

Mary Baldwin College
Assurance #A4452-01
Animal Welfare Assurance
In accordance with the PHS Policy for
Humane Care and Use of Laboratory Animals

Animal Welfare Assurance for Domestic Institutions

I, David Mowen, as named Institutional Official for animal care and use at Mary Baldwin College, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS. 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:
Main Campus, Staunton, VA
- B. The following are other institution(s), or branches and components of another institution:
None

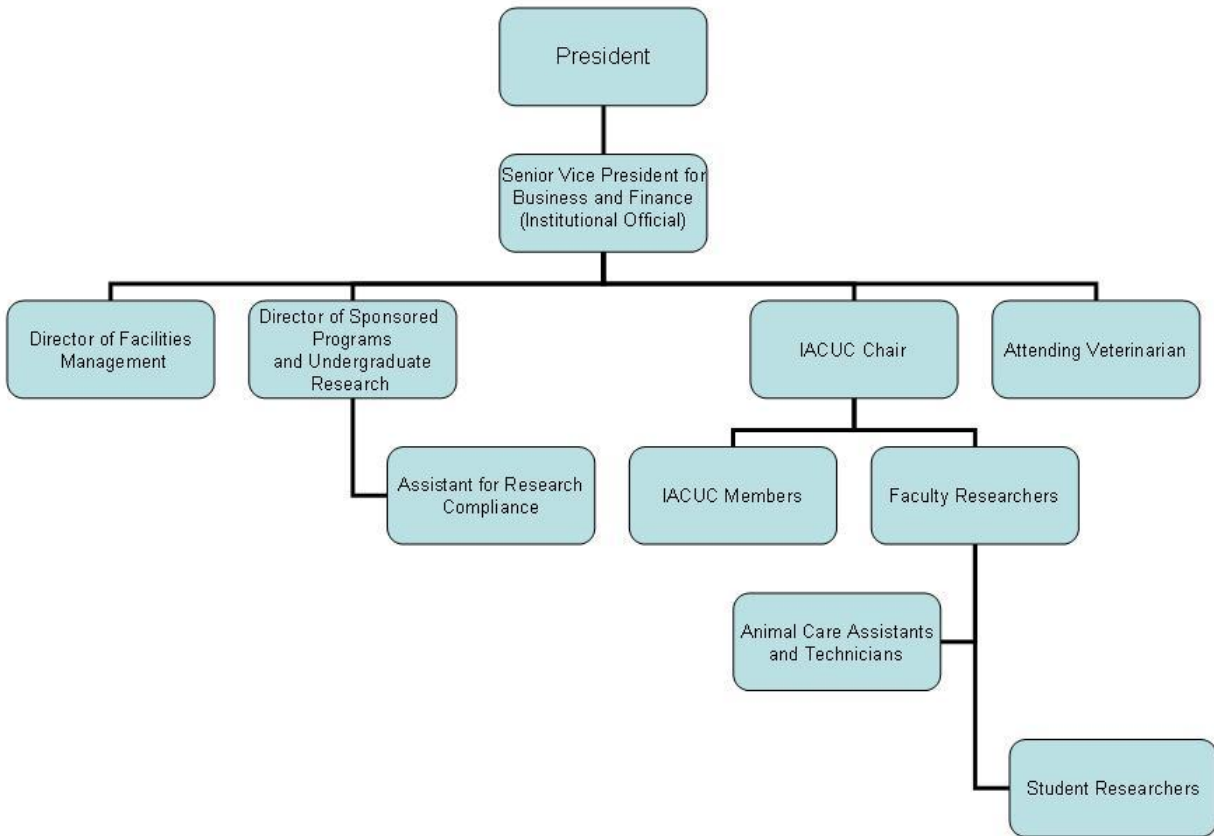
Institutional Commitment

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

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:

Lines of Communication, Authority and Responsibility for AWA Compliance Issues



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

1) **Attending Veterinarian:** Dr. William Olkowski, DVM, DABVP

Qualifications:

- Degrees: DVM, Cornell University, 1982, Certified Avian Specialist
- Training or experience in laboratory animal medicine or in the use of the species at the institution:

Dr. Olkowski maintains a private practice at Cedarcrest Animal Clinic in Fishersville, Virginia, and has 30 years experience in animal medicine and surgery, including the care of exotics.

Authority: Dr. Olkowski 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. Olkowski devotes less than 5% of his time to the program.

2) **Back-up Veterinarian:** Dr. Benjamin Bedore

Qualifications:

- Degree: DVM, Virginia Tech, 2011
- Training or experience in laboratory animal medicine or in the use of the species at the institution:

Dr. Bedore works with Dr. Olkowski in private practice at Cedarcrest Animal Clinic in Fishersville, Virginia. He has experienced in surgery and with exotic animals in both zoos and private practice.

Authority: Dr. Bedore has delegated program authority and responsibility for the Institutions' animal care and use program, including access to all animals, when the Attending Veterinarian, Dr. Olkowski, is not available.

Time contributed to program: Dr. Bedore devotes less than 5% of his time to the program

Principal investigators are responsible for monitoring animal health in their facilities and contacting the attending veterinarian as appropriate. Principal investigators are responsible for supervising student assistants and technicians on a daily basis to carry out animal care and facility management duties.

- C. The IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least five members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.
- 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:
Semiannual program and facility reviews are normally undertaken during the academic year to facilitate full IACUC committee deliberation (April and October). The IACUC semiannual program review is scheduled to follow the semiannual facilities inspection to review and discuss all aspects of the animal care and use program. Topics covered at the program review meeting include: committee composition and membership; veterinary care and animal care staffing levels and performance; facilities reports; IACUC policies; training; occupational health; review of the inspection reports and determination of deficiencies; protocol review process; standard operating procedures; and any departures from PHS policy and the Guide, including reasons for each.
 - 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:
All IACUC committee members are invited to participate in semiannual facility inspections and subsequent program review. Inspection of all facilities in which animals are currently housed or treated, or projected to be housed or treated before the next semiannual inspection, takes place immediately prior to program review meetings. Review and discussion of the facility inspections occurs at the program review meeting. Departures and deficiencies are carefully considered. Any deficiencies are categorized as "major" (significant direct impact on animal health and/or well-being) or "minor," and a plan for correction, including an appropriate timetable, is formulated and incorporated into a final program review report. The report is submitted to the Institutional Official. Any investigator cited for a deficiency receives a letter from the IACUC Chair describing the nature of the deficiency, suggestions for correction, and a deadline for remedy of the deficiency. Any "major" deficiencies are separately and immediately reported to the Vice President for Business and Finance (Institutional Official) and the Director of Sponsored Programs and Undergraduate Research and, after their review, are forwarded to OLAW.

- 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:

Information from the semiannual facility inspection, including all topics discussed at the subsequent program review, is compiled into a written semiannual report by the chair of the IACUC within 30 days of the meeting. Minority views are included. The chair of the IACUC and a majority of the committee members sign the finalized report, which is then forwarded to the Institutional Official (Senior Vice President for Business and Finance) and copied to the Director of Sponsored Programs and Undergraduate Research. Copies of the report are maintained in the Office of Business and Finance, the Office of Sponsored Programs and Undergraduate Research, and by the Assistant for Research Compliance.
- 4) Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:

The IACUC at Mary Baldwin College is obligated to investigate any concerns regarding the care and treatment of animals used in research. This includes any allegations of animal mistreatment or non-compliance with Federal regulations and institutional policies. Signs are posted on the doors of all animal facilities and on official notice boards in the lower lobby of the Administration Building and the lower lobby of the Office of Business and Finance advising individuals of this policy and informing them of numerous options available to them for reporting abuse. Anonymous concerns are also considered and the identity of the individual registering a concern may remain anonymous if the individual so desires. The IACUC guarantees that the reporting individual will be protected against reprisal in accordance with the Animal Welfare Act. Individuals may report their concerns, or suspicions, to any member of the IACUC, the Director of Sponsored Programs and Undergraduate Research, the Attending Veterinarian, animal care facilities directors or staff, or the Vice President for Academic Affairs/Dean of the College. The concern will be forwarded to the IACUC Chair and the Chair may convene either a special meeting of the IACUC or a subcommittee to review the activity in question, excluding individuals with potential conflicts of interest. After review of the matter, the IACUC may suspend a previously approved activity if, in its determination, the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, and this Assurance Statement. The suspension vote must constitute a majority of the quorum. Any suspension of activity will be reported to the Senior Vice President for Business and Finance (Institutional Official) and the Director of Sponsored Programs and Undergraduate Research, who will review the reasons for the suspension with the IACUC, take appropriate corrective action, and report that action together with a full explanation of the circumstances to OLAW.
- 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:

The procedure for making regular recommendations is to submit them as part of the semiannual review. Recommendations occurring as a result of a special meeting may be made in a formal letter composed by the IACUC Chair or another member of the IACUC under the request and guidance of the Chair.

An IACUC meeting may be called at the request of an investigator, IACUC member, or Institutional Official by sending a written request to the Chair of the IACUC at least two weeks before the suggested meeting date. Emergency meetings may be called by any member of the IACUC, the Director of Sponsored Programs and Undergraduate Research, or the Institutional Official.

- 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. All use of vertebrate animals used for PHS-funded research purposes must be approved by the IACUC before any animals are ordered or use of animals begins.
 - b. The IACUC reviews all components of proposed research use of animals and determines whether the proposed projects are in accordance with the *PHS Policy*, the *Animal Welfare Act*, and the recommendations of the *Guide*, unless acceptable justification for exemption from those guidelines is provided. All proposed projects must conform with this Assurance and must meet the following criteria:
 - i. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
 - ii. 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 and approved by the IACUC.
 - iii. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be humanely euthanized.
 1. The living conditions of animals will be appropriate for their species and contribute to their health and comfort; the housing, feeding, and care 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.
 2. Medical care for animals will be available and provided as necessary by a qualified veterinarian.
 3. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
 4. Methods of euthanasia used will be consistent with the recommendations of the 2000 *American Veterinary Medical Association Panel on Euthanasia*, unless appropriately justified for scientific reasons in writing by the investigator.
 - c. Procedures for review of new protocols are as follows:
 - i. Faculty researchers or faculty advisors (on behalf of student researchers) submit proposed new protocols to the IACUC Chair at any time during the academic year, excluding breaks. The Chair forwards protocols to committee members by electronic mail or hard copy within three business days of receipt. Protocols submitted during semester breaks or the summer months may be delayed.
 - ii. IACUC members are provided ten business days to request full committee review (FCR) of any protocol. If no member requests FCR, the Chair may initiate a Designated Member Review (DMR).
 - iii. Under DMR, the IACUC Chair may act as the Designated Member or appoint another IACUC member, excluding any individual with a potential conflict of interest, including herself/himself. The designated member may act on the protocol according to the categories of action listed in c. iv. The Institution does not assign multiple Designated Members to a single protocol.
 - iv. Categories of action are 1) Approved; 2) Not Approved; and 3) Request Modifications to Secure Approval.
 - v. Approved protocols are those that receive approval by majority vote of IACUC members at an FCR meeting, providing that a quorum of qualified members is present, or by the Designated Member (see c.iii.). All minority views are recorded in the minutes of meetings in which FCR protocols are considered.
 - vi. Protocols for which changes are required (Request Modifications to Secure Approval) require additional action.
 1. Protocols considered during FCR that require minor administrative or scientific clarifications or modifications may be shifted to DMR for further consideration and approval. If the IACUC wishes to shift to DMR for the modifications, it will be so noted in the minutes. Protocols that are

missing substantive information or require multiple modifications and clarifications may be considered further under FCR or DMR. If considered under DMR, protocols requiring extensive revisions must be sent out to all IACUC members, including any members absent from the original meeting, according to the procedures outlined in vi.2. below. All such decisions will be voted on and noted in the minutes.

2. Protocols considered during DMR that require only minor administrative or scientific clarifications may be returned to the investigator and resubmitted to the DM for further consideration. Protocols that are missing substantive information or require multiple clarifications should be returned to the investigator for revision and resubmission. Once a revised protocol is returned, the DM must send the revised copy to all IACUC members, including any not present at the original review meeting, by electronic mail or hard copy within three business days of receipt. All IACUC members have ten business days to request full committee review of the revised protocol. Further DMR may be conducted only if all members of the committee have had the opportunity to request FCR and none has done so.
 - vii. Following Full Committee Review, approval may be withheld by a majority vote (see section 8) for notification and appeal procedures).
 - viii. A Designated Member Reviewer may not withhold approval; this action may only be taken following Full Committee Review.
 - ix. Withholding of approval may not be overturned by a higher administrative official.
 - x. IACUC members are recused from a review if potential conflicts of interest exist (e.g., review of an advisee's protocol).
- 7) Review and approve, modifications required 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. Investigators considering modifications to existing protocols should discuss the changes with the IACUC Chair to determine whether they constitute significant changes. Changes that do not require IACUC approval include changes in wording that do not alter content but serve to clarify procedures and changes in student research personnel, as provided in b. below.
 - b. Significant modifications include changes in the objectives of a study; proposals to switch from non-survival to survival surgery; changes in species or in the approximate number of animals used; changes in personnel involved in animal procedures, except for changes in individual student researchers (provided that the students have met training criteria designated in section III.H. and NIH Notice NOT-OD-03-046, June 6, 2003); and changes in anesthetic agent(s), the use or withholding of analgesics, and methods of euthanasia. Additional factors may involve changes in the duration, frequency, or number of procedures performed on an animal.
 - c. Proposals for significant changes are submitted under the procedures for new protocols outlined in section 6) iii. above.
- 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:
- a. After action on a protocol through either FCR or DMR the IACUC Chair notifies the investigator and her/his faculty advisor, if applicable.

- i. If the protocol is approved, an official, signed approval letter is sent by electronic mail to the investigator and faculty advisor, if applicable. A copy is kept in the files of the Assistant for Research Compliance.
 - ii. If the protocol has been designated "Request Modifications to Secure Approval," the Designated Reviewer prepares a letter listing all required changes and clarifications required and requests that the applicant make appropriate modifications, generally within two weeks of receipt. The letter is copied to the IACUC Chair, the Assistant for Research Compliance, and the faculty advisor, if applicable. Additional review and followup is conducted according to the procedures outlined in section 6) above. Copies of correspondence are kept in the files of the Assistant for Research Compliance.
 - ii. If the protocol is Not Approved, the IACUC Chair prepares a letter summarizing the committee's discussion and reasons for the decision and sends it to the investigator, faculty advisor, if applicable, and the Assistant for Research Compliance. The investigator is allowed the opportunity to respond in person or in writing to the IACUC's concerns and may resubmit a new protocol. Copies of correspondence are kept in the files of the Assistant for Research Compliance.
- 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. All protocols have an annual renewal/expiration date from the date they were approved to meet USDA and PHS requirements. Six weeks prior to the renewal/expiration date, the Assistant for Research Compliance sends an electronic mail request to the investigator or faculty advisor for all open protocols subject to annual review, asking them to provide a written update for committee review, including updated literature searches for duplicity and alternatives to painful and distressful procedures. The IACUC must review and approve, or gain the modification to secure approval, prior to the protocol renewal/expiration date as stated in section III D.6. If the appropriate person does not comply with an annual review update, activity is suspended until the activity is reviewed and approved by the IACUC.
 - b. In addition, the IACUC must review and approve or obtain modification to gain approval of all significant changes to approved studies prior to the initiation of the change.
 - c. Protocols may be renewed twice, after which time they must be submitted for complete, *de novo* review according to the procedures outlined in 6) c. above.
 - d. Annual renewals, requests for significant changes, and three-year renewals are all reviewed through the FCR and/or DMR procedures outlined in 6) c. above.
- 10) Be authorized to suspend an activity involving animals as set forth in the PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:
The IACUC may suspend a previously approved activity if it determines that the activity is not being conducted in accordance with the provisions of the Animal Welfare Act, the *Guide*, or section IV.C.1a-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 a suspension vote. If the IACUC suspends an activity involving animals, the Institutional Official or his/her designate, in consultation with the IACUC, will review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW. The IACUC Chair notifies the investigator and faculty advisor, as applicable, in writing, and copies are sent to the Institutional Official, the Vice President for Academic Affairs/Dean of the College, and the Director of Sponsored Programs and Undergraduate Research. Copies of correspondence are maintained by the Assistant for Research Compliance.

- 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. The occupational health and safety program is coordinated by the supervising faculty and animal care technicians. Zoonotic disease risk is minimal with the species in use and the species require no special precautions for pregnant women.
 - a. Prior to animal exposure, individuals working with animals receive a handout that includes questions to screen for known allergies to animal fur or dander. They are cautioned to be alert for the development of any respiratory or contact allergies and to report them immediately.
 - b. Prior to beginning employment or activity that will involve regular animal contact over an extended period, such as animal caretaking or senior research, individuals are screened by the supervising faculty. They complete a health history questionnaire, including questions about known allergens, and must provide evidence of tetanus vaccination within the past ten years. No person displaying allergy symptoms upon contact with animals is permitted to work with them. Health history questionnaires are kept on file by the appropriate facility director; updates and notations are made to record any change in health status, animal bites, or accidents within the facility.
 - c. All students and employees working with animals receive health and safety training from the faculty and animal care technicians. Training includes the proper handling of animals, bite prevention methods, and first aid and reporting procedures in the event of animal bite. Lab coats, latex gloves, cloth gloves, hand-washing facilities, and first aid kits are available in close proximity to all areas where animals are handled.
 - d. Risk assessment and occupational health and safety compliance are monitored by the Director of Physical Plant and Auxiliary Services and the Director of Facilities Maintenance, in cooperation with inspectors from the Occupational Health and Safety Administration.
- F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed there and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table.
- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:
1. The training available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is a cooperative activity involving faculty and staff in all relevant disciplines and offices. The total number of people working with animals (including faculty, animal care staff, and student animal handlers) is typically ten or fewer.
 2. Research investigators, including students and technicians who conduct or assist in scientific studies, receive appropriate training in methods that minimize the number of animals required for valid results and methods to minimize pain and distress. For student investigators, preliminary training takes place during coursework, followed by intensive mentoring during senior research or summer research experiences. All students who conduct senior research complete OLAW-approved online training in animal care and use. Faculty advisors are responsible for seeing that student researchers are competently trained in appropriate techniques. All small-animal surgical procedures are performed by faculty advisors; students may participate only after training, hands on instruction and under strict supervision. Protocols for senior research submitted to the IACUC must also address any possible distress or pain to the animals and describe techniques used to minimize it, including the use of appropriate anesthesia and analgesics for surgical procedure.

3. Training of student animal handlers is reviewed as part of the semi-annual program review. All student animal handlers receive training in the care and handling of animals prior to beginning work. Regular caregivers are closely supervised by supervising faculty and technicians until he or she is satisfied that the caregiver is competent in animal handling.
4. IACUC members serve for renewable three-year terms. New members are provided an orientation that includes receipt of a packet of background materials, the approved Animal Welfare Assurance document, and the IACUC Guidebook. All members have access to the PHS Policy via the internet. New members complete OLAW-approved online training in IACUC issues. On-going training of IACUC members is reviewed as part of the semi-annual program review.

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 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.

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.

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, Vice President for Business and Finance.
 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.

Reporting Requirements

- A. The Institution's reporting period is November 1– October 31. The IACUC, through the Institutional Official, will submit an annual report to OLAW by October 30 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. If there are no changes to report, this Institution will provide written notification that there are no changes.
 - 5. 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 (Senior Vice President for Business and Finance).

- 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.