, 2018, Dr. Anthony Berdis, Associate Professor of Chemistry and Biology, and IACUC Chair presented: *Animal Welfare and the Three "R's": Reduction, Replacement, and Refinement*, to the IACUC and animal users. Some members of S.A.V.E. attended.

### **Protocol Approvals**

During this reporting period, three (3) animal protocols were reviewed. One application was approved. The remaining two (2) are awaiting approval by the committee pending acceptance of revised applications.

### **III. Inspection of Animal Facilities**

The IACUC inspected the Animal Research Facility and satellite facilities on April 11, 2018 using the 8<sup>th</sup> Edition of the Guide. The facility inspections are included in the Semiannual Program Review and Facility Inspection Checklist (*attached*).

### **IV. Minority View**

There were no minority views submitted or expressed from the Committee members during this reporting period.

## II. Semiannual Program Review and Facility Inspection Report

Date: 5-8-18

Deficiency Category*	✓	Checklist section /Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
S			<i>Damaged walls in SI463, SI465, and SI467 Cracks in walls to be repaired. Paint needs to be replaced. These deficiencies were noted on the inspection report submitted in December 2017 and have yet to be repaired</i> **Repaired 6/4/2018	Physical Plant	To be determined by SPRS	Repairs completed 6/4/2018