

INSTITUTIONAL ANIMAL CARE AND USE IN RESEARCH AND TEACHING

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I. OVERVIEW

Northern Illinois University has the responsibility to maintain the highest possible quality research and to provide for the humane care and treatment of animals used in teaching, testing, and research projects conducted at this institution, or under the direction of any employee or agent of this institution, whether funded or not, and regardless of source of funding. In compliance with Public Health Service (PHS) regulations, NIU has established an Institutional Animal Care and Use Committee (IACUC), whose members are appointed by the Vice President for Research and Innovation Partnerships or his or her designee to review all teaching, testing, and research involving animal subjects, and to set forth institutional policy regarding such activities. (See the Northern Illinois University Assurance of Compliance for regulatory and policy details.)

The IACUC is directly responsible to the Vice President for Research and Innovation Partnerships, who has been designated the Institutional Official by the President. All activities involving the use of animals conducted by NIU faculty, staff, and/or students, or sponsored in part or in whole by NIU must be reviewed and approved by the IACUC and/or its agents. This includes teaching activities and research conducted in conjunction with a student dissertation or thesis.

This institution is guided by the ethical principles regarding the humane treatment of animals used in research as set forth in the Animal Welfare Act (7 U.S.C. 2131 et seq., as amended). University policy specifies that (a) the proper management of laboratory animals is essential to the welfare of the animals, to the validity of research data, and to the health and safety of the animal care staff; and that (b) the University will comply with state and federal regulations regarding animal welfare. The IACUC encourages and promotes constructive communication among the research administrators, department chairs/directors of graduate studies, research investigators, and institutional officials, in order to maintain a high level of awareness regarding the safeguarding of the welfare of animal subjects. In addition to the consulting Doctor of Veterinary Medicine trained in laboratory animal science who sits on the IACUC, the committee shall have a consulting Doctor of Veterinary Medicine on call for emergency situations.

Correspondence concerning animal research and requests for additional information should be directed to the IACUC, in care of the Director of the Office of Research Compliance, Integrity, and Safety (ORCIS).

II. DEFINITIONS

NIU has adopted the following definitions included in the federal regulations to guide researchers and other interested parties in determining the necessity for review.

A. ANIMAL:

Any live, vertebrate animal used or intended for use in teaching, testing, or research.

B. ANIMAL FACILITY:

Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal

confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours (more than 12 hours for USDA covered species).

C. ANIMAL WELFARE ASSURANCE:

The document from an institution assuring institutional compliance with the Public Health Service Animal Welfare Policy.

D. GUIDE:

Guide for the Care and Use of Laboratory Animals, HHS, National Academy of Sciences Commission on Life Sciences, 2011 edition or succeeding revised editions.

E. INSTITUTIONAL OFFICIAL:

An individual who signs and has the authority to sign the institution's Animal Welfare Assurance, making a commitment on behalf of the institution that the requirements of this Policy will be met.

F. PUBLIC HEALTH SERVICE:

The Public Health Service (PHS) includes the Centers for Disease Control and Prevention; the Food and Drug Administration; the Health Resources and Services Administration; the National Institutes of Health; and the Office of the Assistant Secretary for Health, Department of Health and Human Services.

G. QUORUM:

A majority of the voting members of the Institutional Animal Care and Use Committee (IACUC).

III. RESPONSIBILITIES OF THE INVESTIGATORS

Faculty, staff, retired faculty or staff, and students who are under the oversight of a faculty or staff advisor who is also listed on the protocol may submit an application to the IACUC. This individual must be the point of contact. Exceptions can be made with the approval of the IACUC. Please contact ORCIS for additional information.

It is the responsibility of the researcher to know and to comply with the review procedures of the IACUC. Should the researcher be a student matriculating at NIU, the student's academic or dissertation/thesis advisor assumes primary responsibility for the proposed activity. The advisor is to familiarize the student with his/her obligation with regard to the welfare of animal subjects of research.

The responsibilities of investigators using animals in research or teaching include obligations to:

1. Become knowledgeable about and conduct all research and inquiries in accordance with approved policies governing the care and use of laboratory animals.
2. Submit to the IACUC, prior to acquisition of animals and data collection, a fully completed Initial Application including a link to any applicable Sponsored Programs Administration (SPA) grant proposals associated with the project.
3. Maintain complete records of procedures undertaken during each animal experiment for a minimum of three years after its completion.
4. Meet research protocol requirements in approved animal care unit facilities whenever possible. Where research protocols dictate unusual environmental, dietary or colony requirements that cannot be met in animal care unit facilities, IACUC approval must be obtained in advance of the proposed animal use activity.
5. Maintain a scholarly, sensitive, respectful environment during all animal experimentation.
6. Participate in continuing education and training programs designed to keep investigators abreast of the latest regulations and procedures in animal research.

7. Immediately inform the departmental animal care administrator and/or the veterinarian on call of any problems which may arise with the health or care of the animals.

Department chairs, through appropriate procedures established within their respective departments, are responsible for reviewing research protocols for scientific merit. Research investigators shall be responsible for insuring that all research involving animal subjects is submitted to the Office for Research Compliance, Integrity and Safety for review by the IACUC in the form of a fully completed Initial Application.

For the section of the form calling for a description of the project, researchers should be sure to provide sufficient detail in nontechnical terms so that the IACUC may evaluate the proposed use of the animal subjects. Assurance from the investigator, no matter how strong, will not substitute for a description of any procedure. Research protocols scheduled for review shall be distributed to all members of the IACUC prior to the meeting. Input from consultants or experts may be sought to assist the IACUC in its review of a protocol. A majority of the voting membership of the IACUC constitutes a quorum and is required in order to convene a meeting for the review of research protocols. For an application to be approved, it must receive the approval of a majority of those voting members present at the convened meeting. No member who has a conflicting interest in the project being reviewed may participate in its review, except to provide information requested by the IACUC.

Additional Responsibilities of the Investigator

A. Project Time Period: Projects are approved for three years. Ongoing projects must be reviewed at least annually, and the IACUC has the right to require more frequent monitoring if necessary. Researchers shall submit an annual review application to inform the IACUC of the status of the project. All projects require a triennial review and approval by the IACUC every three years.

B. Changes in the Research Protocol: The IACUC chair should be notified immediately of proposed changes in a research activity through the use of an amendment submission. (See Section V. Review Procedures, D. Review of Proposed Changes to an Approved Project)

C. Reporting of Adverse Events: It is the researcher's responsibility to immediately report any adverse events impacting an animal to the IACUC. Adverse events include, but are not limited to, severe illness of an animal, undue harm to an animal, or death of an animal.

D. Reporting Accidents or Incidents Impacting Researchers: Any harm to a researcher should be reported through the NIU Accident/Incident Reporting System. This involves accessing a link through the ORCIS Lab Safety website.

E. Reporting of Noncompliance: Research investigators and department chairs/directors are responsible for reporting promptly to the IACUC any serious or continuing noncompliance with federal, state, and/or university regulations.

F. Cooperative Research: Federal regulation of research involving the use of animals includes projects conducted at or in cooperation with another entity by NIU administrators, faculty, staff, or students. The NIU IACUC may accept, for the purpose of meeting the PHS requirements, the approval from another institution's IACUC, provided that said IACUC has on file an approved assurance of compliance with the Office of Laboratory Animal Welfare. Such approval must be in writing and acknowledged in writing by NIU's IACUC chair. For grant proposals, a copy of the agreement must be forwarded to the Office for Laboratory Animal Welfare (OLAW).

IV. IACUC MEMBERSHIP AND FUNCTIONS

A. Membership: The chair and members of the IACUC are appointed by the Vice President for Research and Innovation Partnerships or his or her designee. It is the duty of the IACUC to continually evaluate and report to the Vice President for Research and Innovation Partnerships on the status of the animal care and use program at NIU.

The membership of the IACUC shall meet the requirements of federal and state laws and shall include members who are qualified through experience and/or expertise. The committee must have at least five members, including one Doctor of Veterinary Medicine experienced in laboratory animal science and medicine; three practicing scientists experienced in animal research; one individual not associated with science; and one individual who is neither affiliated with NIU nor the family member of any person affiliated with NIU, who has concern for animal welfare. Although the committee must have at least five members, one member can represent more than one of the required categories. No more than three members of the IACUC shall be from the same administrative unit or

department.

Members are appointed for a term of three years. All members shall be provided with an orientation that is documented in the training records. All new members must complete the “Essentials for IACUC Members” CITI Training Module, and the community member must also complete the “IACUC Community Member” CITI Training Module. In the event a member resigns, a replacement will be appointed for a new three-year term. At least two months prior to the resignation or completion of a term of one of the members, the IACUC chair will notify the Institutional Official (Vice President for Research and Innovation Partnerships) to solicit nominations for membership.

B. Functions: The functions and authority of the IACUC include:

1. Review at least once every six months the institution's animal care and use program for humane care and use of animals, using the *Guide for the Care and Use of Laboratory Animals (Guide)* as a basis for evaluation
2. Inspect semiannually all of the institution's animal facilities (including satellite facilities) using the *Guide* as a basis for evaluation
3. Prepare reports of the IACUC evaluations conducted as required by the PHS policy and submit the reports to the Institutional Official (Vice President for Research & Innovation Partnerships).
4. Review concerns involving the care and use of animals at the institution.
5. Make written recommendations to the Institutional Official regarding any aspect of the institution's animal program, facilities, or personnel training.
6. Review and approve, require modifications to (for approval) or withhold approval of animal use protocols as required by federal regulations.
7. Review and approve, require modification to (for approval) or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as required by federal regulations.
8. Notify investigators and the institution in writing of its decisions to approve or withhold approval of those sections of applications or proposals related to the care and use of animals, or of modifications required to secure IACUC approval as required by federal regulations.
9. At its discretion, to suspend immediately, pending an investigation, any research involving animal subjects that is suspected to violate any federal or state regulations, NIH policy, or NIU policy. Suspension of an activity for minor deficiencies or non-emergency situations will result only after the following procedures have failed to effect compliance:
 - a. Notification in writing to the investigator of the nature of the violation or noncompliance.
 - b. Written notice to the investigator's department chair of the problem and nonresponse to the committee, advising the department chair of the implications of noncompliance.
 - c. Written notice of the continuing noncompliance to the Institutional Official (Vice President for Research and Innovation Partnerships) with the committee's recommended action.
10. The IACUC, through the Institutional Official, must promptly report to the Office of Laboratory Animal Welfare a full explanation of the circumstances and actions taken with regard to:
 - a. Any serious or continuing noncompliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals.
 - b. Any serious deviation from the *Guide*
 - c. Any suspension of an activity
11. All formal committee action requires a majority of the quorum (simple majority of voting members

present).

12. Convened meetings of the IACUC shall occur monthly during the academic calendar year; at the call of the chair when the chair judges a meeting to be necessary or advantageous; or at the call of the chair upon the receipt of a joint written request of three or more members. A regularly scheduled monthly meeting may be cancelled if there is no business to conduct.

V. REVIEW PROCEDURES

A. Review Methods

There are two protocol review methods which may be used for new or triennial renewal applications or significant changes to an approved protocol:

1. Full Committee Review at a Convened Meeting

Protocols may be reviewed at a regularly scheduled meeting of a quorum of IACUC members. Prior to the review, each IACUC member will be provided with a written description of the research project. No member may participate in the IACUC review or approval of a research project in which the member has a conflicting interest except to provide information requested by the IACUC, nor may a member who has a conflicting interest contribute to the constitution of a quorum. Approval may be granted only after a majority of the quorum of members vote to approve the protocol. The IACUC may also vote to require modifications to secure approval or vote to withhold approval.

If modifications to secure approval are required, these modifications may be reviewed at the next convened IACUC meeting if there are substantive revisions required for approval, or it may be reviewed through the designated member review process (see below).

2. Designated Member Review:

All IACUC members receive a list of proposed research projects and access to a written description of the research project. Any member of the IACUC may make the decision that the protocol should be referred for full committee review. If no member calls for full-committee review during a pre-determined time period (usually a week), then the Chair may refer the protocol for designated member review. At least one member of the IACUC, designated by the Chair and qualified to conduct the review, shall review those research projects and have the authority to approve or require modifications in order to secure approval. It is also acceptable for members to share comments with the designated reviewer(s) for consideration. However, the designated reviewer will make the determination. The designated reviewer(s) may not withhold approval but must in such cases refer the protocol for full committee review. If the protocol is assigned more than one designated reviewer, the reviewers must be unanimous in any decision or in any modifications requested.

B. Criteria for Review of Activities Involving Animals

The IACUC must confirm that the protocol is consistent with the *Guide* unless a scientific justification for a departure is presented and is acceptable to the IACUC. The protocol must conform to this institution's PHS Assurance and meet the requirements of the PHS Policy at IV.C.1 a-g as follows:

1. Procedures with animals will avoid or minimize discomfort, distress, and pain to animals, consistent with sound research design.
2. 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.
3. 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.
4. Medical care for animals will be available and provided as necessary by a qualified veterinarian.

5. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
6. Methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.
7. The protocol will be conducted in accordance with the USDA Animal Welfare Regulations, if applicable.

Any project using special procedures (e.g. restraint, multiple survival surgery, fluid restriction) will be reviewed by the IACUC on a case by case basis. Scientific justification for the use of these procedures must be included in the application.

C. Review of Proposed Changes to an Approved Project

Significant changes in research during the period for which IACUC approval has already been given require review and approval either by Designated Member Review (DMR) or by Full Committee Review (FCR) of the IACUC. Significant changes include changes that have, or have the potential to have, a negative impact on animal welfare. In addition, some activities that may not have a direct impact on animal welfare are also considered to be significant.

Examples of significant changes include:

1. Changes in project objectives
2. Changes in principal investigators
3. Changes in species
4. Increases in sample size of more than 20%
5. Increases in invasiveness or anticipated discomfort level
6. Change from non-survival to survival surgery
7. Changes that impact personnel safety
8. Changes in housing and/or use of animals in a location that is not a part of an animal program overseen by the IACUC

The following specific significant changes may be handled administratively in consultation with the attending veterinarian for the IACUC:

1. Changes in anesthesia, analgesia, sedation, or experimental substances
2. Changes in euthanasia to any method approved in the current AVMA Guidelines for Euthanasia of Animals
3. Changes in duration, frequency, type, or number of procedures performed on an animal

Consultation with the veterinarian must be documented. The veterinarian may refer any request to the IACUC for either DMR or FCR for any reason and must refer any request that does not meet the parameters of the IACUC policies.

Changes which are not considered significant changes may be reviewed and approved by the IACUC Chair. The Chair may refer such changes for DMR or FCR at his/her discretion. Examples of changes not considered significant include

1. An increase in sample size of <20%
2. Additions or changes in minimally invasive procedures
3. Changes in the strain of the species being used.

The following minor changes may be handled administratively without consultations or notifications:

1. Corrections of typographical errors or grammar
2. Contact information updates
3. Change in personnel, other than the PI. The administrative reviewer must ensure that all such personnel are adequately trained and qualified, enrolled in occupational health and safety programs, and meet other criteria as required by the IACUC.

D. Review of unchanged ongoing projects

Researchers with projects which have continued for a year beyond the last review, without changes, or projects with minor changes, can use the abbreviated Annual Review application with a IACUC Annual submission. Continuing review of unchanged projects is typically conducted by DMR. All members of the IACUC will receive access to the Annual Review Application and the initial IACUC application and any changes made to the protocol prior to the

Annual Review.

The full protocol for each project is reviewed at least once every three years either by Full Committee Review or by Designated Member Review. This process requires a completed initial application within a Triennial submission.

E. Appeal of IACUC Decisions

Appeals of IACUC decisions should be made in writing to the chair and/or the Institutional Official (Vice President for Research and Innovation Partnerships). The Institutional Official can review IACUC decisions but cannot approve a project for which the committee withheld approval.

VI. MISCELLANEOUS

A. Reporting and Investigation of Animal Welfare Concerns or Noncompliance with the Policies of the Animal Care and Use program

Concerns about the care and use of animals at NIU or noncompliance may be brought to the attention of the Vice President for Research and Innovation Partnerships, the Chairperson of the IACUC, the Attending Veterinarian, or the Office of Research Compliance, Integrity, and Safety (ORCIS). The Vice President for Research and Innovation Partnerships will be notified when the concern does not originate through his/her office. The concerns will be referred to the IACUC for review, and recommendations will be made to the Vice President for Research and Innovation Partnerships who will determine appropriate corrective action.

No members of the University community (e.g., employees, students, or IACUC members) may be discriminated against or subjected to any reprisal for reporting violations or noncompliance with institutional animal care and use policies. Where possible, all reports of such activities will remain confidential.

B. Record-keeping Requirements

The IACUC shall prepare and maintain adequate documentation of IACUC activities, including the following:

1. Records of applications, proposals, and proposed significant changes in care and use of animals and whether IACUC approval was given or withheld.
2. Minutes of IACUC meetings which shall be in sufficient detail to show the attendance at the meetings; actions taken by the committee; the vote on those actions including the number of members abstaining or voting against an action; the basis for withholding approval of a project or requiring its modification; a written summary of the discussion of issues and their resolution; and dissenting reports and opinions.
3. Records of continuing review activities and whether IACUC approval was given or withheld.
4. A list of the IACUC members.
5. Copies of all correspondence between the IACUC and the principal investigators.
6. A copy of the Assurance that has been approved by the PHS.
7. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official.

All records will be maintained for at least three years. The IACUC shall provide for the maintenance of records relating to a specific research activity for at least 3 years after termination of the last IACUC approval period. IACUC records shall be accessible for inspection and copying by authorized representatives of PHS at reasonable times and in a reasonable manner.

C. Occupational Health Program

The NIU Occupational Health Program is mandatory for personnel who work in laboratory animal facilities or have

animal contact, as required by the Guide for the Care and Use of Laboratory Animals and the Occupational Health and Safety in the Care and Use of Research Animals (NRC). Annual physicals are suggested but not required. Immunization against tetanus is not required but is recommended every ten years or if an injury occurs which could cause tetanus in an individual where more than five years has elapsed since the last immunization. Investigators on all protocols involving nonhuman primates (regardless of hazard level) will be required to have an annual tuberculosis (TB) skin test. A waiver may be granted only after consultation with the Occupational Health Specialist.

All new personnel involved in handling animals are advised regarding zoonosis, personal hygiene, precautions for pregnant women, and other considerations by the principal investigator conducting the research project. All personnel are instructed to notify the principal investigator of any suspected work-related illnesses, any injuries, and any suspected or potential health hazard. All work-related accidents or incidents shall be reported through the Incident/Accident Reporting System that can be accessed through a link on the ORCIS Lab Safety website. Documentation of the Occupational Health Program and follow-up of injury/illness related to animal care will be the responsibility of the Biosafety Specialist, Office of Research Compliance, Integrity and Safety. All medical information will be kept confidential and secure in accordance with current federal and state regulations.

D. Training in the Care and Use of Animals

All animal users must complete mandatory online CITI training as follows:

1. All animal users: "Working with the IACUC"
2. Animal Users conducting surgery: "Working with the IACUC" and "Aseptic Surgery"
3. Animal Users conducting any study with the potential to cause more than momentary pain and distress in mice or rats: "Working with the IACUC" and "Minimizing Pain and Distress"

The IACUC will hold annual training sessions for all investigators who use animals in their research. The training sessions will be videotaped for viewing by those investigators who are unable to attend the training session. All animal users are required to attend this training session or complete an acceptable alternative training as determined by the IACUC. Training for use of specific species or techniques will be arranged with the attending veterinarian or other designated expert as needed.

E. Procedures for Approval of Externally Funded Research

Researchers should be aware that some agencies require institutional approval of research using live vertebrate animals at the submission stage of a grant proposal and should allow enough time for the Institutional Animal Care and Use Committee (IACUC) to review and approve their protocol before the grant submission deadline. More often, federal and private agencies require IACUC approval before awarding a grant. The grant proposal submission should be linked to the IACUC protocol record within the data management system.

NIU may be required to certify to the funding agency, for research involving live vertebrate animals, that the institution is operating under an approved Assurance and provide certification that an appropriate Institutional Animal Care and Use Committee has, within 12 months of the budget period start date, reviewed and approved the proposed activity in accordance with the regulatory requirements. The Chair of the IACUC will provide a letter of certification for submission to the funding agency at the request of Sponsored Programs Administration (SPA).

Failure to obtain IACUC approval may delay availability of grant funds. PIs should submit protocol applications in a timely fashion to avoid agency and institutional delays. If aspects of animal research are to be developed as results are obtained, a protocol describing initial activities should be submitted and approved. Additional procedures require an approved amendment prior to data collection.

F. Amendment of IACUC Policy

Amendment of the NIU policy on the care and use of animals in research may be recommended at any time by the IACUC. Proposed amendments shall be submitted to the full committee for review and must be approved by a majority of the voting members. Approved proposed amendments shall then be forwarded to the Institutional Official (Vice President for Research and Innovation Partnerships) for review and final approval. The IACUC will review the NIU policy on the care and use of animals in research at least annually.