

NORTHERN MICHIGAN UNIVERSITY

Assurance Number: D16-00512 (A3894-01)

Animal Welfare Assurance for Domestic Institutions

I, Lisa Schade Eckert, as named Institutional Official for animal care and use at Northern Michigan University, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS, HHS, and/or NSF, and/or NASA. For NSF-funded wildlife research, the PHS "Guide for the Care and Use of Laboratory Animals," and the most recent AVMA Guidelines on Euthanasia will be followed but taxon-specific guidelines may be used as supplemental references as appropriate.

This Assurance covers only those facilities and components listed below.

- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:
All components of the University (Colleges, Schools, Centers, Departments, etc.) that are physically located on the NMU Main Campus in Marquette, Michigan. There are no permanent off-site facilities and/or covered components
- B. The following are other institution(s), or branches and components of another institution:
None

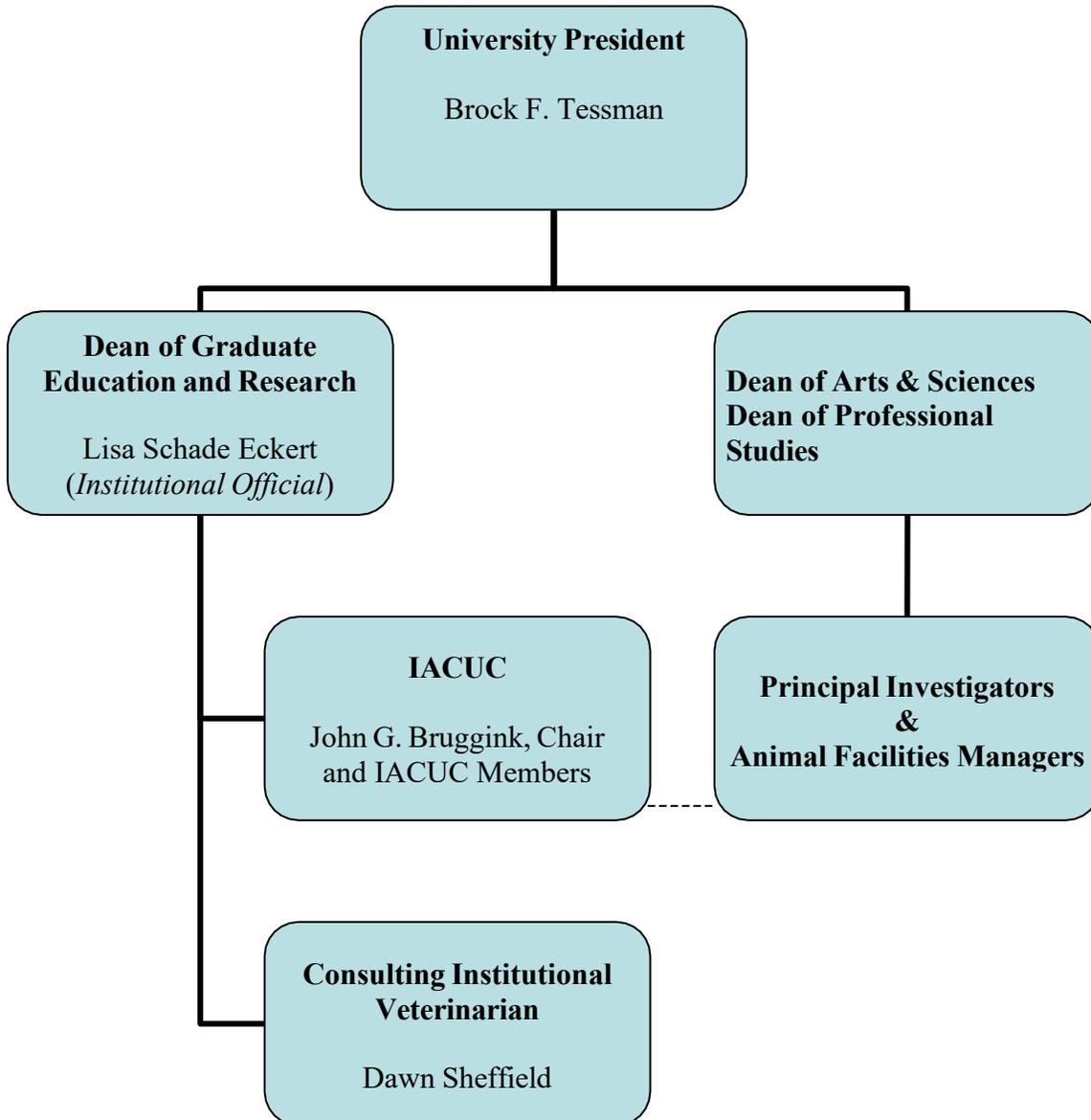
II. Institutional Commitment

- A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, as well as all other applicable laws and regulations pertaining to animal care and use.
- D. This Institution has established and will maintain a program for activities involving animals in accordance with the "Guide for the Care and Use of Laboratory Animals" ("Guide").

E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

III. Institutional Program for Animal Care and Use

A. The lines of authority and responsibility for administering the program and ensuring compliance with this Policy are as follows:



Notes:

1. As Indicated in the organizational chart above, there are open and direct lines of communication between the IACUC and the Institutional Official (IO) and between the Institutional Veterinarian and the IO.
2. The animal facilities are managed by the relevant principal investigators. These facility managers must meet the approval of the IACUC and for all issues pertaining to the care and use of animals, they report directly to the IACUC.

B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

Name: Dawn Sheffield

Qualifications:

- Degrees: B.A. in Biology from Ohio State University (1991), D.V.M. from Ohio State College of Veterinary Medicine earned in 1995.
- Training and/or experience in laboratory animal medicine: Dr. Sheffield has been a veterinarian for 25+ years in general small animal medicine with consistent and extensive experience in exotic and wildlife species. The species housed at NMU (rats and mice) have consistently contributed up to 25% of Dr. Sheffield's patient basis since early in her career. Dr. Sheffield has completed all online training modules relevant to this Institution's animal care and use program that are offered by the Collaborative Institutional Training Initiative organization, and she participates regularly in continuing education opportunities.

Authority: Dr. Sheffield has delegated program authority and responsibility for the Institution's animal care and use program including the authority to implement the PHS Policy and the recommendations of the Guide. This authority includes 24 hour/7 day per week access to all animal facilities at the Institution.

Time Contributed to Program: Dr. Sheffield is present at the Institution about 2–5 hours per month. One hundred percent of this time is contributed to the animal care and use program. In addition, Dr. Sheffield contributes on average about 15 hours per month to the program while off-site reviewing protocols and providing consultation on various program related topics.

Name: Scott Jandron

Qualifications:

- Degrees: B.S. in Biology 1987, D.V.M. from Michigan State University in 1991.
- Training and/or experience in laboratory animal medicine: Dr. Jandron has general professional training in veterinary care for small animals and exotic animals, and treats rodents in his private practice. He has been in practice for 25+ years.

Responsibilities: Dr. Jandron has responsibility for the Institution's animal care and use program when Dr. Sheffield is unavailable (i.e., a back-up veterinarian). This authority includes 24 hour/7 day per week access to all animal facilities at the Institution.

Time Contributed to Program: As needed for back-up veterinary services.

Because our veterinarian is not full time, the following individual facilities managers are responsible for daily animal care and use facility management:

Dr. Jill Leonard, Professor and Head, Biology Department

Dr. Adam Prus, Professor and Head, Psychological Sciences Department
Dr. Erich Ottem, Associate Professor
Dr. Ambre LaCrosse, Assistant Professor

C. The Institutional Animal Care and Use Committee (IACUC) at this Institution is properly appointed in accordance with the PHS Policy IV.A.3.a and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The President has delegated to the Institutional Official the authority to appoint the members of the IACUC. In accordance with the Health Research Extension Act of 1985, this delegation of authority is specific and is in writing. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy, Section IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations (**see Part VIII**).

D. The IACUC will:

1. Review at least once every 6 months the Institution's program for humane care and use of animals, using the "Guide" as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

The IACUC will meet at least once every 6 months to review the Institutional Program for the Humane Care and Use of Animals. All IACUC members are invited to participate in the review. The Committee uses the Guide and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review. To facilitate the evaluation, the Committee will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website.

The evaluation will include, but not necessarily be limited to, a review of the following:

- a) IACUC Membership and Functions;
- b) IACUC Records and Reporting Requirements;
- c) Husbandry and Veterinary Care (all aspects);
- d) Personnel Qualifications (Experience and Training); and
- e) Occupational Health and Safety.

In addition, the evaluation will include a review of the Institution's PHS Assurance.

If program deficiencies are noted during the review, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel. No member will be involuntarily excluded from participating in any portion of the reviews.

2. Inspect at least once every 6 months all of the Institution's animal facilities, including satellite facilities, using the "Guide" as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

At least once every 6 months, members of the IACUC visually inspect all animal facilities, including both housing areas, surgical areas, and experimental areas, at the Institution. All IACUC members are invited to participate. Equipment used for transporting of the animals is also inspected. Moreover, inspectors conduct interviews with principal investigators and any other key animal facility personnel. Inspections are conducted using subcommittees of at least 2 IACUC members and no member wishing to participate in any portion of an inspection is involuntarily excluded. Inspections are conducted using the Guide as a basis for evaluation, and a checklist is used that includes the following items:

- sanitation,
- food and water provisions (including weekends and holidays),
- animal identification,
- waste disposal,
- animal health records,
- controlled and/or expired drugs,
- environmental control,
- occupational health and safety concerns,
- staff training,
- knowledge of applicable rules and regulations, and
- security

If deficiencies are noted during the inspection, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel.

Within two weeks after completing all facility inspections during a semi-annual review, a full meeting of the IACUC is convened to discuss the inspection findings.

3. Prepare reports of the IACUC evaluations according to PHS Policy IV.B.3 and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:

Individual IACUC members will convey their observations to the IACUC Chairperson, or his or her designee, who, in turn, will draft the reports using the sample OLAW Semiannual Report to the Institutional Official format from the OLAW website. The reports will contain a description of the nature and extent of the institution's adherence to the Guide and the PHS Policy, identifying specifically any deficiencies, departures from the provisions of the Guide and the PHS Policy, and state the reasons for each departure or deficiency. The reports will distinguish significant deficiencies and departures from minor deficiencies and departures. If program or facility deficiencies are noted, the reports will contain a reasonable and specific plan and schedule for correcting each deficiency. If some or all of the institution's facilities are accredited by AAALAC International the report will identify

those facilities as such. Copies of the draft reports will be reviewed, revised as appropriate, and approved by the Committee. The final reports will be signed by a majority of the IACUC members and will include any minority opinions. If there are no minority opinions, the reports will reflect such. Following completion of each evaluation, the completed report will be submitted to the Institutional Official in a timely manner.

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

Any individual may report concerns to the IO, IACUC Chair, Institutional Veterinarian, or any member of the IACUC directly or via an anonymous reporting link on the University's Animal Subjects website. Notices are located in the animal facilities advising individuals how and where to report animal welfare concerns and stating that any individual who, in good faith, reports an animal welfare concern will be protected against reprisals. All reported concerns will be brought to the attention of the full Committee and the IO. If necessary, the IACUC Chair will convene a meeting to discuss, investigate, and address any reported concern. The IO will attend this meeting if possible. Reported concerns and all associated IACUC actions will be recorded in the IACUC meeting minutes. The Committee will report such actions to the IO and, as warranted, to OLAW.

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. It is the policy of the University to abide by current applicable whistleblower protection law. No whistleblower who, in good faith reports, is about to report, or participates in the investigation of improper conduct shall be harassed, retaliated against, or suffer adverse employment consequences. An employee of the University who retaliates against a person who in good faith reports improper conduct is subject to discipline up to and including termination of employment as well as any penalties and fines defined by State and Federal law.

The University Non-Discrimination and Retaliation policies provide clear requirements and procedures upholding protections for complainants as well as the institutional mechanisms for reporting and investigating incidents of suspected discrimination and/or retaliation. The IACUC and IO adhere to these policies and procedures.

The University Non-Discrimination policy states: Northern Michigan University does not unlawfully discriminate on the basis of ancestry, race, color, ethnicity, religion or creed, sex or gender, gender identity, gender expression, genetic information, national origin, immigration status (unless restricted by State or federal laws and regulations), age, height, weight, marital status, familial status, pregnancy, disability, sexual orientation, military or veteran status, or any other characteristic protected by federal or state law in employment or the provision of services.

ADA/Section 504 Non-Discrimination policy states: Northern Michigan University formally affirms its commitment to prohibit discrimination against individuals with disabilities, including persons with mental health disabilities, in any aspect of University life including,

but not limited to, physical plant access, employment, services, and the academic process.

The University Retaliation policy states:

It is a violation of University policy to intimidate, discipline, discharge, or harass any individual who has in good faith reported misconduct or fraud, filed a complaint, instituted proceedings, assisted in an investigation or compliance review, or formally or informally objected to sexual misconduct and/or discriminatory practices.

The types of retaliation that are prohibited include but are not limited to intimidation; adverse action with respect to student assignments or grades; adverse action which threatens or endangers a student's access to campus educational and social programs; adverse action with respect to employment assignments, salary, vacation, or other terms of employment; unlawful discrimination; termination of employment; adverse action against a relative of the reporter; or threats of any of the above.

Individuals who violate this policy shall be subject to appropriate disciplinary proceedings. If found to have violated the policy, the individual may be subject to the full range of available sanctions, up to and including termination of employment, dismissal from an academic program, or suspension/expulsion from the University.

Report student complaints to:

Dean of Students

Section 504 Coordinator

Dean of Students Office

Report faculty, staff and third-party complaints to:

Executive Director of Equal Opportunity and Title IX

Equal Opportunity Officer and Section 504 Coordinator - Employees

Equal Opportunity and Title IX Office

5. Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

As part of the semi-annual review report, the IACUC determines ways that the animal care and use program, facilities or personnel training at the Institution may be improved. These recommendations stem from an evaluation of the overall animal care and use program, including such components as the animal environment, housing and management, role of the attending veterinarian, occupational health and safety, personnel training and education, and emergency preparedness. Recommendations to be included in the report are determined through a majority vote of a full-convened meeting of the IACUC, although minority views will be included if so requested. Once the report is compiled, it is signed by the IACUC members present and submitted to the Institutional Official. The report filing is followed up with a meeting between the IACUC Chair and the Institutional Official.

More urgent matters are brought to the attention of the IO by the IACUC chair, Attending Veterinarian, facilities managers, PIs, or operators of the university's physical plant via email or phone.

6. Review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals according to PHS Policy IV.C.1-3. The IACUC procedures for protocol review are as follows:

Protocol Submission

- a. Protocols are submitted electronically to the IACUC, and relevant department head (or other departmental designee) who reviews the protocol based on scientific merit. The IACUC Chair or Administrative Assistant assigns an IACUC number to the protocol and provides the protocol to the IACUC.

Administrative Review (IACUC Chair)

- a. Conducts initial review of all necessary materials for the protocol and determines appropriateness of USDA Pain Category assignment.
- b. Assigns protocol to a primary and secondary reviewer qualified to conduct the review, and assigns a veterinary consult if the protocol will require a USDA D or E pain category
- c. Determines that the protocol will undergo full-committee review (FCR) or proposes using designated-member review (DMR).

IACUC Review

The IACUC Chair will notify each IACUC member and identify the primary and secondary reviewers of protocols via e-mail when proposing DMR. Any member of the IACUC may call for FCR of those protocols within 5 business days following notification by the IACUC Chair. If there is no call for FCR, the primary and secondary reviewers have the authority to approve, require modifications to (to secure approval) or request FCR of those protocols. When modifications are required, both reviewers review identical copies of the modified protocol. Other IACUC members provide the primary designated reviewer with comments and/or suggestions for the reviewer's consideration only. That is, concurrence to use the DMR method is not conditioned. If decisions of the designated reviewers are not unanimous, the protocol will be referred for FCR. Records of approval of protocols via DMR are maintained and recorded in the minutes of the next convened IACUC meeting. The minutes are prepared by the Administrative Assistant and circulated to all IACUC members and the IO. Full Committee Reviews occur during convened meetings of the IACUC with a majority vote of the quorum present required to approve, require modifications to secure approval, or withhold approval.

Required modifications. When the IACUC requires modifications to secure approval of a protocol, such modifications are reviewed as follows:

1. FCR or DMR following the procedures delineated above.
2. When modifications of protocols initially subject to FCR are required:
 - a. If **all** members of the IACUC **are** present, the committee votes on whether to require modifications to secure approval and have the revised protocol reviewed and approved by DMR, or returned for FCR at a subsequent meeting
 - b. The IACUC has a written policy that when **not all** members of the IACUC are present at a convened meeting, the quorum of members present may decide

by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. The policy was signed in advance by all IACUC members at the time of implementation, and is reviewed annually. When electing to use DMR, all members, including members not present at the meeting, are provided with the revised protocol, and any member of the IACUC will have the opportunity to call for FCR within 5 days of receipt of the revised protocol.

3. Minor modifications of an administrative nature, i.e., typographical or grammatical errors, required signatures, etc. may be confirmed by IACUC administrative/support personnel.

No member may participate in the IACUC review or approval of a protocol in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum. The IACUC Chair monitors the number of members present to ensure that a quorum is maintained when a member is recused. The IACUC may invite consultants to assist in reviewing complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also members of the IACUC.

Note: Any use of telecommunications will be in accordance with NIH Notice NOT-OD-06-052 of March 24th, 2006, entitled Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals.

In order to approve proposed protocols or proposed significant changes in ongoing protocols, the IACUC will conduct a review of those components related to the care and use of animals and determine that the proposed protocols are in accordance with the PHS Policy. In making this determination, the IACUC will confirm that the protocol will be conducted in accordance with the Animal Welfare Act insofar as it applies to the activity, and that the protocol is consistent with the Guide unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the protocol conforms to the institution's PHS Assurance and meets the following requirements:

- a. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
- b. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
- c. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
- d. The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals

will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.

e. Medical care for animals will be available and provided as necessary by a qualified veterinarian.

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

g. Methods of euthanasia used will be consistent with the current recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.

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

Requests for increasing the number of animals approved for a study by up to 10% to allow the PI to achieve the original study objectives are handled by administrative review according to IACUC-approved Standard Operating Procedures for Increases in Previously Approved Animal Numbers. The PI and IACUC Administrative Assistant will both keep a record of the change in number.

The institution's Veterinary Verification and Consultation (VVC) Policy states that the IACUC chair will consult with the attending veterinarian on requests for the following significant changes:

- a. Anesthesia, analgesia, sedation, or experimental substances
- b. Euthanasia to any method approved by the most recent AVMA Guidelines on Euthanasia
- c. The duration, frequency, type, or number of procedures performed on an animal unless the changes result in greater discomfort or in a greater degree of invasiveness

The veterinarian does not conduct a designated member review but serves as a subject matter expert to verify that compliance with policy, reviewed and approved by the IACUC, is appropriate for the animals in the project. Consultation will be documented by the veterinarian's email to the IACUC chair verifying that the requested change is consistent with the reference materials and guidance documents approved by the IACUC (see below). The email will be appended to the updated protocol. The changes will also be recorded in the IACUC Meeting Minutes. The veterinarian may refer any request to the IACUC for FCR or DMR for any reason and must refer any request that does not comply with NMU IACUC policies or that would be a departure from the Guide or Animal Welfare Act.

IACUC-Approved Reference Materials (most recent editions unless otherwise indicated):

Anesthesia, analgesia, sedation or experimental substances¹

- Publications in peer-reviewed journals
- A Good Practice Guide to Administration of Substance and Removal of Blood, Including Routes and Volumes (Diehl et al. 2001. Journal of Applied Toxicology 21:15-23)
- Plumb's Veterinary Drug Handbook
- Lumb and Jones' Veterinary Anesthesia and Analgesia
- Ferrets, Rabbits and Rodents Clinical Medicine and Surgery (Quesenberry and Carpenter)
- Handbook of Veterinary Anesthesia (Muir et al.)
- Formulary for Laboratory Animals (Hawk and Leary)
- American College of Laboratory Animal Medicine Series

Euthanasia

AVMA Guidelines on Euthanasia

Duration, frequency, type, or number of procedures performed on an animal (but not new procedures)²

- Publications in peer-reviewed journals (e.g., <https://www.nal.usda.gov/awic/blood-collection-laboratory-animals>)
- A Good Practice Guide to Administration of Substance and Removal of Blood, Including Routes and Volumes (Diehl et al. 2001. Journal of Applied Toxicology 21:15-23)
- American College of Laboratory Animal Medicine Series

Review and approval of other significant changes are handled in the same manner as new protocols. See Paragraph III.D.6.

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

- a. in the objectives of a study
- b. from non-survival to survival surgery;
- c. resulting in greater discomfort or in a greater degree of invasiveness;
- d. in Principal Investigator;
- e. in housing and or use of animals in a location that is not part of the program; overseen by the IACUC;
- f. in species;
- g. that impact personnel safety.

¹ Use of non-pharmaceutical grade chemicals or substances may not be approved via VVC

² Examples include changes related to: blood collection (frequency, volume, and location), sample collection intervals, number of samples collected, interval between procedures, injection techniques, food deprivation, and enrichment

8. Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

Upon approval of a new protocol or modification to an approved protocol by the IACUC, the final version of the application is signed electronically by the Principal Investigator, the relevant Department Head or other designee, the IACUC Chair, indicating approval by the IACUC, and then the application is forwarded to the Institutional Official. A signature of approval also is required of the Institutional Official. Upon approval by the Institutional Official, all signatories are notified that the approval is complete and receive a link to, or copy of, the approved protocol.

Upon a decision by the IACUC to withhold approval of a new protocol or modification of an approved protocol, the principal investigator will be notified in writing of the IACUC's decision and be reminded that the proposed studies using animals cannot be conducted at the Institution. The written notification will include a statement of the reasons for the committee's decision and give the investigator an opportunity to respond in person or in writing. The IO also will receive a copy of the notification.

9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review at least once every three years in accordance with the PHS Policy IV.C.1-5. The IACUC procedures for conducting continuing reviews are as follows:

Animals and facility conditions are examined by trained animal care personnel during scheduled visits for animal care (i.e., feeding, watering, cage cleaning) and cleaning as specified in the relevant protocol (s) and consistent with recommendations in The Guide. Concerns are communicated to the PI, Institutional Veterinarian and/or facilities personnel as appropriate. The Institutional Veterinarian examines the condition of all animals during at least one of the Semi-annual Facilities Inspections conducted by the IACUC each year.

Protocols, procedures, and study/care records are reviewed by a member or members of the IACUC at least annually as part of Post-approval Monitoring (PAM) meetings with each PI. These meetings also provide PIs the opportunity to describe any adverse or unanticipated events and updates on work progress. Completion of PAM meetings is recorded in the IACUC meeting minutes. The IACUC meeting minutes are reviewed and approved by the Committee.

Protocols are approved for a maximum of 36 months. That is, protocols expire no later than the 3-year anniversary of the IACUC-approved beginning date for the project. If activities will continue beyond the expiration date, a new protocol must be submitted, reviewed, and approved [prior to expiration of the current protocol] as described in Paragraph III.D.6. above.

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

The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, the institution's Assurance, or IV.C.1.a.-g. of the PHS Policy. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. If the IACUC suspends an activity involving animals, or any other institutional intervention results in the temporary or permanent suspension of an activity due to noncompliance with the Policy, Animal Welfare Act, the *Guide*, or the institution's Assurance, the Institutional Official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW.

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

All individuals listed as personnel on IACUC protocols are required to complete CITI training modules and pass the associated quizzes before IACUC approval is granted. These CITI modules address many of the mechanisms used for hazard and risk identification and assessment, including those from zoonoses and allergies. The Animal Care and Use Application form includes a section on occupational safety and hazardous materials that requires the investigator(s) to describe relevant animal hazards, hazardous agents, and what will be done to minimize risks.

The Occupational Safety Office is responsible for the occupational health and safety program that covers all personnel who work in laboratory animal facilities or have frequent contact with animals.

1. Hazard and Risk Identification and Assessment

Hazards are defined as an inherent danger in a material or system. Risk is defined as the measure of likelihood of a consequence emanating from that hazard. The principal objective of this occupational health and safety program is to reduce to an acceptable level the risk associated with using materials or systems that might have inherent danger. It is the Policy of this Institution that all hazardous materials will be managed in accordance with the Federal Hazard Communication Standard and Michigan's Right to Know Law, as they apply to: Acquisition of Hazardous Materials, Storage and Transportation, Health Assessment, and Disposal of Hazardous Waste. All new employees at this Institution, regardless of assigned responsibilities, are required to attend "Right to Know" training during orientation, that covers how to read hazard labels, material safety data sheets, chemical hygiene training, and potential biological and physical hazards that may be encountered in Institution Facilities. Animal facility-specific standard operating procedures contain detailed information about potential risks in research areas. The recommendations from the Guide were used in developing these standard operating procedures, which were approved by the IACUC prior to implementation. The IACUC uses the Occupational Health and Safety portion of the Facility Review Checklist from the OLAW website during all semi-annual facilities inspections to

assess risks and identify hazards. Risks and hazards also are identified during the protocol review process.

2. Personal hygiene

Personal hygiene issues are described in all standard operating procedures, which are consistent with the Guide and have been approved by the IACUC, of all animal facilities at the Institution. A laundering service is used for laboratory coats or scrubs worn in animal facilities, and wearing disposable gloves and N95 masks are recommended when handling animals, and they are required for personnel who are involved in cleaning animal cages. Signs are posted to remind personnel that food and drinks are not permitted in animal facilities. Smoking is banned in buildings at the Institution.

3. Facilities, procedures, and monitoring

All animal facilities used at the Institution were designed for housing animals or conducting animal experiments. Animal facilities are physically separated from other working areas. Animal facilities include a ventilation system that is separate from the building ventilation system and creates negative air pressure in all animal facilities, and emergency lighting, smoke detectors, and eyewash stations. Exits from these facilities are clearly marked and any equipment, furniture or other items are prohibited from being placed in hallways or other places that may prevent quickly vacating the facility in an emergency. All safety equipment is properly maintained and routinely calibrated.

Other hazards are facility-specific and are addressed in the standard operating procedures for these areas, which are consistent with the recommendations made in the Guide, and have met the approval of the IACUC prior to implementation.

4. Animal experimentation involving hazards

No protocols for animal experimentation involving hazards will be approved by the IACUC unless all safety equipment and procedures appropriate to meet occupational health and safety standards described in the Guide have been met. Special attention will be given to procedures for animal care and housing, use of special safety equipment, storage and disbursement of the agents, dose preparation and administration, body fluid and tissue handling, waste and carcass disposal, and personal protection. Depending on the particular hazards involved in the study, the IACUC may require approval from the department-level safety committee or may request outside consultation. In addition, recommendations provided by the Center for Disease Control or the National Institutes of Health may be sought.

Hazardous agents must be contained within the study environment, which must have proper ventilation, separate from the main building ventilation system, and must have any special air filtration equipment appropriate to use with those agents. Scavenging equipment must be used when working with anesthetic gases.

5. Personal protection

Personal protection equipment is available for all personnel working in animal facilities. This equipment includes labcoats or scrubs, aprons, disposable gloves

(latex or nitrile), disposable masks, goggles, and shoe covers. None of this protective equipment may be worn beyond the boundary of the animal facilities. Personnel working with hazardous agents will be provided personal protective equipment appropriate for those agents.

6. Medical evaluation, care and preventive medicine for personnel

The laboratory species currently housed at Northern Michigan University include rodents (rats and mice) and fish. The primary risk to humans from these animals is allergies. However, field researchers at times have direct contact with animals, and there is a potential risk of rabies or other zoonotic diseases. The CITI Wildlife Research module provides detailed information on these diseases, their distribution, and advice for prevention. Tetanus shots are required for all personnel that have direct contact with animals. Medical care for bites, scratches, illnesses, or injury is available at the NMU Health Center during business hours and at the Superior Walk-in Clinic during non-business hours. Emergency care is available at the UP Health System Emergency Room. This information is posted within animal care facilities. Field researchers are responsible for determining the location of appropriate medical facilities that are closest to their field sites. University policy requires campus residents, employees and visitors to inform their supervisors, persons of authority, or NMU Public Safety whenever an incident takes place, including injuries or illnesses, that requires more than self-administered first aid. A university incident report must be prepared by the supervisor, Public Safety, or other persons of authority within 24 hours of the incident. The university maintains an electronic incident report system.

7. Provisions for personnel with direct contact with laboratory animals

Prior to having direct contact with laboratory animals, workers at Northern Michigan University must complete an IACUC Health Form and submit this form to the director of the Northern Michigan University health center. The health director will review this form, provide consultation with the worker, if deemed necessary, and notify the IACUC if this worker is approved to have direct contact with laboratory animals. Workers have 24 hour/7 day access to medical care.

8. Training provided regarding precautions that should be taken during personal pregnancy, illness or decreased immunocompetence.

Personnel are advised during training that if they are planning to become pregnant, are pregnant, are ill, or have impaired immunocompetence they should consult a health care professional/physician regarding such conditions and how they might pertain to their working with laboratory animals. If warranted, any work restrictions and/or accommodations are coordinated among the individual, his/her health care professional, human resources, etc.

9. Provisions for personnel who are not involved in animal care and/or use but nevertheless need to enter areas when animals are housed or used. For example, personnel involved in building maintenance, security, housekeeping, etc.

The housekeeping staff is not routinely allowed access to the animal facilities. In situations where housekeeping, maintenance, or other non-animal care and use

personnel must access the animal rooms, they are briefed on appropriate precautions and provided any appropriate PPE and are then are permitted in for a limited amount of time. A member of the animal care staff will be available for escort if needed. If there is extensive or prolonged work to be done the animals are removed prior to the individuals being allowed into the room.

F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table (**see Part X**).

G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

Training is provided for all levels of participants in the animal care and use program at the Institution.

IACUC Members

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

- 1) The PHS Policy for the Humane Care and Use of Laboratory Animals;
- 2) The National Research Council (NRC) Guide for the Care and Use of Laboratory Animals;
- 3) The ARENA/OLAW IACUC Guidebook;
- 4) The AVMA Guidelines on Euthanasia;
- 5) A copy of this Assurance.

All new IACUC members are provided an orientation to the IACUC during the first full meeting of the IACUC in which they attend. New members are also mentored in protocol review and semi-annual review activities until they are comfortable conducting these activities on their own. In addition, they are required to take the "Training for IACUC Members" module offered through www.CITIProgram.org.

Efforts also are made to send new and established members to IACUC workshops (e.g., IACUC 101), and all IACUC members are kept apprised of new policies and procedures through reading notices and FAQs at OLAW's website and through newsletters and other postings offered by PRIM&R.

Scientists, Animal Technicians and other Personnel involved with Animal Care

Animal Care and Use Personnel involve all individuals with designated responsibility for the care and use or supervision of care and use of animals at the Institution. All personnel and supervisors (e.g., department heads) with roles in the care and use of animals at the Institution are required by the Institutional Official, in consultation with the IACUC, to take online training relevant to specific responsibilities in the animal care program from www.CITIProgram.org. In addition, all personnel must be trained according to standard operating procedures, specific to the assigned responsibilities within the animal care and

use program, which were developed in consultation with, and ultimately approved by, the IACUC. Moreover, the IACUC holds an annual informational session for the purpose of educating all personnel involved in the care and use of animals at the Institution about key components of the animal care and use program, the procedures for protocol approval, the procedures for significant and minor changes to IACUC-approved protocols, the semi-annual review process, post-approval monitoring, and any updates to the Institution policies on the care and use of animals. The effectiveness of personnel training is determined through interviews and assessing training logs during semi-annual reviews and post-approval monitoring.

All personnel performing procedures using animals must be identified in the Institutional Animal Care and Use Protocol. A description of each individual's qualifications, experience and/or training with the specific animal species, model and procedures must be provided for IACUC review. Any person needing additional protocol-specific training will be identified during the review process and such required training will be a condition of approval of the protocol. Protocols are not approved until all personnel identified on the protocol have completed the required CITI training modules.

All persons involved in animal care and use, including the IACUC, will receive training that covers the laws and regulations covering laboratory animal care and use with an emphasis on the contents of the NRC Guide and the 3R's through the following CITI modules that are part of the Investigators, Staff, and Students course: 1. Federal Laws, Policies, and Guidelines, and 2. Planning Research and Completing the Protocol Form. The training includes training or instruction on research or testing methods that minimize the numbers of animals required to obtain valid results and limit animal pain or distress as well as other requirements delineated in 9 CFR, Part 2, Subpart C, Section 2.32(c). Species-specific modules (e.g., Working with Mice, Reducing Pain and Distress) will be required when relevant to the protocol. The effectiveness of the training is evaluated by successful completion of the relevant CITI modules and quality of the animal care and use applications.

Specifically, training and instruction of personnel must include guidance in at least the following areas:

1. Humane methods of animal maintenance and experimentation, including:
 - a. The basic needs of each species of animal;
 - b. Proper handling and care for the various species of animals used by the facility;
 - c. Proper pre-procedural and post-procedural care of animals; and
 - d. Aseptic surgical methods and procedures;
2. The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress;
3. Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility;
4. Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. 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;

5. Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information:
 - a. On appropriate methods of animal care and use;
 - b. On alternatives to the use of live animals in research;
 - c. That could prevent unintended and unnecessary duplication of research involving animals; and
 - d. Regarding the intent and requirements of the Animal Welfare Act and USDA-APHIS Regulations

On-line training may be used and accepted in lieu of in-house training. Any use of on-line training to fulfill training requirements must be approved by the IACUC. Approval and completion of on-line training will be documented.

Specialized Training: Training in experimental methods, i.e., specific animal manipulations and techniques and in the care of new and nontraditional laboratory animal species, will be conducted based on the types of research being conducted and the species being used at the institution.

Note: For investigators transferring from other facilities at which they have received similar training, verification of previous training may be accepted in lieu of some Institutional required training. Acceptance of previous training in lieu of the Institution's training is solely at the IACUC's discretion.

IV. Institutional Program Evaluation and Accreditation

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past six months and will be re-evaluated by the IACUC at least once every six months thereafter, in accord with the PHS Policy IV.B.1-2. Reports have been and will continue to be prepared in accord with the PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the "Guide." Any departures from the "Guide" will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

This Institution is Category Two (2)—not accredited by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request. The report of the most recent evaluations (program review and facility inspection) was attached and reviewed.

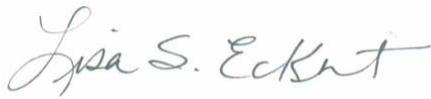
V. Recordkeeping Requirements

- A. This Institution will maintain for at least three years:
1. A copy of this Assurance and any modifications thereto, as approved by the PHS.
 2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations.
 3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.
 4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Dr. Lisa Schade Eckert.
 5. Records of accrediting body determinations.
- B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements

- A. This Institution's reporting period is the federal fiscal year (October 1 – September 30). The IACUC, through the Institutional Official, will submit an annual report to OLAW after September 30, but on or before December 1 of each year. The report will include:
1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC), any change in the description of the Institution's program for animal care and use as described in this Assurance, or any change in the IACUC membership. If there are no changes to report, this Institution will provide written notification that there are no changes.
 2. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, Dr. Lisa Schade Eckert.
- B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
1. Any serious or continuing noncompliance with the PHS Policy.
 2. Any serious deviations from the provisions of the "Guide."
 3. Any suspension of an activity by the IACUC.
- C. Reports filed under sections VI.A. and VI.B. of this document shall include any minority views filed by members of the IACUC.

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official	
Name: Lisa Schade Eckert	
Title: Dean, College of Graduate Studies and Research	
Name of Institution: Northern Michigan University	
Address: <i>(street, city, state, country, postal code)</i> 1401 Presque Isle Avenue Marquette, MI USA 49855	
Phone: 906-227-2300	Fax: 906-227-2315
E-mail: leckert@nmu.edu	
Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.	
Signature: 	Date: February 28, 2023

B. PHS Approving Official <i>(to be completed by OLAW)</i>	
Temeri Wilder-Kofie, DVM, MPH, DACLAM Animal Welfare Program Specialist Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6700 B Rockledge Drive Suite 2500, MSC 6910 Bethesda, MD USA 20892-6910 (FedEx Zip Code 20817) Phone: +1 (301) 496-7163	
Signature: Temeri D. Wilder-kofie - S <small>Digitally signed by Temeri D. Wilder-kofie - S Date: 2023.03.02 10:03:14 -0500</small>	Date: March 2, 2023
Assurance Number: D16-00512 (A3894-01)	
Effective Date: March 2, 2023	Expiration Date: November 30, 2026

VIII. Membership of the IACUC

Date: December 16, 2022	
Name of Institution: Northern Michigan University	
Assurance Number: D16-00512 (A3894-01)	
IACUC Chairperson	
Name*: John G. Bruggink, Scientist	
Title*: Professor	Degree/Credentials*: Ph.D.
Address*: (street, city, state, zip code)	
Biology Department, 1401 Presque Isle Avenue, Marquette, MI, 49855	
E-mail*: jbruggin@nmu.edu	
Phone*: 906-227-2342	Fax*: 906-227-1063

IACUC Roster

Name of Member/ Code**	Degree/ Credentials	Position Title**	PHS Policy Membership Requirements****
Dawn Sheffield	D.V.M.	Attending Veterinarian	Veterinarian
A.P.	Ph.D.	Professor	Scientist
J.L.	Ph.D.	Professor	Scientist
E.O.	Ph.D.	Associate Professor	Scientist
D.R.	Bachelor of Mathematics, M. Sc.in Mathematics Ph.D. in Mathematics	Assistant Professor	Nonscientist, Mathematician
M.I.	Ph.D.	Assistant Professor	Nonscientist, Ethicist
A.L.	Ph.D.	Assistant Professor	Scientist
K.L.	M.S. in Biology (botany thesis)	Small Business Owner (Embroidery)	Nonaffiliated Member
J.F. Alternate for K.L.	B.S. in Dental Hygiene	Dental Hygienist	Nonaffiliated Member
K.G. Alternate for J.L.	Ph.D.	Associate Professor	Scientist

* This information is mandatory.

** Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member

must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

*** List specific position titles for all members, including nonaffiliated (e.g., banker, teacher, volunteer fireman; not “community member” or “retired”).

**** [PHS Policy](#) Membership Requirements:

Veterinarian veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals at the institution.

Scientist practicing scientist experienced in research involving animals.

Nonscientist member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).

Nonaffiliated individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

[Note: all members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Non-voting members and alternate members must be so identified.]

IX. Other Key Contacts (optional)

If there are other individuals within the Institution who may be contacted regarding this Assurance, please provide information below.

Contact #1	
Name: Tesse Sayen	
Title: Director of Research Administration and Sponsored Programs	
Phone: 906-227-2322	E-mail: tsayen@nmu.edu
Contact #2	
Name:	
Title:	
Phone:	E-mail:

X. Facility and Species Inventory

Date: December 16, 2022			
Name of Institution: Northern Michigan University			
Assurance Number: Unassigned			
Laboratory, Unit, or Building*	Gross Square Feet [include service areas]	Species Housed [use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog]	Approximate Average Daily Inventory
001	700	Rats	40
		Zebrafish	750
002	1,626	Mice	300
		Brook trout and splake	200
		Burbot	1
		Gulf killfish	6
		Guppies	200
		Yellow perch	2
		Mummichog	100

*Institutions may identify animal areas (buildings/rooms) by a number or symbol in this submission to OLAW. However, the name and location must be provided to OLAW upon request.

