

**Department of Health and Human Services
National Institutes of Health**

What Investigators Need to Know About the Use of Animals

“Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative.”

U.S. Government Principle IV, 1985

Principal Investigators are responsible for the scientific and technical aspects of a grant award and must ensure compliance with Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals when using live, vertebrate animals. PHS Policy incorporates U.S. Government Principles, the Guide for the Care and Use of Laboratory Animals, and the Report of the American Veterinary Medical Association (AVMA) Panel on Euthanasia. Vertebrate animals include traditional laboratory animals, farm animals, wildlife, and aquatic animals. Animal use encompasses research, teaching, or testing. Generation of custom antibodies is considered an activity involving vertebrate animals.

Who Must Comply With the PHS Policy?

The PHS Policy on Humane Care and Use of Laboratory Animals applies to extramural and intramural activities supported by any PHS agency, including the National Institutes of Health (NIH), the Food and Drug Administration, and the Centers for Disease Control and Prevention. All funding mechanisms, including research and training grants, cooperative agreements, and contracts, conducted at domestic and foreign institutions, are covered by the Policy.

What Is an IACUC?

Institutional Animal Care and Use Committees (IACUCs) are local institutional committees with federally mandated oversight responsibilities, including:

- Reviewing animal-use protocols;
- Reviewing significant changes to protocols;

- Evaluating institutional compliance with PHS Policy, U.S. Department of Agriculture (USDA) Animal Welfare Regulations,¹ and institutional policies;
- Monitoring institutional animal care and use programs, including inspecting animal facilities;
- Reviewing concerns about animal care or use; and
- Reporting noncompliance and suspensions to the Office of Laboratory Animal Welfare (OLAW).

Institutional and Investigator Responsibilities

- Describing proposed use of animals in grant applications.
- Obtaining IACUC approval prior to using animals and prior to implementing significant changes.
- Ensuring research is conducted in accord with the protocol.
- Complying with institutional policies and procedures.
- Addressing significant changes to the use of animals in progress reports.
- Addressing changes in the use of animals that may be a potential change in scope.²

How to Write an Application Involving Research Animals:

<http://www.niaid.nih.gov/ncn/clinical/researchanimals/tutorial/index.htm>

Applying for Funding

The proposed involvement of vertebrate animals is evaluated as part of the agency peer review process. In addition to providing IACUC approval status,³ applicants must address five points in the Research Plan of the grant application:

1. A detailed description of the proposed use of the animals, including species, strains, ages, sex, and numbers.
2. Justification of the use of animals, choice of species, and numbers to be used.
3. Information on the veterinary care of the animals.
4. A description of the procedures for ensuring humane treatment (i.e., minimization of discomfort, distress, pain, and injury).
5. The method of euthanasia, the reasons for its selection, and consistency with the AVMA Euthanasia Report.

Failure to address these elements will result in the application being designated incomplete and is grounds for PHS to defer the application or may negatively affect the priority score.

“Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals...”

U.S. Government Principle VIII, 1985

¹ The USDA implements the Animal Welfare Act through requirements found in the Code of Federal Regulations, Title 9, Chapter 1, Subchapter A, Parts 1-4. These regulations are congruent with PHS Policy but exclude birds, rats of the genus *Rattus*, and mice of the genus *Mus*, bred for use in research.

² A change in scope is a change in the direction, type of research, aims, objectives, or purpose of the project.

³ An application may be submitted with IACUC approval “pending.” The date of approval will be required prior to award.

Obtaining IACUC Review

IACUC approval is required prior to award except in rare circumstances. Your IACUC will require you to submit information about the care and use of animals on a protocol form. Most animal-use protocols require a description of the following elements:

- Research project;
- Rationale for animal use and consideration of alternatives;
- Justification for the choice of species and number of animals;
- Research procedures involving animals;
- Procedures to minimize pain and distress;
- Animal living conditions and veterinary care;
- Names and qualifications of personnel who will perform work with animals;
- Method of euthanasia; and
- Endpoint criteria.

The use of animals as described in the protocol approved by the IACUC must be congruent with the description in a competing grant application. Any modification required by the IACUC that affects the content of the application must be submitted to the agency along with the IACUC approval date.

Good animal care and good science go hand in hand.

Receiving an Award

To receive an award the grantee organization and every performance site where animal work will be performed must have an Animal Welfare Assurance approved by OLAW. OLAW will contact an organization with specific instructions when an Assurance is required. An inter-institutional Assurance is negotiated when the grantee does not have its own animal facilities and the animal work will be performed at an institution with an Assurance.

Foreign institutions provide a Statement of Compliance with Standards for Humane Care and Use of Animals.

SBIR/STTR investigators should be aware of the requirements in order to address them in a timely fashion so that the necessary Assurances are in place and grants can be awarded.

The date of IACUC approval is essential in order to receive an award and will be requested if not previously provided.

Post Award

IACUC approval is required at least every 3 years (annually if covered by USDA regulations). Significant changes in animal care and use are to be approved by the IACUC prior to implementation. Check with your IACUC to determine what constitutes a significant change.

Conducting research in the absence of a valid IACUC approval or implementing a significant change without IACUC approval constitutes noncompliance.

Investigators also must be aware of and comply with additional institutional policies that may be more restrictive.

Visit the following Web sites for additional information:

NIH Office of Laboratory Animal Welfare

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

1996 Guide for the Care and Use of Laboratory Animals

<http://www.nap.edu/readingroom/books/labrats/>

NIH Grants Policy Statement (2003)

http://grants.nih.gov/grants/policy/nihgps_2003/index.htm

PHS 398 Grant Application

<http://grants.nih.gov/grants/funding/phs398/phs398.html>

SF424 (R&R) Application and Electronic Submission Information

<http://grants.nih.gov/grants/funding/424/index.htm>

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Extramural Research

Office of Laboratory Animal Welfare

6705 Rockledge Drive, Suite 360

Bethesda, MD 20892

The National Institutes of Health (NIH), part of the Department of Health and Human Services, is the principal health research agency of the U.S. Federal Government. The Office of Extramural Research (OER) provides policies and guidelines for extramural research grants administration. OER has primary responsibility for developing and implementing NIH Grants Policy, including policies related to data and safety monitoring; protection of human subjects; humane use and care of laboratory animals; program guidelines; invention reporting requirements; and the information systems for grants administration. Within OER, the Office of Laboratory Animal Welfare has primary responsibility for animal welfare policy matters.

NIH Publication No. 06-6009