

MICHIGAN TECHNOLOGICAL UNIVERSITY
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

POLICIES AND PROCEDURES

Institutional Animal Care and Use Committee (IACUC)
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INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE MEMBERS

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1 INTRODUCTION

The Michigan Technological University (Michigan Tech) Institutional Animal Care and Use Committee (IACUC) is dedicated to the humane care and use of all animals in activities related to research and teaching conducted at Michigan Tech or by individuals associated with the University. Michigan Tech's IACUC is guided by federal regulations and ethical principles intended to ensure the humane care and use of animals in research. **All instruction and research involving living vertebrate animals that is conducted or authorized under the jurisdiction of Michigan Tech is subject to review by IACUC.**

These Policies and Procedures were developed by IACUC based upon requirements set forth by the following:

U.S. Department of Agriculture (USDA) under statutory law (Title 7, Section 2131 of the United States Code [7 USC 2131])

[\[http://www.nal.usda.gov/awic/legislat/awa.htm\]](http://www.nal.usda.gov/awic/legislat/awa.htm)

Public Health Service (PHS) under statutory law [42 USC 289d], the PHS Policy on Humane Care and Use of Laboratory Animals (Policy)

[\[http://grants1.nih.gov/grants/olaw/references/phspol.htm\]](http://grants1.nih.gov/grants/olaw/references/phspol.htm),

The Guide for the Care and Use of Laboratory Animals (Guide)

[\[http://oacu.od.nih.gov/regs/guide/guide.pdf\]](http://oacu.od.nih.gov/regs/guide/guide.pdf)

References to these resources are made throughout these Policies and Procedures.

2 REGULATORY AUTHORITIES GOVERNING ANIMAL USE

2.1 U.S. Department of Agriculture

USDA, through its division of the Animal and Plant Health Inspection Service (APHIS), administers the Animal Welfare Act (AWA) of 1966 and its amendments, codified at 7 USC 2131 et seq. and 9 CFR 2.31 et seq. The AWA regulates the transportation, purchase, care, and treatment of animals used for exhibition, sold as pets, or used in basic and biomedical research, education, and product safety testing. The AWA specifically applies to the use of nonhuman primates, dogs, cats, guinea pigs, hamsters, rabbits, and wild animal species.

The AWA requires the establishment of an Institutional Animal Care and Use Committee (IACUC) at all institutions that use animals in research, teaching, or testing. The Michigan Tech IACUC is responsible for reviewing all activities that involve animals in research, teaching, or testing to ensure humane use of animals. IACUC is also responsible for conducting semiannual assessments of Michigan Tech's animal care and use program, including inspections of all animal study areas and facilities. As a research facility, Michigan Tech is subject to random inspections by USDA and must file an annual report concerning its animal care and use program. Failure to comply with USDA laws and regulations pertaining to the use of live animals can result in civil or criminal prosecution and suspension of animal research activities.

Every Principal Investigator (PI) at Michigan Tech is referred to the IACUC website listing links to the AWA and related regulations. In addition, a current copy of the AWA and related regulations are accessible to everyone who works with animals.

2.2 National Institutes of Health, Office of Laboratory Animal Welfare

The PHS Policy was created to implement the provisions of the Health Research Extension Act of 1985. The National Institutes of Health (NIH), Office of Laboratory Animal Welfare (OLAW) administers the Policy. The Policy applies to institutions conducting PHS-supported projects involving live, vertebrate animals.

The Policy requires that such institutions establish an IACUC. In accordance with the Policy, the Michigan Technological University IACUC, using the Guide, is responsible for reviewing the use of animals and conducting semiannual assessments of the institution's animal care and use program, including inspections of all animal study areas and facilities.

Failure to comply with the Policy and/or Guide may lead to various actions, including the termination of PHS funding for all projects at Michigan Tech involving the use of animals.

3 ADMINISTRATIVE ORGANIZATION

Regulations and guidelines governing the use of laboratory animals apply to all persons at Michigan Tech involved in animal use. A quality animal care and use program requires the integrated support of many individuals at Michigan Tech, including the Institutional Official, investigators, students, research technicians, the Veterinarian in Charge, the Animal Facility Supervisor, and the animal care staff.

3.1 Institutional Official

Michigan Technological University's Director of Research Integrity and Compliance serves as the Institutional Official and has the authority to legally commit, on behalf of Michigan Tech, that regulatory requirements will be met under the AWA. The Research Compliance Administrator is responsible for appointing members to Michigan Tech's IACUC. As Institutional Official, the Director of Research Integrity and Compliance signs Michigan Tech's Institutional Assurance.

3.2 Veterinarian

The Veterinarian(s) serves on IACUC as a voting member and has delegated authority and responsibility to implement the PHS Policy and recommendations of the Guide and the AWA. The Veterinarian routinely inspects the animal facilities and all animals at Michigan Tech. The Veterinarian is available to make recommendations concerning preventive health programs for animals, disease treatment, analgesia, post-operative recovery, euthanasia, general animal welfare, and technical training. The Veterinarian provides routine veterinary care, preventive medical care, and on-call emergency care and consultation for Michigan Tech's animals. The Veterinarian has the authority to suspend any protocols that do not follow the Guide or the AWA.

3.3 Institutional Animal Care and Use Committee

IACUC was established pursuant to the AWA and the Policy and reports to the Research Compliance Administrator. The Director of Research Integrity and Compliance appoints the members of IACUC, who serve until they are removed or resign.

3.3.1 Membership

IACUC consists of members of varying professional and personal backgrounds, including at least one veterinarian, one non-scientist, one practicing scientist, and one person who is not affiliated with Michigan Tech in any way other than as a member of IACUC (i.e., a community member). The community member may be either a scientist or non-scientist. No more than two members are from the same department within Michigan Tech.

A University faculty member who is not the Supervisor of the Animal Facility or the Veterinarian in Charge is selected by the Institutional Official as the IACUC Chair.

IACUC may, from time to time, consult with other professionals (e.g., biostatisticians, legal counsel) in fulfilling its responsibilities.

3.3.2 Meeting and Quorum Requirements

IACUC meets at least once bi-annually. IACUC will meet more than bi-annually if necessary to fulfill its responsibilities. Reviews of protocols may also be conducted via a secure website located on the IACUC web.

A quorum requires the presence of a majority of the current voting members of IACUC. Any member who has a conflict of interest in a matter under consideration by IACUC (e.g., is personally involved in the matter) shall not be counted toward a quorum for that portion of the meeting.

3.3.3 Responsibilities

IACUC has general oversight responsibility for Michigan Tech's animal welfare program and Michigan Tech's animal facilities. Specific responsibilities of IACUC include the following:

Review of Animal Use

- * Review and approve, require modifications in, or withhold approval of all new Applications or revisions to existing protocols involving animals.
- * Conduct continuing reviews of approved protocols, not less than annually.
- * Conduct "de novo" review (similar to an initial review) of all active protocols at least once every three years.

Inspection and Review of Animal Care and Use Program

- * Recommend procedures to be followed for the proper care and humane treatment of animals and review them every six months using Title 9 CFR (USDA) and the Guide (OLAW) as a basis of review, providing a written report to the Research Compliance Office.
- * Inspect every six months all of Michigan Tech's animal facilities using Title 9 CFR and the Guide as a basis of inspection, providing a written report to the Research Compliance Office.
- * Provide recommendations to the Research Integrity and Compliance Office and Facility Supervisor regarding any aspect of the animal program, facilities, or personnel training.

Compliance Activities

- * Review and investigate noncompliance with the animal care and use program, applicable regulations, or the Guide.
- * Suspend any activity that is not in compliance with the Policy and Guide, the USDA regulations, or IACUC guidelines.

Record Keeping—Maintain records of IACUC activities as required by regulation or the Policy.

Community Relations—Serve as the liaison between the University and the community for all matters involving animal research and welfare.

3.4 **Animal Facility Personnel**

Facility Technicians/Support Staff—The animal care staff works closely with the animals. Facility technicians and support staff should be well qualified, by training or experience, to handle and care for the animals in the facility. They should be knowledgeable about the requirements for the species involved and about any special requirements imposed by specific research, testing, or teaching programs.

3.5 **Faculty Using Animals**

Faculty that use animals in research and teaching are responsible for complying with applicable regulations and University policies. IACUC is available to assist faculty members in fulfilling their responsibilities under this program. Nevertheless, each faculty member is ultimately responsible for the conduct of his or her individual projects.

In addition to University mandated and federally mandated responsibilities, the Association of American Medical Colleges and the Association of American Universities have made recommendations that serve as a useful guide for investigators and faculty. An excerpt adapted from these Recommendations for Governance and Management of Institutional Animal Resources (October, 1985) is provided below:

Since the support of investigators is crucial to maintaining high standards of animal care in any research setting, the following recommendations are provided for implementation by research faculty and staff.

- * Submit research protocols, as required by institutional animal care and use committees.
- * Maintain complete records of procedures undertaken during all animal experiments.
- * Provide thorough orientation for students, post-doctoral fellows, technicians, animal care workers, and others participating in research on the rationale for the use of animals in each protocol. Be sensitive to the needs of newcomers to adjust to participating in research performed on animals.
- * Maintain a scholarly, sensitive, respectful environment during all animal experimentation.
- * Participate in continuing education and training programs designed to keep investigators abreast of the latest techniques and procedures in animal research.

- * Devote time and effort to institution-wide activities to promote a general understanding within the academic community and the lay public of the need for animals in research and instruction.
- * Emphasize the role of laboratory animals when presenting research results or discussing human diseases with lay audiences and describe the contributions of humanely conducted animal studies to the discovery of new knowledge and development of new technologies and treatment capabilities.

Responsibilities of Faculty Using Animals for Instructional Purposes— Although there has been a dramatic reduction in the use of animals for instructional purposes over the past two decades, live animals remain an important and necessary adjunct teaching model in certain courses. The following recommendations are therefore directed to faculty members involved in this type of instruction.

- * Ensure that animals used for instructional purposes in classrooms or laboratories receive the same humane care and treatment as those used for research purposes.
- * Review any teaching methods involving animals to ensure that all regulations and guidelines are being followed.
- * Promote sensitivity and concern among students for the need for humane care and treatment of animals.
- * Promote understanding among students of the importance of humanely conducted animal studies to the discovery of new knowledge and the development of new technologies and treatment capabilities.

4 **PROTOCOL REVIEW PROCESS AND PROCEDURE**

Every animal used in teaching, testing, and research at Michigan Tech must be under an IACUC-approved protocol. Animal use is not allowed until it has been approved by IACUC, regardless of funding status. IACUC's process for reviewing and approving animal use is described in this section.

4.1 **Activities Requiring IACUC Approval**

The following activities involving live animals must be approved by IACUC before any action is initiated:

All research, teaching, and biological testing projects conducted by anyone at Michigan Tech regardless of the source of funding.

All research, teaching, and biological testing projects conducted at another institution or elsewhere by faculty, students, staff, or other representatives of Michigan Tech in connection with the investigator's institutional responsibilities.

IACUC may accept an approval statement from any other PHS-approved IACUC.

Activities involving the study of animals in their natural habitat without investigator intervention may not require IACUC approval but **DO** require IACUC notification that a study is being conducted.

4.2 **Types of Review**

All protocols may be subject to full committee review.

4.3 **Categories of Biomedical Research**

When reviewing protocols, IACUC uses the following categories to evaluate the extent of pain, discomfort, or distress anticipated for animals used in the proposed research:

- * Category A—The research involves animals which are not covered under the animal welfare act (these include laboratory mice/rats, birds, animals in agriculture research and cold blooded vertebrates)
- * Category X—Animals covered under the animal welfare act and the research involves either no pain, distress, or use of pain relieving drug.
- * Category Y—Animals covered under the animal welfare act and the research potentially involves minor short-term pain, discomfort, or distress that will be treated with appropriate anesthetics, analgesics, or tranquilizing drugs were used.

- * Category Z—Animals covered under the animal welfare act and the research involves procedures potentially inducing moderate pain, discomfort, or distress and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests, and/or the chronic maintenance of animals with a disease or functional deficit.

4.4 Review Criteria

Federal requirements state that IACUC must review proposals for animal use based on the following criteria:

1. **Potential Value of the Study**—Activities involving live animals are designed and performed with the reasonable expectation that such use of animals will contribute to the enhancement of human or animal health, the advancement of knowledge, or the good of society (PHS Policy).
2. **Selection of Animal Species**—The animals selected are of an appropriate species and the number of animals requested is the minimum number needed to obtain valid results (PHS Policy).
3. **Minimization of Pain and Distress**
 - a. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design [9 CFR 2.31(d)(1)(i) and PHS Policy, Section IV.C.1.a].
 - 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 PI justifies, in writing, the scientific reasons for the procedure [9 CFR 2.31(d)(1)(iv)(A) and PHS Policy, Section IV.C.1.b].
 - c. The PI has consulted with the attending veterinarian or his or her designee in planning procedures that may cause more than momentary or slight pain or distress to the animals [9 CFR 2.31(d)(1)(iv)(B)].
 - d. Procedures that cause more than momentary or slight pain or distress to the animals (excluding rats, mice, and birds) will not include the use of paralytics without anesthesia [9 CFR 2.31(d)(1)(iv)(C)].
 - e. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure, or if appropriate, during the procedure [9 CFR 2.31(d)(1)(v) and PHS Policy, Section IV.C.1.c].

4. **Alternatives**—The PI has considered alternatives to procedures that may cause more than momentary or slight pain and has provided a written narrative description of the methods and sources used to determine that alternatives are not available [9 CFR 2.31(d)(1)(ii)].
5. **Duplication**—The PI has provided written assurance that proposed activities involving animals do not unnecessarily duplicate previous experiments [9 CFR 2.31(d)(1)(iii)].
6. **Living Conditions and Housing**—Animal living conditions and housing are appropriate for the species and contribute to the health and comfort of the animals [9 CFR 2.31(d)(1)(vi) and PHS Policy, Section IV.C.1.d].
7. **Personnel**—Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures [9 CFR 2.31(d)(1)(viii) and PHS Policy, Section IV.C.1.f].
8. **Surgery**
 - a. Activities that involve surgery include appropriate provision for pre-operative and post-operative care of the animals in accordance with established veterinary medical and nursing practices [9 CFR 2.31(d)(1)(ix)].
 - b. No animal will be used in more than one major operative procedure from which it is allowed to recover unless it is:
 1. Justified for scientific reasons in writing by the PI, or
 2. Required as routine veterinary procedure or to protect the health or wellbeing of the animal as determined by the attending veterinarian [9 CFR 2.31(d)(1)(x)].
 3. **Euthanasia**—Methods of euthanasia are consistent with the recommendations of the American Veterinary Medical Association Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the PI [9 CFR 2.31(d)(1)(xi) and PHS Policy, Section IV.C.1.g].

4.5 Review Process

Two separate forms are used by IACUC for reviewing animal use, as follows:

- * **Application to Use Living Vertebrate Animals in Research or Classroom Situations** (the Application)—The Application must be used for new projects, revisions to existing protocols, and three-year renewals.

- * **Continuing Review for the Use of Living Vertebrate Animals in Research or Classroom Situations** (the Continuing Review form)— The Continuing Review form must be used to submit information for continuing IACUC review of previously approved projects, which occurs at least annually for each approved protocol.

Instructions, Application, and Continuing Review form are available on the IACUC Web site (<http://www.admin.mtu.edu/research/vpr/reviewboards/animal.htm>) and in the IACUC Office.

4.5.1 New Project

Submitting the Application—An IACUC Application must be completed for any new projects. The Application must be submitted to the IACUC Office at least two weeks in advance of the date which IACUC approval is requested. All sections of the Application must be completed according to the [Application Instructions](#). Those submitting an Application should carefully review and follow the Instructions. All correspondence regarding the Application should include the protocol title.

Processing the Application—Upon receipt of the Application by the IACUC Office, the following occurs:

- * The Application is given an IACUC number.
- * Copies of the Application are distributed to all members of IACUC via a secure web site maintained by the IACUC Coordinator.
- * PI's may be encouraged to attend the meeting at which their Application will be considered to answer any questions from IACUC members.

Reviewing the Application—Applications are considered for approval by full IACUC or by designated review.

The IACUC membership decides the action to be taken on the Application, either by full committee review or by designated review. The PI will be given written notice of IACUC's decision concerning the Application. Reviewed Applications will be assigned to one of the following five categories:

- * **Approved**—The Application is approved as presented with no modifications required. The Coordinator will provide the PI with approval notification. For activities funded by an external agency, the PI bears the responsibility of forwarding the IACUC approval information to the agency.
- * **Approved Pending Clarification**—The Coordinator will notify the PI of the required clarification. The Coordinator will disseminate the requested clarification to the Committee. Once the clarification has been verified, the Coordinator will notify the PI once the Application is approved.
- * **Tabled**—IACUC requires additional information and/or has a concern. The Coordinator will notify the PI of the decision and will arrange to discuss the

protocol with the investigator. Before IACUC review can continue, the PI must revise and resubmit the Application, clearly identifying changes. In addition, the PI must provide a separate cover letter to IACUC specifically responding to each item listed in IACUC's written notice of its decision to table the protocol.

- * **Disapproved**—The Coordinator will notify the PI if the Application is disapproved, providing the basis for IACUC's decision. If a protocol is disapproved, the PI has the right of appeal to IACUC. IACUC may, in its discretion, obtain external review of the Application by a PHS-approved IACUC of an equivalent institution and/or by expert consultants in the field of that research. The Michigan Tech IACUC, however, shall be the final authority in determining the acceptability of the protocol.

- * **Decline to Review**—Where the Application has significant deficiencies in information, or where the PI has failed to follow the Instructions for completing the Application, or other similar situations, IACUC will return the Application to the PI with an indication of why the Application was not reviewed. In those situations, the PI is encouraged to discuss the Application with the IACUC Coordinator to receive assistance in correcting the situation. The completed Application should be resubmitted for IACUC review.

Protocols are valid for three years and are subject to Continuing Review on **at least an annual basis**. Approval runs from the latest date the Application was signed.

4.5.2 Revisions to an Existing Protocol

Any revisions to an existing protocol that result in significant changes must be reviewed and approved by IACUC before the changes are implemented. A PI who wishes to revise an existing protocol should submit the Application two weeks prior to the date a review is requested. IACUC will review the Application using the procedures set forth above in Section 4.5.1. Revisions to an existing protocol do not extend the original three-year approval period. Revisions cannot be implemented until approved by IACUC.

4.5.3 Continuing Review

All protocols are reviewed by IACUC at least annually. The purpose of this continuing review is to provide IACUC with current information concerning the status of protocols. IACUC sends the Continuing Review form to the PI at least one month prior to the protocol anniversary date. The PI must complete the Continuing Review form and return it to the IACUC Office within two weeks. If the PI fails to complete and return the Continuing Review form on time, IACUC approval is suspended, effective at the end of the anniversary date, and no further activities can be conducted with animals until IACUC reinstates the protocol. Upon receipt of a completed Continuing Review form by the IACUC Office, copies are distributed to each member of IACUC. IACUC reviews the completed Continuing Review form during the anniversary month of the protocol and takes one of the following actions:

- * **Approved**—If IACUC approves the Continuing Review Form, the Coordinator signs the form and sends a copy of the approved, signed form to the PI for his or

her records.

- * **Disapproved**—If IACUC does not approve the Continuing Review form, the Coordinator will notify the PI in writing of IACUC's decision and what action is required to reinstate the protocol.

4.5.4 **Three-Year Renewal**

If a protocol is expected to continue beyond three years, the PI must submit an Application to IACUC two weeks prior to the month in which the three-year anniversary date occurs. Upon receipt of the Application, IACUC reviews the Application as an original new submission (de novo review) using the procedures set forth in Section 4.5.1 above. Failure to complete and submit a new Application on time will result in suspension of the protocol, effective at the anniversary date, and no further activities can be conducted with animals until IACUC approves the protocol.

5 SEMIANNUAL REVIEWS AND MONITORING

Twice each year IACUC reviews Michigan Tech's Animal Care and Use Program and inspects all Michigan Tech facilities where animals are housed and/or used. IACUC uses the Guide and the AWA regulations as the principal reference documents in conducting these reviews.

5.1 Types of Semiannual Review

5.1.1 Review of the Animal Care and Use Program

IACUC is required to semiannually conduct an evaluation of the animal care and use program. This semiannual evaluation includes the following:

1. IACUC membership and functions, including proposal review practices
2. IACUC records and reporting requirements
3. Veterinary care, to include:
 - a. Preventive medicine, animal procurement, and animal transportation
 - b. Surgery
 - c. Pain, distress, analgesia, and anesthesia
 - d. Euthanasia
 - e. Drug storage and control
4. Personnel qualifications and training
5. Occupational health and safety of personnel

IACUC may use the NIH Sample Semiannual Program and Facility Review Checklist as a guide when conducting its review of the Animal Care and Use Program at Michigan Tech.

5.1.2 Review and Inspection of Animal Facilities

As part of its semiannual review, IACUC will inspect all facilities where animals are kept longer than twelve hours and areas in which surgical manipulations are performed. Other areas, such as laboratories in which only routine immunizations, dosing, and weighing occur, will be monitored by random site visits and evaluations as necessary to assure compliance. IACUC maintains an updated list of all facilities to be inspected during its semiannual review. This semiannual review includes the following:

1. Animal housing and support areas
2. Cagewash

3. Aseptic surgery
4. Procedure areas, non-survival surgeries, laboratories, and rodent surgeries

IACUC may use the NIH Sample Semiannual Program and Facility Review Checklist as a guide when conducting its review of the animal facilities at Michigan Tech.

5.2 Semiannual Review Subcommittee and Reports

No IACUC member wishing to participate in any review shall be excluded. The Committee may invite ad hoc consultants to assist in the reviews.

Upon completion of the reviews, the Committee shall prepare a written report. The report shall describe Michigan Tech's adherence to the Guide and the AWA and state the reasons for any deficiencies. Deficiencies identified during the reviews are categorized as either minor or significant. A significant deficiency is defined, by USDA regulations and the PHS Policy, as something that is or may be a significant threat to animal health or safety. The report shall include a plan and schedule with dates for correction of each program or facility deficiency. All individuals to be involved in the corrections shall be consulted to ensure that the plan is realistic.

The report must be reviewed and signed by a majority of IACUC members and shall include minority views. IACUC shall submit the approved report to the Institutional Official and shall maintain a copy in its files. The report shall be made available to USDA, OLAW, and any federal funding agencies upon request.

Any failure to adhere to the plan and schedule identified in the report for correcting deficiencies that results in a significant deficiency remaining uncorrected shall be reported in writing by IACUC, through the Institutional Official, within 15 business days to APHIS. If the uncorrected deficiency is related to a federally funded activity, the relevant funding agency shall also be informed.

5.3 Monitoring

IACUC shall provide a copy of the final semiannual report to the Research Integrity and Compliance Office. The Research Integrity and Compliance Office shall monitor compliance with required corrective actions, as identified in the final semiannual report, and shall submit a written report to IACUC. If any deficiencies are not remedied within the time period set forth in the final semiannual report, IACUC shall take appropriate corrective action.

6 REVIEW AND INVESTIGATION OF NONCOMPLIANCE

One of the basic functions of IACUC, as specified in USDA regulations is to “review and, if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints and from reports of noncompliance received from laboratory or research facility personnel or employees” [9 CFR 2.31(c)(4)].

6.1 Reporting Concerns about Animal Care and Use

Anyone who has a concern about any aspect of animal care and use at Michigan Tech or who wants to express a complaint about how animals are being treated is encouraged to either contact the Director or Coordinator at 906-487-2902. Reports made through the Director will be delivered to the IACUC Chair for further action. Strict confidentiality will be maintained to the extent possible and allowable by law. No adverse action will be taken against anyone making a good-faith report of noncompliance.

6.2 Procedures for Dealing with Compliance Issues

Non-compliance with animal care and use policies is defined as using animals in research, teaching, and outreach programs in a manner that disregards or violates federal, state, or local regulations and guidelines, and/or Michigan Tech policies or guidelines.

6.2.1 Suspension of Protocol

6.2.1.1 Veterinarian Suspension of Protocol

The Veterinarian has authority to immediately suspend IACUC approval if he or she has reason to believe that any animal is in danger. The Veterinarian shall immediately notify the Research Integrity and Compliance Office of any suspension. The Research Integrity and Compliance Office shall notify the affected PI and the IACUC Chair in writing of any such suspension. An emergency meeting of IACUC will be called to review the suspension pursuant to the procedures set forth in Section 6.2.3 below. If IACUC upholds the suspension and the PI disagrees with the suspension, IACUC shall consult with an Independent Veterinarian.

6.2.1.2 Compliance Office Suspension of Protocol

The Research Integrity and Compliance Office has authority to immediately suspend any research being conducted that does not have IACUC approval. An emergency meeting of the IACUC will be called to review the suspension pursuant to procedures set forth in these policies.

6.2.2 Review of Compliance Issues Prior to an IACUC Meeting

The IACUC Chair, Investigator, and/or Animal Facility staff can handle most compliance issues. However, if an issue cannot be resolved without IACUC intervention, a subcommittee of IACUC will be appointed by the Chair to continue the investigation. All persons involved shall be informed of the purpose of the investigation and the manner in which it will be conducted. The subcommittee shall evaluate the status of any animals involved and the interim status of the PI's protocols and shall prepare a report to be presented at the next IACUC meeting. Prior to the

meeting, the individual against whom the complaint is addressed shall be notified in writing by the Chair of the findings and potential action by IACUC and shall be given the opportunity to appear at the meeting. If necessary, the Chair shall convene an emergency meeting of IACUC to deal with a compliance issue.

6.2.3 Review of Compliance Issues During an IACUC Meeting

IACUC shall examine the report of the subcommittee, interview potential participants and the person against whom the complaint is addressed, and decide whether there has been a violation of applicable regulations or procedures. All members shall have the opportunity to present minority views. A majority vote of a quorum of IACUC is required for any findings of IACUC and any action based on those findings. If there is a finding of noncompliance, IACUC must consider whether the noncompliance resulted in harm to animals or personnel, the seriousness of the noncompliance, and the nature of the noncompliance. The final results of the investigation shall be made available to all parties involved, the Dean of the area involved, and the Institutional Official. IACUC may, in its discretion, obtain external review of the matter; however, the Michigan Tech IACUC shall be the final authority.

6.2.4 Potential Actions of IACUC

Depending on the seriousness of the noncompliance, IACUC may take the following actions:

- * Suspend some or all of an individual's use of animals until it is clear that the personnel and procedures have been brought into compliance with federal laws and policies. A majority vote of a quorum of IACUC is required to impose a suspension or uphold a suspension imposed by the Veterinarian.
- * Notify the NIH and USDA (if regulated animals are involved) and any funding agencies involved. This notification is mandatory for any suspended protocols.

7 REPORTING AND RECORD KEEPING REQUIREMENTS

7.1 Reporting Requirements

7.1.1 U.S. Department of Agriculture Registration and Public Health Service Assurance

The Research Integrity and Compliance Office is responsible for completing the USDA Registration and PHS Assurance. The Research Integrity and Compliance Office may seek input from the Animal Facility Supervisor, General Counsel, and other individuals as necessary to complete these documents. The most recent USDA Registration was submitted July, 2008 and is valid for three years. Michigan Tech's Assurance was submitted October 18, 2005 and is valid for four years. The Registration and Assurance are signed by the Institutional Official and submitted to the appropriate agency.

7.1.2 Annual Reports

USDA/APHIS—IACUC is required to submit an Annual Report to APHIS. The Annual Report shall outline Michigan Tech's compliance with the AWA, the location of all facilities where animals are housed or used, and specific animal information as required by the AWA. The report shall cover the previous federal fiscal year, October 1–September 30. IACUC shall submit the signed Annual Report to the Animal Care Regional Director for Michigan on or before December 1 of each calendar year.

PHS/OLAW— (if applicable) At least once every 12 months IACUC, through the Institutional Official, shall submit a written report, to include any minority views, to OLAW. The report shall include the following:

1. Changes to Michigan Tech's program or facilities that would place it in a different category than specified in our Assurance.
2. Changes in IACUC membership.
3. Changes in the description of Michigan Tech's program for animal care and use as outlined in the Assurance.
4. Dates that IACUC conducted its semiannual evaluations and submitted its reports to the Institutional Official.

If there are no changes, the report shall state that there are no changes and inform OLAW of the dates of the semiannual evaluations and submission of semiannual reports to the Institutional Official.

7.1.3 Semiannual Reports

Upon completion of semiannual reviews (Section 5.1), IACUC shall submit written semiannual reports (Section 5.2) to the Institutional Official.

7.1.4 Other Reporting Requirements

The Research Integrity and Compliance Office shall report the suspension of any activity involving animals to OLAW, APHIS, and any federal agency funding the activity. The report shall include an explanation of appropriate corrective action taken.

The Research Integrity and Compliance Office shall report any failure to adhere to a plan and schedule identified in a semiannual report for correcting deficiencies that results in a significant deficiency remaining uncorrected. IACUC shall make this report in writing within 15 business days to APHIS and, if the uncorrected deficiency is related to a federally funded activity, to the relevant funding agency.

The Research Integrity and Compliance Office shall provide prompt written notice to OLAW of any serious or continuing noncompliance with the PHS Policy or deviation from the Guide.

7.2 Record Keeping Requirements

The Research Integrity and Compliance Office shall maintain 1) Applications and Continuing Review forms submitted for review; 2) minutes of meetings, including records of attendance; 3) activities of IACUC and deliberations, records of proposed activities, and proposed significant changes, including whether IACUC approval was given or withheld; 4) records of semiannual reports and recommendations; and 5) Michigan Tech's Assurance, USDA Registration, and annual reports to government agencies. These records shall be retained as follows:

1. **Five-Year Retention** - The Research Integrity and Compliance Office shall retain the Assurance for at least five years or until such time as a new Assurance is approved, whichever is longer.
2. **Three-Year Retention** - The Research Integrity and Compliance Office shall retain the following records for at least three years:
 - a. Records of semiannual IACUC reports and recommendations
 - b. Records of animals
 - c. Records of any accrediting body determinations, if applicable
 - d. Annual reports
 - e. USDA Registration
3. **Other** - The Research Integrity and Compliance Office shall retain records relating to proposed activities and significant changes in ongoing activities reviewed and approved by IACUC for the duration of the activity and three years after the end of the activity. Such records include, but are not limited to, records of Applications, Continuing Review forms, minutes of IACUC meetings, and records of investigations of noncompliance related to an approved protocol.

TRAINING

7.3 Personnel Involved in the Use And/or Care of Animals

Michigan Tech is required by Federal Regulations to provide training for all personnel involved in the use and/or care of live vertebrate animals in research, testing, or teaching. PHS Policy and USDA regulations require that training be made available in the following areas:

1. Humane methods of animal maintenance and experimentation, including the basic needs of each species of animal, proper handling and care for the various species of each animal used by the facility, and proper pre-procedural and post-procedural care of animals
2. Research and testing methods that minimize the number of animals required to obtain valid results and minimize animal distress
3. Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility
4. Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility

7.4 IACUC Members

All IACUC members shall receive initial training, to include an overview of the PHS Policy, the Guide, and AWA requirements.

7.5 Investigators (Principal and co-principal)

All Investigators including all students listed on the project, regardless of funding, are required to complete on-line CITI training. This required education can be obtained by completing the **Basic Lab Animal Welfare Course** modules (regarding lab mice and rats). You will receive a certificate of completion, and our office will be notified electronically of this completion. Investigators should maintain a file with copies of all relevant training.

The link for more information is found at:

<http://www.mtu.edu/research/administration/integrity-compliance/review-boards/animal-subjects/training-recommendations.html>

Click on the CITI Course link to go to the log in and registration page. You will be able to register your affiliation with Michigan Tech, and revisit the site if needed to complete the training.