

**MICHIGAN TECHNOLOGICAL UNIVERSITY**  
**INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE**

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**POLICIES AND PROCEDURES**

**Approved by the IACUC on 8/5/2022**

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## 1. INTRODUCTION

The Michigan Technological University (Michigan Tech) Institutional Animal Care and Use Committee (IACUC) is guided by federal regulations and is dedicated to the humane care and use of all animals used in research, teaching, and biological testing projects conducted by anyone at Michigan Tech or by individuals associated with the University. **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 the 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>]

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>],

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

[<http://oacu.od.nih.gov/regs/guide/guide.pdf>]

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

Please contact the IACUC Chair or the Research Integrity office if you have any questions or concerns about IACUC policies or procedures: [iacuc@mtu.edu](mailto:iacuc@mtu.edu), 906-487-2902

## 2. REGULATORY AUTHORITIES GOVERNING ANIMAL USE

### 2.1 U.S. Department of Agriculture

The United States 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 all research, research training, experimentation, biological testing, and related activities. 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 Public Health Service (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 and requires that such institutions establish an IACUC. Michigan Tech's assurance of PHS compliance also extends to all such activities supported by HHS, NSF, and/or NASA

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 animals apply to all persons at Michigan Tech using vertebrate animals in research or teaching. 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 Care Facility (ACF) Supervisor and the animal facility husbandry staff.

### **3.1 Institutional Official**

Michigan Technological University's Associate Vice President for Research Development (AVPRD) serves as the Institutional Official (IO) and has the authority to legally commit, on behalf of Michigan Tech, that regulatory requirements will be met under the AWA and PHS Policy. The Institutional Official signs Michigan Tech's Institutional Assurance with OLAW. The Institutional Official appoints the members of the IACUC, who serve until they are removed or resign.

### **3.2 Attending Veterinarian**

The Attending Veterinarian serves on the 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 or their designee routinely inspects the animal facilities and all animals on the Michigan Tech campus. 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 or their designee provides on-call emergency care and consultation for Michigan Tech's animals.

### **3.3 Institutional Animal Care and Use Committee**

Michigan Technological University's IACUC was established pursuant to the AWA and PHS Policy. In accordance with AWA requirements and PHS/OLAW Policy, Michigan Tech's

IACUC is responsible for reviewing all activities that involve animals in all research, research training, experimentation, biological testing, and related activities to ensure humane use of animals. The 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.

### **3.3.1 Membership**

The IACUC consists of a minimum of five (5) 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 the IACUC (i.e., a community member). A member may represent more than one required element (i.e. they could be both the "non-scientist" and "community member,") as long as there are a minimum of five (5) members. No more than three (3) members may be from the same department within Michigan Tech. There is no maximum number of members that may concurrently serve on the IACUC. The IO may appoint an alternate to a regular voting member; however, the alternate may not vote when the regular member is present at a convened meeting.

The IACUC may consult with other professionals (e.g. biostatisticians, legal counsel) in fulfilling its responsibilities and deliberations; however, such consultants may not vote at a convened meeting unless they are official members of the IACUC.

### **3.3.2 Meeting and Quorum Requirements**

The IACUC meets at least once semi-annually and will meet more than frequently to fulfill its responsibilities. Designated member reviews of protocols may also be conducted via a secure website.

During a convened meeting, a quorum requires the presence of a simple majority of the current voting members of the IACUC (i.e half the voting members plus one (1) additional voting member). Any member who has a conflict of interest in a matter under consideration by the 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**

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

#### **Review of Animal Use:**

1. Review and approve, require modifications in, or withhold approval of all new applications or revisions to existing protocols involving animals used in all research, research training, experimentation, biological testing, and related activities;
2. If the IACUC chooses to do so, conduct continuing reviews of specific approved protocols; and
3. Conduct "de novo" reviews (similar to initial reviews) of all active protocols every three years.

### **Inspection and Review of Animal Care and Use Program:**

1. Recommend procedures to be followed for the proper care and humane treatment of animals;
2. Inspect and review Michigan Tech animal facilities and its animal care and use program every six months using Title 9 CFR and the Guide as a basis of inspection;
3. Provide a written report to the Director of the Animal Research Protection Program (ARPP) summarizing the semi annual inspection and review with recommendations for improvement of any aspect of the animal program, facilities or personnel training; and
4. All inspection and review summaries and recommendations are synthesized into a report and presented to the Institutional Official.

### **Compliance Activities:**

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

### **Record Keeping:**

1. Maintain records of IACUC activities as required by regulation or the Policy.

### **Community Relations:**

1. 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**

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, teaching, and biological testing projects are responsible for complying with applicable regulations and University policies. The IACUC is available to assist faculty members in fulfilling their responsibilities under this program. Nevertheless, each faculty member is ultimately responsible for conducting their individual projects following the appropriate rules and regulations.

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:

1. Submit research protocols, as required by institutional animal care and use committee;
2. Maintain complete records of procedures undertaken during all animal experiments;
3. 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;
4. Maintain a scholarly, sensitive, respectful environment during all animal experimentation;
5. Participate in continuing education and training programs designed to keep investigators abreast of the latest techniques and procedures in animal research;
6. 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; and
7. 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 should be implemented by faculty members using animals for instructional activities:

1. Ensure that animals used for instructional purposes in classrooms or laboratories receive the same humane care and treatment as those used for research purposes;
2. Review any teaching methods involving animals to ensure that all regulations and guidelines are being followed;
3. Promote sensitivity and concern among students for the need for humane care and treatment of animals; and
4. 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. IACUC PROTOCOL REVIEW PROCESS AND PROCEDURE**

Every animal used in all research, research training, experimentation, biological testing, and related activities at Michigan Tech must be under an IACUC approved protocol, regardless of funding status.

## **4.1 Activities Requiring IACUC Approval**

The following activities involving live animals must be approved by the IACUC before researchers or other personnel can procure or use animals:

1. All research, teaching, and biological testing projects conducted by anyone at Michigan Tech regardless of the source of funding; and
2. 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.

The IACUC may accept an approval statement from any other PHS-approved IACUC. When one or more institutions or entities is involved in using animals in research, research training, experimentation, biological testing, and related activities, the IACUC may use a formal Memorandum Of Understanding (MOU) agreement to specify responsibilities for animal care and use, ownership, and IACUC review and oversight.

Activities involving the study of animals in their natural habitat without investigator intervention require IACUC notification and may require subsequent IACUC approval upon review.

## **4.2 Types of Review**

### **4.2.1 Full Committee Review**

Under a Full Committee Review (FCR) the protocol is scheduled for review at the next convened meeting of the IACUC and the PI is notified.

If the IACUC desires more scientific and technical expertise to evaluate aspects of a proposal it may contact outside consultants to provide information. Such consultants may not vote. The responsibility lies with the PI to justify and explain their proposed protocol to the satisfaction of the IACUC.

The PI may, but is not required to, attend the meeting in order to be available to clarify protocol issues that arise. The PI will leave the meeting prior to final discussion and voting on the protocol.

In order to complete the review and approve the protocol, a quorum (a simple majority of voting members) must be present at the meeting in person, interacting in real-time using web based conferencing applications, or by telephone conference call.

Any IACUC member listed on the protocol must recuse themselves and leave the meeting during the final discussion and during the vote; they may not be included as part of the quorum.

The convened committee may approve, require more information or modifications to secure approval, or withhold approval.



Following a Full Committee Review (FCR), if the committee requires more information or modifications it has the option of requiring subsequent revisions be approved by FCR or Designated Member Review (DMR). DMR can be used under the following options:

1. Currently, all members of the IACUC have agreed to a written policy (IACUC policy #9) 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; or
2. If the written policy outlined in 1 is revoked, and all members of the IACUC are present at a meeting, the committee may vote to require modifications to secure approval and have the revised research protocol reviewed and approved by designated member review (DMR), or returned for FCR at a convened meeting; or
3. Alternatively, if the written policy outlined in 1 is revoked and all members are not present at the meeting, if the committee elects to use DMR, all members, including the members not present at the meeting, must have the revised research protocol available to them and must have the opportunity to call for FCR. A DMR may be conducted only if all members of the committee have had the opportunity to request FCR and none have done so.

#### **4.2.2 Designated Member Review**

The IACUC chair may designate one or more members to review the protocol by Designated Member Review (DMR). All members must be informed of this decision, given access to the protocol, and given 3 business days to request a Full Committee Review. If any IACUC member requests it, it must be reviewed using FCR.

If a FCR is not requested, the designated reviewer may approve, require modifications to secure approval, or send the protocol to the full committee. If more than one designated reviewer is assigned, they must come to a unanimous agreement.

The designated reviewer does not have authority to deny approval. If they can not approve or require modifications, or if assigned to two or more reviewers and they can not reach unanimous agreement, then it must be reviewed using FCR.

The designated reviewer will apply the same criteria in review as the full committee would.

If the designated reviewer requires modifications to secure approval, the protocol will be returned to the PI. After the modified protocol is resubmitted for review, the full committee will be notified that the modified protocol is available. The IACUC chair may reassign the resubmitted protocol as DMR. All members must be informed of this decision, given access to the protocol, and given 3 business days to request a Full Committee Review. If any IACUC member requests it, it must be reviewed using FCR.

#### **4.2.3 Administrative Review**

Administrative review may be used for minor modifications of an administrative nature, including but not limited to typographical or grammatical errors, required signatures, personnel changes

(except the Principal Investigator), changes in funding sources, and requests for up to a 10% increase in laboratory mice or rats. These may be approved or acknowledged by the IACUC chair or their designee.

Initial protocol submissions may be administratively reviewed by the IACUC chair, or their designee, to confirm the submitted forms are correctly filled out, to identify missing information, to correct errors in details, and to suggest grammar or writing style changes. These comments do not represent an official IACUC review. The protocol must be resubmitted with the corrections or additions for official review.

### 4.3 Review Criteria

Federal requirements state that the 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** - For animals that might undergo pain or 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 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 will not include the use of paralytics without anesthesia [9 CFR 2.31(d)(1)(iv)(C)]; and
  - 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** - For animals that will undergo surgery:
  - a. Activities that involve surgery [will] 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:
    - i. Justified for scientific reasons in writing by the PI within the protocol, or
    - ii. 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)].
  - c. See IACUC Policy #2: Rodent Survival Surgery for additional policies specific to rodent surgeries.
9. **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].

#### 4.4 Review Process

Two separate forms are used by the IACUC for reviewing animal use:

1. **FORM: Animal Use Application - New and 3 Year Renewals** (the Application)—The Application must be used for new projects and three-year renewals (also referred to as “de novo” renewals); and
2. **FORM Renewal or Modification Request** - used for requesting modifications to existing protocols including protocol specific activity changes, changes in pain or distress categories, changes in surgery from non-survival to survival surgeries, or adding additional survival surgeries to the same animal, changes in species, requests to increase total animal numbers, and personnel additions.

##### 4.4.1 New Project

###### Submitting the Application

An IACUC Application must be completed for any new projects. All sections of the Application must be completed according to the Application 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:

1. The Application is given an IACUC number;
2. The IACUC Chair/Administrator performs a pre-review to ensure the form is complete.
3. Copies of the Application are distributed to all members of the IACUC via a secure web site maintained by Research Integrity Staff; and
4. 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**

The IACUC decides the action to be taken on the Application, either by Full Committee Review or by Designated Member Review. The PI will be given written notice of the IACUC's decision concerning the Application. Reviewed Applications will be assigned to one of the following four categories:

1. **Approved**—The Application is approved as presented with no modifications required. The Chair or their designee 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; or
2. **Modifications or Information Required**—The IACUC Chair or their designee will notify the PI of the required clarification or modifications. Once the clarification has been verified by the committee, the Chair or their designee will notify the PI the Application is approved; or
3. **Disapproved**—The Chair or their designee will notify the PI if the Application is disapproved, providing the basis for the IACUC's decision. If a protocol is disapproved, the PI has the right of appeal to the IACUC. The IACUC may 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; or
4. **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, the 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 Chair or their designee to receive assistance in correcting the situation. The completed Application must be resubmitted for IACUC review.

Protocols are valid for a maximum of three years from the date of the approval. Protocols that will be continued beyond the original 3 year approval period are required to be submitted as a *de novo* review, using the most current IACUC Protocol form.

#### **4.4.2 Revisions to an Existing Protocol**

Any revisions to an existing protocol that result in significant changes must be reviewed and approved by the IACUC before the changes are implemented. A PI who wishes to revise an existing protocol should submit the Application four weeks prior to the date a review is requested.

Revisions to an existing protocol do not extend the original three-year approval period. Activities outlined in the revisions cannot be implemented until they are approved by the IACUC.

After an existing protocol has undergone three (3) significant changes that are reviewed and approved by either Designated Member Review or Full Committee Review, the Application form must be resubmitted for the protocol in its entirety, and it will undergo

a complete review.

#### 4.4.3 Continuing Review

While most PHS and USDA projects do not require “continuing reviews” on an annual basis,, the IACUC reserves the right to add this requirement to specific protocols. Annual Reviews will be conducted for funding agencies that require it. Any protocols that require annual continuing reviews must have that requirement added at a full committee review and have clear instructions in the project’s determination letter that this is a requirement.

The following will take place when the IACUC has established the requirement for a continuing review. The PI will receive email reminders 45 days, 30 days, and 15 days prior to the expiration date. It is the responsibility of the PI to complete the Continuing Review form and return it to the IACUC Office before the expiration date. If the PI fails to complete and return the Continuing Review form on time, IACUC approval is suspended, effective on the anniversary date, and no further activities can be conducted with animals until the IACUC reinstates the protocol. Upon receipt of a completed Continuing Review form by the IACUC Office, copies are distributed electronically to each member of the IACUC. The IACUC or IACUC office reviews the completed Continuing Review form when it is submitted and takes one of the following actions:

1. **Approved**—If the IACUC or IACUC office approves the Continuing Review Form, the Coordinator sends an approval memo to the PI for their records; or
2. **Disapproved**—If the IACUC does not approve the Continuing Review form, the Coordinator will notify the PI in writing of the IACUC’s decision and what action is required to reinstate the protocol.

#### 4.4.4 Three-Year Renewal

If a protocol is expected to continue beyond three years, the PI must submit a new and updated Application to the IACUC six weeks prior to the month in which the three-year anniversary date occurs. Upon receipt of the Application, the IACUC reviews the Application as an original new submission (*de novo* review) using the procedures set forth in Section 4.4.1 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 the IACUC approves the protocol.

### 5. SEMIANNUAL PROGRAM REVIEW AND ANIMAL FACILITIES INSPECTIONS

Twice each year the IACUC reviews Michigan Tech’s Animal Care and Use Program and inspects all Michigan Tech facilities where animals are housed or used. The 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

The IACUC is required to conduct a semiannual 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, including:
  - a. Preventive medicine, animal procurement, and animal transportation;
  - b. Surgery;
  - c. Pain, distress, analgesia, and anesthesia;
  - d. Euthanasia; and
  - e. Drug storage and control.
4. Personnel qualifications and training; and
5. Occupational health and safety of personnel.

The 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, the 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. The 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. Cage Wash;
3. Aseptic surgery; and
4. Procedure areas, non-survival surgeries, laboratories, and rodent surgeries.

The 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 or inspection shall be excluded. The Committee may invite ad hoc consultants to assist in the reviews.

Upon completion of the reviews, the review 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 or personnel 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. The 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 correct significant deficiencies shall be reported in writing by the 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**

The IACUC shall provide a copy of the final semiannual report to the Director of the Animal Research Protection Program (ARPP). The ARPP shall monitor compliance with required corrective actions, as identified in the final semiannual report. If any deficiencies are not remedied within the time period set forth in the final semiannual report, the IACUC shall take appropriate corrective action.

## **6. REVIEWING AND INVESTIGATING NON-COMPLIANCE**

One of the responsibilities of the IACUC 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 contact the Research Integrity Office at 906-487-2902. Individuals may also report concerns directly to the IO, IACUC Chair, Institutional Veterinarian, or any member of the IACUC. Call complaints and concerns 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. The university adheres to procedures outlined in “Division A, Title XV, section 1553, Protecting State and Local Government and Contractor Whistleblowers.”

If individuals are not comfortable reporting directly to the Research Integrity Office, Michigan Tech has partnered with a third party service to provide a confidential and anonymous way to report activities that may involve fraud, misconduct, or violations of Michigan Tech policy. The instructions for reporting and a link to the third party service website can be found at: <https://www.mtu.edu/internal-audit/resources/hotline/>.

### **6.2 Procedures for Dealing with Compliance Issues**

Non-compliance with animal care and use policies is defined as using animals in all research, research training, experimentation, biological testing, and related activities 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**

The suspension of a protocol is a significant situation. This section outlines the how an approved protocol might be stopped, suspended and have the suspension rescinded

#### **6.2.1.1 Veterinarian Stopping work on an existing Protocol**

The Veterinarian has authority to stop the immediate work defined in an IACUC-approved protocol if they have reason to believe that any animal is in danger. The Veterinarian shall immediately notify the IACUC chair and/or Institutional Official when stopping any work. The IACUC Chair shall notify the affected PI in writing of any such suspension. An emergency meeting of the IACUC will be called to review if the protocol should be suspended pursuant to the procedures set forth in Section 6.2.3 below.

#### **Director of Animal Research Protection Program stopping work on an existing Protocol**

The Director of the Animal Research Protection Program has authority to stop the immediate work on an existing protocol. The Director shall immediately notify the IACUC chair and/or Institutional Official of stopping any work. The IACUC shall notify the affected PI in writing of any such work being stopped. An emergency meeting of the IACUC will be called to review if the protocol should be suspended pursuant to the procedures set forth in Section 6.2.3 below.

#### **6.2.2 Review of Compliance Issues Prior to an IACUC Meeting**

The IACUC Chair, Animal Facility staff and/or the Attending Veterinarian are the subcommittee for non-compliance and will investigate any compliance issues in conjunction with the Principal Investigator.

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 the IACUC and shall be given the opportunity to appear at the meeting. If necessary, the Chair shall convene an emergency meeting of the IACUC to discuss the compliance issue(s).

#### **6.2.3 Review of Compliance Issues During an IACUC Meeting**

The 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 the IACUC at a convened meeting is required for any findings of the IACUC and any action based on those findings. If there is a finding of noncompliance, the 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 results of the investigation shall be made available to all parties involved, the Dean of the area involved, and the Institutional Official. The IACUC may obtain external review of the matter; however, the Michigan Tech IACUC shall be the final authority.

#### **6.2.4 Potential Actions of the IACUC**

Depending on the seriousness of the noncompliance, the IACUC may take one or more of the



following actions:

1. 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;
2. Outline the actions required to bring the project back into compliance; and
3. In conjunction with the IO, Notify OLAW and USDA (if regulated animals are involved) and any funding agencies involved. This notification is mandatory for any suspended protocols.

### **6.2.5 Reversal of a Suspended Protocol**

Only the IACUC has the authority to reverse a protocol suspended by the IACUC. The reversal of a suspended protocol may only be authorized by a majority vote of IACUC members at a convened meeting.

## **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 ARPP Director is responsible for completing the USDA Registration and PHS Assurance. The ARPP Director may seek input from the Animal Care Facility supervisor, General Counsel, IACUC Chair, and other individuals as necessary to complete these documents. The Registration and Assurance are signed by the Institutional Official and submitted to the appropriate agency.

#### **7.1.2 Annual Reports**

**USDA/APHIS**—The institution 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. The IACUC shall submit the signed Annual Report on or before December 1 of each calendar year.

**PHS/OLAW**— At least once every 12 months the 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; and
4. Dates that the 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), the IACUC shall submit written semiannual reports (Section 5.3) to the Institutional Official.

### 7.1.4 Other Reporting Requirements

The ARPP Director 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 ARPP Director, in coordination with the I/O, 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. The 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 ARPP Director, in coordination with the I/O, 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 ARPP Director shall maintain:

1. Applications and Continuing Review forms submitted for review;
2. Minutes of meetings, including records of attendance;
3. Activities of the 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 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 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; and
  - e. USDA Registration.
3. **Other** - The Research Integrity Office shall retain records relating to proposed activities and significant changes in ongoing activities reviewed and approved by the 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.

## **8.0 TRAINING**

### **8.1 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 all research, research training, experimentation, biological testing, and related activities. 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; and
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

### **8.2 IACUC Members**

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

### **8.3 Investigators (Principal and co-principal)**

All Investigators including all students and other personnel listed on the protocol, regardless of funding, are required to complete the applicable web modules offered by the CITI Training Program before they have contact with animals. Approval and completion of on-line training will be documented, and in addition, Investigators should maintain a file with copies of all relevant training.

In addition to CITI training, submitted protocols will include protocol-specific training and experience for each individual listed on the protocol

## **9 ADDITIONAL POLICIES AND PROCEDURES**

The IACUC may add new, or modify existing, policies at a convened IACUC meeting. All additions and changes can be passed by a simple majority at a convened meeting unless otherwise prohibited by OLAW or USDA policy. The new or amended policy will then be published on the Michigan Tech website.

Current IACUC policies are listed at:

<https://www.mtu.edu/research/integrity/animal-subjects/iacuc/policies-procedures/>