



NORTHWESTERN UNIVERSITY

Responsible University Official: Vice President for Research
Responsible Office: Office of the Institutional Animal Care and Use Committee
Origination Date: March 10, 2014

Reporting and Investigating Suspected Noncompliance in Animal Research

Policy Statement

An important component in fulfilling the research mission of Northwestern University is the use of animals in research. The University must ensure that all research animals are used responsibly and in compliance with applicable laws, regulations and policies.

Reason for Policy/Purpose

In order to promote the humane and ethical use of animals at Northwestern University and to facilitate compliance with laws, regulations and policies governing animal research, this Policy informs members of the research community on how to report allegations of noncompliance in the animal research program and establishes the framework for the review of such allegations.

Table of Contents

Page #

Table with 2 columns: Table of Contents and Page #. Rows include Policy Statement, Reason for Policy/Purpose, Who Approved This Policy, Who Needs to Know This Policy, Website Address for this Policy, Contacts, Definitions, Policy/Procedures, Forms/Instructions, Appendices, Related Information, and History/Revision Dates.

Who Approved This Policy

Provost
Vice President for Research

Who Needs to Know This Policy

All members of the Northwestern University research community.

Website Address for this Policy

<http://www.iacuc.northwestern.edu/reporting-concerns/>

Contacts

If you have any questions on the Reporting and Investigating Suspected Noncompliance in Animal Research Policy, you may:

1. Call the Office of the Institutional Animal Care and Use Committee at 312-503-9339, or
 2. Send an e-mail to acuc@northwestern.edu
-

Definitions

Center for Comparative
Medicine (CCM)

Administrative unit responsible for the housing and care of research animals under the authority of the attending veterinarian.

Continuing
noncompliance

As defined in the *Guide for the Care and Use of Laboratory Animals*, an action of either minor or serious noncompliance occurring repeatedly or without efforts to correct the noncompliance.

*Guide for the Care and
Use of Laboratory
Animals*

Published by the National Research Council, the *Guide for the Care and Use of Laboratory Animals* is an internationally accepted primary reference on animal care and use. Northwestern University is required to comply with the Guide pursuant to Public Health Service policy.

Institutional Animal
Care and Use
Committee (IACUC)

The committee, appointed by the IO, responsible for the oversight of the animal care program in accordance with the Health Research Extension Act of 1985, the Animal Welfare Act and implementing regulations, and the *Guide for the Care and Use of Laboratory Animals*.

Institutional Official
(IO)

Individual with overall responsibility for the animal research program, including ensuring adequate funds and resources are available to remain compliant with regulations. The Vice President for Research serves as the IO.

Minor noncompliance

As defined in the *Guide for the Care and Use of Laboratory Animals*, a deviation from approved procedures, regulations or guidelines that does not pose a significant potential for causing harm to the health or safety of an animal or to personnel working with animals.

Office of Institutional
Care and Use
Committee
(IACUC Office)

Administrative unit that provides support for the
IACUC.

Serious noncompliance

As defined in the *Guide for the Care and Use of
Laboratory Animals*, a deviation from approved
procedures, regulations or guidelines that poses, or may
pose, a significant potential for causing harm to the
health or safety of an animal or to personnel working
with the animal.

Policy/Procedures

1.0 General Information

Any person having concerns about the treatment of research animals at Northwestern is strongly encouraged to report incidents involving perceived noncompliance through one of the following mechanisms:

- 1) Office of the Institutional Animal Care and Use Committee (IACUC Office):
 - Main number: (312) 503-9339
 - Hotline: (847) 467-ACUC (2282)
- 2) EthicsPoint <https://secure.ethicspoint.com> or (866) 294-3545

The University prohibits retaliation against individuals who, in good faith, report alleged noncompliance. See the University's [Policy On Non-Retaliation](#).

2.0 Initial Inquiry of Allegations of Noncompliance

The IACUC Office, in consultation with the IACUC Chair and/or Vice-Chair, the Center for Comparative Medicine (CCM) and IACUC member(s), acts on behalf of the IACUC in conducting an initial review of all reports of noncompliance. Reports of an urgent nature may, however, require an immediate response from the IACUC Office. The Principal Investigator (PI) will be informed of the allegation of noncompliance as soon as possible.

All reports are discussed by the initial reviewers to determine the seriousness of the alleged noncompliance. Following its initial inquiry, the reviewers, on behalf of the IACUC, may:

- Dismiss the allegation as unsubstantiated and notify the PI that no further action is required;
- Determine that the noncompliance constituted a minor violation and notify the PI what, if any, further action is required;
- Require that the PI submit a corrective action plan for minor violations; when a corrective action plan is required for minor issues of noncompliance, the matter is considered resolved if: a) the plan submitted by the PI is acceptable to the IACUC; and b) the actions outlined in the plan have been completed;

- Require that the PI provide a written response to the allegation; and/or
- Move to review allegations of serious or continuing noncompliance by the convened IACUC.

3.0 IACUC Investigation of Allegations of Noncompliance

At a convened meeting of the IACUC, the members will review the information gathered during the initial inquiry concerning the alleged noncompliance and discuss possible corrective actions. All IACUC members will receive information regarding the alleged noncompliance prior to the meeting.

If further review is needed, the IACUC Chair and/or Vice Chair may delegate a subcommittee, consisting of at least two IACUC members and IACUC Office staff, to continue the investigation of alleged serious or continuing noncompliance. Any person with a potential conflict of interest may not participate in the investigation.

The investigation by the subcommittee may include interviews and written documents from relevant parties involved in or with knowledge of the alleged noncompliance. A review of research records, medical records, facility access reports, and other items as necessary may be included in the investigation. The subcommittee may request a written response from the PI and/or the PI's attendance at an IACUC meeting.

Additional information gathered by the subcommittee will be presented at a convened IACUC meeting for discussion. After consideration of all information, the IACUC may:

- Determine that corrective actions taken by the PI are sufficient;
- Impose conditions and/or restrictions on the PI and his/her laboratory regarding the use of animals;
- Suspend the PI's animal research protocol(s);
- Refer the matter to other University offices as appropriate (e.g. Office for Research Integrity, Human Resources, Office of General Counsel); and/or
- Require additional corrective actions such as:
 - Protocol amendments
 - Continued monitoring of research
 - Retraining or mentoring of the PI, students and/or staff in the laboratory
 - Periodic reporting to the IACUC
 - Restrictions of research activities, facility access and/or use of research data

4.0 Reporting

The IACUC informs the IO of all IACUC decisions regarding serious or continuing issues of noncompliance. The IO may impose additional corrective actions, up to and including barring an individual from performing animal research at Northwestern. The IO will, as appropriate, report serious and continuing noncompliance to the United States Department of Agriculture (USDA), the National Institutes of Health (NIH) Office of Animal Welfare (OLAW), and/or the

Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).

Forms/Instructions

NA

Appendices

NA

Related Information

Health Research Extension Act of 1985:

<http://grants.nih.gov/grants/olaw/references/hrea1985.htm>

Animal Welfare Act (7 U.S.C. 54) <http://www.gpo.gov/fdsys/pkg/USCODE-2009-title7/html/USCODE-2009-title7-chap54.htm> and regulations (9 CFR, Subpart C)

http://www.aphis.usda.gov/animal_welfare/awa_info.shtml

National Research Council (2011). *Guide for the Care and Use of Laboratory Animals*. National Academy Press: Washington, D.C. http://www.nap.edu/catalog.php?record_id=12910

PHS Policy: <http://grants.nih.gov/grants/olaw/references/phspol.htm>

Office of Laboratory Animal Welfare: <http://grants.nih.gov/grants/olaw/olaw.htm>

Northwestern University Policy for Reviewing Alleged Research Misconduct:

http://www.research.northwestern.edu/ori/misconduct/documents/ORI_Misconduct_Procedures_FINAL_131017.pdf

Northwestern University Policy on Non-Retaliation:

<http://www.northwestern.edu/provost/policies/civility-and-campus-safety/non-retaliation.html>

History/Revision Dates

Origination Date: March 10, 2014

Last Amended Date: NA

Next Review Date: May 2020