

**Procedures and Policies of the Northland College Institutional Animal Care and Use Committee
(IACUC)**

Table of Contents

Mission Statement

- I. The Institutional Animal Care and Use Committee
- II. Applicability
- III. Regulatory Authorities
- IV. IACUC Responsibilities
- V. IACUC Structure and Administration
- VI. IACUC Membership
 - Appointment of IACUC Chair, Length of Service and Duties
 - Appointment of IACUC Members, Length of Service and Duties
 - IACUC Membership Requirements
 - Conflict of Interest
 - Initial Training, Continuing Education, and Professional Development of IACUC Members
 - Expectations of IACUC members
 - Compensation of IACUC Members
- VII. IACUC Meetings
 - Schedule
 - Quorum
 - Procedure
- VIII. IACUC Record Keeping and Required Documentation
 - IACUC Records
 - Contents of Minutes
- IX. IACUC Review Requirements
- X. Protocol Categories
- XI. Review Procedures
- XII. Outcome of IACUC Review
 - Designated Member Review Process (DMR)
 - Reviewing the Protocol by DMR
 - Protocols Requiring Full Committee Review (FCR)
- XIII. Continuing Reviews
 - Yearly Re-approval
 - Three-Year Review
- XIV. Other IACUC Actions
 - Suspension of Research or Teaching Activity
 - Modifications to Approved Research
 - Personnel Changes
- XV. Monitoring of Animal Care Program
 - IACUC Semiannual Inspections
 - Investigator Review
 - Reminders
- XVI. Additional Considerations
 - Institutional Endorsement
 - External Research
 - Use of Appropriate Nomenclature When Identifying Research Animals
 - Research Involving Administration of Hazardous Materials

Appendices

Appendix 1: Preparing Animal Use Protocols

Appendix 2: Mistreatment of Animals and Deficiencies in Their Care

Appendix 3: Animal Transfer, Disposition and Euthanasia Policy

Appendix 4: Animal Use and Handling Training Program

Mission Statement

Northland College (Northland or College) recognizes its ethical and scientific responsibility for the humane care and use of animals (defined as living vertebrates) involved in research and education, and enjoins faculty, students, and staff to maintain the highest standards of animal care and consideration.

Northland College recognizes and supports the Institutional Animal Care and Use Committee as the agent for its obligations for the humane care and use of animals. The Committee will a) assure all activities involving animals meet the ethical and legal requirements for the humane care and use of animals, and b) educate the Northland College community concerning the ethical and regulatory considerations for the humane care of animals.

I. The Institutional Animal Care and Use Committee.

Northland College shall establish and maintain an Institutional Animal Care and Use Committee (IACUC) for activities involving animals according to the *Guide for the Care and Use of Laboratory Animals (Guide)*. The IACUC shall promote the humane care and use of animals in accordance with all applicable provisions of the [Animal Welfare Act](#) (AWA) and other Federal statutes and regulations relating to animals.

The Northland College IACUC is guided by the "[U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training](#)." The IACUC will not apply any more stringent standards to the review of research and teaching involving animals unless specifically directed to do so by College policy approved by the appropriate faculty governance bodies.

The IACUC shall 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.

Consistent with the federal regulations, decisions by the IACUC to disapprove research may not be appealed to any authority outside the IACUC. In all instances, to the best of its abilities, the IACUC will work with investigators to revise protocols that are not approved so as to meet the standards set forth in the regulations. On the other hand, review of research and teaching protocols by the IACUC does not guarantee permission to conduct any particular research project. IACUC approval does not override other College policies or authorities.

II. Applicability

Federal regulations delegate the right solely to the IACUC to determine what must be reviewed. All research and teaching involving the care and use of animals conducted by College employees or students at Northland or outside of the College in their capacity as an employee/student is subject to prospective review and approval by the IACUC and may not proceed without it, unless specifically excluded from review by the IACUC.

III. Regulatory Authorities

Northland College recognizes the following regulatory and accrediting agencies for the care and use of animals.

US Department of Agriculture (USDA)

The Animal Care Staff of the Animal and Plant Health Inspection Service (APHIS) of the United

States Department of Agriculture (USDA) is responsible for enforcing the regulations established by the Secretary of Agriculture under the mandate of the (AWA). These regulations set standards for humane handling, housing, space, feeding and watering, sanitation and ventilation, adequate veterinary care, and transportation. Compliance requirements include annual reports documenting adequate veterinary care and periodic unannounced inspections by APHIS personnel.

Office of Laboratory Animal Welfare (OLAW)

The College does not currently hold an Animal Welfare Assurance (Assurance), approved by the Office of Laboratory Animal Welfare (OLAW), of the Public Health Services. An Assurance will be applied for if the College pursues PHS funding involving animals.

OLAW is responsible for the general administration and coordination of PHS policy regarding animal care and use. Federal awarding units may not make an award for a project involving animals unless the institution submitting the application or proposal is on the list of institutions that have an approved Assurance on file with OLAW, and the responsible institutional official has provided verification of approval by the IACUC.

IV. IACUC Responsibilities

The IACUC is responsible for abiding by the commitments as stated in the Assurance. These commitments include, but may not be limited to:

- A. Review and evaluation of the institution's program for the humane care and use of animals in research and teaching at least once every six months.
- B. Inspection of all animal facilities for compliance with approved standards for hygiene and animal comfort at least once every six months.
- C. Preparation of reports of evaluations and inspections according to PHS Policy IV.B.3., and submission of such reports to the Institutional Official.
- D. Reviewing and investigating legitimate concerns involving the care and use of animals resulting from public complaints and from reports of noncompliance received from facility personnel, students, faculty or any other employee of the College or any person having official business with the College.
- E. Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training, and developing procedures for the submission of research protocols for review
- F. Reviewing and approving, requiring modifications, or withholding approval of all protocols, and all changes or amendments to approved protocols in conformity with the federal regulations with regard to care and use of animals in teaching and research.
- G. Notifying investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval according to PHS Policy IV.C.4
- H. Re-examination, once a year, of all current protocols for the use of USDA covered species, especially the current status of the activity, compliance with the protocol, and adherence to changes in IACUC policy or procedures.
- I. Evaluation of the qualifications of all personnel involved in the care and use of animals.

- J. Ensuring that proper training is provided as needed prior to the person being approved to participate in the protocol.
- K. Assuring that all animals are provided with proper husbandry and veterinary care, and receive pain-relieving drugs when necessary, and requiring justification for the use of animals in protocols with unrelieved pain or distress.
- L. Suspending activities involving animals when necessary and take corrective action and report findings and actions through the Institutional Official to all appropriate funding, regulatory and accrediting agencies.

V. IACUC Structure and Administration

- A. Delegation of Authority. The president of the College has the option to delegate to the chief academic officer the responsibilities of the Institutional Official (IO). The IO appoints the IACUC chair and IACUC members, and b) provides oversight to the IACUC.
- B. Responsibilities. The IACUC will report to the Institutional Official (IO). The IO will provide sufficient resources for the efficient conduct of IACUC business, including an administrative staff person to serve as Administrative Liaison. The Administrative Liaison's duties include: 1) assisting in the development and implementation of procedures to ensure the efficient flow of all IACUC records; 2) maintaining documentation and records in accordance with federal regulatory requirements; 3) tracking records; and 4) ensuring meetings are conducted according to federal regulations, i.e., recording attendance and preparing and distributing materials for meetings. The Administrative Liaison will attend all IACUC meetings, and will report informally to the IACUC Chair, and formally to the IO.

VI. IACUC Membership

The IACUC will have sufficient expertise to review the broad variety of research in which the College becomes involved, will be knowledgeable about all relevant regulatory requirements and will make every effort to be impartial and objective in its review.

- A. Appointment of IACUC Chair, Length of Service and Duties. The IACUC chair shall be appointed by the IO for a term of three years. In addition to the responsibilities of IACUC membership, the chair has primary responsibility for conducting IACUC meetings and directing the IACUC members to ensure operation of the IACUC within all applicable regulatory requirements. The IACUC chair works with members and investigators to ensure that the welfare of animals used in teaching and research is adequately protected. The chair shall sign all official IACUC correspondence, unless otherwise indicated, and shall report directly to the IO.
- B. Appointment of IACUC Members, Length of Service and Duties. The IO will appoint members to the IACUC for three year renewable terms, typically in consultation with current and past members. Members are responsible for ensuring that the rights and welfare of research subjects are protected. Members vote to approve, require modifications in, disapprove, or table protocols. Members are expected to attend IACUC meetings on a regular basis, serve as primary reviewers for research within their expertise, and serve as general reviewers on all research discussed at convened meetings. A vice-chair may be appointed by the IO to manage committee business in the event that the chair has a conflict of interest.

- C. IACUC Membership Requirements. In accordance with the compositional requirements of PHS Policy IV.A.3.a. and b., membership shall be composed of at least five members, with varying backgrounds to promote complete and adequate review of animal care and research activities commonly conducted at Northland. The IACUC shall include, at minimum, a) faculty members who represent the many uses of animals in teaching and research at Northland College, b) at least one member whose primary concerns are in nonscientific areas; c) the attending veterinarian with programmatic responsibilities (or his/her delegate), and d) one person who is not currently affiliated with Northland and is not part of the immediate family of a person who is currently affiliated with the College. Members will be drawn from diverse backgrounds including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the welfare of animals used in teaching and research. Members must be committed to the ethical and scientifically sound conduct of research and teaching involving animals, as well as to the care of animals used for these purposes.

The IACUC may, in its discretion, invite individuals with relevant competence to assist in the review of issues which require expertise beyond or in addition to that available on the IACUC. These individuals may not vote.

- D. Conflict of Interest. No IACUC member may participate in the IACUC's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IACUC. Conflicts of interest include, but may not be limited to, the following:
1. The IACUC member is currently engaged, or expects to be engaged, in the animal research or teaching project under review
 2. The IACUC member has a direct financial interest in the principal investigator or the entity funding the research proposed by the principal investigator, as defined by the College and/or federal regulations.
 3. The IACUC member and the principal investigator of the application under consideration share an immediate (rather than extended) familial relationship.
 4. The IACUC member has other reasons to feel that he/she cannot render an independent assessment of an application.

The IACUC member shall disclose the conflict of interest at the following time(s):

1. When the IACUC member is contacted to participate in the review of a project from a principal investigator with whom the IACUC member has a conflict of interest.
2. Prior to the discussion at a convened meeting of a project for which the IACUC member has a conflict of interest.
3. Immediately upon discovery of the conflict of interest if at other than the foregoing times.

The members of the IACUC retain the right to question and discuss other IACUC members regarding their potential conflicts of interest at the time of protocol submission. The Chair or any IACUC committee member may request that a member be excused from committee deliberations on a specific protocol because of possible or perceived conflict of interest.

E. Initial Training, Continuing Education, and Professional Development of IACUC Members.

1. Each IACUC member will be provided with an electronic link to or a copy of the following:
 - i. The PHS Policy for the Humane Care and Use of Laboratory Animals
 - ii. The National Research Council (NRC) Guide for the Care and Use of Laboratory Animals
 - iii. The ARENA/OLAW IACUC Guidebook;
 - iv. The AVMA Guidelines on Euthanasia;
2. All members of the IACUC will complete the specified modules for IACUC training in the Collaborative Institutional Training Initiative (CITI) website, at www.citiprogram.org.
3. All IACUC members will visit the OLAW website at least semi-annually and will familiarize themselves with the other pertinent modules and information, e.g., OLAW FAQs, Policies and Laws, Guidance, Educational and other Resources.
4. Attendance at an IACUC 101, IACUC 102, IACUC Advanced, PRIM&R/ARENA IACUC meeting, or similar course may be substituted for any required IACUC training session.

F. Expectations of IACUC members. IACUC members are expected to a) attend all meetings, programmatic reviews and facility inspections b) attend introductory and regular training for investigators and IACUC members, and c) review and maintain knowledge of pertinent documents concerning appropriate animal care for research and teaching activities at Northland College.

G. Compensation of IACUC Members. Certain IACUC members may be provided with a token honorarium for their service on the IACUC.

1. Faculty Chair: No compensation is provided, however the Committee Chair is exempted from service on college committees, i.e., FPC, P&B, AP&SC as provided for in the Faculty Handbook.
2. Community/External Member and Alternate(s): The College, through the Office of the Dean, will provide \$100 for each campus meeting attended plus mileage.
3. Veterinarian(s): The College, through the Office of the Dean, will provide compensation at the rate of \$80 per hour for on campus meetings plus mileage.
4. Outside Specialist Reviewers (non-voting): The College, through office of the Dean, will provide \$100 for each campus meeting attended plus mileage.

VII. IACUC Meetings

A. Schedule. Meetings will be convened at the call of the chair, or vice-chair acting on behalf of the chair. It is within the discretion of the IACUC chair to cancel or add a meeting in the event there is no business or additional business to conduct. The IACUC must meet in full committee under the following circumstances:

1. to review Humane Use Category E proposals (unalleviated pain and/or distress),

2. to review the results of the semiannual inspections two times per year or,
 3. at the request of any voting committee member or the Institutional Official.
- B. Quorum. A simple majority of the voting members of the IACUC is necessary to convene a meeting of the “full committee” and to conduct IACUC business.
- A. If a member of the IACUC is excused because of conflict of interest, and a quorum is no longer present, the protocol will not be considered.
 - B. Should a member or members of the IACUC not be able to be physically present during a convened meeting, the member(s) may participate in the meeting by speakerphone or other electronic means provided (1) they have had an opportunity to review all materials available to all other members attending the meeting, and (2) provided all committee members, whether attending in person or by phone, can hear and respond to all other members at all times.
 - C. The IACUC may invite consultants to assist in the review of complex issues. Consultants may not be considered members for determination of a quorum.
- C. Procedure. All convened IACUC meetings shall be conducted under and pursuant to Robert's Rules of Order.
1. In the absence of the Chair or in instances where the Chair may have a conflict of interest, the Chair shall recuse him/herself and designate the Vice-Chair or another member of the committee to conduct the activities of the Chair.
 2. For a research protocol to be approved it must receive the approval of a majority of those members present at the convened meeting. While the committee strives to reach consensus on issues presented for its consideration, it operates by majority rule. Those with opinions differing from the majority may file minority reports, and minority opinions must be included in the minutes of all meetings as well as the semiannual reports to the Institutional Official (IO).
 3. At any meeting of the full committee, the committee shall also approve and place the results of, any unrecorded Humane Use Category C (no or momentary pain and/or distress) and D (alleviated pain and/or distress) reviews conducted by designated reviewers among the records of the committee, and shall review the recommendations of any subcommittees pertaining to other animal care and use activities.

VIII. IACUC Record Keeping and Required Documentation

The AWA stipulates, “the research facility must maintain documentation of the Committee’s reviews and investigations in response to complaints received in order to demonstrate its compliance with these regulations.” All records that directly relate to applications, proposals, and proposed changes in animal care and use reviewed by IACUC must be maintained and must be accessible to the OLAW with reasonable notice.

- A. IACUC Records. Federal regulations require that the IACUC retain all records for at least three years and retain records relating to research for at least three years after the termination of the research protocol. All IACUC records shall be kept in a secure place. Access to IACUC records shall be limited to the IACUC chair, the administrative staff of the IACUC, the IACUC members, the IO, and officials of federal and state agencies. IACUC records will

include the following:

1. IACUC policies, standard operating procedures (SOP), or best practices
2. IACUC membership roster
3. *Curriculum vitae* for IACUC members
4. Record of certification of specialized training for IACUC members and principal investigators when required by federal grant or IACUC.
5. IACUC research application files for all submitted protocols, including all required documentation, continuing review reports, and correspondence.
6. Minutes of the convened IACUC meetings
7. IACUC Semi Annual Reports
8. IACUC Assurance documents

The Administrative Liaison shall ensure that a current IACUC membership roster is maintained pursuant

- B. Contents of Minutes. The minutes of IACUC meetings shall be compiled by and approved by the IACUC. The following specific information shall be included in the minutes:
1. Attendees by name, absent members, alternate members and the name of the person for whom they are the alternate, consultants, invited investigators and guests, and whether quorum requirements have been met. Members present via teleconference shall be noted as such in the meeting minutes.
 2. Actions taken by the IACUC on new and continuation applications; review of protocol and modifications or amendments; protocol deviations; adverse event reports; reports from sponsors; waiver or alteration of elements of informed consent; suspensions or terminations of research; and other actions. Votes on these actions are categorized as "for", "against" and "abstain". The basis for requiring changes in or disapproving research shall be noted.
 3. A list of research approved since the last meeting utilizing expedited review procedures and specific citation for the category of expedited review of the individual protocol, as well as a list of exempt and non-research protocols.
 4. Report of other business.
 5. Members who absented themselves by name, name of protocol and reason for the conflict.

IX. IACUC Review Requirements

- A. All teaching and research studies involving the care and use of animals must be submitted for IACUC review by the principal investigator¹. Submissions should be made by using the IACUC Animal Use Protocol form. This form includes all submission requirements (See appendix A for protocol submission requirements).
- B. No activities with animals may begin without prior review and approval by the IACUC.
- C. Protocol Submission and Dissemination to the IACUC. Members shall be notified via electronic mail that a new protocol has been submitted and they will be polled to see if any member wishes a full committee review of a Category C or D protocol. If no member requests a full committee review, then the Chair will assign a “designated reviewer” to evaluate Category C and D protocols. All Category E protocols will be reviewed in a full committee -meeting called by the Chair.

X. Protocol Categories

The following are the categories of pain and distress for animals used in research and teaching programs.

- Humane Use Category C - No or momentary pain and/or distress
- Humane Use Category D - Alleviated pain and/or distress
- Humane Use Category E - Unalleviated pain and/or distress (corresponding to USDA reporting categories C, D, and E respectively)

XII. Review Procedures

- A. Designated Member Review Process (DMR)
 1. Protocols will be provided by email. All IACUC members shall have access to the web site and will be notified via electronic mail that a protocol has been submitted.
 2. The IACUC members shall be polled by the Chair following submission of new protocols to see if a full committee review is requested by any member for a Category C or D submission.
 3. If full committee review is required or requested, the Chair shall then call a meeting of the full committee.
 4. If full committee review is not requested for a Category C or D research protocol submission, a designated member reviewer appointed by the Chair will then review the protocol. The designated reviewer is encouraged to ask another IACUC member knowledgeable in specific aspects of the protocol for advice as needed. The designated reviewer may also seek advice from experts who are not IACUC members provided the principal investigator’s identity is kept in confidence.
 5. The designated reviewer has the authority to approve, to withhold approval pending modifications, or to request full committee review of assigned protocols. The Chair, however, communicates with the principal investigator concerning protocol approval, required modifications, clarifications, or notification that a full committee review will occur.
 6. Results of designated reviews will be provided by email for the full committee at the

¹ This includes faculty principal investigators, as well as students who are submitting protocols.

next scheduled meeting. The Committee at such meetings shall place and retain the results of all reviews completed by designated reviewers among the records of the IACUC.

7. The designated reviewer may begin reviewing the protocols at any time upon receipt and shall complete the review without undue delay. If for some reason, the designated IACUC member cannot review the particular protocol assigned, he or she must let the Chair know immediately so it can be re-assigned.

B. Reviewing the Protocol by DMR

1. The reviewer must provide the Chair with a description of all concerns in an electronic message. These comments should be concise and clearly indicate to which question they refer. The comments should be written in a professional manner (excluding opinions) so that they may be sent to the principal investigator with minimal changes.
2. Any administrative comments will be added to the reviewer's comments and then be sent to the principal investigator.

C. Protocols Requiring Full Committee Review (FCR)

1. Humane Category E protocols require review by the full Committee because of the high risk of unalleviated pain associated with these protocols. The Committee may request input from other individuals who may be able to assist in the review, but must protect the identity of the principal investigator from disclosure.
2. The Committee will decide on one of the four protocol designations, a) approve, b) withhold approval pending modifications, c) table for substantive changes, or d) disapprove.
3. A vote shall be taken and the minutes shall reflect the number voting for and against the decided upon designation. Those opposing approval of a protocol may submit a minority report. The minutes shall also reflect the discussion of the major issues presented by the protocol.
4. Category E protocols will not be considered if a veterinarian is not in attendance. Committee members submitting a written review and recommendation of a protocol who are not present at a meeting of the full committee will not be considered as a part of the quorum.

XII. Outcome of IACUC Review

A. "Approve as Submitted"

The Chair will inform the principal investigator of the IACUC's approval. The investigator will be sent an approval notice indicating that the research or teaching covered by the protocol may begin, including purchase of animals if necessary. The approval notice also includes additional information regarding the principal investigator's responsibility in regard to modifications, re-approval and termination of the research.

B. "Withhold Approval Pending Modifications"

The IACUC Chair shall notify the principal investigator that the Committee requires minor clarification or modification of certain aspects of the protocol. Upon receipt of satisfactory clarifications or modifications from the principal investigator, the Chair can certify that the clarifications are adequate and proceed as in "Approve as Submitted." After receiving the clarification, if the information is not adequate or raises new points requiring further minor

clarification or modification, the Chair can request additional information from the principal investigator, or bring the investigator's response to the full IACUC for review. Regardless of the nature of the clarifications or modifications requested, all clarifications or modifications must be incorporated into a revised protocol. This revised document will be the protocol of record. Only when approval has been given can the animal research begin.

C. "Table for Substantive Changes"

This action requires approval by a majority of the IACUC convened in a regular meeting as described in the section entitled Conduct of Meetings and Quorum. The investigator shall be sent notice by the IACUC Chair describing the reasons for tabling the study and describing the revisions necessary for reconsideration by the IACUC.

D. "Disapprove as Submitted"

This action requires approval by a majority of the IACUC convened in a regular meeting as described in the section entitled Conduct of Meetings and Quorum. The investigator shall be sent notice by the Chair describing the reasons for disapproval. Disapproval of the protocol usually occurs when the IACUC determines that the risk(s) of the procedures outweighs any benefit to be gained. The investigator may discuss the review with the Chair and/or submit a revised protocol for re-review by the full IACUC.

XIII. Continuing Reviews (Annual Reports)

A. Yearly Re-approval

The IACUC requires that all research involving the care and use of live vertebrates be reviewed annually, as long as the study continues. A reminder to apply for re-approval shall be sent to each principal investigator approximately five weeks prior to the approval anniversary date. The investigator is responsible for making sure the yearly re-approval form is completed no later than two weeks before the expiration of the current protocol. If the protocol is not updated and approved by its anniversary date, it will be put on administrative hold, which means that no animal research will be allowed and no additional animals may be ordered or purchased until the protocol is re-approved.

Yearly review of annual reports is performed by the IACUC Chair or his/her designee.

1. Administrative Approvals by the Chair or designee may be performed if there are no changes in protocol, no adverse events, or changes are determined to be insignificant by the IACUC Chair. Such insignificant changes may include:
 - i. A change in student assistant or student researcher
 - ii. An increase in the number of animals used is less than 10 percent of the number listed in the original protocol.
 - iii. A decrease in the number of animals used in the protocol.

2. If there are significant changes noted on the annual report, the annual report must be reviewed by the Committee following the review procedure for a new protocol. Designated Member Review (DMR) or Full Committee Review (FCR) may be used. The Committee, at its discretion may require an amended, revised, or new protocol. Significant changes include:
 - i. Changes in experimental design
 - ii. Changes in experimental procedure.
 - iii. The inclusion of additional Principal Investigators on the protocol

- iv. An increase in animal numbers in excess of 10 percent of that number listed in the original protocol.
- v. Changes in reported levels of pain and distress, or other concerns of the IACUC chair regarding any other aspects of the annual review.

Investigators must notify the IACUC chair, via electronic mail and/or on the Annual Report Form, when a project is terminated.

B. Three-Year Review

Animal care and use activities are approved for a maximum period of three years and cannot be extended past the expiration date. If the activity is not completed before the end of three years, the principal investigator must submit a new proposal, indicating that it is a request for renewal. The renewal will be reviewed in the same way as a new proposal.

XIV. Other IACUC Actions

A. Suspension of Research or Teaching Activity

1. The IACUC may temporarily or permanently stop or suspend any 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 Law, the Institution's Assurance or policies outlined in this publication. The IACUC may permanently 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. A temporary suspension may be immediately imposed at the direction of the Chair, depending on the severity of the concern giving rise to the suspension. Any such temporary suspension will be reviewed by convened meeting of a quorum of the IACUC as soon as practicable.
2. If the IACUC suspends an activity involving animals, the Institutional Official in consultation with the IACUC shall review the reasons for the suspension, require that appropriate corrective action be taken, and forward a full explanation of the incident and resulting action to the Office of Laboratory Animal Welfare (OLAW), other funding agencies and the USDA as required.
3. Applications and protocols that have been approved by the IACUC may be subject to further appropriate review and approval by officials of Northland College. However, those officials may not approve those sections of an application or protocol related to the care and use of animals if they have not been approved by the IACUC.

B. Modifications to Approved Research (Amendments)

1. Modifications are changes to an approved IACUC protocol. Depending on the level of changes proposed, the modifications must be reviewed and approved by either the IACUC or its Chair prior to implementation by the principal investigator. The Chair will first determine whether the changes proposed are minor or of such significance as to merit review by the full IACUC (see below). Minor modifications may be reviewed and approved by the Chair or his/her designee. The decision of the Chair, or designated reviewer, will be conveyed to the full IACUC at its next meeting. Major modifications must be reviewed and approved by the Committee. The modified protocol will become part of the protocol for the research project and shall become kept among the records maintained by the Committee.

2. Major modifications include, but are not limited to: changes in category from C to D, or D to E; changes which deviate considerably from the original procedures described by the investigator; changes in the genus used or a request for additional USDA covered animals which exceeding 10% of that approved by the IACUC for the protocol; changes from non-survival to survival surgery or from survival to multiple survival surgery must be referred to the full IACUC for review.
3. The principal investigator's request for modification should include a complete description and justification of the modifications, and should be sent to the IACUC Chair via email as an amendment to an approved protocol.
4. Personnel Changes.
 - a. The Principal Investigator must note any and/all changes in personnel on the protocol. The IACUC Committee will determine if the changes should be considered significant or insignificant.
 - b. It is the principal investigator's responsibility to request or provide formal training for all personnel who handle animals. This includes students on short-term projects, and temporary as well as permanent employees. No one may work with animals until they have completed the required IACUC training and Occupational Health Risk Assessment and Training.
5. Animal Numbers. The number of animals approved in a protocol is considered to be the number of animals required for the research project.
 - a. Additional animals are allowed only with the approval of the IACUC. The principal investigator is generally the most knowledgeable person regarding the consequences of his/her study on his/her animals, and is responsible for making an estimation of the numbers of animals in each Humane Use Category and reporting them to the IACUC. The principal investigator may request additional animals by providing adequate justification. Justification includes the reason for the additional animals and the number of additional animals required to complete the study. (See guidance on modifications above). Principal investigators of research or teaching protocols using wild animals that will be captured and released in the field may submit estimates of animal numbers.
 - b. The use of fewer animals on a protocol does not require that an amendment to be filed for IACUC review. This information should instead be noted on an Annual Report.

XV. Monitoring of Animal Care Program

The Northland College IACUC has approved the following mechanisms to provide periodic monitoring for compliance with IACUC policy for animal care:

A. IACUC Semiannual Inspections

It is the responsibility of the IACUC to inspect, at least once every six months all of the College's animal facilities, satellite facilities, individual laboratories, and study areas using the standards in the Guide as the basis for evaluation. (Study areas are those sites where animals are maintained

for more than 12 hours and/or are subject to USDA inspection.) A quorum of IACUC members and, ideally, a designee of the Executive Director of IT and Facilities shall perform the inspections.

This group shall prepare a report of its evaluation, including any minority reports and all such reports shall be added to the next IACUC agenda for discussion. The report must then receive approval of the majority of the voting members of IACUC at a convened meeting. The IACUC Chair shall send letters to all parties (e.g. investigator, department chair, facilities management, etc.) responsible for animal care informing them of any deficiencies and a deadline for correcting the deficiencies. The IACUC may shut down any facility immediately and for an indeterminate amount of time depending on the severity of the deficiencies. Conditions that seriously affect the health and well-being of animals must be reported immediately to the IACUC Chair for action.

B. Investigator Review

The IACUC may ask an investigator to meet with the committee to discuss the review of his/her protocol or discuss compliance with any or all of the requirements of the IACUC.

C. Reminders

IACUC will promptly send notice to investigators who have approved protocols or who have protocols pending of any changes in policy or procedures. Other investigators will find changes to policy or procedure on the IACUC website.

XVI. Additional Considerations

A. Institutional Endorsement

Agencies, which fund research, require certification by an authorized Official of the Institution stating that research involving the care and use of animals as described in the application has been approved by the IACUC. The IACUC Chair will provide the sponsor with appropriate documentation of the IACUC approval. It is the investigator's responsibility to insure that the description in the IACUC protocol covers all work proposed.

B. External Research

External research is that in which the animals will be housed and/or used at another institution but Northland College is to administer the sponsored project through grants or subcontracts. The principal investigator must submit to the IACUC Chair a cover letter, a copy of the protocol reviewed, and an approval letter from the Animal Care and Use Committee of the collaborating institution.

C. Use of Appropriate Nomenclature When Identifying Research Animals

PHS guidelines require that some mechanism exist within funded institutions for informing investigators of the importance of using standardized nomenclature when identifying the animals they use in biomedical research. Accordingly, the purpose of this policy is to serve as the mechanism by which this information is relayed to all personnel involved in animal research at Northland College.

International committees have developed rules for standardized nomenclature of inbred mice, out bred rodents and rabbits. These widely accepted conventions permit accurate description of the animals used in research. Investigators are encouraged to use standard nomenclature conventions (found in supplier catalogs) to describe the genetic background of their experimental animals when placing animal orders, recording scientific data, and in publications. For animals obtained from commercial vendors, the strain (inbred animals) or stock (out bred animals) is that found in the breeder's price list.

D. Special Considerations for Field-related Animal Research and Teaching

While the IACUC's priority is ensuring animal welfare, the IACUC members should be considerate of the unique challenges associated with field-related animal research and teaching. When reviewing field-related animal research and teaching activities the IACUC should be cognizant of the differences between field- and laboratory-related research so as to avoid direct comparison between field- and laboratory-related protocols. Additionally, the IACUC should anticipate that field-related protocols may have more frequent protocol modifications and wider estimates in animal numbers due to the often unpredictable nature of fieldwork. IACUC members unfamiliar with field-related animal research or teaching should familiarize themselves with the commonly used field techniques for sampling, handling, marking, and releasing of species listed in a protocol.

Appendix 1: Preparing Animal Use Protocols

Protocol Preparation

The protocol is the complete description of the research or training plan that involves the care and use of animals. In order to facilitate review, protocols must be prepared carefully and completely in accordance with IACUC Guidelines. The protocols become part of the records maintained by the Committee and are subject to inspection and review by various granting, accrediting and governmental agencies.

A departmental faculty sponsor must review any protocols written by students for completeness and accuracy before they may be submitted for review.

Investigator Certification Statement (Attached to IACUC Protocol)

- I certify that appropriate pain-relieving drugs have been or will be used throughout the entire study to relieve pain or distress whenever it occurs, including postoperative or post procedural care, unless specifically stated otherwise in this protocol.
- I further certify that the activities in this protocol do not unnecessarily duplicate previous experiments.
- I certify that all personnel performing any procedures on animals will receive the proper training and will participate in the training programs available. A description of this training and experience of personnel is provided in this protocol. Proof of such training for all personnel and myself will be provided to the Institutional Animal Care and Use Committee (IACUC) upon request.
- I am not using radioactive materials, infectious agents or other biologically hazardous materials in the animal facility other than those included in this protocol and approved by the appropriate committees.
- I agree to abide by the provisions of the National Research Council Guide for the Care and Use of Laboratory Animals, the Public Health Service Policy on Humane Care and Use of Laboratory Animal, and current United States Department of Agriculture animal care and use regulations.
- If I wish to change any of the procedures described in this protocol, I will request IACUC approval by submitting the details of the change(s) to the IACUC Chair via electronic mail. If requested, I will submit a new protocol.
- I understand that any failure to comply with the guidelines and requirements set down by the IACUC may result in suspension of my studies.

Review by the Attending Veterinarian

The attending veterinarian must review all category E protocols (those involving unrelieved pain or distress) and all Category D protocols for USDA covered species before the protocols are submitted.

The attending veterinarian shall notify the Chair and the principal investigator that he or she has reviewed such protocols, and in the same message will provide the investigator and Chair with any suggestions or recommendations for modifications.

If the principal investigator disagrees with the veterinary recommendations, he or she may forward the protocol to the IACUC for review along with the veterinarian's recommendations and a statement by the principal investigator regarding his/her reasons for disagreeing with the veterinary recommendations.

Appendix 2 Mistreatment of Animals and Deficiencies in Their Care

IACUC Policy for Review and Investigation of Animal Welfare Concerns (“Whistle Blower”)

Northland College requires that the care, use, and treatment of College-owned laboratory animals must be of high quality and in compliance with all applicable laws and regulations. It is important that all persons involved or in any way associated with the use of animals in research know how to report deficiencies in animal care and treatment. There are no restrictions on who at Northland can report an alleged incident. Anyone associated with Northland College who has knowledge of a deficiency is obligated to report it to College officials. ***Under no circumstances will good faith reporting of such incidences be detrimental to an individual’s employment or position within Northland College.***

The definition of animal mistreatment and deficiencies in care include the abusive physical or psychological treatment of an animal and non-compliance with established procedures, policies or protocols.

Background

Congress amended the Animal Welfare Act (AWA) in 1985 in Public Law 99-198. The Secretary of Agriculture was directed to promulgate new rules governing the humane handling, care, and treatment, and transportation of animals by dealers, research facilities, and exhibitors. A requirement under the AWA is that the IACUC, as an agent for the research facility, “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 from reports of noncompliance received from laboratory or research facility personnel or employees [Federal Register Vol. 54, No. 168, Thursday, August 31, 1989, final rule 2.31[c][4]:p. 36152]. “The research facility must maintain documentation of the Committee’s reviews and investigations conducted in response to complaints received in order to demonstrate its compliance with these regulations”. The research facility determines the form and method of such documentation [ibid. p. 36128].

Reporting

It is the responsibility of the IACUC to investigate complaints or concerns about the animal care and use program.

Concerns involving the care and use of animals at Northland College may be reported to the Institutional Official or to a member of the IACUC by any employee of the College or any person having official business with the institution. Complaints may be handled in a confidential or anonymous manner if requested by the originator. Should any valid concerns of reprisal be involved, they will be discussed with the Institutional Official, and a report of the pertinent concerns and actions will be submitted to OLAW.

Procedures

The Chair will decide on a case-by-case basis how to proceed based upon the content and context of the complaint or concern. The Chair will ultimately report to the full committee and the Institutional Official any formal complaints. The results of any IACUC investigation shall be reported to Institutional Official. The Institutional Official will provide required reports to funding agencies, OLAW, or the USDA, as appropriate.

Appendix 3: Animal Transfer, Disposition and Euthanasia Policy

The College is committed to minimizing the number of animals needed to satisfactorily conduct its teaching and research activities, while being in full compliance with applicable federal, state, and local laws and regulations. The policy that follows indicates methods for the transfer or disposition of animals, for the disposal of the remains of those requiring euthanasia, and the commitments stated in the Assurance for the euthanasia of animals.

A. Animal Transfers or Movements (See also Appendix 7)

1. Requests for transfers or movements of animals will be evaluated by the IACUC attending veterinarian may be allowed on a limited, local, case-by-case basis. The following conditions must be met to allow a transfer:
 - a) Approval of the representative veterinarian and appropriate state or federal agencies has been secured.
 - b) Both sending and receiving IACUC's have approved the transfer, documentation of which will be retained by the Northland IACUC.
 - c) Animals may be transferred within a 200 mile radius of Northland College.
 - d) Animals, if transported by vehicle, must be in the passenger compartment to assure temperature control appropriate to the animal being transferred
 - e) Animals and containers must be packed to avoid injury to the animal.
2. The attending veterinarian will report all such recommendations to the full IACUC at its next meeting.

B. Disposition of organs and tissues

1. Requests for the disposition of animals and their organs and tissues will be evaluated by the IACUC attending veterinarian on a case-by-case basis. The attending veterinarian will report all such recommendations to the full IACUC at its next meeting.
2. Animals that will not be transferred to another approved project will be killed humanely. All animal remains will be disposed of in accordance with local, state and federal laws and regulations.

C. Euthanasia

1. The investigator in charge of the research or teaching protocol, or a qualified designee, shall use only those methods that are recommended and as approved in the protocol by the IACUC.
2. If animals are suffering pain and/or distress exceeding that described in the IACUC approved protocol, they may require euthanasia, which will be performed by the attending veterinarian or a qualified designee, in the absence of the principal investigator.

Appendix 4: Animal Use and Handling Training Program

Required Training

Any new employee of Northland College involved in animal care and use will undergo training prior to beginning her or his duties. The employee's supervisor is primarily responsible for providing this training and for keeping documentation that it has been completed. The training will cover each of the following:

- Regulations of the Animal Welfare Act, 9 CFR Section 2.32. and the most recent editions of the Guide and the PHS Policy on Humane Care and Use of Laboratory Animals.
- The training will include instruction/information on research methods that minimize the numbers of animals required to obtain valid results and methods that limit animal pain and distress.
- Activity-specific training will be provided for individuals in each animal use project. The training will include handling and technical procedures including administration of test substances, use of anesthetics-analgesics-tranquillizers, and sample collection.

Required training for change of species or manipulation

Before any new species, procedures or major change in existing procedures is introduced into a facility or animal activity, all employees caring for or handling the new species or carrying out the procedure will be appropriately trained. The attending veterinarian, supervisor or principal investigator will provide appropriate training. It will be the responsibility of the principle investigator or supervisor to assure and document that the support staff are adequately trained.

Continuing education

It is the responsibility of each principle investigator and supervisor working with laboratory animals to acquire current information in the care and handling of the animals and to update the research technicians and animal care staff accordingly.

Assurance of orientation and training

Each animal activity protocol will include a statement through which the supervisor assures the IACUC in writing that the required orientation and training, including familiarity with the Guide and PHS Policy, were provided prior to initiation of the protocol and that the supervisor will continually acquire current information relevant to the protocol as it becomes available and will provide training as appropriate.