Central Michigan University
Animal Welfare Assurance
A4076-01

I. David Ash, Interim 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. 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 (Colleges, Schools, Departments, Etc.) 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 ~32 miles off shore in northern Lake Michigan. Across the water transportation, departing from Charlevoix, MI, is by ferry (2.5 hours) or charter air (20 minutes). Driving time from main campus to Charlevoix is ~2.25 hours.

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

3. The Office of Research Compliance (ORC) is the designated office in charge of administering the Institutional Animal Care and Use Committee (IACUC).

4. 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.

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 IACUC is appointed by the President of the university. 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 the appropriate 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).

8. 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 report directly to the Vice President for Research whenever necessary.

9. One (1) FTE is provided for the Coordinator of the Health Professions Animal Facility who is responsible for oversight of animal husbandry in the Health Professions vivarium. Student employees provide a preponderance of animal care in the HP facility, as well as in the other animal holding facilities on campus. Training for the student employees is provided by either the coordinator of the HP vivarium or by other qualified staff or faculty.

For research animals housed on Beaver Island, husbandry is provided by the Project Director or one or more students named in the research protocol. Typically, a Project Director is responsible for training the students to provide standard daily care and procedural methods specific to the study.

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.

   **Authority:** Dr. Werner has delegated program authority and responsibility for the Institution's animal care and use program including 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 per month. 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. **Provisions for Back-Up Veterinary Care:** The back-up veterinarian that will provide veterinary care in the absence of Dr. Werner is Dr. Joseph Kline of Erwin's Veterinary Clinic in St. Charles, Michigan.

3. **Provisions for Veterinary Care at the Beaver Island Biological Station:** Animals are housed on Beaver Island only during the summer months. During the summer, Dr. Werner visits the island at least once. Additionally, 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. Joseph Kline of Erwin's Veterinary Clinic in St. Charles, Michigan.

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

D. The IACUC will:

1. **Review at least once every six months the Institution’s program for humane care and use of animals, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:**
The IACUC will meet at least 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 Code of Federal Regulations (Animal Welfare) as a basis for the review.

To facilitate the evaluation, the Committee will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website.

The evaluation will include, but not necessarily be limited to, a review of the following:
   a. IACUC Membership and Functions;
   b. IACUC Records and Reporting Requirements;
   c. Husbandry and Veterinary Care (all aspects);
   d. Personnel Qualifications (Experience and Training); and
   e. Occupational Health and Safety
   f. Emergency and Disaster Plans

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:
   a. At least once every six months at least two (2) members of the IACUC will visit all of the institution's facilities where animals are housed or used i.e., holding areas, animal care support areas, storage areas, animal surgical areas, procedure areas, and laboratories where animal manipulations are conducted. Beaver Island is visited once in the summer while animals are present. Equipment used for transporting of the animals will also be inspected.
   b. 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.

3. Prepare reports of the IACUC evaluations according to PHS Policy IV.B.3. and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:
   a. 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.
   b. 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 identify specifically 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 or DMR as delineated below in Section III.D.6.

- Departures from the provisions of the Guide that are not IACUC approved are considered deficiencies and 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 which 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 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 HP vivarium manager and the IACUC coordinator act as liaisons between CMU’s Facilities Management and the point person 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 providing 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.

- 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 ORC and subsequently to the IACUC chair. The ORC 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.

- When appropriate, the IO will be made aware of the situation and the committee’s actions to resolve the matter.
• If a violation is not corrected within the specified time or the problem is too severe 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.

• 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. Reports to OLAW will be in writing and through the IO. 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:

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 insofar as it applies to the activity, and that the protocol is 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. The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.
e. Medical care for animals will be available and provided as necessary by a qualified veterinarian.

f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.

g. Methods of euthanasia used will be consistent with the current 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 unless they are also members of the IACUC.

- Meetings are conducted in person on a monthly basis from September through May of each year and, as necessary, for the remaining months.

- 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.

- The review process begins when a 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 five (5) business days to request the project undergo full committee review (FCR). Any one member may request 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 vote or, in certain circumstances, by secret ballot.

- The possible outcomes of FCR are as follows:
  - Approval
  - Requirement of modifications in order to secure approval
  - Approval withheld

- If the IACUC requires modifications (to secure approval) of a protocol, subsequent to FCR, such modifications are reviewed as follows:
a. FCR or Designated Member Review (DMR) following the 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 at the meeting at which the required modifications are developed AND if all IACUC members have agreed in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote 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.

• If FCR is not requested, the proposal is reviewed by Designated Member Review (DMR). The chairperson will assign two (2) 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 five (5) 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 IACUC Coordinator with comments and/or suggestions only. The IACUC Coordinator will forward this input to the designated reviewers for consideration. Concurrence to use the designated-member review (DMR) method may not be conditioned.

• The possible outcomes of DMR are as follows:
  ▪ Approval
  ▪ Requirement of modifications (to secure approval)
  ▪ Refer to full committee for review; assigned reviewers cannot withhold approval

• After required modifications are made, a final revised copy of the protocol is provided to each assigned reviewer for review and approval.

• The approval date for a protocol reviewed by DMR is the date the assigned reviewers approve the study.

• There are no alternate processes or procedures for special or expedited reviews.

7. Review and approve, require modifications in (to secure approval), withhold approval (FCR) or refer to full committee (DMR) of proposed significant changes regarding the use of animals in ongoing activities according to PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

• Review and approval of significant changes are handled in the same manner as new protocols. See Section 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 species or in approximate number of animals used;
  e. in Principal Investigator;
  f. in anesthetic agent(s) or the use or withholding of analgesics;
  g. in the method of euthanasia; and
  h. in the duration, frequency, or number of procedures performed on an animal
8. Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval according to PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

- The IACUC procedure is to notify an investigator and the institution, in writing, of the committee’s decision by letter or e-mail. The correspondence contains a listing of the required modifications necessary to secure approval. Notification is typically sent to the investigator within 5-7 days of the committee’s decision.

- 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 applications (whether approved or not) with copies of the notifications are on file in the IACUC Coordinator’s office.

- 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.

- USDA Covered Species – Protocols are reviewed by a member or members of the IACUC at least annually.

- Non-USDA Covered Species – Protocols are reviewed by a member or members of the IACUC annually. However, if the number of applications increases significantly, this may be extended to every two years for non-USDA covered species.

- Annual protocol reviews are recorded in the IACUC meeting minutes. The IACUC meeting minutes are reviewed and approved by the Committee.

- Protocols are approved for a maximum of 36 months. That is, all protocols expire no later than the three-year anniversary of the initial IACUC review. If activities will continue beyond the expiration date, a new protocol must be submitted, reviewed, and approved as described in Paragraph III.D.6. above.

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

- The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, 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.

- If the IACUC suspends a PHS funded activity involving animals, or any other institutional intervention results in the temporary or permanent suspension of an activity due to noncompliance with the Policy, Animal Welfare Act, the Guide, or 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 verbally.
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 Risk Management, in conjunction with an Occupational Health physician contracted by the university, is responsible for the overall management 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 (Lab Safety) 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.


  e. Lab Safety 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 responds 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 EHS.

  h. The Hazardous Waste Manager is employed by the Chemistry Department, but reports one half time to EHS.

  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 and Evaluations.**

- All personnel, at the time they are engaged to work with animals or in rooms containing animals, will complete a health screening questionnaire that includes a brief health history, including questions regarding pregnancy and decreased immunocompetence. These are screened by a qualified occupational health physician.

- 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 by personnel and species involved.

4. **Hazard Identification and Risk Assessment.**

- A risk-based assessment of all persons involved in contact with animals or animal tissues is done to determine their level of participation in the Occupational Health and Safety program. This assessment considers: 1) hazards posed by the animals, 2) hazardous biological, chemical, or physical agents used in the animal activity, and 3) susceptibility of personnel. Based on the extent of exposure, the next step may be a review of information provided to CMU’s consulting occupational health physician on a complete ‘Initial Medical Questionnaire for Individuals Who Work with Animals’. 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.

- The Institutional Animal Care and Use Committee (IACUC) protocol submission form queries investigators regarding potential use of biological agents, hazardous chemicals, and radionuclides. 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 Lab Safety to provide ongoing hazard and risk assessment, as well as to assess the adequacy of control measures. Medical professionals contribute to the comprehensive risk assessment process by evaluating the health status of the individual with respect to particular animal species contacted, potential exposure to harmful materials or activities, and the nature and extent of the contact with the animal.

- 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.

- 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.

- 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.

- 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 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.

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

● There are occasions when personnel who are not involved in animal care and/or use nevertheless have a need to enter areas when 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.

All participants should be familiar with CMU’s Guidelines for Handling Injuries on Campus, which can be found at www.rmi.cmich.edu

a. Individuals must notify their supervisor of suspected zoonoses or suspected work-related illness or work-related injury.

b. Supervisors must report work-related illness or injury as prescribed in CMU’s Guidelines for Handling Injuries on Campus.

c. Bites and scratches should be flushed immediately with water and then scrubbed with soap and water prior to reporting for treatment.

d. 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 McClaren Central Michigan Ready-Care, 989-773-1166. After hours, injured personnel should go to the McClaren Central Michigan emergency room.

e. CMU Workers Compensation will report and track injuries and illnesses and maintain appropriate paperwork as required by Michigan Occupational Safety and Health Administration (MOSHA).

f. 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.

g. With the exception of outside contractors, non-CMU affiliated individuals should see their normal health care provider.

h. 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, and other personnel involved in animal care, treatment, or use is as follows:

1. IACUC Members

   ● Each IACUC member will be provided with a copy of the following:

      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 American Association for Laboratory Animal Science website, www.aalaslearninglibrary.org or 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:
  - Animal Welfare Act
  - The Guide for the Care and Use of Laboratory Animals (a.k.a. "the Guide")
  - U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training
  - Other applicable laws and standards

• The university’s Assurance document is available on the Office of Research and Graduate Studies (ORGS) 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 are responsible for providing training for all personnel involved in research or teaching using animals.

• 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 animal care personnel are required to receive training following the procedures in the IACUC Policies and Procedures Manual.

• All personnel involved in animal care and use 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 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 tranquillizers 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 is now available for modules regarding handling/restraint of mice and rats, and administering oral medicines to mice and rats. Additional modules scheduled for completion include 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. Training modules are as follows:

**Listing of Training Modules for Clinical Procedures, Husbandry, Health and Safety, Laws and Regulations. In addition to these CMU specific training options, CMU employs the use of the CITI collaborative (University of Miami) to offer additional training to all animal care and use personnel.**

- Sample Collection Techniques
  - Blood collection from laboratory animals (COL-NS-001-00)
  - Blood collection from a dorsal vein of the mouse hind foot (COL-MO-003-00)
  - Tail bleeding technique in the mouse (COL-MO-001-00)
  - Tail bleeding technique in the rat (COL-RA-001-00)
  - Blood collection from rats via intravenous catheter (Col-RA-002-00)
  - Drawing blood from the tail artery of a rat or mouse (COL-RO-002-00)
  - Blood collection from rabbits via intravenous catheter (COL-RB-001-00)
  - Cardiac blood collection in the mouse (COL-MO-002-00)
  - Cardiac blood collection in the rat (COL-RA-003-00)
  - Blood collection in the dog and cat (COL-CD-001-00)
  - Placement and care of intravenous catheters in the dog and the cat (COL-CD-002-00)
  - Urethral catheterization in the dog and cat (COL-CD-003-00)
Anesthesia
- Anesthesia, analgesia and euthanasia of rodents and rabbits (ANE-RR-002-00)
- Controlling pain in rodents (ANE-RO-002)
- Isoflurane or halothane anesthesia of rodents and rabbits (ANE-RR-003-00)
- Mouse anesthetic regimes (ANE-MO-001-00)
- Rat anesthetic regimes (ANE-RA-001-00)
- Guinea pig anesthetic regimens (ANE-GP-001-00)

Administration Techniques
- Preparation for injections (ADM-NS-001-00)
- Needle sizes, sites, and volumes (NS-001-00)
- Intraperitoneal injection in rodents and rabbits (ADM-RR-001-00)
- Subcutaneous injections in rodents and rabbits (ADM-RR-002-00)
- Intramuscular injections in rodents and rabbits (ADM-RR-003-00)
- Intradermal injections in rabbits (ADM-RB-001-00)
- IV injections in the mouse tail vein (ADM-MO-002-00)
- IV injections in the rat tail vein (ADM-RA-002-00)
- Stomach tubing (gavage) in the mouse (ADM-MO-001-00)
- Stomach tubing (gavage) in the rat (ADM-RA-001-00)
- Administration of liquid medication by mouth in rodents (ADM-RO-005-00)

Injection techniques in the cat and dog (ADM-CD-001-00)
- Oral medications in the dog and cat (ADM-CD-002-00)
- Intubation of the dog and cat (ADM-CD-004-00)

Physical Exam and Restraint Techniques
- Physical exam and restraint of the mouse (PER-MO-001-00)
- Physical exam and restraint of the rat (PER-RA-001-00)
- Physical exam and restraint of the rabbit (PER-RB-001-00)
- Physical exam and restraint of dogs and cats (PER-CD-001-00)

Husbandry
- Biology and Husbandry of the Mouse (HUS-MO-001-00)
- Mouse-Signs and Symptoms of Disease (HUS-MO-002-00)
- Biology and Husbandry of the Rat (HUS-RA-001-00)
- Rat-Signs and Symptoms of Disease (HUS-RA-002-00)

Health and Safety
- Zoonotic Diseases in Exotic Pets and Laboratory Animals (HAS-LA-001-00)
- Zoonotic Diseases in Wild Rodents (HAS-WR-001-00)
- Disease Communicable from Domestic Animals to People (HAS-NS-001-00)

Laws, Regulations, and Policies that Impact on the Care and Use of Animals
- Animal Welfare Act (LAW-NS-003-00)
- PHS Policy (NIH) on Humane Care and Use of Laboratory Animals (LAW-NS-004-00)
- PHS Animal Welfare Policy (LAW-NS-006-00)
- Investigators Responsibilities (LAW-NS-008-00)
- Continuing Education Training in Animal Use and Care (LAW-NS-012-00)

Surgery
- Surgery Guidelines for Incision Site Preparation and Surgeon’s Scrub (SUR-NS-001-00)

Reproduction Techniques
- Mouse Estrus Detection (RPR-MO-001-00)
- Mouse Breeding (RPR-MO-002-00)
Euthanasia

- Morbidity/Euthanasia of Rodents (EUT-RO-001-01)
- CO₂ Euthanasia: Mouse Protocol using Pressurized Cylinder/Flow Meter (EUT-MO-001-00)

- 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. MSDS 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, inappetence, 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 Coordinator of the Health Professions Animal Care Facility 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 animal facility managers or the IACUC Coordinator.

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., Interim 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., Interim Vice President for Research.

5. Any minority views filed by members of the IACUC

B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

1. Any serious or continuing noncompliance with the PHS Policy

2. Any serious deviations from the provisions of the Guide

3. Any suspension of an activity by the IACUC

C. Reports filed under VI.A. and VI.B. above should include any minority views filed by members of the IACUC.