



**Central Michigan University
Animal Welfare Assurance to Public Health Service
D16-00580 (Legacy A4076-01)**

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

I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS and/or the National Science Foundation (NSF). This Institution will apply the same standards of animal care and use outlined in this assurance regardless of the source of support. This Assurance covers only those facilities and components listed below.

A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:

1. All components of the University that are physically located on the CMU Main Campus in Mount Pleasant, MI.
2. The CMU Biological Station on Beaver Island. This facility is located approximately 175 miles from the CMU Main Campus. Beaver Island is located approximately 32 miles off-shore in northern Lake Michigan.
3. The Beaver Island Boathouse Facility. This facility is located approximately five miles from the CMU Biological Station on Beaver Island.

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 are as follows:
 - 1. Organizational Chart: Please see Appendix A
 - 2. The Vice President for Research is the Chief Research Officer and serves as the Institutional Official (IO). The IO reports to the Provost and President on conflict resolution, remedies to deficiencies in the animal program, need for space and remodeling, and capital improvement and has the authority to commit the resources needed to ensure the program's overall effectiveness, including compliance with all applicable Federal and State laws and regulations and all institutional policies.
 - 3. As indicated in the organizational chart, there are open and direct lines of communication between the Institutional Animal Care and Use Committee (IACUC) and the Institutional Official (IO) and between the Attending Veterinarian and the IO.
 - 4. The IACUC reports directly to the IO. The IACUC is appointed by the President of the University and is properly appointed according to PHS Policy IV.A.3.a. The IACUC is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. Its membership meets the composition requirements set forth in the PHS Policy, Section IV.A.3.b and consists of not less than five members, and includes at least: (1) a Chairperson; (2) one Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use; (3) one practicing scientist experienced in research involving animals; (4) one member whose primary concerns are in a nonscientific area; and (5) one individual who is not affiliated with the institution in any way other than as a member of the IACUC and is not a member of the immediate family of a person who is affiliated with the institution. An IACUC member who meets the requirements of more than one of the categories detailed above may fulfill more than one requirement. No more than three IACUC members can be from the same administrative unit (e.g., an academic department).

5. The Director of the Office of Research Compliance is the President's Administrative Liaison to the IACUC. The Director of Research Compliance helps to ensure the effective flow of information between the Vice President for Research and the IACUC. However, while correspondence [e.g., meeting minutes, recommendations, reports, etc.] between the IACUC and the IO may be routed through administrative channels for informational purposes, such correspondence will not be changed, influenced, or delayed in any manner whatsoever. In addition, there are direct and open lines of communication between the IACUC and the Vice President for Research.
 6. The Vice President for Research is in frequent contact with the IACUC chair and IACUC Coordinator. Moreover, each member of the IACUC has the right to communicate directly with the Vice President for Research on any matter the member feels necessary, and may do so without fear of reprisal.
 7. The veterinarian serves on the IACUC, is involved in the semi-annual facility inspection, and reviews all applications to use vertebrate animals for research or teaching at the Institution. The veterinarian is primarily responsible for insuring that proper guidelines for animal care and use are established and followed. In addition, the veterinarian provides advice to coordinators of the animal facilities and provides direct medical care to animals when necessary. Because the veterinarian has an important role in assuring that the animals receive proper care and treatment, this person not only reports to the IACUC regularly, but may communicate directly to the Vice President for Research when necessary.
- B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:
1. Name: Robert Werner

Qualifications:

- Degrees: DVM, University of Georgia, 1970; MS, DACLAM 1977
- Training and/or experience in laboratory animal medicine: Dr. Werner has nearly 45 years of experience in the practice of veterinary medicine involving zoo, laboratory, and domestic species of animals.
- He is licensed to practice veterinary medicine in the State of Michigan.
- Current veterinarian at West Michigan Regional Lab (WMRL) at Calvin College

Authority: Dr. Werner has been delegated program authority in accordance with the American College of Laboratory Animal Medicine's (ACLAM) "Guidelines for Adequate Veterinary Care" by the Institutional Official and has responsibility for the Institution's animal care and use program. This includes the authority to implement the PHS Policy and the recommendations of the Guide. Dr. Werner has unfettered access to all animals housed in University facilities.

Time Contributed to Program: Dr. Werner is present at the Institution an average of approximately eight hours every other month, alternating with the back-up veterinarian. One hundred percent of this time is contributed to the animal care and use program. In addition, Dr. Werner contributes on average approximately seven

hours per month to the program while off-site reviewing protocols and providing consultation on various program related topics.

2. Name: Kathleen Cannady

Qualifications

- Degrees: DVM, Michigan State University, 1995
- Training or experience in laboratory animal medicine or in the use of the species at the institution: Dr. Cannady has served as WMRL's Clinical Veterinarian since 2011. Served as a Licensed Veterinary Technician (LVT) working as a Veterinary Technology extern at Upjohn Pharmaceuticals; then worked at the University of Michigan Hospitals for eight years as an LVT in the Unit For Laboratory Animal Care; as Research Assistant in the Department of Anesthesiology and The Upjohn Center for Clinical Pharmacology, and an Allied Health Technical Specialist for the Department of Anesthesiology. She has served on WMRL's IACUC since 2008.
- Veterinarian at West Michigan Regional Lab (WMRL) at Calvin College

Responsibilities: Dr. Cannady will provide veterinary care in the absence of Dr. Werner.

Time contributed to program: Dr. Cannady is present at the Institution approximately eight hours every other month and contributes an average of four to eight hours per month to the program while off-site reviewing protocols and providing consultation on various program related topics.

3. Provisions for Veterinary Care at the Beaver Island Biological Station: Animals are housed on Beaver Island only during the summer months. The director of the facility may contact either Dr. Werner or the back-up veterinarian at any time. The back-up veterinarian that will provide veterinary care in the absence of Dr. Werner is Dr. Kathleen Cannady. Veterinary care is available via real time video conferencing with either Dr. Werner or Dr. Cannady.

- 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 is appointed by the President of the University. 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 approximately 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:

- The IACUC will meet approximately once every six months 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 Animal Welfare Act 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.
 - i. Security (personnel and facility)
- In addition, the evaluation may include a review of the Institution's PHS Assurance.
- If program deficiencies are noted during the review, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel.
- Subcommittees may be used to conduct all or part of the reviews. However, no member will be involuntarily excluded from participating 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 at least two voting members of the IACUC will visit all of the institution's animal facilities and animal surgical areas.
- The areas inspected include, but are not necessary limited to the following: any and all buildings, rooms, areas, enclosures, or vehicles and equipment, including satellite facilities, used for animal confinement, transportation, maintenance, breeding, or experiments inclusive of surgical manipulation.
- 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 or personnel.
- No member will be involuntarily excluded from participating in any portion of the inspections.
- The same procedures apply if the species are USDA or non-USDA regulated with a single exception; the IACUC may invite ad hoc consultants to assist in conducting the evaluation for facilities which house only non-USDA regulated species. However, the IACUC remains responsible for the evaluation and report.

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:

- Individual IACUC members will convey their observations to the IACUC Chairperson, or his or her designee, who, in turn, will draft 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.
- The reports will specifically identify any departures from the provisions of the Guide and the PHS Policy, if any exist, and state the reasons for each departure. If there are no departures the reports will so state.
- Approved departures must be approved as part of a protocol, protocol amendment, or other written document, using either FCR (Full Committee

Review) or DMR (Designated Member Review) as delineated below in Section III.D.6.

- Departures from the provisions of the Guide that are not IACUC approved are considered deficiencies and will be 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. A significant deficiency is one that is or may be a threat to the health or safety of the animals or personnel. If program or facility deficiencies are noted, the reports will contain a reasonable and specific plan and schedule for correcting each deficiency.
- If some or all of the institution's facilities are accredited by AAALAC International or another accrediting body recognized by PHS, the report will identify those facilities as such.
- Copies of the draft reports will be reviewed and revised as appropriate by the Committee.
- The final report that will be submitted to the IO 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.
- Following each evaluation, the reports will be completed and submitted to the IO in a timely manner.
- The Vivarium Managers and/or the IACUC coordinator act as liaisons between CMU's Facilities Management and the animal facility contact for the building in which the deficiency has been noted. In addition, progress or resolution of a deficiency is reported at monthly IACUC meetings until the problem is resolved.

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

- Signs describing the procedure for reporting concerns are placed throughout the animal care and use areas. Reporting animal welfare concerns is also addressed as part of the training provided by the animal care personnel. Instructions for reporting concerns are available in multiple locations on the Office of Research Compliance web page and a mechanism for providing anonymous reports through the web page is also available.
- No individuals, who in good faith report concerns or file a complaint, shall be discriminated against or be subject to any reprisal.

- All concerns are reported to the Office of Research Compliance and subsequently to the IACUC chair. The Office of Research Compliance conducts a preliminary investigation and forwards findings to the chair.
- The Chairperson reviews each concern to determine if an inquiry is necessary. If a concern is found to be valid, the IACUC will contact the parties involved and recommend appropriate steps for remediation within a specified time period.
- The full committee is notified of all concerns reported to the Chairperson, regardless of nature or validity.
- Where appropriate, animal care and use by the party or parties involved will be monitored to ensure compliance with university procedures.
- The IO is made aware of concerns at a minimum via periodic compliance activity reports delivered at a minimum of once per quarter or as often as once per month. The IO is made aware of all individual concerns that may represent serious or continuing noncompliance.
- If a violation is not corrected within the specified time or the problem is too complex for immediate remedy as determined by a majority of the IACUC then the committee will:
 - a. Immediately suspend animal care and use by the accused;
 - b. Notify the IO, the department chairperson, and the college dean of the suspension; and
 - c. Notify OLAW when the activity is supported by PHS funding.
- Reported concerns and all associated IACUC actions will be recorded in the minutes of a convened meeting.
- The Committee will report such actions, in writing, to the IO and, as warranted, to OLAW. If necessary, initial reports to both the IO and OLAW may be made verbally.

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 providing the IO with recommendations regarding any aspect of the institution's animal care and use program or animal facilities is via meeting minutes, semi-annual reports, or separate letters or emails.
- Recommendations are developed and approved by the Committee prior to being sent to the IO.

- In addition, specific recommendations from the Chair of the IACUC and/or the Attending Veterinarian that need immediate attention (e.g., suspension of permission to use animals by an Institutional member) can be given at any time. Such recommendations or actions will be reported to the IACUC at the next scheduled meeting or sooner as warranted.

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:

Submission, Pre-review, & Distribution

- The protocol is sent electronically to the IACUC coordinator who conducts an administrative review for completeness. The Principal Investigator (PI) or Program Director (PD) is notified of the need to make corrections or if information is missing. After making the necessary changes, the PI re-submits the proposal to the IACUC coordinator.
- Protocols are distributed electronically to the full committee and the members are allowed seven (7) business days to request the project undergo full-committee review (FCR). Any one member may request FCR.

IACUC Reviews (General Information)

- In order to approve proposed protocols, the IACUC will conduct a review of those components related to the care and use of animals and determine that the proposed protocols are in accordance with the PHS Policy and the Animal Welfare Act. The IACUC will confirm that the activities described in the protocol are consistent with the Guide unless acceptable justification for a deviation 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, and be 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 humanely euthanized 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.

- e. 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.
 - f. Medical care for animals will be available and provided as necessary by a qualified veterinarian or licensed veterinary technician or by animal care staff under the direction of a qualified veterinarian or licensed veterinary technician.
 - g. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
 - h. Methods of euthanasia used will be consistent with the current recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals unless a deviation is justified for scientific reasons in writing by the investigator.
- No member may participate in the IACUC review or approval of a protocol 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.
 - The IACUC may invite consultants to assist in reviewing complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC.
 - Meetings are conducted in person approximately once a month throughout the year.
 - Any use of telecommunications will be in accordance with NIH Notice NOT -OD-06-052 of March 24th, 2006, entitled Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals.

Full-Committee Review (FCR)

- If Full Committee Review (FCR) is requested, approval of those protocols may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote by a majority of the quorum present.
- There are no special attendance requirements other than a quorum of eligible voting members must be present.
- Following discussion, the Chairperson calls the question and voting is carried out by voice or hand vote or, in certain circumstances, by secret ballot.
- The possible outcomes of FCR are as follows:

- a. Approval
 - b. Requirement of modifications in to secure approval
 - c. Approval withheld
- Review of Required Modifications Subsequent to FCR. The review of required modifications subsequent to FCR will be done in accordance with PHS Notice Number: NOT-OD-09-035, January 2009. If the IACUC requires modifications (to secure approval) of a protocol, subsequent to FCR, such modifications are reviewed as follows:
 - a. FCR or DMR following all applicable procedures as delineated in the PHS Policy and elsewhere in Part III.D.6 of this Assurance.

OR

- b. DMR if approved unanimously by all members present at the meeting at which the required modifications are developed/delineated AND if all current IACUC members have previously agreed in writing (e.g., documented a policy) that the quorum of members present at a convened meeting may decide by unanimous decision to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol. This use of the DMR method has been unanimously approved in advance in writing by all IACUC members. The IACUC has agreed in advance to allow DMR subsequent to FCR when there is unanimous consent of the quorum of members present at a convened meeting when modification is needed to secure approval. New members are provided with training regarding IACUC procedures and are informed of the DMR subsequent to FCR method.

Designated-Member Review (DMR)

- If FCR is not requested, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, may be assigned to review those protocols and have the authority to approve, require modifications in (to secure approval) or request FCR of those protocols. Generally, the chairperson may assign two committee members to conduct the review. At least one assigned reviewer must be qualified/have experience in the research topic proposed.
- Records of polling members to obtain concurrence to use the DMR method, or concurrence by silent assent after seven (7) working days, and approval of protocols via DMR are maintained and recorded in the minutes of the next convened IACUC meeting.
- Other committee members may provide the Designated Reviewer with comments and/or suggestions only. Concurrence to use the designated-member review (DMR) method may not be conditioned.

- After required modifications are made, a final revised copy of the protocol, i.e., an identical document with all required modifications included, is provided to each assigned reviewer for review and approval.
- If multiple members are assigned to DMR, their decisions must be unanimous or the protocol will be referred to FCR.
- The possible outcomes of DMR are as follows:
 - a. Approval
 - b. Requirement of modifications (to secure approval)
 - c. Refer to full committee for review; assigned reviewers cannot withhold approval

Special or Expedited Reviews

- CMU IACUC Policy allows for review by Administrative Handling or Veterinary Verification and Consultation (AH/VVC) as described in OLAW Guidance and as listed in 7.k and 7.h-j below. There are no other special or expedited review mechanisms.

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:

- Other than the specific exceptions delineated in OLAW Guidance, Notice NOT-OD-14-126, August 26, 2014 and as delineated below and in IACUC approved policies, review and approval of significant changes will be handled in the same manner as new protocols. See Part III.D.6. above.
- 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 housing and or use of animals in a location that is not part of the animal program overseen by the IACUC
 - e. in the species;
 - f. in Principal Investigator;
 - g. that impact personnel safety;
 - h. in anesthetic agent(s) or the use or withholding of analgesics;
 - i. in the method of euthanasia; and
 - j. in the duration, frequency, or number of procedures performed on an animal
 - k. in approximate number of animals used

- Review and approval of items a. – g. must be by FCR or DMR. See Part III.D.6. above.
 - Review and approval of items h. – j. may also be handled administratively in consultation with a Central Michigan University veterinarian who is authorized by the IACUC and as described in an IACUC approved written policy(ies) that is compliant with OLAW Guidance, Notice NOT-OD-14-126, August 26, 2014. Such policies will include specific evaluation criteria, e.g., published drug formularies, AVMA Guidelines for the Euthanasia of Animals, allowable blood draw data/charts, etc. Such policies will also address possible negative impacts on animal welfare
 - Review and approval of item k. may also be handled administratively, but without requiring additional veterinary consultation, as described in IACUC approved written policies that are compliant with OLAW Guidance, Notice NOT-OD-14-126, August 26, 2014. Such policies will address the rationale for the original number of animals used, approved study objectives, the rationale for the additional animals, and possible negative impacts on animal welfare.
 - All such aforementioned policies related to administrative review will be adopted by formal action by the IACUC.
 - All authorizations of individuals by the IACUC to handle changes administratively will be specific (by name or position title and change(s) authorized to handle) and in writing.
 - All such aforementioned policies and authorization of individuals related to administrative review may be approved for a maximum of 36 months only. That is, all such policies expire no later than the three-year anniversary of the IACUC approval.
 - If the IACUC wishes to continue the procedures/policies and/or authorizations beyond the expiration date, prior to expiration of the policy, the existing or a new policy must be reviewed and adopted by formal action by the IACUC using FCR or DMR.
 - All approved changes will be documented in the associated protocol file.
- 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:**
- Notification of the committee's decision is provided in writing, by letter or e-mail. Notification is typically sent to the investigator within 5-7 days of the committee's decision.

- If modifications are required to secure approval, the correspondence contains a listing of the required modifications necessary to secure approval.
- If approval is withheld, the reasons are specified in the notification, and the investigator is given an opportunity to respond in writing or in person to the reasons for withholding approval.
- Copies of all completed pre-2016 applications (whether approved or not) with copies of the notifications are on file in the IACUC Coordinator's office. Copies of all applications and correspondence submitted after January 2016 are maintained electronically.
- The Vice President for Research (the Institutional Official) is notified of the IACUC's decisions regarding each protocol by receiving copies of the minutes from each IACUC meeting.

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 by the facility managers and the Office of Research Compliance. At least five percent of all active protocols are subject to Not-For-Cause (NFC) Quality Assurance audits annually.

Continuing / Periodic Protocol Review

- USDA Regulated Species - Protocols are reviewed by a member or members of the IACUC at least annually.
- Non-USDA Regulated Species –The same procedures are applied for USDA and non-USDA regulated species.
- Annual protocol reviews are recorded in the IACUC meeting minutes, which 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 initial IACUC approval.
- If activities will continue beyond the expiration date, prior to expiration of the original or preceding protocol 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, the institution's 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.
- In the event the IACUC cannot be convened to address a concern warranting suspension, the IACUC Chair, Attending Veterinarian, Institutional Official, Director of Research Compliance or the Director of Laboratory and Field Safety may temporarily halt research activities in emergency situations where in their judgment there is an imminent risk to the health or welfare of personnel or animals. Emergency holds will be resolved as rapidly as is practicable. In the event of an emergency hold, the IACUC must be informed as soon as possible and will be kept informed regarding remediation efforts. The IACUC will resume its normal role with regard to suspension of animal activities as soon as quorum of the IACUC is available for a convened meeting.
- If the IACUC suspends a PHS funded activity involving animals, or any other institutional intervention results in the temporary or permanent suspension of a PHS funded activity due to noncompliance with the Policy, Animal Welfare Act, the Guide, or the institution's 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 by telephone or by e-mail.

E. The risk-based occupational health and safety program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals is as follows:

1. Administration/management.

- The Office of Research Compliance (ORC) has responsibility for the overall management of the Occupational Health and Safety Program.
- The ORC, in conjunction with The Office of Laboratory and Field Safety (OLFS) and an Occupational Health physician contracted by the university, are responsible for coordinating implementation of the occupational health and safety program for personnel who work in laboratory animal facilities or have frequent contact with animals.
- Additionally, the program involves the joint responsibility of several CMU units:

- a. University Health Services (UHS) administers the student health program.
- b. The Benefits and Wellness Office oversees the employee health program, the worker's compensation program, the wellness program, the fitness and rehabilitation program, and the ergonomics program.
- c. Office of Laboratory and Field Safety (OLFS) has responsibility for occupational health and safety training and inspection programs, including the university-wide Right-to-Know program, and investigations and reports for MIOSHA.
- d. OLFS provides training programs on a number of topics, including: Asbestos Awareness, Bloodborne Pathogens, Confined Space Awareness, Emergency Preparedness, Fire Extinguisher Awareness/Fire Safety, Hazard Communication, Lockout/Tagout, New Employee Safety, Office Safety, Powered Industrial Trucks, Respiratory Protection, Biosafety, Radiation Safety, Laser Safety, and Severe Weather.
- e. OLFS performs regulatory inspections, develops/reviews/ maintains written plans and procedures, conducts accident investigations, maintains the University's Material Safety Data Sheets, works with regulatory agencies, selected responses to health/safety concerns and indoor air quality issues, conducts chemical spill cleanups, tests fire alarm systems, tests emergency showers and eyewashes, performs air monitoring, conducts sound level surveys, handles environmental issues such as Superfund Amendments and Reauthorization Act (SARA), Title III reporting, and assists in the selection of appropriate personal protective equipment.
- f. Lab Safety functions are administered through the Office of Laboratory and Field Safety. The Director of Laboratory and Field Safety serves as the Radiation Safety Officer, the Chemical Hygiene Officer, and the Laser Safety Officer for CMU.
- g. The Biosafety Officer is employed by the Biology Department, but reports one quarter time to OLFS.
- h. The Hazardous Waste Manager is employed by the Chemistry Department, but reports one half time to OLFS
- i. The Police Department has responsibility for public safety, fire prevention, and emergency management.
- j. Facilities Management has responsibility for day-to-day operations, maintenance, and routine cleaning of all of the university facilities.
- k. Residence Life is responsible for the university's pest management program.

2. Scope.

- As defined in the university's policy Animal Handler Occupational Health and Safety Program, all personnel involved in animal care and use shall participate in the university animal handler occupational health and safety program. Supervisors (e.g., department chairs, faculty and other CMU employees or affiliates who have oversight of University employees, students or other individuals) are responsible for implementing this policy with individuals under their supervision.
- Supervisors are required to identify employees who are required to participate in the occupational health program. The unaffiliated member of CMU's IACUC is also eligible to participate in the medical surveillance program.

3. Health Histories / Evaluations and Risk Assessment.

- All persons having contact with animals or animal tissues must participate in the Animal Handler Occupational Health and Safety Program.
 - The first step in the program involves the conduct of a risk self-assessment. This assessment considers: 1) hazards posed by the animals, 2) hazardous biological, chemical, or physical agents used in the animal activity, and 3) personnel health history.
 - After completing the assessment, individuals are advised of their risk level and whether participation in a program of further assessment is warranted.
 - Protected Health Information (PHI) provided at this stage is only accessible to the participant. The assessment consists of an automated workbook that references, and links directly to, educational materials related to risks associated with working with animals. Only the final page of the workbook is transmitted to the ORC/OLFS as confirmation that a risk assessment was conducted. The confirmation page contains no PHI. HIPAA regulation considerations do not apply to this form as it contains no PHI.
 - Individuals in job bands designated as higher risk are automatically required to continue to the second stage of the program and submit medical questionnaires to the CMU consulting Occupational Health Physician (OHP).
 - At no point in the process is PHI accessible by anyone other than the OHP and the participant. The OHP manages all medical records in compliance with HIPAA.
- Individuals may decline to participate in medical surveillance but must do so in writing at the conclusion of the risk assessment. Individuals who choose to participate in medical surveillance complete an 'Initial Medical Questionnaire for Individuals Who Work with Animals', which is reviewed by CMU's consulting Occupational Health physician, who may recommend precautionary measures such as use of a respirator.

- Upon completion of the risk assessment an individual may elect to participate in the health surveillance program by submitting a health screening questionnaire that includes a brief health history, questions regarding pregnancy and decreased immunocompetence. These are screened by a qualified occupational health physician. Individuals are advised that they may elect to opt out of medical surveillance or participate in health screening regardless of their level of risk but are strongly encouraged to participate if their risk is determined to be moderate or high. While this is a participant driven program, the University reserves the right to require participation in medical surveillance for any individual at increased risk.
- Once a medical questionnaire has been completed, the occupational health physician may choose to further screen any individual that indicates an increased risk. The questionnaires are based on hazard identification and risk assessment of the types of activities performed and the species involved.

4. Hazard Identification and Risk Assessment.

- The Institutional Animal Care and Use Committee (IACUC) protocol submission form queries investigators regarding potential use of biological agents, hazardous chemicals, and radioisotopes. Protocols involving the use of biological agents or radioisotopes require pre-approval from specialized committees (i.e., Institutional Biosafety Committee, Exposure Control Committee, and Radiation Safety Committee, respectively) prior to IACUC approval. The Office of Laboratory and Field Safety assists with evaluating proposals or activities involving unique hazards (e.g., chemicals, UV light, noise, lasers, electrical hazards, compressed gas, etc.).
- Routine facility inspections are performed by the IACUC and Office of Laboratory and Field Safety to provide ongoing hazard and risk assessment, as well as to assess the adequacy of control measures.
- The most common biological hazards and risks that have been identified include allergy/asthma, zoonotic infections, and bites/scratches. The most common chemical hazards include the use of anesthetic gases, disinfectants/cleaners, and chemicals for preserving tissues. The most common physical hazards include slips, trips, falls, and lifting hazards.
- Hazard identification and risk assessment is a dynamic, ongoing process performed throughout the animal care and use program by a range of personnel and committees. Cornerstone elements include protocol review, specialized committee evaluations, routine facility inspections, and medical assessment and surveillance.
- All animal care facilities use Animal Hazard Control Forms that alert any individual entering an animal room of the nature of the hazard(s) in that room and the appropriate protective measures. Signs posted in cage wash areas remind

employees when they are working with hazardous chemicals and the appropriate protection to use. Coordinators provide safety information updates. CMU maintenance employees or outside contractors who enter an animal facility are accompanied by coordinators who explain any hazards and provide PPE if needed.

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

- Safety measures, including PPE, must be followed within animal rooms, in corridors, in storage rooms, in cage wash areas, on loading docks, and in vehicles.
- Detailed work practice engineering control measures are specified in relevant IACUC protocols. Some fundamental measures applicable to nearly all animal care and use activities are described below.
- Hand washing is recommended after handling animals and prior to leaving animal care and use areas. In areas where sinks are not available in the immediate vicinity, hand sanitizer dispensing stations are typically provided to readily facilitate infection control until proper hand washing facilities become available. Eating, drinking, and smoking are prohibited in all animal rooms.
- Laboratory coats, scrub tops, gowns, disposable coveralls, or garments are worn as appropriate to protect street clothes from contaminations when handling animals. Gloves are worn whenever handling animals, their fluids, tissues, excreta, or soiled bedding to reduce exposure to allergens and potentially zoonotic agents.
- Protective equipment such as head covers, shoe covers, eye protection, hearing protection, and respirators may be required as determined by risk assessment. Personnel who use respirators are enrolled in the University Respiratory Protection Program managed by Lab Safety. Essential elements of this program include medical clearance, respiratory selection and fit testing, and training. Protective clothing and equipment is not worn beyond the boundary of animal work areas.
- When handling dirty cages and bedding, protective equipment including head covers, shoe covers, eye, and face protection (N95 mask/respirator, N95 mask and shield or full or partial face respirator) and/or the use of a ventilated dump station are required. Use of hearing protection and respirators may also be required as determined by risk assessment. Personnel who use respirators are enrolled in the University Respiratory Protection Program managed by Lab Safety. Essential elements of this program include medical clearance, respiratory selection and fit testing, and training. Protective clothing and equipment is not worn beyond the boundary of animal work areas.
- Sharps precautions are rigidly enforced, as are methods to minimize human exposure to biological agents and hazardous experimental or laboratory

chemicals (e.g., anesthetic gases, tissue fixatives). Lab Safety tracks and manages certification of all chemical fume hoods and biological safety cabinets used to protect personnel.

- Personnel who are not involved in animal care and/or use but nevertheless need to enter areas where animals are housed or used (e.g., facilities management, custodial staff, outside contractors) must be escorted by an authorized person who can inform them of the risks and provide the necessary personal protective equipment for the area.
- All CMU employees, including student employees, must receive lab safety training provided by the Environmental Health & Safety Department. This training covers the safe use of chemicals at CMU and complies with MIOSHA Part 431 (Michigan OSHA Hazardous Work in Laboratories Standard).
- Workplace ergonomic concerns for employees and research staff are addressed upon request by the staff of CMU's Central Health Improvement Program.

6. Immunizations.

- Vaccination against tetanus is recommended and is provided by the CMU consulting Occupational Health Physician.
- Immunizations will be updated according to recommendations of the Immunizations Practices Advisory Committee (ACIP) of the Center for Disease Control. Booster doses will be recommended as needed.
- Other vaccination recommendations will be determined on an individual basis after the risk assessment that reviews animal species, risk exposure, and personal health issues.
- The CMU consulting occupational physician, with added consultation as needed from the CMU Biosafety Officer or the Principal Investigator of the project, will make this determination.
- Individuals may decline to participate in an immunization program recommended by CMU's consulting occupational physician by signing appropriate waivers acknowledging their awareness of risks and agreeing to waive, release and hold harmless, CMU, provide said individuals have first undergone the training described in this policy and have conferred with CMU's consulting occupational physician. CMU's consulting occupational physician shall obtain any such waiver and only share it with CMU as appropriate. CMU, however, reserves the right to require individuals to participate in a preventative medicine program, as it deems necessary.

7. Precautions taken during pregnancy, illness or decreased immunocompetence.

- Prior to participating in procedures involving contact with animals, personnel are required to complete a risk assessment as described in section 3 above.
- Following completion of a risk assessment, individual participants who are required or elect to participate in the medical surveillance program submit an “Initial Medical Questionnaire for Individuals Who Work with Animals.”
- The occupational health physician will review the questionnaire and determine which personnel require a medical appointment. During the appointment, the physician discusses risk factors relevant to the individual’s work.
- During training, individuals who are pregnant, want to become pregnant, or are immunocompromised are advised to consult with the occupational health physician.
- Work restrictions and accommodations (such as respirator fit testing) are coordinated between the Occupational Health Physician and OLFS. Student Disability Services provides advice and covers the cost of any accommodations for students who participate in medical surveillance or who are approved to work with animals with restrictions (e.g. medical appointments, respirators).

8. Provisions for personnel who are not involved in animal care and/or use but nevertheless need to enter areas where animals are housed or used.

- There are occasions when personnel who are not involved in animal care and/or use nevertheless have a need to enter areas where animals are housed or used (for example, personnel involved in building maintenance, security, housekeeping, etc.). Signs are placed on the entrance to all animal facilities describing the animals housed in the facility and potential health issues with which to be concerned. The signs additionally provide information on whom to contact should an adverse event occur.
- Students in courses that include contact with animals are informed of the same by means of the syllabi for said courses.
- In addition to employees performing animal care, several other sectors of the CMU community are exposed to research and educational animals or animal tissues: faculty, post-doctoral fellows, visiting scientists, undergraduate, graduate, and professional students, and research technicians. Investigators must identify these individuals on the IACUC Project Review Form. Training is mandatory for all of those groups, and training records are available on request. Training topics vary with the project details and the individual’s involvement in the project. There is no charge for training.
- On some occasions, the public may tour the laboratory animal facilities. These tours involve primarily observation and discussion with the opportunity to interact with well socialized animals. Visitors are reminded at the beginning of the tour that allergies to animals are common, and asked if there are any allergies to

latex. In addition, Personal Protective Equipment (PPE) is available and in some areas required. Access to hand sanitation is available at the end of the tour.

9. Availability and procedures for treatment of bites, scratches, illness or injury.

- a. Bites and scratches should be flushed immediately with water and then scrubbed with soap and water prior to reporting for treatment.
- b. Injured personnel must report injuries to CMU Workers Compensation by calling 989-774-7177 and should report for medical attention as follows:
 - i. During clinic hours, non-employee students should go to University Health Services (989-774-5695) for treatment or referral.
 - ii. During clinic hours, employees, faculty, staff, and student employees should report to the Central Occupational Medicine Program (COMP), 989-773-2339.
 - iii. In the event of clinic closure, all injured personnel should go to McLaren Central Michigan Ready-Care, 989-773-1166. After hours, injured personnel should go to the McLaren Central Michigan emergency room.

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

- a. All participants should be familiar with CMU's Guidelines for Handling Injuries on Campus, which can be found at the Risk Management web page.
- b. CMU Workers Compensation will report and track injuries and illnesses and maintain appropriate paperwork as required by Michigan Occupational Safety and Health Administration (MIOSHA).
- c. Employees, students, volunteers, outside contractors, and visitors should report all unsafe conditions, practices, or equipment to the supervisor, instructor, or RMEHS whenever deficiencies are noted.
- d. With the exception of outside contractors, non-CMU affiliated individuals should see their normal health care provider.
- e. Individuals must notify their supervisor of suspected zoonoses or suspected work-related illness or work-related injury.
- f. Supervisors must report work-related illness or injury as prescribed in CMU's Guidelines for Handling Injuries on Campus.
- g. Outside contractors should contact their workplace Workers' Compensation office.

- 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:

1. IACUC Members

- Each IACUC member will be provided with access to:
 - a. The PHS Policy for the Humane Care and Use of Laboratory Animals;
 - b. The National Research Council (NRC) *Guide for the Care and Use of Laboratory Animals*;
 - c. The ARENA/OLAW IACUC Guidebook;
 - d. The AVMA Guidelines on Euthanasia;
 - e. A copy of this Assurance.
- All members of the IACUC will complete the Essentials for IACUC Members Curriculum located at the Collaborative Institutional Training Initiative website, www.citiprogram.org
- All IACUC members will visit the OLAW website at least semi-annually, will complete the IACUC tutorial module (initial visit), and will familiarize themselves with the other pertinent modules and information, e.g., OLAW FAQs, Policies and Laws, Guidance, Educational and other Resources.
- Attendance at an IACUC 101, IACUC 102, IACUC Advanced, PRIM&R/ARENA IACUC meeting, or similar course may be substituted for any required IACUC training session.

2. Animal Care and Use Personnel

- Central Michigan University has an approved animal welfare "Assurance Statement" on file with the Office of Laboratory Animal Welfare (OLAW). The Assurance Statement identifies the responsibilities of the Institutional Animal Care and Use Committee (IACUC), the research community as well as animal care personnel. The Assurance is written to comply with the laws and standards contained in the following documents:
 - a. Animal Welfare Act
 - b. The Guide for the Care and Use of Laboratory Animals (a.k.a. "the Guide")
 - c. U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training
 - d. Other applicable laws and standards
- The University's Assurance document is available on the Office of Research Compliance website. One element of the training program for all new animal care

and use personnel includes instruction on where the document is located, how to access the document as well as the essence of the document.

- Training documentation is included in animal use applications submitted to the IACUC for personnel involved in animal use studies. Training documentation for personnel involved in animal care (husbandry) is compiled by the facility managers and is available upon request.
- Animal facility managers provide training for all personnel involved in research or teaching use of animals.
- Investigators are tasked with ensuring participation in the training programs provided by the Institution for personnel under their supervision and for ensuring that individuals under their supervision have adequate training in protocol specific procedures prior to conducting research involving animals.
- Animal facility managers are tasked with ensuring adequate training of / for animal care personnel under their supervision.
- Training is designed to present the most up-to-date guidelines and procedures to all animal care and use personnel, and includes training on research or testing methods that minimize the number of animals required to obtain valid results and minimize animal distress.
- All personnel involved in animal use and care are instructed by the professional staff in proper procedures for handling and restraining animals, standard operating procedures and the use of specialized equipment.
- Facility managers conduct training related to specific job responsibilities where needed and are available for individual instruction.
- 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, §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:
 - i. The basic needs of each species of animal;
 - ii. Proper handling and care for the various species of animals used by the facility;
 - iii. Proper pre-procedural and post-procedural care of animals; and
 - iv. Aseptic surgical 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 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 Animal Welfare Act;
 5. Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information:
 - i. On appropriate methods of animal care and use;
 - ii. On alternatives to the use of live animals in research;
 - iii. That could prevent unintended and unnecessary duplication of research involving animals; and
 - iv. Regarding the intent and requirements of the Animal Welfare Act.
- Employees are encouraged to participate in local AALAS branch meetings and Michigan Society for Medical Research (MISMR) training programs.
 - A web-based training site, located at CHP Media under the name of the HP Vivarium manager, is now available for modules regarding handling/restraint of mice and rats, and administering oral medicines to mice and rats, subcutaneous and intra-peritoneal injection techniques in mice and rats and blood collection techniques in mice and rats.
 - Throughout the year special training sessions are offered that include discussion of regulations as well as hands-on techniques, to ensure that professional and technical personnel and students are qualified to handle animals in a humane and scientifically acceptable manner.
 - Research personnel can also request training on special topics. Training sessions include supervised laboratory practice with the animal species of interest, and handout material is provided. In addition, lecture demonstration sessions are conducted as an introduction to pertinent animal diseases, including zoonotics, and animal- handling techniques for students enrolled in CMU courses utilizing animals.
 - The facility managers have materials on laboratory and research animal care and welfare. Audiovisual materials on the proper care and use of animals, individualized instruction by the attending veterinarian or veterinary technicians, and reference materials relating to the humane care and use of animals in research are also available.
 - University Health Services offers a wide variety of health-related counseling services for students and student employees, and the Central Health

Improvement Program provides similar services for faculty and staff. All personnel involved in animal care and use are informed by the facility director of potential hazards and precautions associated with their work. SDS are available to all employees.

- Facility managers review zoonotic diseases as part of an overall training program in animal care and use. CMU is responsible for training university personnel in the safe handling of radiological, biological, and chemical materials, including blood-borne pathogens.
- The university attending veterinarian, is available for consultation in developing IACUC Project Review Forms (i.e., protocols) that require the use of anesthetics, analgesics, and tranquilizers. Agents are selected to provide relief from pain or distress with consideration for surgical procedures or technique, species, efficacy of pain control, and potential effects on experimental protocol. Postoperative analgesia to reduce the incidence of pain, weight loss, inappetance, discomfort, and inactivity is also emphasized.
- The IACUC reviews each protocol for appropriate use of anesthetics and analgesics. Research staff is required to monitor animals closely during procedures requiring anesthesia and in the postoperative period, document observations and treatment.
- Animal care staff is trained to observe animals. They report abnormal behaviors and may provide additional monitoring.
- Professional and technical personnel and students who perform anesthesia, surgery, or other experimental manipulations are qualified through training and/or experience to accomplish tasks in a humane and scientifically acceptable manner.
- Additionally, the Manager of the Health Professions Vivarium conducts technical skills training in the use of various anesthetic agents, surgical prep of the animal and the surgeon, suturing, donning gloves, maintaining a sterile field, postoperative monitoring.

3. Documentation – All training is documented and training records are maintained by the PI/PD, animal facility managers or electronically within CITI.

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 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.

- 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, David Ash, Ph.D., Vice President for Research.
 - 5. Records of accrediting body determinations
- B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after 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, David Ash, Ph.D., Vice President for Research.
 5. Any minority views filed by members of the IACUC
- B. When an activity is supported by PHS funding, 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.

Appendix A – Lines of Authority

