

**POLICIES AND PROCEDURES PERTAINING TO ACTIVITIES
INVOLVING THE USE OF ANIMALS**

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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 President 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 Appendix A for the Northern Illinois University Assurance of Compliance for regulatory and policy details.)

The IACUC is directly responsible to the Vice President for Research and Dean of the Graduate School, 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 Assistant to the Dean for Research Compliance, the Graduate School.

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, 1996 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; 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. REVIEW PROCEDURES

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 vis-à-vis 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 "Application for Approval" accompanied by a copy of the methods section related to animal subjects from a grant application, if applicable.
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 for review by the IACUC in the form of a fully completed "Application for Approval".

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

Extension of Project Time Period: Ongoing projects must be reviewed at least annually, and the IACUC has the right to require more frequent monitoring if necessary. To obtain an extension of approval of a previously approved project without changes to the protocol, the researcher should submit a completed "Application for Continuation of Approval" to the IACUC. Approval must be obtained in writing from the IACUC chair before the researcher may continue data collection past one year from the date of the original approval.

Changes in the Research Protocol: The IACUC chair should be notified immediately of proposed changes in a research activity. Significant changes in research during the period for which IACUC approval has already been given require review and approval at a convened meeting of the IACUC; minor changes can be granted executive approval by the Chair, subject to review by the members at the next meeting. Significant changes include changes in project objectives, principle or co-investigators, or species; increases in sample size of more than 20%; increases in invasiveness or anticipated discomfort level; and changes involving analgesia, anesthesia, or surgery.

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

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

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 for Protection from Research Risks. 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 President or his or her designee. It is the duty of the IACUC to continually evaluate and report to the Vice President for Research 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 six members, including one Doctor of Veterinary Medicine experienced in laboratory animal science and medicine; four practicing scientists experienced in animal research; one individual not associated with science; a representative from the university's Office of Sponsored Projects or other individual designated by the Vice President for Research and Dean of the Graduate School; 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 six members, one member can represent more than one of the required categories.

Members are appointed for a term of three years, beginning in August. 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 faculty members with laboratory animal expertise, the IACUC chair will notify the Institutional Official (Vice President for Research and Dean of the Graduate School) to solicit nominations for membership.

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

- 1) Review semiannually the institution's animal care and use program.
- 2) Inspect semiannually all of the institution's animal facilities, including satellite facilities.

- 3) Review concerns involving the care and use of animals at the institution.
- 4) Make written recommendations to the Institutional Official (Vice President for Research) regarding any aspect of the institution's animal program, facilities, or personnel training.
- 5) Review and approve, require modifications to (for approval) or withhold approval of animal use protocols as required by federal regulations.
- 6) 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.
- 7) 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.
- 8) At its discretion, to suspend immediately, pending an investigation, any research involving animal subjects that is suspected to violate any federal or state regulations, N.I.H. 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 Dean of the Graduate School) with the committee's recommended action.

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:

1. Any serious or continuing noncompliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals.
 2. Any serious deviation from the *Guide*
 3. Any suspension of an activity
9. All formal committee action requires a majority of the quorum (simple majority of voting members present)
10. The IACUC will operate in accordance with the Illinois Open Meetings Act, and therefore shall be open to the public except for the discussion of security, safety, personnel, and proprietary issues. Minutes of the open sessions of the IACUC meetings are to be available to the public ten days after their approval.
11. Convened meetings of the IACUC shall occur: (1) monthly during the academic calendar year; and (2) at the call of the chair during the summer months and when the chair judges a meeting to be necessary or advantageous; or (3) 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 by the Chair if there is no business to conduct.

V. MISCELLANEOUS

A. Procedures for Approval of Externally Funded Research

Researchers should obtain IACUC approval prior to submitting a proposal to an external granting agency to avoid possible delays in the review of the grant application. Some granting agencies require approval prior to or concurrent with the submission of the grant proposal to the agency. The IACUC chair is responsible for submitting a certification of approval or continuation of approval to the funding agency. In any event, no external funding will be

distributed to the investigator prior to IACUC approval of the project.

B. Procedures for Review of Applications

1. Full Committee Review at a Convened Meeting. - Applications are normally reviewed at a regularly scheduled meeting of a quorum of IACUC members.
2. Designated Review. - Although its use is discouraged, Designated Review of applications is available, at the discretion of the chair, outside of a convened meeting in extraordinary situations when review is required before the next scheduled IACUC meeting. The procedure for Designated Review involves the circulation, to all members, of a copy of the full proposal, with a review form. The review form asks each member to recommend approval as submitted, disapproval, the need for modification(s), or the need for review at a full convened meeting. If no member requests Full Committee 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, require modifications in to secure approval, or request full committee review. If Full Committee Review is requested, approval of those research projects may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present.
3. Review of modifications to ongoing projects.- The chair may grant executive approval of modifications to ongoing projects that the chair deems to be minor (e.g., changes in student workers, increases in sample size of less than 20%, changes to husbandry practices). Significant modifications must be reviewed by the IACUC at a convened meeting. (See page 5, "Additional Responsibilities of the Investigator - Changes in Research Protocol".
4. 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 "Continuation Application". Continuing review of unchanged projects includes review of the complete project file, including the "Continuation Application", by at least one member designated by the chair and qualified to conduct the review (usually the veterinarian); the remaining members receive the "Continuation Application" and a project summary. Each project receives Full Committee Review at least once every three years.

C. 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). The Institutional Official can review IACUC decisions, but cannot approve a project for which the committee withheld approval.

D. 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 Dean of the Graduate School, the Chairperson of the IACUC, the Attending Veterinarian, or the Office of Research Compliance (ORC). Vice President for Research and Dean of the Graduate School 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. Vice President for Research and Dean of the Graduate School 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.

E. Record-keeping Requirements

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

- (1) Copies of all applications for approval of research involving the use of animals, including applications for continuation of approval and approval of changes in the protocol.
- (2) Minutes of IACUC meetings which shall be in sufficient detail to show the names of attendees at the meetings; actions taken by the committee; the vote on those actions including the name 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.
- (4) A list of the IACUC members.
- (5) Copies of all correspondence between the IACUC and the principal investigators.

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.

E. 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 to the Care and Use of Laboratory Animals and the Occupational Health and Safety in the Care and Use of Research Animals (NRC). All such personnel will be initially screened by a review of their medical and work records; thereafter an annual physical examination, tubercular test, and tetanus immunization or booster are recommended.

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. Each investigator is required to inform the department chair and the Biosafety Specialist of individual work assignments, bite or other wounds and their treatment, unusual illnesses, and allergies. All personnel are instructed to notify the principal investigator of any suspected work-related illnesses and any suspected or potential health hazard. Documentation of the Occupational Health Program and follow-up of injury/illness related to animal care will be the responsibility of the Biosafety Specialist, Department of Environmental Health and Safety. All medical information will be kept confidential and secure in accordance with current federal and state regulations.

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) for review and final approval.

G. Annual Training in the Care and Use of Animals

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.