



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Division of Assurances
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Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

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Office of Laboratory Animal Welfare
Division of Assurances
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May 13, 2015

Reference: Renewal Assurance #A3536-01

Michael Y. Ogawa, Ph.D.
Vice President for Research and Economic Development
Bowling Green State University
120 McFall
Bowling Green, Ohio 43403

Dear Dr. Ogawa:

I am pleased to inform you that The Office of Laboratory Animal Welfare (OLAW) reviewed and approved the renewal of your institution's Animal Welfare Assurance (Assurance) that was submitted in compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), as revised August 2002.

Your Assurance renewal, number **A3536-01**, became effective on **May 13, 2015** and expires on **January 31, 2019**. This Assurance supersedes all previously issued Assurances. Please include the Assurance number in all correspondence to OLAW. A copy of the Assurance signature page is enclosed.

The Assurance is a key document in defining the relationship of your Institution to the PHS. It sets forth the responsibilities and procedures of your Institution regarding the care and use of laboratory animals. Among the important elements of the Assurance, I would especially call your attention to the reporting requirements that are essential for continued compliance with the PHS Policy. Please note that a Report to OLAW is required at least once every 12 months. The reporting period, unless requested otherwise in writing, is the calendar year. Reports, for the previous calendar year, are due **January 31**.

If we may be of further assistance, please do not hesitate to contact me or Dr. Parlett.

Thank you for your attention in these matters.


Sincerely,

for Eileen M. Morgan
Director, Division of Assurances
Office of Laboratory Animal Welfare, NIH


Enclosure

cc:
Dr. Lee Meserve
Dr. Hillary Snyder

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official	
Name: Michael Y. Ogawa, Ph.D.	
Title: Vice President for Research and Economic Development	
Name of Institution: Bowling Green State University	
Address: 120 McFall Bowling Green State University Bowling Green, OH 43403	
Phone: 419-372-0433	Fax: 419-372-8569
E-mail: mogawa@bgsu.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: April 23, 2015

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B. PHS Approving Official (to be completed by OLAW)	
Eileen M. Morgan-Director, Division of Assurances Office of Laboratory Animal Welfare National Institutes of Health 6705 Rockledge Drive RKL1-Suite 360-MSB 7982 Bethesda, MD 20892-7982	
Signature: 	Date: 5/14/15
Assurance Number: A3536-01	
Effective Date: 5/13/15	Expiration Date: 1/31/19

BOWLING GREEN STATE UNIVERSITY

A3536-01

Animal Welfare Assurance

I, Michael Ogawa, as named Institutional Official for animal care and use at Bowling Green State University by means of this document, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), hereinafter referred to as PHS Policy.

I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities hereinafter referred to as activities, involving live vertebrate animals supported by the PHS. 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:
- Life Science Annex (LSCA)
 - Behavioral Neuroscience Animal Facility (BNAF)
 - Selected rooms within the Life Science Building (LSC)
 - Ecological Research Station (ERS)

All of the above listed facilities are physically located in the University's main campus in Bowling Green, Ohio 43403 except the ERS which is located approximately 2 miles NE of the main campus. There are no other off-campus satellite facilities and/or other covered components.

- B. The following are other institution(s), or branches and components of another institution: None / Not applicable.

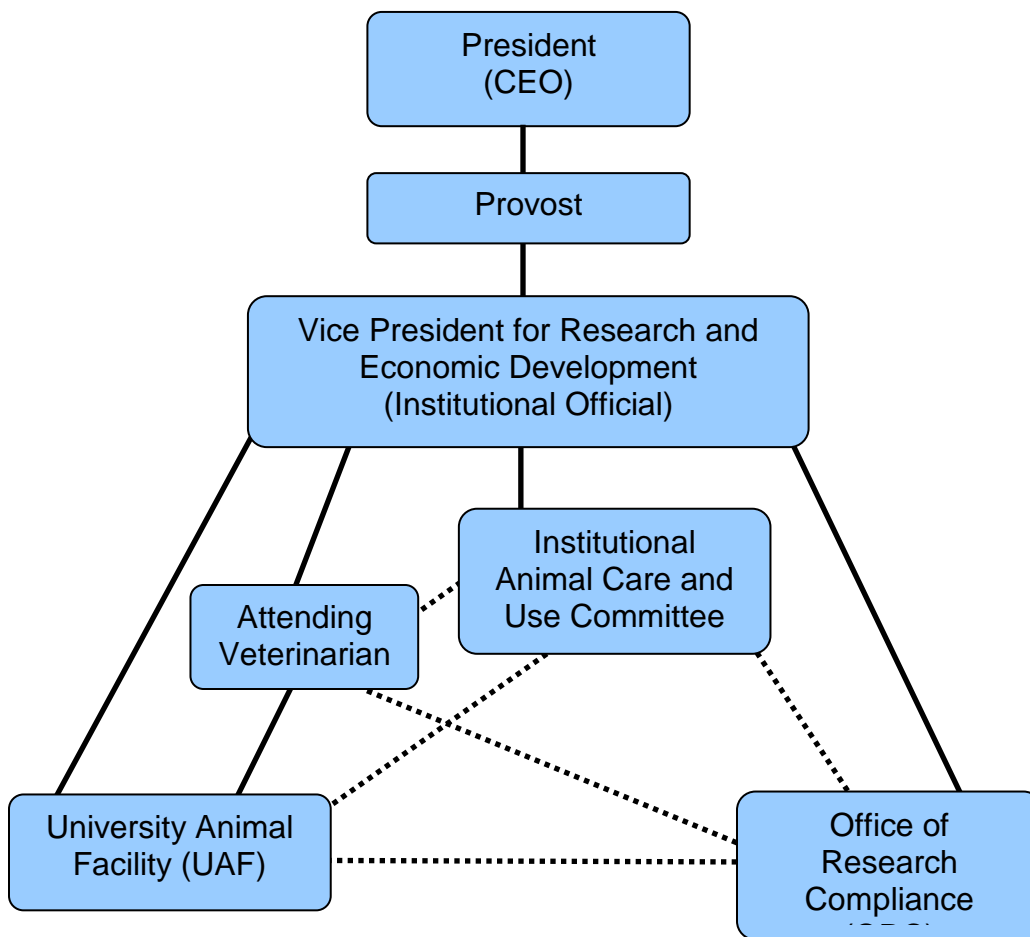
II. Institutional Commitment

- 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 Guide for the Care and Use of Laboratory Animals (Guide).

E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (sub-award) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

III. Institutional Program for Animal Care and Use

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



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

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

1. Name: Susan E. Orosz

Qualifications:

- Degrees: Ph.D. (University of Cincinnati, 1980), D.V.M. (Ohio State University 1984)
- Certifications: Diplomate ABVP, Avian Practice and Diplomate, European College of Zoological Medicine and Surgery (Avian)
- Training or experience in laboratory animal medicine or in the use of the species at the institution and training and/or experience in small and exotic animal medicine, specializing in avian medicine. Taught veterinary courses, chief of the Avian, Wildlife and Exotic Animal Medicine Service in at Veterinary Teaching hospital for 10 years and trained fellows/residents/graduate students for 18 years, has practiced avian and exotic animal medicine and surgery for 30 years; has numerous peer reviewed publications; attends and presents at national and international veterinary conferences; and serves as a reviewer or editor for various veterinary journals.

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

Time Contributed to Program: 16 hours each month with 100% dedicated to the Care and Use program.

Responsibilities:

- a. Site visits to Bowling Green State University; conduct of clinical rounds at least once a month
- b. Train and provide consultation to researchers (faculty, staff, or student), as necessary
- c. Serve as an IACUC member, including the pre-review of new submissions to the IACUC
- d. Participate in semiannual Program and Facility reviews
- e. Work to enhance to Program of Veterinary Care

2. Name: David P. Ernsthause

Qualifications:

- Degrees: D.V.M. (Ohio State University 1994)
- Training and/or experience in laboratory animal medicine: 17 years of veterinary experience with small animal medicine and surgery

Authority: Dr. David Ernsthause has delegated responsibility to implement the PHS Policy and recommendations of the "Guide" in the event that Dr. Susan Orosz is not available.

Responsibilities: Back-up Veterinarian. Dr. Ernsthause is available for emergency animal care services for evenings, weekends and holidays, on an as-needed basis. He advises Dr. Orosz on the condition of the animal(s) and any treatments that were provided in her absence.

Time Contributed to Program: As need to provide back-up / emergency veterinary care.

- 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 President, as Chief Executive Officer, has delegated to the Institutional Official the authority to appoint the members of the IACUC. In accordance with the Health Research Extension Act of 1985, this delegation of authority is specific and in writing.

The IACUC consists of at least five members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Part VIII is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

- D. The IACUC will:

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

- A quorum of the IACUC will meet at least once every six months (e.g., February and August) to review the Institutional Program for Humane Care and Use of Animals.
- The Committee uses the "Guide" and other pertinent resources (e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare)) as a basis for the review.
- To facilitate the evaluation, the Committee will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website.
- The evaluation will include, but not necessarily be limited to, a review of the following:
 - a. Institutional and Individual Responsibilities
 - b. IACUC Membership and Functions;
 - c. IACUC member Experience and Training
 - d. IACUC Records and Reporting Requirements;
 - e. Husbandry and Veterinary Care (all aspects);
 - f. Personnel Qualifications (Experience and Training);
 - g. Occupational Health and Safety;
 - h. Emergency and Disaster Planning; and
 - i. Security (Personal and Facility)
- In addition, the evaluation will include a review of the Institution's PHS Assurance.
- To ensure that the program complies with the "Guide", the IACUC has created a written document, mirroring the flow of the "Guide", that states how each aspect of

the “Guide” is currently being addressed. This document is reviewed and updated semiannually.

- 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.
- No voting IACUC member will be involuntarily excluded from participation in any portion of the reviews.

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

- At least once every six months (e.g., February and August) at least two voting members of the IACUC will visit all of the Institution’s facilities where animals are housed or used (i.e., holding areas, animal care support areas, all locations that have been identified as areas that may be used for animal housing or testing including facilities housing animals for 12 hours, storage areas, animal surgical areas, procedure areas, and laboratories where animal manipulations are conducted). Equipment used for transporting animals is also inspected.
- An effort is made to arrange for all Principal Investigators using animals during the time of inspection to be present during the inspection. Questions may be asked to any research staff present.
- The Committee uses the “Guide” and other pertinent resources (e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare)) as a basis for the review.
- To facilitate the evaluation, the Committee will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website.
- 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.
- No voting IACUC member will be involuntarily excluded from participation 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:

- The program review is conducted as a formal IACUC meeting, with notes being taken by the Research Compliance Officer. The facility inspection is conducted

more informally, with IACUC members sending their observations in written form to the Research Compliance Officer. The Research Compliance Officer drafts the reports using the sample OLAW Semiannual Report to the Institutional Official format from the OLAW website.

- The reports will contain a description of the nature and extent of the Institution's adherence to the "Guide" and the PHS Policy, identify specifically any IACUC approved departures from the provisions of the "Guide" and the PHS Policy, and state the reasons for each departure. If there are no departures, the report will state that there are no departures.
- If the IACUC approves departures from PHS Policy and the "Guide", the departures must be approved as part of a protocol, protocol amendment or other written document, using either FCR or DMR as delineated below in Section III.D.6.
- Departures from the provisions of the Guide that are not IACUC approved are considered deficiencies and addressed as such (i.e., the IACUC will develop a reasonable plan and schedule for discontinuing the departure or for having the departure properly reviewed and approved.
- The reports will distinguish significant deficiencies from minor deficiencies. If program or facility deficiencies are noted, the reports will contain a reasonable and specific plan and schedule for correcting each deficiency, which is determined by the IACUC at a convened meeting.
- If some or all of the institution's facilities are accredited by AAALAC International the report will identify those facilities as such.
- Copies of the draft reports will be reviewed, revised as appropriate, and approved by the IACUC.
- The final reports will be signed by a majority of the IACUC members and will include any minority opinions. If there are no minority opinions, the reports will so state.
- The completed reports will be submitted to the Institutional Official within 60 days following the evaluation. If at any time the IACUC has a concern they feel needs immediate attention, the IO will be contacted by the IACUC Chair within a reasonable amount of time (i.e., typically within 1-2 days) either by phone or in-person.
- IACUC members or the Research Compliance Officer verify that deficiencies have been corrected and this is reported to the IACUC at a convened meeting.

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

- Any individual may report concerns to the IO, IACUC Chair, Attending Veterinarian, Research Compliance Officer, UAF Director or any member of the IACUC.

- Notices are located in the animal facilities advising individuals how and where to report animal welfare concerns and stating that any individual who, in good faith, reports an animal welfare concern will be protected against reprisals. The notice is also posted on applicable institutional website(s).
- Individuals who use the University Animal Facilities are also provided with this information during their “orientation” meeting with the UAF Director.
- All reported concerns will be brought to the attention of the full Committee.
- If necessary, the IACUC Chair will convene a meeting to discuss, investigate, and address any reported concern.
- Reported concerns and all associated IACUC actions will be recorded in the IACUC meeting minutes.
- The Committee will report such actions to the IO via formal written report and, as warranted, to OLAW. Reports to the IO may be either via meeting minutes, semiannual report of IACUC evaluations, or separate document. Reports to OLAW will be in writing and through the IO. Preliminary reports to both the IO and OLAW may be made verbally. If concern requires immediate attention of the IO, he will also be notified via phone or in-person by the IACUC Chair.

5. Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

- Recommendations regarding any aspects of the Institution’s animal program or facilities are discussed and developed by the Committee.
- The Committee’s recommendations are included in the IACUC Meeting minutes, or a report of the IACUC’s evaluations, or a separate letter. Such documents are approved by the Committee and then submitted to the IO.

6. Review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals according to PHS Policy IV.C.1-3. The IACUC procedures for protocol review are as follows:

- Protocols are submitted and received through a secure electronic protocol system managed by the Office of Research Compliance.
- When using FCR or DMR, the Attending Veterinarian must pre-review new protocol submissions and proposed significant changes from a veterinarian perspective before the submission goes to the IACUC. It is recommended that that UAF Director pre-review the submission from a feasibility standpoint.

- The IACUC uses three methods as proscribed by the PHS Policy to review new protocols, continuing reviews, and those with proposed significant changes:
 - a. Full Committee Review (FCR),
 - b. Designated Member Review (DMR) following Full Committee Review (FCR), and
 - c. Designated Member Review (DMR).

- The IACUC typically uses the FCR method when presented with proposed animal work that will involve invasive procedures, which include but are not limited to invading a body cavity, biopsy, amputation, or procedures that cause more than momentary pain and distress.

- Prior to the review, each IACUC member will be provided with a list of proposed activities/projects to be reviewed and written descriptions of activities/projects (protocols) that involve the care and use of animals shall be provided or available to all IACUC members, and any member of the IACUC may obtain, upon request, full committee review (FCR) of those protocols.

- IACUC Policy on Conflict of Interest: No member may participate in the IACUC review of a protocol if the member has a conflicting interest, such as is personally involved in the project, except to provide information requested by the IACUC. Additionally, a member with a conflict of interest must recuse him/herself from participating in the vote and may not contribute to the quorum required to conduct protocol review at a convened meeting.

- Invited Consultants Policy: The IACUC may invite consultants to assist in the review of complex issues. Consultants may not vote with the IACUC unless they are also members of the IACUC.

FCR Method of Review

- Prior to each convened meeting, the material under review is distributed electronically to all members.

- FCR may only be conducted at a convened meeting with at least a quorum of the voting members present.

- Meetings are conducted in person or a combination of in person and teleconference.

- Any use of telecommunications will be in accordance with NIH Notice NOT-OD-06-052 of March 24, 2006, entitled Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals.

- At the convened meeting, the members discuss each protocol in depth after which a motion is made and seconded.

- The possible outcomes of FCR are as follows: A majority vote of the members present at the convened meeting is required to:
 - a. approve,
 - b. require modifications in (to secure approval), or
 - c. withhold approval.
- The Chair (or his/her delegate) calls for a vote on the motion. Members raise their hand to indicate their vote of “yes”, “no” or “abstain”. A roll call vote may be utilized if necessary due to teleconference.

Review of Required Modifications Subsequent to FCR. If the members vote to require modifications in a protocol to secure approval, the IACUC has established in writing the following methods for review of revised protocols:

- a. If all voting members are present at the meeting then the decision as to how the subsequently modified protocol will be reviewed is determined at the convened meeting. If no member expresses a desire to have the subsequently modified protocol reviewed by FCR, DMR may be employed. If this occurs, then the IACUC Chair selects at least one member qualified to conduct the review to serve as the Designated Reviewer (DR).
 - i. The DR(s) is/are responsible for reviewing the revised material submitted by the investigator and has/have the authority to approve, require additional modifications in (to secure approval), or refer back for FCR. DMR may not result in withholding approval.
 - ii. If more than one DR is selected, then each DR is provided with and reviews the same material as the other DR(s).
 - iii. The DRs must be unanimous in their decision to approve or require modifications in (to secure approval). If they are unable to unanimously agree on the outcome, then the protocol must be returned for FCR.
 - iv. The decisions resulting from DMR are final and are recorded in the IACUC meeting agendas/minutes.
- b. When less than all and at least a quorum are present at the convened meeting and the outcome of the review and the vote is to require modifications in (to secure approval), the IACUC has in place a written policy that all members have agreed to that states that the members present at the convened meeting may, by unanimous agreement, choose to use DMR to review the subsequently modified protocol. In this case, a vote is not taken since DMR may only be utilized if no member requests FCR. The written policy is reviewed at least once a year and whenever new members are appointed to the committee.

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

DMR Method of Review

- DMR is generally not used as the initial review method for any protocol or proposed change that describes invasive procedures.

- All voting IACUC members are provided with the material(s) to be reviewed before DMR is implemented.
- If no voting member requests FCR of the material within a three day period, then DMR may be employed.
- The IACUC Chair selects at least one member qualified to conduct the review to serve as the Designated Reviewer (DR).
- The DR(s) is/are responsible for reviewing the material and has/have the authority to approve, require additional modifications in (to secure approval), or refer back for FCR. DMR may not result in withholding approval.
- If more than one DR is selected, then each DR is provided with and reviews the same material as the other DR(s).
- The DRs must be unanimous in their decision to approve or require modifications in (to secure approval). If they are unable to unanimously agree on the outcome, then the protocol must be reviewed using FCR at a convened meeting with at least a quorum of voting members present.
- The decisions resulting from DMR are final and are recorded in the IACUC meeting agendas/minutes.
- The approval date is the date that the designated member(s) approved the study.
- In order to approve proposed protocols or proposed significant changes in ongoing protocols, the IACUC shall conduct a review by FCR or DMR of those components related to the care and use of animals and determine that the proposed protocols are in accordance with this Policy. In making this determination, the IACUC shall confirm that the protocol will be conducted in accordance with the Animal Welfare Act insofar as it applies to the activity, and that the protocol is consistent with the "Guide" unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the protocol conforms to the institution's PHS Assurance and meets the following requirements:
 - a. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
 - b. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
 - c. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

- d. The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.
 - e. Medical care for animals will be available and provided as necessary by a qualified veterinarian.
 - f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
 - g. Methods of euthanasia used will be consistent with the current American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals 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:**
- Review and approval of significant changes are handled in the same manner as new protocols (see paragraph III.D.6 above) or as described in IACUC approved policies that are compliant with Notice NOT-OD-14-126.
 - Examples of changes considered to be significant include, but are not limited to, changes:
 - a. in the objectives of a study
 - b. from non survival to survival surgery;
 - c. resulting in greater discomfort or in a greater degree of invasiveness;
 - d. in the species or in approximate number of animals used
 - e. in Principal Investigator;
 - f. in anesthetic agent(s) or the use or withholding of analgesics;
 - g. in the method of euthanasia; and
 - h. in the duration, frequency, or number of procedures performed on an animal
- 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:**
- Principal Investigators are notified electronically of IACUC decisions.
 - If the IACUC's decision is to require modifications to secure approval, the required modifications are delineated in the written notification letter.

- Also, if the IACUC withholds approval, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
- The Institutional Official is notified by a monthly report of protocol-related IACUC actions. In addition to the monthly report, the Institutional Official can be notified by receiving a copy of the PI's approval notice or a copy of the IACUC meeting minutes.

9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review at least once every three years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

- Post-approval Monitoring – All ongoing activities are monitored continuously by the animal care and use staff. The AV makes clinical rounds at least monthly. The IACUC meets with most, if not all, Principal Investigators semiannually.
- Non-USDA Regulated Species – Protocol annual renewals are typically reviewed by the IACUC via the DMR process (as described in III.D.6) approximately annually. If a continuing review submission is not received by the annual continuing review deadline, the protocol will be inactivated.
- USDA Regulated Species – Protocols annual renewals with USDA covered species are typically reviewed by the IACUC via the DMR process (as described in III.D.6) no less than annually.
- If a continuing review is not approved by the IACUC by the one year expiration date, the protocol is inactivated and animals are transferred to the UAF holding protocol or euthanized.
- Continuing reviews are recorded in the IACUC meeting minutes. The IACUC meeting minutes are reviewed and approved by the Committee.
- Protocols are approved for a maximum of 36 months. That is, all protocols expire no later than the three-year anniversary of the date of initial IACUC approval. If activities are to continue beyond the expiration date, a new protocol must be submitted, reviewed, and approved as described in Paragraph III.D.6 above.

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

- The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the "Guide", this Assurance, or IV.C.1.a.-g. of the PHS 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.
- If the IACUC suspends an activity involving animals, or any other institutional intervention results in the temporary or permanent suspension of an activity due to noncompliance with the Policy, Animal Welfare Act, the “Guide”, or 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 a full explanation in writing to OLAW. Preliminary reports may be made verbally.
- Non-compliance is reported to OLAW following the most current OLAW guidance on prompt reporting.

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 Occupational Health and Safety (OH&S) program is overseen by the Office of Environmental Health and Safety.
- Occupational Health Professionals/Specialists are involved in the monitoring of the program.

2. Scope.

- Personnel covered by the OH&S portion of the Animal Care Program include everyone who has contact with animals on an active IACUC protocol or enter areas when animals are housed or used.
- Before a new protocol is approved or an individual is added to an approved IACUC protocol, all individuals must complete a medical history questionnaire which the individual faxes to a trained health professional who evaluates if the individual is cleared to work on the protocol, denied access to work on the protocol, or requires that the individual meet with trained health professional before a decision is made. That decision is forwarded to the University Animal Facility Director who shares the decision with the Office of Research Compliance for processing. The entity the trained health professional is associated with protects the health information according to HIPPA requirements.

3. Health Histories and Evaluations.

- As described above, a health history form that meets federal, state and local HIPPA regulations as part of the risk assessment process is used.

4. Hazard Identification and Risk Assessment.

- The program is based on hazard identification and risk assessment.

- Hazardous are identified during the IACUC protocol/amendment review process. Potential hazardous include, but are not limited to, chemical hygiene, bloodborne pathogens, radiation safety, laser safety, personal protective equipment including respiratory protection, hazardous waste, fire safety, animal bites, exposure to allergens, chemical cleaning agents, wet floors, heavy item lifting, ladder use, zoonoses. The most common hazard is exposure to allergens.
- Protocols/amendments are reviewed by a member of the Office of Environmental Health and Safety in order to assist with the identification of hazardous. If hazardous are identified, the Office of Environmental Health and Safety will assist in the development of procedures to manage the risks.

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

- Measures taken to alleviate identified risks include but are not limited to: latex or vinyl gloves, cotton laboratory coats and dust masks are provided to reduce allergen exposure. Individuals are trained in proper animal handling technique under supervision prior to working on their own with the animals. Open toed shoes are not allowed in UAF. Correct operation of all machinery is taught to those individuals who will use the equipment prior to using it. Wet floors are identified when possible by moveable signage and permanent signage where water is a frequent hazard.
- Personal hygiene is addressed by the provision of hand soap and paper towels in all animal housing rooms and throughout each facility. Dust masks, respirators, latex or vinyl gloves, lab coats, shoe covers, and other personal safety equipment as needed are provided to clients. Shower facilities are located adjacent to the lobby of the LSCA. All University Animal Facility (UAF) employees change from street clothes into designated work clothes before entering the facility. UAF provides laundry facilities in the LSCA for UAF designated clothing.
- Allergen information is provided during mandatory web based training and by the trained health professional if it is determined that the individual may be more susceptible to allergens.
- The UAF Director provides information on the available PPE to all individuals who use the animal facilities during new user orientation. The UAF Director also provides information about injury related procedures.
- The Office of Environmental Health and Safety provides in-person training on chemical hygiene, radiation safety, laser safety, and conducts respirator training and annual fit tests. The office also administers the PPE program.
- The Attending Veterinarian provides in-person training on zoonoses. This topic is also discussed in the mandatory online training. The AV or UAF staff provide in-person training on the proper usage of anesthetic agents and equipment for delivery of those agents.

6. Immunizations.

- All animal care personnel (i.e, University Animal Facility staff) are required to have a current tetanus vaccination. The vaccination is provided to these individuals.
 - It is recommended that all individuals who routinely come into contact with animals have a current tetanus vaccination. The vaccination is not provided.
 - Other immunizations (e.g., rabies, hepatitis B virus, etc.) are recommended on a case by case basis.
7. Precautions taken during pregnancy, illness or decreased immunocompetence.
- This risk is assessed during the evaluation of the health questionnaire by the trained health professional.
 - Personnel are advised by the UAF Director that if they are planning to become pregnant or are ill that they should consult a trained medical professional on how this will pertain to their working with laboratory animals.
8. Provisions for personnel who are not involved in animal care and/or use but nevertheless need to enter areas when animals are housed or used.
- Personnel protection: latex or vinyl gloves, respirators (if needed), dust masks, and lab coats are available to all individuals who enter areas where animals are housed or used.
9. Availability and procedures for treatment of bites, scratches, illness or injury.
- First aide kits are centrally located in both the BNAF and LSCA facilities. If additional treatment is required individuals go to/are taken to the BGSU Health Center or to the Wood County Hospital.
10. Procedures/program for reporting and tracking injuries and illnesses.
- Injuries are reported to the UAF Director. The injury is assessed by the Director and either first aide is applied or the injured person is sent/taken to the BGSU Health Center or to the Wood County Hospital.
 - All reported injuries are documented by the Director and are reported to the Office of Environmental Health and Safety using the injury and illness reporting form. The Office of Environmental Health and Safety may follow up on the reported injury if necessary.
 - The Office of Environmental Health and Safety tracks all injuries and illnesses.
- F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein, and the average daily inventory of animals by species, in each facility is provided in Part X., Facility and Species Inventory.

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

1. IACUC Members

- New IACUC members are provided with the “Guide”, the Animal Welfare Act and Animal Welfare Regulations, the Public Health Service Policy on Human Care and Use of Laboratory Animals, and the Institution’s PHS Assurance.
- The online CITI module “Essentials for IACUC Members” is required for IACUC Members. Topics covered in this training include, but are not limited to, authority of the IACUC, quorum, reviewing protocol forms, review outcomes, types of reviews, semiannual evaluations, investigating allegations of improper animal care or use.
- New members attend a short orientation session with the Research Compliance Officer before attending a convened meeting of the IACUC.
- In addition to the above, the Institution provides opportunities for IACUC members, UAF staff, and Office of Research Compliance staff to attend various local, regional and national workshops and conferences on animal care and use. UAF staff are encouraged to attain American Association for Laboratory Animal Science (AALAS) certifications.

2. Animal Care and Use Personnel

- The Institution’s PHS Assurance is available on appropriate institution website(s) so that all personnel have access to the document and are aware of its contents.
- When new protocols are submitted, the activities to be conducted by each personnel member is indicated. The training that has been completed by each person is disseminated by the Office of Research Compliance staff to the IACUC. The IACUC verifies that each person has completed appropriate training based upon the activities to be conducted. If appropriate training has not yet been completed, the IACUC informs the person of this in the written letter detailing the review of the submission and staff member(s) or the Attending Veterinarian is assigned by the IACUC to verify that the required training is completed before the protocol is approved or before the activities is conducted (depending upon which training needs to be completed).
- The online training “Working with the IACUC” via CITI (www.citiprogram.org) is required. Topics covered in this training include, but are not limited to, federal mandates, justifying species and number of animals needed, alternatives, avoiding unnecessary duplication, endpoint criteria, surgery, occupational health and safety, euthanasia, reporting misuse, mistreatment or non-compliance.
- Online supplemental training via CITI is available. These include, but are not limited to:
 - a. Working with Mice in Research Settings

- b. Working with Rats in Research Settings
 - c. Working with Amphibians in Research Settings
- In-person euthanasia training is required for anyone who will be conducting euthanasia.
 - Special training sessions may be arranged at the request of the IACUC Chair, UAF Director, Attending Veterinarian, or researchers. For example, periodically group in-person orientation, surgical and euthanasia training sessions are provided.
 - If researcher is new to BGSU, but has previous surgical experience, the Attending Veterinarian must observe at least the first surgical procedure conducted by the researcher.
 - Individual faculty/staff researchers provide species and technique specific training to graduate and undergraduate students and other personnel in their laboratories on a continuing, as-needed basis.
 - The Attending Veterinarian is available at all reasonable times for consultation with IACUC members, researchers, and UAF staff via telephone, e-mail, or in person.
 - Training provided by the Institution's Environmental Health and Safety department on topics such as BGSU's Chemical Hygiene Plan, Fire Safety, and Bloodborne Pathogens.
 - The training includes training or instruction on research or testing methods that minimize the numbers of animals required to obtain valid results and limit animal pain or distress as well as other requirements delineated in 9 CFR, Part 2, Subpart C, Section 2.32(c). Specifically, as applicable, training and instruction of personnel includes guidance in at least the following areas:
 1. Humane methods of animal maintenance and experimentation, including:
 - a. The basic needs of each species of animal;
 - b. Proper handling and care for the various species of animals used by the facility;
 - c. Proper pre-procedural and post-procedural care of animals; and
 - d. Aseptic surgical methods and procedures;
 2. The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress;
 3. Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility;
 4. Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, Committee member, or laboratory

personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act;

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

3. Training Documentation

- Training is documented via the following:
 - a. Sign-in/attendance logs for group in-person training
 - b. Completion/attendance certificates from workshops, conferences, and individual training sessions
 - c. CITI completion reports
 - d. Principal Investigators maintain training logs of protocol staff they train on protocol specific activities
- Training documentation is maintained by Office of Research Compliance.

IV. Institutional Program Evaluation and Accreditation

- A. All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past six months and will be reevaluated by the IACUC at least once every six months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the PHS Policy and the Guide. Any departures from the Guide will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.
- B. This Institution is Category 2 — not accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request. The report of the most recent evaluations (program review and facility inspection) is attached.

V. Recordkeeping Requirements

- A. This Institution will maintain for at least three years:
 - 1. A copy of this Assurance and any modifications 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 and Economic Development.
 - 5. Records of accrediting body determinations
- B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements

- A. 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, the Vice President for Research and Economic Development.
 - 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.