

**Northern Michigan University**

**Institutional Animal Care and Use Committee (IACUC)**

**Policy on Humane Care and Use of Animals**

**Northern Michigan University  
Institutional Animal Care and Use Committee (IACUC)  
Policy on Humane Care and Use of Animals**

**Table of Contents**

Introduction.....	1
Purpose.....	1
Applicability of NMU IACUC Policy .....	2
United States Department of Agriculture .....	2
Office of Laboratory Animal Care.....	2
U.S. Government Principles .....	3
NMU IACUC.....	4
Frequency of Meetings .....	4
IACUC Membership.....	4
Composition of the IACUC .....	4
IACUC Chairperson.....	4
Attending Veterinarian.....	5
Non-Scientist.....	6
Scientist.....	6
Non-Affiliated Member .....	6
Institutional Official.....	7
Reporting Structure .....	8
Access to Animal Facilities .....	8
Occupational Health and Safety.....	8
Risk of Zoonoses.....	9
Disaster Planning .....	10
List of Important Items .....	10
Type of Emergency or Disaster .....	10
Emergency Animal Care Principles.....	11
Preparations for Emergencies .....	11
Utility Failures .....	12
Major Storms .....	12
Fire .....	12
Animal Activist Activities .....	13
Bomb Threat, Bomb or Suspicious Item Found .....	13
Animal Care and Use Applications.....	15
Forms .....	15
Due Dates for Animal Care and Use Applications .....	15
Review Exemption Policy.....	15
USDA Pain Categories .....	16
Significant Change to Approved Animal Care and Use Policy (Amending Approved Applications .....	17
Collaborations with Other Institutions (Duplicative Review) .....	17
Field Studies.....	17
Use of standard operating procedures (SOPs) in lieu of repeating descriptions of identical procedures in multiple protocols.....	17

Review System and Process for NMU IACUC Animals Use Applications and Colony Applications .....	18
Conflict of Interest .....	20
Conflict of Obligation .....	20
Amending Approved Protocols.....	20
Post-Approval Monitoring .....	20
Holding Protocols .....	20
Records of Approved IACUC Applications .....	21
Animal Acquisition and Disposition.....	21
Acquisition.....	21
Breeding Colonies.....	21
Disposition .....	22
Adoption Policy .....	22
Inspections of Animal Housing and Use Sites.....	22
For Inspectors.....	23
Conduction the Inspection .....	23
Reporting Inspection Findings.....	23
For Principal Investigators.....	23
Record Keeping Requirements .....	24
Management of Deficiencies and Concerns .....	25
Policy on Persons Reporting Violations .....	25
Definitions.....	25
Reporting.....	25
Significant Deficiencies .....	26
Minor Deficiencies.....	26
Concerns and Complaints .....	26
Confidentiality of the Complainant .....	30
Relevant Authority Citations .....	30
References for the NMU IACUC Policy .....	32
Appendix.....	33
Type of Emergency or Disaster – Categories and Levels.....	34
Emergency Procedures Posting.....	36

## INTRODUCTION

It is the policy of Northern Michigan University (NMU) to establish and maintain proper measures to ensure the appropriate, humane, and ethical care and use of animals involved in research and research training activities conducted or supported by NMU. This Policy complies with the Animal Welfare Act, the Animal Welfare Act Regulations and the Public Health Service Policy on Humane Care and Use of Laboratory Animals. In accordance with these policies and regulations, the care and use of animals at NMU are consistent with the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training, the Guide for the Care and Use of Laboratory Animals, and the recommendations of the American Veterinary Medical Association.

## PURPOSE

The Institutional Animal Care and Use Committee (IACUC) represents society's concerns regarding the welfare of animals used in activities associated with NMU. This Committee ensures the appropriate care and use of animals used in research, research training, biological testing, experimentation, teaching, and in breeding colonies that supply animals for these purposes.

This Committee reviews NMU's program of animal care and use to ensure animal health and well-being. NMU's program includes administrative policies and procedures for:

- (1) IACUC organization, membership, and procedures;
- (2) qualifications and training of personnel involved in care and use of animals used in research, research training, biological testing, experimentation, teaching, and in breeding colonies that supply animals for these purposes;
- (3) occupational health and safety of personnel working with animals used in research, research training, biological testing, experimentation, teaching, and in breeding colonies that supply animals for these purposes;
- (4) animal environment, housing, and management meeting recommendations of the Public Health Service (PHS), Office of Human Research Protection (OHRP), United States Department of Agriculture (USDA), the Animal Welfare Act Regulations (AWAR), and the American Veterinary Medical Association and;
- (5) veterinary medical care.

To this end, the IACUC

- (1) inspects NMU's animal facilities at least every 6 months,
- (2) reviews animal use protocols when animals are used in activities associated with NMU,
- (3) develops and maintains records of the activities of IACUC.

### **List of abbreviations**

**APHIS**, Animal and Plant Health Inspection Service; **AWAR**, Animal Welfare Act Regulations; **the Guide**, Guide for the Care and Use of Laboratory Animals; **IACUC**, Institutional Animal Care and Use Committee; **IO**, Institutional Officer; **NIH**, National Institutes of Health; **NMU**, Northern Michigan University; **OLAW**, Office of Laboratory Animal Welfare; **PHS**, Public Health Service; **PI**, Principal Investigator; **PIND**, Principal Investigator, Animal Facility Manager or other pertinent individual; **PPE**, Personal Protection Equipment; **SOP**, Standard Operating Procedure; **USDA**, United States Department of Agriculture

## **APPLICABILITY OF NMU IACUC POLICY**

These policies are applicable to studies, or components of studies, performed by NMU personnel in connection with his/her NMU responsibilities and/or using NMU property, resources, funds, or the name of NMU is being used in applying for funds (intra or extramural). Applicability of these policies will be deferred to those of another institution when the animals are owned or under legal responsibility of that institution, unless the study is funded by NMU. These policies are not applicable to whole or parts of dead animals obtained commercially or found in nature (e.g., animal tissues, fluids, organs, eggs, embryos, and fetuses) or as a byproduct of another approved research project.

## **RESPONSIBILITIES**

Animal care and use at NMU is regulated by the United States Department of Agriculture, Office of Laboratory Animal Welfare, and U.S. Government Principles for the Utilization and Care of Vertebrate animals Used in Testing, Research, and Training. The NMU IACUC policies were developed from these federal regulations, policies, and principles.

United States Department of Agriculture (USDA): The USDA interprets and enforces compliance of institutional animal care and use specified by the Animal Welfare Act and Animal Welfare Act Regulations. USDA-regulated species are defined in the Animal Welfare Act. According to the Animal Welfare Act, an *“Animal means any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warmblooded animal, which is being used, or is intended for use for research, teaching, testing, experimentation, or exhibition purposes, or as a pet. This term excludes: Birds, rats of the genus Rattus and mice of the genus Mus bred for use in research, and horses not used for research purposes and other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. With respect to a dog, the term means all dogs, including those used for hunting, security, or breeding purposes”*. NMU is required by the USDA to conduct semi-annual animal facility and program evaluations and to submit to the USDA an annual report that describes minor or major discrepancies found in the animal facility and program evaluations and a census of USDA-regulated animals used during the last annual reporting period. The USDA performs unannounced site visits to NMU that occur at least once annually.

Office of Laboratory Animal Care (OLAW): The OLAW interprets and enforces compliance of institutional animal care and use of PHS-funded or -assured animals as specified by the Public Health Service Policy on Humane Care and Use of Laboratory Animals (referred to as the ‘PHS Policy’). The OLAW defines an animal as *“any live, vertebrate animal used in research, research training, experimentation, or biological testing or for related purposes”*. The PHS Policy is based upon the AWA and the Guide for the Care and Use of Laboratory Animals. The IACUC and the Institutional Officer (the Dean of Research) submit an annual report to OLAW describing changes made to the Animal Care and Use Program, dates when the semiannual program and facility evaluations were conducted, and any minority viewpoints expressed by IACUC members during the reporting period.

U.S. Government Principles for the Utilization and Care of Vertebrate animals Used in Testing, Research, and Training: NMU is also expected to use vertebrate animals in accordance with the nine U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training. “The development of knowledge necessary for the improvement of the health and well being of humans as well as other animals requires *in vivo* experimentation with a wide variety of animal species. Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible institutional officer shall ensure that these principles are adhered to:

1. The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. et. seq.) and other applicable Federal laws, guidelines, and policies.
2. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.
3. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and *in vitro* biological systems should be considered.
4. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.
5. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.
6. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
7. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must 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. In any case, veterinary care shall be provided as indicated.
8. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their inservice training, including the proper and humane care and use of laboratory animals.
9. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an

institutional animal research committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.”

**NMU Institutional Animal Care and Use Committee (IACUC):** The NMU IACUC oversees the implementation of all applicable federal regulations and policies, as described above, in the care and use of all vertebrate animals (cold- and warm-blooded) associated with NMU research, training, and biological testing activities.

The IACUC shall:

1. Develop policies and improve existing policies to ensure compliance with federal regulations and policies and seek to attain best practices for the care and use of animals in NMU research and research training activities;
2. Evaluate the animal care and use program and facilities semi-annually and report findings to the USDA and to OLAW;
3. Evaluate new and existing applications for the use of animals in research, research training, biological testing, experimentation, teaching, and in breeding for NMU activities;
4. Respond to animal care and use complaints;
5. Respond to non-compliance incidents; and
6. Maintain records of IACUC meetings and activities

### **FREQUENCY OF MEETINGS**

Meetings will occur monthly, assuming there is pending business. IACUC meetings are open to the public. Contact the IACUC office ([IACUC@nmu.edu](mailto:IACUC@nmu.edu)) for meeting times and locations.

### **IACUC MEMBERSHIP**

Members of IACUC are appointed by the Dean of Graduate Studies and Research, who serves as the Institutional Official at NMU.

### **Composition of the IACUC**

The Committee must be composed of at least 5 members. Members of the IACUC must include the IACUC Chair, IACUC Vice Chair, Scientist, Non-scientist, Veterinarian, and Unaffiliated Member. If possible, 1 of the 5 members is to have a background in ethical issues.

### **IACUC Chairperson**

Definition: The chairperson must be a knowledgeable and effective leader. This individual must have the full support of the Institutional Officer and sufficient stature to perform the functions of the positions without jeopardy to career or position. The chairperson is appointed by IACUC members, through a majority vote. The chairperson plays an active role in the oversight of all IACUC activities. The Chair serves five constituent groups: Senior Administration (CEO and IO); the scientific community; other members of the IACUC; the federal government; the public. It is not recommended that the Attending Veterinarian be the IACUC chairperson due to real or perceived conflicts of interest. The Committee shall elect a Chair who shall serve for at least 2 years. The Vice-Chair assumes the duties of the Chair when the Chair is unavailable or if there is a conflict of interest or obligation involving the Chair.

Responsibilities: The IACUC Chair has the responsibility for overseeing the coordination and implementation of effective, efficient systems for protocol review and program review by the IACUC in compliance with the PHS policy and the AWA. Specifically the Chair should:

1. Ensure that the IACUC has a quorum present at all meetings;
2. Declare the loss of a quorum resulting in the end of official business if a sufficient number of members depart;
3. Prepare and/or oversee the preparation of meeting minutes, agendas and reports and submit appropriate documents to the IO in accordance with PHS policy and the AWA;
4. Report to the IO any activities which have been suspended by the IACUC for non-compliance as required by PHS policy;
5. Ensure the establishment of a written system of communication for the IACUC with the investigators concerning the approval status of protocols and the steps necessary to secure approval;
6. Stay abreast of the most recent regulatory trends and interpretations
7. Evaluate and champion policy and practice initiatives to improve the animal care and use program;
8. Be a point person for interacting with other institutional committees, occupational health and safety, physical plant, human resources;
9. Conduct administrative review (see Review System and Process section);
10. Advise PIs;
11. Educate and support IACUC members, PIs and others regarding the IACUC process;
12. Participate in facility inspections;
13. Communicate regularly with the IO, Attending Veterinarian, IACUC Administrator and staff;
14. Serve as spokesperson for the IACUC.

### **Attending Veterinarian**

Definition: The Attending Veterinarian (appointed by the I.O. as the University Veterinarian with direct or delegated program authority and responsibility for activities involving animals at the institution as defined under the Animal Welfare Act and PHS policy) serves on the Institutional Animal Care and Use Committee. This individual should have graduated from an accredited veterinary school. (PHS Policy (IV,A,3,b,1) and AWAR (2.31,b,3,i).

Responsibilities: The role of the IACUC Attending Veterinarian is to:

1. Provide veterinary consultation on the recognition and palliation of pain;
2. Provide medical care;
3. Serve as a resource for IACUC members, PIs, and graduate students on issues related to animal welfare, such as providing expertise on matters of animal health and welfare, including, but not limited to: use of proper anesthesia and analgesia in laboratory animals in the relief of pain and distress; discussion of the possible complications related to procedures used or a disease model proposed; provide a review of the plans for appropriate and timely medical intervention;
4. Provide consultation with Principle Investigator and other key staff members for proposed USDA Category D and E research prior to review by the IACUC committee;



5. Serve as a voting member of the IACUC;
6. Serve as designated reviewer when appropriate;
7. Have the ability to immediately stop animal use and/or care activities that violate standards of veterinary practice unless these activities have received prior approval in an IACUC protocol.

### **Non-Scientist**

Definition: A person whose primary concern is in a non-scientific area having no obvious connections to any area of science. Individuals may have some scientific training, but clearly do not qualify as a practicing scientist with experience in research involving animals.

Responsibilities: The role of the Non-Scientist member is to:

1. Play an active role in all IACUC activities;
2. Make persistent, straightforward inquiries about matters that are undetected by the institutional members of the IACUC;
3. Critically review protocols;
4. Serve as designated reviewer when appropriate;
5. Attend monthly IACUC meetings;
6. Participate in six-month facility inspection and program reviews.

### **Scientist**

Definition: A practicing scientist knowledgeable about the types of research and teaching being reviewed and conducted, and who has laboratory animal experience. NMU policy is to represent all departments having involvement with animal research. No more than three scientists from one department unit shall be on the NMU IACUC.

Responsibilities: The role of the Scientist member is to:

1. Play an active role in all IACUC activities.
2. Make persistent, straightforward inquiries about matters that are undetected by the institutional members of the IACUC.
3. Critically review protocols
4. Serve as designated reviewer when appropriate
5. Attend monthly IACUC meetings.
6. Participate in six month facility inspection and program reviews.

### **Non-affiliated Member**

Definition: Someone who is not affiliated with NMU in any manner who represents the general community interests in the proper care and treatment of animals. This person may not be the immediate family member of a person affiliated with the institution, and this person cannot participate in other committee or activity at NMU,. Public members may not be laboratory animal users. (AWAR 2.31,b,3,ii;PHS Policy IV, A, 3,b,4)

Responsibilities: The role of the Non-Affiliated member is to:

1. Play an active role in all IACUC activities.
2. Make persistent, straightforward inquiries about matters that are undetected by the institutional members of the IACUC.
3. Critically review protocols

4. Serve as designated reviewer when appropriate
5. Attend monthly IACUC meetings.
6. Participate in six-month facility inspection and program reviews.

### **Institutional Official**

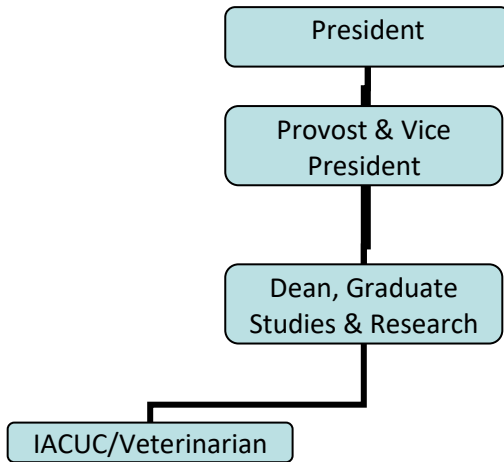
Definition: The individual at Northern Michigan University who is authorized to legally commit on behalf of the research facility that it will meet the requirements of the AWA. PHS policy defines the IO as the individual who signs and has the authority to sign the institution's Assurance, which commits the institution to meet the requirements of PHS policy.

Responsibilities: The role of the Institutional Official:

1. Has the authority to sign the University's Assurance and commit the institution to meet the requirements of AWA.
2. Commits the institution to meet the requirements of PHS policy.
3. Receives inspection reports and recommendations from the IACUC.
4. In consultation with the IACUC, determines whether deficiencies are minor or significant, determines corrective actions or suspensions and reports such actions to regulatory and funding agencies.
5. Receives notification of the IACUC's decision to approve or withhold its approval of animal activities.
6. Receives and transmits annual reports to NIH/OPRR and to APHIS.
7. May subject protocols that have been approved by the IACUC to further review and approval, but may not approve an activity that has not been approved by the IACUC.
8. Ensures that all personnel involved in animal care, treatment and use are qualified to perform their duties and that specific training is provided to those personnel.
9. Ensures that training and instruction and the qualifications of personnel are reviewed with sufficient frequency to fulfill the research facility's responsibilities.
10. Ensures the University has an attending veterinarian who provides adequate veterinary care to its animals in compliance with the AWA.
11. Ensures that the University maintains the required records for the specified time periods.

## Reporting structure

The lines of authority and responsibility for administering the program and ensuring compliance with this Policy at NMU, as described in the most current PHS Assurance, are shown below. The Institutional Officer at NMU is the Dean of Graduate Studies and Research.



## ACCESS TO ANIMAL FACILITIES

Access to animal facilities must be limited to key personnel, which may consist of faculty, staff, and students, that are responsible for the care, use, and oversight of animals at NMU. Visitors to these facilities must have permission of the principle investigator or other individuals in a supervisory role (e.g., an animal colony manager) and be directly supervised by key personnel. A security system must be in place to insure that unauthorized personnel cannot enter these facilities, and a system of granting access to personnel must including adequate documentation, including appropriate identification and evidence of qualifications to perform assigned responsibilities for animal use and care. These measures protect both animals used in these facilities, and personnel working in these facilities.

## OCCUPATIONAL HEALTH AND SAFETY

The Guide for the Care of Laboratory Animals, which is the basis for PHS Policy, states that “An occupational health and safety program must be part of the overall animal care and use program” and provides an outline of the principal requirements for such a program. This risk assessment and the implementation of health programs at NMU will rely heavily on input from persons knowledgeable in occupational safety and health, biosafety, and radiation safety, and include both preventive as well as diagnostic and treatment features. During semi-annual animal program and facility reviews, the NMU IACUC will assess the quality of the Occupational Health and Safety program as it pertains to animal workers. The following recommendations on maintaining an acceptable occupational health and safety program provided in the Guide will be considered during this review:

1. Professional staff who conduct and support research programs that involve hazardous biological, chemical, or physical agents (including ionizing and nonionizing radiation)

should be qualified to assess dangers associated with the programs and to select safeguards appropriate to the risks;

2. Personnel at risk should be provided with clearly defined procedures for conducting their duties, should understand the hazards involved, and should be proficient in implementing the required safeguards;
3. Personnel should be trained regarding zoonoses, chemical safety, microbiologic and physical hazards (including those related to radiation and allergies), unusual conditions or agents that might be part of experimental procedures (including the use of genetically engineered animals and the use of human tissue in immunocompromised animals), handling of waste materials, personal hygiene, and other considerations (e.g., precautions to be taken during personnel pregnancy, illness, or decreased immunocompetence) as appropriate to the risk imposed by their workplace;
4. All personnel must maintain a high standard of personal cleanliness, and clothing suitable for use in the animal facility and laboratories should be supplied and laundered by NMU;
5. Facilities, equipment, and procedures should also be designed, selected, and developed to provide for ergonomically sound operations that reduce the potential of physical injury to personnel (such as might be caused by the lifting of heavy equipment or animals and the use of repetitive movements); Safety equipment should be properly maintained and routinely inspected;
6. Experimental animals should be housed so that potentially contaminated food and bedding, feces, and urine can be handled in a controlled manner; Facilities, equipment, and procedures should be provided for appropriate bedding disposal;
7. In selecting specific safeguards for animal experimentation with hazardous agents, careful attention should be given to procedures for animal care and housing, storage and disbursement of the agents, dose preparation and administration, body-fluid and tissue handling, waste and carcass disposal, and personal protection; Special safety equipment should be used in combination with appropriate management and safe practices.
8. Hazardous agents should be contained within the study environment;
9. Exposure to anesthetic waste gases should be limited; this is usually accomplished by using various scavenging techniques;
10. Personal protective equipment should be provided, and other safety measures should be adopted when needed. Animal care personnel should wear appropriate institution-issued protective clothing, shoes or shoe covers, and gloves.

### **Risk of Zoonoses**

To prevent transmission of infectious diseases, all commercially obtained live animals that enter NMU facilities will be quarantined for 7 days and wild caught live animals will be quarantined for 10 days. Handling procedures and proper PPE should be appropriate for the species.

## DISASTER PLANNING

The requirement for institutional disaster planning is found in the Guide (p. 46) which states “A disaster plan that takes into account both personnel and animals should be prepared as part of the overall safety plan for the animal facility.”

([http://grants.nih.gov/grants/olaw/disaster\\_planning.htm](http://grants.nih.gov/grants/olaw/disaster_planning.htm))

The purpose of this plan is to document an effective preparation and response strategy for emergencies that may result in an inability to maintain normal conditions in animal facilities and/or an inability of personnel to reach an animal facility, thus potentially threatening the health and welfare of animals. All personnel working with animals in NMU facilities are strongly encouraged to read the entire disaster plan carefully.

### List of Important Items:

**Emergency information:** Contact information is posted near the main entrance to the animal facilities.

**Posted Floor Plan:** All personnel should be aware of the facility floor plan and evacuation routes for their facilities. Evacuation routes will be conspicuously posted in the main corridor near the main entrance of each facility.

**Telephones:** A phone is located in each animal facility.

**Fire alarms:** Located in each animal facility.

**Fire extinguishers:** Located in each facility.

**First aid kits:** Located in each facility.

**Eye-wash stations:** Located in each facility.

**Flashlight and fresh batteries:** Flashlights and extra batteries are located in all animal housing rooms.

**Clear Hallways:** In the event that an evacuation takes place, hallways should be clear of equipment and other barriers that would interfere with quickly leaving the area, particularly during low light conditions.

### Type of Emergency or Disaster: Categories and Levels

The Federal Emergency Management Agency (FEMA) describes 3 **categories** of emergencies:

- Natural disasters & emergencies (e.g., earthquake, major storms, flooding),
- Technical emergencies (facility malfunction such as HVAC or power failures as well as hazardous material spills)
- Civil emergencies (bomb threats, animal rights demonstrations).

Emergencies may also be ranked by the **level of impact**, ranging from limited equipment failure to catastrophic building damage. The operational organization necessary for responding to each level of emergency depends upon the size and complexity of the emergency and of the facility impacted.

- **Level 1 emergencies** will typically be handled by animal facility personnel with little or no assistance (see Appendix for a listing of types of emergencies by level). The IACUC chair will be notified of emergencies related to animal health and safety.
- **Level 2 emergencies** will require outside assistance from other departments and/or city emergency response personnel (see Appendix for a listing of types of emergencies by level). For instance, a bomb threat may involve University Security personnel, local

Emergency Medical Services, and Marquette City and Marquette County Law Enforcement.

Level 2 emergencies typically involve a single facility or building. Damage assessment will be conducted by the Animal Laboratory Director and reported to the IO and the IACUC Chair. The animal facility member on site with highest seniority will assume these responsibilities in the absence of the Director. While level 2 emergencies may be extensive, local University and community resources are readily available to assist.

- **Level 3 emergencies** are infrequent, catastrophic, and will likely exceed the capacity of local emergency response teams. Animal facility personnel may need to respond to the crisis for several hours or longer without outside assistance. Emergencies of this level are under the direction of the President of the University or his or her designee, as outlined in the Northern Michigan University Disaster Plan. All animal facility personnel will follow all directives and instructions issued by these authorities.

### **Emergency Animal Care Principles**

*In all emergencies, human life and safety will take precedence over animal life. The animal facility personnel must not put themselves or their colleagues in danger in order to evacuate animals.*

**Critical Functions:** As far as possible, critical animal facility specific functions and systems should be maintained:

- Air temperature surrounding the animals should remain within a normal room temperature range.
- The air surrounding the animals should be free of harmful contaminants.
- All animals should be observed periodically, with the interval depending on conditions, but at least every 24 hr, to the extent possible.
- Animal identification should be retained; loose animals should be captured.
- If an emergency lasts 6 hr or more, the following functions should be maintained:
  - Air ventilation and/or accessory heating/cooling should be provided.
  - All animals should have access to a bottle of potable water.
  - All animals should have access to uncontaminated food.
- If an emergency lasts 24 hr or more, the following additional functions should be maintained:
  - Animals' cages should be cleaned as needed.
  - Perishable food should be kept at 4°C or lower.
  - Veterinary care should be provided, including care for post-surgical animals.
  - Accessory power should be supplied to freezers with animal carcasses.

### **Preparations for Emergencies**

- Flashlights and extra batteries should be located in several places within the animal facility. All staff and faculty who work in the animal facility should know where they are located.
- Large containers of potable water should be kept in the animal facility. The quantity should be sufficient to provide drinking water for all the animals for at least one day.
- Extra food should be available.

- Large fans should be available to the animal facility staff to provide air circulation if ventilation is lost.
- Important files on the animal facility computers should be backed up regularly, and the backup discs should be kept outside of the animal facility.
- It may be necessary to evacuate animals to a new location(s) under emergency conditions. In the event of a large-scale disaster, euthanasia of animals may be necessary. Euthanasia will be a last resort and will be conducted under the direction of the Attending Veterinarian.

### **Utility Failures**

The most common facility malfunctions that impact the laboratory animals are utility failures such as malfunction of the heating, ventilation, and air conditioning (HVAC) system and power outages.

#### ***Response Actions:***

- Monday through Friday workday: Call Operations and Maintenance (phone # On Campus 2292, Off Campus 227-2292)
- After hours and on weekends: Call NMU Public Safety (On Campus 2151, Off Campus 227-2151) to notify the emergency Operations and Maintenance personnel on call.
- Room temperatures that exceed normal temperatures by +/- 5 degrees C for an animal facility should be reported.
- Describe the problem, the location of the problem (use specific room numbers), and your specific request that facility services be notified.
- In the event of power failure, locate a flashlight and exit the facility.

### **Major Storms**

Road conditions may preclude staff from arriving to work on time or at all. The safety of human life is always the priority in these situations. Employees should not risk their personal safety to take care of animals in the facility. However, employees who live near the University are asked to make efforts to arrive even if the University has been officially closed for classes.

If a major storm occurs when bedding changes and full cage washes are scheduled, personnel who are able to make it to work should perform daily health checks in all animal rooms first. If time allows AFTER daily health checks have been done, then check food levels, topping as necessary and do the scheduled bedding changes as time allows. If the entire room cannot be completed, required daily health checks should be conducted on remaining animals and note where the bedding changes or full cage washes were stopped. Cage changing should be continued on the next day, or sooner if weather conditions improve.

### **Fire**

Smoke, heat, and toxic gases from a fire are the most common causes of fire-related deaths and injuries, not flames. Be aware that these deadly fire elements rise and collect at ceiling levels, pushing cooler, cleaner air toward the floor. While toxic gases and heat are often fire's invisible killers, rising smoke may cover and hide exit signs above doorways. Do not attempt to evacuate any animals.

- Notify the Fire Department immediately (911)
  - Pull a fire alarm.
  - If a phone is closer than a fire alarm, call the Fire Department (911) first. Then pull a fire alarm as you are evacuating the building.
- Fire suppression
  - Some small, well-contained fires, such as trash can fires, may be dealt with using a fire extinguisher if one is nearby.
- Evacuation procedures
  - Leave the building by following the fire exit route posted in the main corridors of animal facilities and near stairwells and elevators. Do not use elevators for evacuation.
  - “GET LOW and GO” to avoid contaminated, smoke-filled air.
  - “STOP, DROP, and ROLL” if your clothing catches on fire.
- After the fire marshal approves the building for re-entry, move animal cages from top shelves on racks to bottom shelves away from any remaining toxic gases near the ceiling.
- Evacuate animals only at the direction of the Animal Facility Director or the Attending Veterinarian.

### **Animal Activist Activities**

Personnel need to be aware of their surroundings at all times and of unauthorized or suspicious persons attempting to gain access to animal facilities. Activists may pretend to have authority to gain access or may claim to “have a delivery,” an “appointment,” or to have left their access card elsewhere. All animal areas are secure areas. Employees and animal users are required to carry their ID cards at all times when in the animal facilities.

### ***Response Actions:***

- Remain calm.
- Be courteous.
- Avoid an incident.
- If you arrive during a disturbance, leave the area at once.
- If you are inside the building, stay in your office or work area.
- If you are inside the building and need to leave, request an escort from NMU Public Safety ( On campus 2151, Off Campus 227-2151)
- Use alternative methods of departing the building, which can be arranged by NMU Public Safety.
- If you learn of animal activists targeting NMU in any way, including researchers’ homes, main facilities, or other; alert NMU Public Safety (On Campus 2151, Off Campus 227-2151)

### **Bomb Threat, Bomb or Suspicious Item Found**

Bomb threats are usually received by telephone but can also come by note or letter. Most telephoned bomb threats are made by callers who want to create an atmosphere of general anxiety and panic, but all such calls are to be taken seriously and handled as though an explosive is in the building. If you receive a bomb threat by telephone, do not hang up. It is important that you remain calm and try to prolong the conversation to get as much information as possible.



After the call has ended, immediately call NMU Public Safety ( On Campus 2151, Off Campus 227-2151). ASSUME THAT BOMB THREATS ARE REAL.

Check mail and packages for anything that appears out of place, such as unusual packaging, lack of return address, or signs of stains or leakage on the package. Carefully survey all mail after a bomb threat has been received by phone, note, or e-mail. Note any package, foreign object, or odd device. Building evacuation may be necessary after a bomb threat or the finding of a suspicious package or item. Evacuation should proceed along established fire evacuation routes, and do not attempt to evacuate any animals.

***Response Actions- Bomb Threat by Phone:***

- Remain calm
- Stay on the telephone
- Collect as much information as possible. Follow the bomb threat checklist.
- Report the threat to NMU Public Safety (On Campus 2151, Off Campus 227-2151). If possible, get a co-worker to do this while you continue talking to the caller.
- Survey your work area for unusual packages or foreign objects. If you find something, do not touch it. Contact NMU Public Safety ( On Campus 2151, Off Campus 227-2151) to alert them of the location.

***Response Actions- Suspected Bomb or Suspicious Item Found:***

- If you see a package or foreign object in an unusual place, leave it alone. Do not touch it.
- Quickly study the size, location, and any other specific details you can remember about the object.
- Call NMU Public Safety (On campus 2151, Off Campus 227-2151 )

***Response Actions - Bomb Threat Evacuation:***

- Leave the building immediately using established fire evacuation routes and do not evacuate any animals.
- Note the size and location of any unfamiliar, strange, or suspicious objects on your way out.
- Go directly to the assembly area so that all personnel can be accounted for.
- Move at least 200 feet away from the building.
- Stay outside the building until you are told by NMU Public Safety that is safe to re-enter the building.

## ANIMAL CARE AND USE APPLICATIONS

Approval of an NMU Animal Care and Use Application is required before conducting any procedures for research or research training procedures on vertebrate animals at NMU, unless the animal use qualifies for an Exemption (see below), based upon applicability of the NMU IACUC policies or other reasons listed in the Exemption Request, pending approval of the IACUC Chair. For animals used strictly for breeding purposes (i.e., an animal colony), an Animal Colony Application must be submitted in place of the Animal Care and Use Application. All sections in the Animal Care and Use Application, the Animal Colony Application, and the Exception form must be written at a level understandable by laypersons, which is generally defined as an eighth grade reading level.

Animal Care and Use Applications have the following components:

1. Investigator Information
2. Project title and funding source
3. Basic information on proposed animals to be used (i.e., Species, Number, and USDA Use Category)
4. Project description, including the Aims and Objectives of the work and the predicted Significance and Outcomes of this work
5. Evidence of the supporting the three R's (Reduction, Refinement and Replacement)
6. Experimental protocol
7. Listing of Personnel Involved in Project (Including training completed)
8. Occupational Health and Safety and Hazardous Materials information
9. Sources, Conditioning and Location of the Animals
10. All necessary approvals

### Forms

All forms are available for download at the Animals in Research site at <http://www.nmu.edu/grantsandresearch/node/96>

### Due Dates for Animal Care and Use Applications

The due dates for Animal Use Applications depend on the USDA Use Category

USDA B and C categories: These applications may be submitted any time and will be reviewed using the Designated Member Review system within 2 weeks of receipt of the application. However, all applications are subject to potential review in Full Committee.

USDA D and E categories: Due two weeks prior to the next scheduled Full Committee meeting.

Due Dates for other IACUC applications and forms Colony Applications: These applications may be submitted any time and will be reviewed using the Designated Member Review system within 2 weeks of receipt of the application. However, all applications are subject to potential review in Full Committee.

### Review Exemption Policy

The use of vertebrate animals involved in a project may only be exempt from IACUC review if the procedures fall entirely in one or more of the categories below:

- A. Non-intrusive field research (observation only, no significant manipulation of the animal or its environment)
- B. Faculty approved internship or field practicum in which animals are owned or under the legal responsibility of a non-NMU entity (e.g., institution, business)

### **USDA Pain Categories**

The NMU IACUC will use the USDA Pain Categories to evaluate the pain animals may be caused during an experiment. The categories are described below.

**USDA CATEGORY B:** Animals that will be bred or purchased for breeding, but not used for experiments. This includes breeders, offspring that cannot be used because of improper genotype or gender and any other animals that will not participate in research studies.

**USDA CATEGORY C:** Animals used in research, experiments, or tests which involve no pain or distress or only momentary or slight pain or distress that **WOULD NOT REQUIRE** anesthetic, analgesic or tranquilizing agents (for example: s.c., i.m., i.p., or percutaneous i.v. injection, PIT tag insertion, a brief period of restraint, tissue harvesting after euthanasia).

**USDA CATEGORY D:** Animals used in research, experiments, or tests where appropriate anesthetic, analgesic, or tranquilizing agents are required to avoid pain or distress (e.g., major and minor surgery, tissue or organ collection prior to euthanasia, retro-orbital blood collection, prolonged restraint accompanied by tranquilizers or sedatives).

Animals used in research, experiments, or tests that may cause pain or distress, which cannot be treated with an anesthetic, analgesic or tranquilizer, but the agent or procedure producing the pain/distress is immediately discontinued or the animal is euthanized to prevent pain and/or suffering.

**USDA CATEGORY E:** Animals used in research, experiments, or tests involving pain or distress where the investigator is unable or unwilling to administer anesthetic, analgesic or tranquilizing agents (e.g., studies which allow endpoints that are painful or stressful, addictive drug withdrawals without treatment, pain research, noxious stimulation).

### **Significant Change to Approved Animal Care and Use Policy (Amending approved applications)**

The IACUC must be notified of any changes to approved Animal Care and Use applications. Significant changes will require IACUC review, and non-significant changes will require Administrative Review. The IACUC will abide by the recommendations and examples put forth by OLAW ([http://grants1.nih.gov/grants/olaw/faqs.htm#proto\\_9](http://grants1.nih.gov/grants/olaw/faqs.htm#proto_9); Accessed 1/23/2009) when determining if an amendment to an approved animal care and use protocol is a significant change.

Examples of changes considered to be significant include, but are not limited to, changes:

1. in the objectives of a study;
2. from non survival to survival surgery;
3. resulting in greater discomfort or in a greater degree of invasiveness;
4. in the species or in approximate number of animals used;
5. in Principal Investigator;
6. in anesthetic agent(s) or the use or withholding of analgesics;
7. in the method of euthanasia;
8. in the duration, frequency, or number of procedures performed on an animal.

### **Collaborations with Other Institutions (Duplicative Review)**

There is no requirement for duplicative review (in compliance with the National Institutes of Health Guide for Grants and Contracts, NOT-OD-01-017). When there is collaboration with another institution, or when the performance site is not NMU, the NMU IACUC will only evaluate components of animal care and use activities associated with or funded by NMU. In this case, for procedures that are applicable for the NMU IACUC policy (see Applicability section, page 2), a copy of the collaborating institution's approval letter must be submitted to the IACUC office.

### **Field studies**

The NMU IACUC will apply the principles in the Guide for the Care and Use of Laboratory Animals to field studies as appropriate, and the IACUC must be apprised of the circumstances under which studies are conducted so that they can consider risks to personnel and impact on study subjects. This description should include information about the study sites. When animals will be held at a site for more than 12 hours (e.g., trapping), a site visit is required. In lieu of a site visit, this assessment by the IACUC may be accomplished by written descriptions, photographs, or videos that document specified aspects of the study site. The IACUC must also ensure that all appropriate permits, as legally required, are in place (9 CFR, Part 2, Section 2.31(c)(2) of AWA).

### **Use of standard operating procedures (SOPs) in lieu of repeating descriptions of identical procedures in multiple protocols**

Consistent with OLAW recommendations, the NMU IACUC allows the use of standard operating procedures in lieu of repeating descriptions of identical procedures, generally considered routine aspects of research, as subject to review and approval on a project-specific

basis, taking into account a number of factors, including the aims of the study, consideration of alternatives, and minimization of pain and distress. The standard operating procedure must first be reviewed and approved by the IACUC; however, the SOP will be approved at appropriate intervals, which will not exceed three years, to ensure that the SOP is up-to-date and accurate. A copy of each approved SOP will be maintained in the IACUC office.

## **Review System and Process for NMU IACUC Animal Use Applications and Colony Applications:**

1. Application Submission
  - a. Signatures must be made on a hardcopy signature page
  - b. IACUC Number typed on application before distribution to IACUC members
  - c. Application distributed to members in format received by the IACUC administrative assistant (i.e., if copy sent by email, then the application is sent to other members by email).
  
2. Administrative Review
  - a. Receive new applications and amendments to approved applications for animal care and use at NMU
  - b. Conduct initial review for all necessary materials, appropriateness of USDA Pain Category assignment, and determine if the application is Exempt from IACUC review.
  - c. Assign Non-exempt applications to a primary and secondary reviewer and assign a veterinary consult if appropriate
  - d. Determine if application undergoes either A) Designated Member Review or B) Full Committee Review
  - e. Approve non-significant changes to approved IACUC applications and SOPs
  - f. Distribute non-exempt applications to IACUC members
  
3. Designated Member Review
  - a. Only USDA Category B and C applications may be approved through Designated Member Review
    - i. USDA Category B and C procedures are those that involve little/no pain and do not require analgesia
  - b. Application is reviewed by the primary and secondary reviewer. Other committee members may contribute to the review, as well.
  - c. Any committee member may have the application sent to Full Committee Review
  - d. Primary Reviewer Responsibilities
    - i. Assess appropriateness of USDA Category B and C designation
    - ii. Collect comments/questions/concerns from other IACUC members
    - iii. Respond to PI within two weeks of reviewers receiving application
    - iv. Decide to
      1. Require modifications to application (modifications are sent directly to the Primary Reviewer)
        - a. In the form of an addendum or revision of application at discretion of primary reviewer

2. Send the application to full committee review
3. Approve the application (Note: The IACUC committee chair must either A) sign the application or B) send the application to full committee review)

4. Full Committee Review

- a. USDA Category D and E applications require Full Committee Review
- b. USDA Category D and E applications require consultation with the NMU veterinarian. Consultation will consist of:
  - i. Review of application by veterinarian
  - ii. Communication with PI (by email, phone or in-person) to address concerns or questions about animal use in the application. These concerns and questions may be restricted to those procedures requiring USDA Category D and E designations
  - iii. Results of consultation should be communicated to the Primary Reviewer
- c. After the Animal Use Application is received by the IACUC office, the PI is informed when the application is scheduled to be reviewed.
- d. Primary Reviewer Responsibilities
  - i. Conduct Pre-review
    1. Review animal use application and send comments raised by committee members to the PI prior to the Full Committee Review meeting.
      - a. Inform other committee members of the comments sent to the PI and the PI's responses, if available
    - ii. Introduce the application with the PI's responses (if available) during Full Committee Review
    - iii. Request further modifications from the PI if requested during Full Committee Review
      - a. In the form of an addendum, if revisions are simple, to the application or as a revision of application, if revisions are complicated, as determined by the primary reviewer
    - iv. Lead the Designated Member Reviewer for approving modifications for "Conditional Approval" decisions made in after Full Committee Review.
- e. Requests for a consultant may be approved by the IACUC chair or a majority vote of all committee members present during full review.
- f. A majority vote is required to approve any protocol during full committee review
  - i. When approval decisions are not unanimous, members with dissenting votes may submit a minority opinion. Minority opinions must be included in the meeting minutes.
  - ii. Conditional approval may be decided when specific modifications to the application must be made prior to approval.
    1. The committee must decide if the modifications can be approved through Designated Member Review or should be reviewed during Full Committee Review
  - iii. Deny approval of application

- iv. Postpone for later discussion. Reasons for postponing a protocol for discussion at a later meeting may include:
  1. Incomplete application / waiting for additional materials
  2. Greater meeting attendance
  3. Request for review by consultant
  4. Request for review by veterinarian
5. Approval:
  - a. Upon approval after Designated Member Review or Full Committee Review the application will be signed by the IACUC Chair and the Institutional Officer
  - b. Information about the application (e.g., PI, IACUC Protocol #, and expiration date) will be entered into a database.
  - c. A letter of approval will be written and submitted to the PI

### **Conflict of Interest**

No NMU IACUC member may contribute to a quorum to review an application for animal use or application for an animal colony or provide administrative approval of any application to use animals when there is a conflict of interest. A conflict of interest consists of any situation in which a member may benefit from (or be impacted by) any committee action regarding review of an application.

### **Conflict of Obligation**

A conflict of obligation consists of having conflicting duties. The IACUC should be made aware of conflicts of obligation and may decide to ask a committee member to recuse him or her self.

### **Amending approved protocols**

Proposed amendments to approved animal use protocols may be submitted for review by the IACUC in the form of a memo or a revised application. Significant changes must be reviewed by the IACUC (see Significant Changes Policy above) whereas non-significant changes will be reviewed administratively.

### **Post-Approval Monitoring**

IACUC shall conduct continuing review of each previously approved, ongoing activity covered by this Policy at appropriate intervals as determined by IACUC. A complete review of all active approved projects shall occur once every 3 years. The IACUC may suspend activities that it previously approved if it determines that they are not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide for the Care and Use of Laboratory Animals, and NMU's Animal Care and Use Policy. However, the IACUC may suspend activities only through a review of the matter at a convened meeting of a quorum of IACUC and with the suspension vote of a majority of the quorum present. If IACUC suspends an activity involving animals, the IO, in consultation with IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with full explanation to OLAW, if PHS-funded, or the USDA, if USDA-regulated species are involved.

### **Holding Protocols**

**Purpose:** To be used to care for animals housed in NMU facilities that are not covered by an active protocol.

**Procedure:** Care of the animals covered under the Animal Holding Protocol will be delegated to the Chair of the Institutional Animal Care and Use Committee or, at the discretion of this committee, the head of the department where the animals are housed. No experimental procedures can be conducted on animals covered by the Animal Holding Protocol. Feeding, watering, sanitation, and all other basic care animal functions will be performed as expected for the species. All appropriate veterinary animal care will be provided, as needed. The Animal Holding Protocol is temporary. For renewal, new or amended applications, the application must be submitted within one week of the IACUC transferring these previously covered animals to the Animal Holding Protocol. If a new or amended protocol has not been submitted, then the animals will be euthanized or adopted out.

The Holding Protocol may remain in effect for four weeks (in order to allow for review) upon which time it is expected that the new or amended protocol will go into effect or the animals will be euthanized or adopted out. Should it be necessary under extraordinary circumstances, the Chair of the IACUC may renew a Holding Protocol once for an additional four weeks. Thus, animals should remain on a Holding Protocol for no more than eight weeks under extraordinary circumstances.

During the period of a Holding Protocol, the financial responsibility for the care of the affected animals remains with the originating investigator. This financial responsibility may include transportation, feed costs, and labor; rates are at the discretion of the IO in consultation with the IACUC. During this period, no costs may be applied to existing grants/contracts associated with the original research project for which the animals were brought on campus.

#### **Records of approved IACUC applications**

Applications shall be maintained for at least 3 years. Applications and proposed significant changes in ongoing activities reviewed and approved by IACUC shall be maintained for the duration of the activity and for an additional 3 years after the completion of the activity.

### **ANIMAL ACQUISITION AND DISPOSITION**

#### **Acquisition**

NMU's policy covers all vertebrates. Animals used in research, research training, biological testing, experimentation, teaching, or in breeding colonies must be an appropriate species for the purpose in the appropriate number (i.e., the minimum number of animals necessary). Use of animals destined to be used as a food source for other animals does not require IACUC approval if it is the only use of those animals. Food source animals housed at NMU facilities must be properly cared for until they are disposed of.

Animals are to be acquired by lawful means. Animals that are purchased are to come from animal vendors with a tradition of producing consistently healthy animals in compliance with applicable laws, statutes and regulations, and institutional needs. Collection of animals in the wild must be in accord with appropriate permits.



**Breeding Colonies**

The director of a facility that houses breeding colonies is required to provide an annual report of the species and numbers of animals generated by the breeding colonies. Breeding colonies are allowed to produce animals in reasonable excess of projected needs. Animals can be transferred between studies having IACUC-approved protocols. Thus, excess animals from breeding colonies may be used for other IACUC-approved purposes.

## **Disposition**

Animals used for research, research training, experimentation, teaching or in breeding colonies may be disposed by 5 methods.

1. Euthanasia: Methods of euthanasia will be consistent with the recommendations of the most recent version of American Veterinary Medical Association Panel on Euthanasia unless a deviation is justified for scientific reasons in writing by the investigator.
2. Adoption: Adoption on a limited basis is possible for non-transgenic animals that are healthy as determined by the principal investigator. Adoptions require review and approval of the principal investigator (PI) after which the PI will submit a request for approval to IACUC. Adoption may occur only after approval by both the PI and IACUC. Prospective adopters shall use the NMU adoption form. See the Adoption Policy below.
3. Retirement: Animals that are endangered or threatened may be placed in an appropriate protected, managed refuge if allowed by a permit.
4. Release to wild: Healthy animals may be released to the wild if permitted. Considerations in this determination include experimental history (i.e., acclimation to humans, exposure to chemicals, toxins, radiation, or drugs).
5. Transfer to another project: Transfer of animals to another project may occur only if both projects (original and second) have IACUC approval.

## **Adoption Policy**

Although not legally required by Animal Welfare Act, Animal Welfare Act Regulations, or the Public Health Service Policy, the IACUC allows adoption of animal research subjects not currently in an active study for private adoption. The IACUC acknowledges that PHS funds cannot be used to support an adoption program. NMU will ensure that the adoption procedures meet pertinent state and local regulations for transfer of animal ownership.

The person adopting NMU laboratory animals must agree in writing that the health and temperament of the animal is not guaranteed (i.e., the animal is adopted “as is”), that all reasonable attempts to appropriately care for the animal are made, that the animal is to be only kept as a pet and not to be released from the person’s care, and that neither NMU nor any employee or student of NMU will be held liable for the actions or circumstances that arise from the adopted animal. No more than two animals will be adopted to an individual per year. An adoption form is located in the appendix of the NMU IACUC Policy.

## **INSPECTIONS OF ANIMAL HOUSING AND USE SITES**

The IACUC will prepare reports of evaluations and submit the report to the Dean of Graduate Studies and Research (Institutional Official). (NOTE: the reports shall be updated at least once every six months upon completion of the required semiannual evaluations and shall be maintained by the institution and made available to OLAW upon request.) The reports will be submitted by the Chair of the IACUC and contain description of the nature and extent of the institution’s adherence to the Guide and this Policy and will identify specifically any departures from the provision of the Guide and this Policy, and must state reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, consistent with this Policy, and, in the judgment of the IACUC is or

may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency. The IACUC shall report in writing the results of visits to the animal housing and use sites. These reports shall be maintained for 3 years.

### **For Inspectors**

#### **Preparation for Animal Facility or Laboratory Inspection**

Prior to conducting an inspection, the inspector should review the following:

- Entry and exit restrictions in areas to be inspected
- Previous inspection findings or deficiency history in areas to be inspected
- IACUC protocols approved for use in areas to be inspected
- Consult the Guide for the Care and Use of Laboratory Animals (pp. 38-41) for standards on quality, storage, and provision of water, food, bedding, medications, and other supplies
- Arrange, if feasible, an inspection date and time when the investigator(s) is available for any questions the inspector may have.

#### **Conducting the inspection**

The inspection should be conducted by two or more IACUC members simultaneously. Inspectors must use the Animal Facility and Laboratory Inspection Checklist when conducting these inspections.

#### **Reporting inspection findings**

An inspection report must be submitted to the Chair of IACUC. The Chair of IACUC will then submit the findings from the report to the Institutional Officer.

The report should list the deficiencies found and categorize these deficiencies as Significant or Minor. Significant deficiencies are those that jeopardize the health and well being of animals in the facility and must, therefore, be resolved quickly. Inspectors are encouraged to communicate with principle investigators to insure the accuracy of this report as well as to develop a reasonable time line for the deficiencies to be resolved. If the deadline set for resolving these deficiencies is not met, then, according to Animal Welfare Act Regulations, the Principal Investigator will have 15 days to resolve the matter before a report must be filed to the USDA or OLAW. Further, the IACUC will suspend all animal research activities associated with the deficiency.

### **For Principal Investigators**

Principle Investigators are encouraged to be present while an inspection takes place, in order to answer questions and discuss concerns with the inspectors. This is especially important with inspection items that may not be applicable to a certain project. A reasonable deadline for resolving any deficiencies must be developed, preferably through consulting with the animal facility inspectors or the IACUC Chair. Principle investigators are allowed to respond to any deficiencies that are raised in the report and these responses will be discussed, and potentially reconsidered, at the next IACUC meeting.

## **RECORD KEEPING REQUIREMENTS**

1. Copy of the PHS Assurance to OLAW. This report must be approved by PHS, indicating compliance with PHS policy.
2. Minutes of IACUC meetings as described above.
3. Records of applications, proposals, proposed significant changes in care and use of animals, and whether IACUC approval was given or withheld.
4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the IO.
5. Records of USDA inspection reports and our responses.
6. Records shall be maintained for at least 3 years. Records relating directly to applications, proposals, and proposed significant changes in ongoing activities reviewed and approved by IACUC shall be maintained for the duration of the activity and for an additional 3 years after the completion of the activity.

## MANAGEMENT OF DEFICIENCIES AND CONCERNS

The NMU IACUC investigates reports of the conduct of animal-related research and/or teaching/training activities that occur without IACUC review and approval, or failure to comply with IACUC approved protocols, disregard for institutional policies and procedures, violation of laws, regulations, or policies governing animal use, or participation in activities that may have misused or abused animals.

### **Policy on Persons Reporting Violations**

According to the Animal Welfare Act Regulations “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 Act” (AWA Chapter 1, Subchapter A, Section 9CFR2.32). Concerns about the treatment of animals at NMU can be reported to any member of the IACUC or to the IO. The NMU IACUC will evaluate the treatment of those who report violations or “whistleblowers” as they occur or during its semi-annual review of the animal care and use program to ensure that they are treated in a just manner. The IACUC will report any legitimate concerns to the IO.

### **Definitions**

Deficiency: Non-compliance with approved protocols, NMU policies, or federal or state laws, policies, or regulations.

For the purposes of this policy, Deficiencies are categorized as Significant or Minor:

1. Significant: one that is or may be a threat to the health or safety of the animals (9CFR2.31(c)(3) and PHS IV.B.3). Further, animals being used for research, teaching or other activities on campus that are not covered by an approved IACUC (including expired protocols) shall be considered under significant deficiency.
2. Minor: any deficiency not considered significant.

For the purposes of this policy, Concerns include

1. Concerns or reports received from members of the public regarding the care and use of animals at any of the NMU facilities (including field sites), or
2. Reports of noncompliance received from laboratory or research facility personnel or employees regarding the care and use of animals at any of the NMU facilities (including field sites).
3. Formal Complaints filed with the IACUC (see below)

### **Reporting**

All potentially significant deficiencies will be immediately reported by an IACUC member to the University veterinarian and the IACUC chair or vice chair for review and discussion. [An exception will be made when the deficiency occurred from activities supervised by one of the aforementioned individuals.] These individuals will collectively agree upon and follow an immediate course of action deemed to be in the best interest of the welfare of the animals. The Institutional Official will be included in such deliberations if deemed necessary; otherwise the IO will be apprised of the situation as expeditiously as possible. A written report of the deficiencies and subsequent action will be submitted to the IACUC on the next working day, and an emergency meeting will be held if appropriate.

The University's veterinarian, or his/her designee, unilaterally may decide to euthanize an animal in extreme distress or pain that cannot be alleviated, if euthanasia is determined to be in the best interest of the animal. Similarly, the University's veterinarian, or his/her designee, unilaterally may ask an investigator to cease procedures in process when the veterinarian determines the animal to be in extreme distress or pain, if cessation of work in progress is determined to be in the best interest of the animal. All reasonable attempts to receive advice from the above individuals and the principal investigator (PI) should be exhausted before such decisions are made. A written record of such action will be submitted to the IACUC on the next working day.

### **Significant Deficiencies**

Following the immediate care decisions described above, discovery of Significant Deficiencies will initiate the procedures outlined below under Concerns and Complaints. During this time it may be necessary to remove control of the animals involved from the Principal Investigator while the matter is being investigated. This may be accomplished by a majority vote of a quorum of the IACUC such that the animals are transferred to an approved Holding Protocol.

### **Minor Deficiencies**

Minor deficiencies encountered during an IACUC inspection of facilities should be addressed and, if feasible, corrected at that time with a notation made on the inspection report. IACUC inspectors will follow-up on those not corrected at the time of the inspection. Minor deficiencies that are discovered as a result of a reported concern should immediately be addressed with the PI and remedied as appropriate. The complainant should be informed of the outcomes of this action. The process of remedy for minor deficiencies should include a reasonable timetable agreed upon by the PI and the IACUC. Failure to correct minor deficiencies in this timetable may lead to the filing of a Formal Complaint with the IACUC.

### **Concerns and Complaints**

All reported concerns will be documented by the IACUC. The IACUC will review and/or investigate any concern relating to animal care and use brought to the attention of the Committee. This includes claims regarding any aspect of the animal care and use program by the public, employees, or students about alleged instances of animal abuse, violation of approved protocols, use of animals not covered by approved protocols, violation of any animal-related regulation or standard (such as the Animal Welfare Act, PHS Policy, or IACUC policy), or the care received by animals housed in University laboratory animal or wild animal facilities.

Concerns should first be addressed to the implicated individual(s) or unit. If the concern is not adequately addressed, or if there is fear of retribution, the concern should be taken immediately to the next level by contacting any member of the IACUC or the IO.

The following information is to be documented for any concern brought to the IACUC:

- (a) The complainant's name, unless the complainant requests anonymity
- (b) The individual(s) or unit the complaint is against
- (c) Description of the event or charge including dates of observation of the alleged violation(s)
- (d) Any written, photographic, or taped documentation to substantiate the charges
- (e) Names of any other witnesses to the events/charges being described or made

The contacted IACUC member must report the concern to the IACUC chair or designee, and the merits of filing a formal complaint will be determined.

Either a phone call, verbal report, written contact or completion of the Anonymous Reporting of Animal Research Concerns [online form](#) can initiate the report of a concern, but a formal signed complaint will be necessary prior to the IACUC's review. The IACUC Chair, or IACUC member will assist the complainant in completing the written description and will submit the Formal Complaint to the IACUC chair. The Formal Complaint may be initiated by an IACUC member.

While hearsay complaints cannot be formally filed, individuals who have serious concerns based on hearsay evidence can contact any member of the IACUC or the Institutional Officer. An IACUC member will follow up on concerns by means other than the formal complaint process (such as review of protocols, discussions with other employees, or unannounced laboratory inspections). Documentation of concerns may be collected at this time. This process may lead to the filing of a Formal Complaint.

Complainants in a Formal Complaint must be the actual individual(s) who have witnessed the violation. Significant deficiencies that are identified at any stage of this process will be addressed as described above.

#### *Initial Review of a Formal Complaint*

The Formal Complaint will be presented at an IACUC meeting held as soon as possible with a quorum of members present. The IACUC will review the Formal Complaint and accompanying documentation and talk with the IACUC member who has brought the complaint forward.

- If evidence warrants a formal investigation, the committee members will so recommend by a majority vote of those present. The IACUC chair shall then document the review findings of the IACUC and inform the Complainant that the IACUC will be performing an investigation of the complaint.
- Should the IACUC, following review of the complaint, find that the complaint is insufficiently substantiated, the IACUC will:
  - a. Document the review findings and,
  - b. Provide a confidential written response to the Complainant explaining

the findings of the IACUC and,

c. Inform the Pertinent Individual (principle investigator, facility director, etc.), in writing, that a complaint was made. The investigator will then receive a summary of the concerns and a copy of the IACUC's Report.

#### *Investigation of a Formal Complaint*

The Committee as a whole will review the documentation and determine a course of action, which may include assignment of the investigation to a sub-committee or individual. The Chair will notify the Institutional Official of the initiation of the investigation.

The IACUC Chair will notify the Principal Investigator, animal facility administrator, or other pertinent individual (known hereafter as the PIND) of the IACUC's intention to carry out the investigation. This notification will include:

- Citation of the section of the federal regulations which allow for investigations of concerns related to animal care and use.
- Description of the complaint and the IACUC's initial report.
- An invitation to meet with the IACUC Chair, to personally discuss the allegation.

The IACUC may use a variety of methods to obtain information to assist in the investigation. These will include, but are not limited to the following:

- a. Unannounced visits to the laboratory or animal facility in question to review procedures, lab/facility documents, or talk with personnel.
- b. Submission of documentation from the PIND, co-workers or employees, or from the animal facility where animals were housed. Such documentation could include: research records relating to animal experimentation, surgical records, animal health records, purchase orders, standard operating procedures, diagnostic laboratory reports, quality assurance reports, or others which will provide information which will assist in the investigation.
- c. Documentation supporting the allegations provided by the Complainant. The PIND will be invited to provide a written response to the Complaint and any additional documentation provided by the Complainant.
- d. Review of Animal Care and Use Protocols, IACUC inspection reports, Reports of Programmatic Reviews, or USDA inspection reports, or any other pertinent IACUC record.
- e. Letters or documentation solicited from other University employees who can provide insight into the investigation.
- f. Letters of outside evaluation of protocols, programs, or documentation related to the complaint performed by external reviewers chosen by the Committee. Such reviews



would be done confidentially, with signed confidentiality statements by reviewers. The PIND may be asked to assist the IACUC in selection of reviewers.

- g. Invited site visits by external reviewer(s) to critique facilities or programs.
- h. IACUC interviews with the PIND, Complainant or other individuals who can provide information for the investigation.

Once the IACUC has completed its fact gathering period, the IACUC will reconvene to review all of the information. A quorum of the Committee must be present at the meeting. Several individual members of the IACUC may be selected to review and summarize information which will be presented to the IACUC. Individual members will have access to all documentation, should they wish to review the entire package. The Committee will review the package and fully discuss all issues. Once discussion is complete, the Committee will form recommendations for action. Recommendations will be individually voted on and all actions must pass by a majority vote. Such actions could include, but are not limited to:

- Find that the Complaint was unwarranted or unsubstantiated. Should charges be brought that are false and in a malicious manner by the Complainant to purposely harm the University or any of its departments, divisions, or units, the IACUC, or any individual, then such will be handled according to pertinent policies of Northern Michigan University which are applicable to the given case.
- Requiring an amendment to the IACUC approved protocol.
- Requiring a change in procedures previously approved in an IACUC protocol or requiring a change in procedures or program of the animal facility in question.
- Requiring a re-submission of a currently approved IACUC protocol
- Conducting unannounced laboratory inspections or unannounced facility visits to observe conditions, procedures, and/or review programs. The end result of the inspection(s) may include any of the actions outlined in this section.
- Suspension of the research activity (Protocol).
- Sanction of the Animal Care Program in question.

With the Investigation complete and actions initially recommended, the IACUC will invite the PIND to meet with the IACUC to review the findings. This meeting will provide an opportunity for the PIND and IACUC to resolve issues and work together to find solutions to the issues raised in the investigation. Harsh actions such a suspension or sanction can hopefully be avoided by this process and result in the mutual agreement and satisfaction of the IACUC and the PIND. After the PIND has met with the IACUC, the IACUC will formulate its final actions and vote on these individually. All actions must pass by a majority of quorum vote and minority opinions be

recorded. The Committee shall complete the investigation by the following documentation and notifications:

- a. The Institutional Official shall receive a summary document of the findings of the Committee and the final actions to be taken.
- b. If suspension is imposed on a PHS-supported activity, the Institutional Official shall file a full report with OLAW. A full report, for suspensions involving covered species, must also be filed with the USDA.
- c. If sanction of the animal care program is to occur, the letter will be directed to the administrator of the program and will be written jointly with the Institutional Official.
- d. The Complainant will receive a summary of the actions taken, but confidential information concerning protocols will not be included.
- e. The PIND will be informed, in writing, of the final conclusions/actions of the Committee and of any response that is required from the PIND.
- f. If the Complaint was found to be unwarranted or unsubstantiated, a strong letter of support will be provided to the PIND from the Committee for the research, animal care facility, or other program, as appropriate.
- g. The Committee will complete a final report and close the file, keeping all documentation for the complaint, review, investigation, and all other information.
- h. The IACUC Chair will provide letters of appreciation to all individuals who assisted in the completion of the investigation.

### **Confidentiality of the Complainant**

The confidentiality of any complainant will be maintained to the extent possible according to University policy and state law by all individuals involved in the review and/or investigation of alleged violations of animal care and use regulations and standards. Information on any documentation which is provided to individuals other than the members of the IACUC and the Institutional Officer which would identify the complainant shall be removed when possible.

### **Relevant Authority Citations**

**Related to inspections and the semi-annual review of programs:** 9CFR2.31(c)(3): "If [in the semi-annual review of programs] program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency. Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the Institutional Official, to APHIS and any Federal agency funding that activity;

PHS: IV.B.3: Report of the semi-annual review of programs "must identify specifically any departures from the provisions of the *Guide* and this Policy, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency."

**Suspension of work in progress:** 9CFR2.31(d)(6) and PHS: IV.C.6: "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."

9CFR2.31(d)(7) and PHS: IV.C.7: "If the IACUC suspends an activity involving animals, 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 to OLAW [APHIS] and any Federal agency funding that activity".

**Review of concerns about the use of animals:** 9CFR2.31(c)(4): "Review, and, if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees;"

PHS IV.B.4: With respect to PHS-conducted or supported activities, the IACUC shall "review concerns involving the care and use of animals at the institution" and "be authorized to suspend an activity involving animals" as set forth in IV.C.6.

**Reporting requirements in addition to the above:** PHS: IV.F.3: The IACUC, through the Institutional Official, shall promptly provide OPRR with a full explanation of the circumstances and actions taken with respect to:

- any serious or continuing noncompliance with this Policy;
- any serious deviation from the provisions of the *Guide*; or
- any suspension of an activity by the IACUC.

**Authority:** 9CFR2.31(d)(6): "The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of that activity provided by the principal investigator and approved by the Committee. "

PHS IV.C.6: "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 this Policy."

9CFR2.31(c)(8): The IACUC shall "be authorized to suspend an activity involving animals in accordance with the specifications set forth in"

9CFR2.31(d)(6) above.

9CFR2.31(c)(3): With respect to activities involving animals, the IACUC shall conduct evaluations and prepare reports of such evaluations. "The reports must contain a description of

the nature and extent of the research facility's adherence to this subchapter, must identify specifically any departures from the provisions of title 9, chapter I, subchapter A--Animal Welfare, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies.

#### **REFERENCES FOR THE NMU IACUC POLICY**

IACUC sources of information include, but not are limited to the most recent version of following list of references:

Animal Welfare Act Regulations (USDA)

Health Research Extension Act (NIH)

Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS)

US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training

Office of Laboratory Welfare (OLAW) website: <http://grants1.nih.gov/grants/olaw>

Guide for the Care and Use of Laboratory Animals (ILAR/NAS)

Guidelines for the Care and Use of Fish in Research (ILAR)

Guidelines for the Care of Amphibians and Reptiles in Academic Institutions (ILAR)

The IACUC Handbook

# APPENDIX

**TYPE OF EMERGENCY OR DISASTER - CATEGORIES AND LEVELS**

Level of emergency	Description	Contact	Response action
<b>LEVEL 1</b> Handled by animal facility personnel	Minor illness/injury	Animal facility director [phone#] Campus Security [phone #]	Administer first aid, report to animal facility director, report to Campus Security; if medical tx needed, it will be provided at MGH.
	Small chemical, radiation or biohazard exposure or spill	Radiation safety officer [phone #] Campus Security [phone #]	Administer first aid if safe to do so; if medical tx needed, it will be provided at MGH.
	Equipment or temperature alarm, power failure	Operations and maintenance [phone #] Animal facility director [phone#]	Check room temperatures; open doors to vent rooms or provide portable heat source if temperatures fall below __°C, fans if temperatures fall above 24°C.
	Peaceful demonstration	Campus security [phone #] Animal facility director [phone #] Public relations director [phone #]	Be courteous; do not interact with demonstrators; leave area.
	Bomb threat; suspicious items	Campus security [phone #]	Calmly evacuate the facility; assist Campus Security in identifying items that are suspicious.

Level of emergency	Description	Contact	Response action
<b>LEVEL 2</b> Requires outside assistance	Major medical	Ambulance [911] Campus security [phone #]	Administer first aid; call out for help.
	Fire	Dial 911 Campus security [phone #]	Pull fire alarm; call 911 first if closer to phone than fire alarm; evacuate building; report to assigned assembly

			point; account for fellow employees
	Large chemical, radiation or biohazard exposure or spill	Ambulance [911] Campus security [phone #] Radiation safety officer [phone #]	Leave room; post sentry; call support personnel.
	Illegal/criminal activity	Dial 911 Campus security [phone #]	Seek safety away from threat
	Localized flooding	Operations & maintenance [phone #] Campus security [phone #]	Unplug electrical equipment; move rodent cages from bottom shelves to top; evacuate building

Level of emergency	Description	Contact	Response action
<b>LEVEL 3</b> Outside emergency responders may be overwhelmed; expect delayed assistance	Major natural disaster (earthquake, storm, major flooding, large-scale terrorism)	Dial 911 Campus security [phone #]	Safety check; administer first aid as possible; damage assessment; evacuate building if safe to do so.

# Emergency Procedures

Laboratory / Facility Supervisor: \_\_\_\_\_

Contact Information:

Report suspicious activities or major environmental concerns (e.g., major temperature change), to Public Safety at 227-2151 (on campus, dial 2151)

For emergencies, call 911.

For reporting minor concerns after hours, contact the following individuals in order:

- 1.
- 2.
- 3.

Concerns regarding the treatment of animals: Contact the facility or laboratory supervisor. You may also contact Dr. Brian Cherry, IACUC Officer, at 227-2300 (on campus, dial 2300) or any member of the IACUC. An anonymous reporting form is available online at: <http://www.nmu.edu/grantsandresearch/node/96>

**Institutional Veterinarian: Dr. Laura Klar, DVM**

Phone: 226-7400

24 hr Emergency Line: 1-800-422-3216