

# How to Write an Application Involving Research Animals

Explains procedures for writing an application and then applying for and maintaining an NIH ("the Agency") grant application for research that uses animals. You can also visit our [Other About Grants Tutorials](#)

## Table of Contents

- x [Requirements for Grantees Using Research Animals](#)
- x [Research Planning Is a Team Effort](#)
- x [Consider Alternatives to Using Animals](#)
- x [Check for Limits on Your Planned Animal Species or Source](#)
- x [Is Your Institution Assured by OLAW?](#)
- x [How to Get an Assurance](#)
- x [What OLAW Looks For](#)
  - o [Veterinary Care](#)
  - o [Personnel Qualifications and Training](#)
  - o [Occupational Health and Safety](#)
  - o [Animal Facilities and Species Inventory](#)
- x [Working With Your IACUC](#)
- x [How Your IACUC Is Structured](#)
- x [Write Your Protocol](#)
- x [Write the Application: Indicate Use of Animals](#)
- x [Answer the Five Points in the Vertebrate Animals Section](#)
- x [How the Agency Reviews Applications Using Research Animals](#)
- x [Understand Codes on Your Summary Statement](#)
- x [The Agency Will Send a Just-Time Request](#)
- x





Considering alternatives during the planning stage gives you enough time to incorporate methods that benefit the animals and the science. It also shows peer reviewers that you are thorough and reduces your chances of a bar to award because of animal welfare concerns.

#### Limit Animal Use and Discomfort

- x Limit animal involvement by using the minimum number required to obtain valid results.
- x Use nonanimal methods, such as mathematical models, computer simulation, or vitro biological systems.

x qes (.)JTJ 0 Tc 04. -1.64 0 Td ( )Tj EMCinkBody <</M2CID 9 >>BDC /C2\_0 1 Tf 9.96 -0 0 9.96444 0 9.72 T

## Dogs

Your ongoing NIH supported research may not use or procure dogs from Class B (“random source”) dealers using NIH funds. Instead, use only approved legal sources such as the following:

- x USDA Class A dealers
- x Privately owned colonies (e.g., colonies established by donations from breeders or owners)
- x Client owned animals (e.g., animals participating in veterinary clinicals)

For details, see the [December 17, 2013 Guidenotice](#).

## Cats

Awardees must not use NIH funds to get cats from Class B dealers. See [February 8, 2012 Guidenotice](#).

## Resources

- x [NIH's Model Organisms for Biomedical Research](#)
- x [National Research Council Scientific and Humane Issues in the Use of Random Source Dogs and Cats in Research \(2009\)](#)

Is Your Institution Assured by OLAW

A foreign entity must state that it will comply with the International Guiding Principles for Biomedical Research Involving Animals and the applicable laws, regulations, and policies of the country in which the research will be conducted. For example, a German institution or performance site should adhere to German laws governing the care and use of laboratory animals.

- o Foreign assurances are approved for up to five years.
  - Foreign assurances may be renewed if there is a current or pending award that involves vertebrate animals.
  - Even without an assurance, an institution may apply for funding or be named as a performance site.
  - If we plan to fund a new award, we will ask OLAW to negotiate a new assurance with your institution. For a direct award, foreign institutions do not need to submit certification of IACUC approval.
- o For an indirect or subaward from a domestic institution, the domestic institution must provide the verification of IACUC approval for all activities conducted at the foreign institution (i.e., certification that the activities conducted at the foreign performance site are acceptable to the grantee.)

Learn about IACUC requirements for foreign and domestic awards and subawards at IACUC Requirements Vary for Domestic and Foreign Institutions

Institutions that collaborate with grantees through a subaward are required to have an assurance, whether domestic or foreign.

- x If the institution doesn't have an assurance, OLAW will negotiate one with the grantee.
- x The grantee may amend its assurance to include a collaborating institution; in this case, the grantee takes full responsibility for the animal care and use program of the collaborating institution.
- x Read more in the Subawards (Consortium Agreements) for Grants SOP

Resources

x

for Foreign Institutions

OLAW will review your institution's domestic assurance for compliance with federal policies. If acceptable, OLAW approves it and your institution is assured. If not, OLAW will prompt your institution for more information until the responses describe your animal care and use program in com

## Resources

- x [Animals in Research](#) portal
- x [OLAW Topic Index](#) [Veterinary Care](#)

## Personnel Qualifications and Training

Your institution must ensure that staff working with animals are appropriately trained. This includes investigators, animal technicians, and other personnel involved in animal care, treatment, or use on research or testing methods that minimize the number of animals used as well as animal pain and distress.

For more information, read [Education and Training in the Care and Use of Laboratory Animals: A Guide for Developing Institutional Programs](#), developed by the [Institute for Laboratory Animal Research](#)

## Resources

- x [Animals in Research](#) portal
- x [IACUC 101 Ses](#)
- x [OLAW Topic Index](#)



and evaluate the adequacy of other program components, e.g., veterinary care and occupational health and safety.

## Resources

- x [Animals in Research Portal](#)

## Working With Your IACUC

Your IACUC is an oversight body appointed by an official at your institution, such as the chief executive officer. See [OLAW Who Is the Chief Executive Officer?](#) OLAW relies on the IACUC to enforce PHS policy and your institution's animal policies.

As outlined in [PHS Policy IV.B 1 through 1A](#), IACUCs do the following:

- x Review and approve animal use protocols, including significant changes to previously approved protocols.
  - o Institutional definitions of a "significant change" vary. Be sure you know your institution's policy. Implementing a significant change without IACUC prior approval is a serious violation of PHS policy.
  - o For more information, see [OLAW Topic Index Protocol Review](#)
- x Monitor the animal care and use program, including semiannual program review and facility inspection and report of the IACUC evaluations to the institutional official.
- x Review concerns involving the care and use of animals.
- x Make recommendations to the institutional official on the institution's animal program, facilities, or personnel training.
- x Be authorized to suspend a previously approved protocol in instances of noncompliance.
- x Evaluate compliance with institutional policies.
- x Report annually and notify OLAW of suspensions and instances of serious noncompliance with PHS policy. See [OLAW Reporting Noncompliance](#) for guidance on what an IACUC should report to OLAW.
- x Ensure that personnel working with animals are appropriately trained and qualified.

Find out your institution's policies before you plan your research. In most institutions, policies for research animals are a combination of institutional and USDA and PHS requirements. Some are more stringent than others, so a procedure you performed at another institution may not be acceptable at your current workplace.

## IACUC Requirements Vary for Domestic and Foreign Institutions

Identify your situation below for a summary of IACUC requirements.

- x Domestic grantees with no foreign subawards
  - o Follow all the IACUC requirements outlined in this tutorial and by OLAW.
- x Domestic grantees with a foreign subaward
  - o The domestic institution's IACUC reviews and approves the animal activity as described in the application.
  - o B0 1 Tf 0.005 Tc BTT0 1 Tf 0.005 T.0 (f)-( a)4 (p)1t2 BTT0n.

- x Foreign grantees and subawardees
  - o The foreign institution doesn't need its own IACUC unless required by local law.
  - o The foreign institution must have an assurance. Follow the format shown at OLAW's sample Animal Welfare Assurance for Foreign Institutions states that the institution will comply with your country's laws, regulations, and policies governing the care and use of laboratory animals and follow International

send the veterinarian draft of your protocol to resolve any issues before it goes to the IACUC. A standard animal protocol includes the following information.

- x Description of project Help IACUC members understand your animal procedures by avoiding technical language only people in your field will understand. Use visual aids, such as flow charts and bullets, to illustrate your points or break up text.
- x Justification for using animals Describe why an animal model is necessary. If you're studying a human health problem, state its use, existing therapies, and the potential

- x [Animals in Research Portal](#)
- x [ClinicalTrials.gov](#)
- x [Index Medicus](#)
- x [Medline Plus](#)
- x [PubMed](#)
- x [Sample Animal Study Proposals](#)
- x [American Association for Laboratory Animal Science](#)

Write the Application: Indicate Use of Animals

If you're using live vertebrate animals (including production of custom antibodies and animals obtained for their tissues), you'll need to answer "Yes" to the question "Vertebrate animals, yes or no" in Item 2 of the Other Project Information component in your grant application package. Remember that your application covers all performance sites, including subaward partners, collaborators, and others involved in the research. Even if the animal work will be done somewhere other than your institution, mark "yes."

Follow the instructions for Vertebrate Animals in the [SE 424 Application Guide](#)

Go to [Show Resources, Institutional Support](#) on the [Strategy for NIH Funding](#) for a brief description of what you need to put in the application.

To see if your institution or performance site is assured, refer to [OLAW Domestic Institutions With a PHS Approved Animal Welfare Assurance](#) or [Foreign Institutions With a PHS Approved Animal Welfare Assurance](#)

#### Resources

- x [Animals in Research Portal](#)
- x [Sample Applications and Summary Statements](#)

Answer the Five Points in the Vertebrate Animals Section

Peer reviewers can adjust your overall impact/priority score based on your responses to the five points below. An incomplete or missing response could exclude your application from review or lead to a bar to award.

Address these five points in the Vertebrate Animal Section (VAS) of the Research Plan:

1. Provide a detailed description of the use of animals in the research. Identify species, strains, ages, sex, and numbers of animals to be used.
2. Justify the use and number of animals and choice of species with additional justification if animals are in short supply or are costly or if you plan to use large numbers.
3. Provide information on veterinary care for the animals.
4. Describe procedures for ensuring that discomfort, pain, and injury will be limited to what is unavoidable. Describe the use of analgesic, anesthetic, tranquilizing drugs, and restraining devices to minimize discomfort, distress, pain, and injury.
5. Describe any euthanasia method to be used and the reasons for its selection. State whether this method is consistent with the recommendations of [American Veterinary Medical Association Guidelines for the Euthanasia of Animals](#). If not, justify not following the recommendations.

Note that NIH updated the Vertebrate Animals Section requirements. All applications due on or after January 25, 2016, except those for fellowship (F) and training (T) grants, should follow the new guidelines. Applications for F and T grants due on or after May 25, 2016, should also follow the new guidelines. Under the changes, you are no longer required to:

- x Describe veterinary care.
- x Justify the number of animals.
- x Describe and justify the method of euthanasia unless the method is not consistent with AVMA guidelines.

Follow the instructions for Vertebrate Animals in [SE 424 Application Guide](#) and NIH's [Worksheet for Review of the Vertebrate Animal Section \(VAS\)](#) describes requirements and provides an example of a complete VAS.

Since there is no page limit for this section, use as much space as you need to convince reviewers that you'll do everything right. Don't assume reviewers will automatically know what you're talking about. Help them understand why your approach will yield the best results and how you will limit animal pain and distress to that which is scientifically necessary.

See [Strategy to Write the Research Plan](#) and [Strategy to Prepare the Forms and Justify Time in the Strategy for NIH Funding](#) for more advice on drafting your application.

#### Resources

- x [Animals in Research portal](#)
- x [VAS Factsheet \(PDF\)](#)

#### How the Agency Reviews Applications Using Research Animals

When assessing the scientific merit of an application, all NIH initial peer review committees use the same review criteria. For information on NIH review criteria, [read NIH Review Criteria Affect Your Score](#) in the [Strategy for NIH Funding](#)

Peer reviewers also evaluate your project's compliance with federal requirements for animal research, rating your application based on your responses to the five points in the Vertebrate Animals Section. Any problems may negatively affect your [overall impact/priority score](#).

#### Resources

- x [Review Criteria SOP](#)
- x [Animals in Research portal](#)
- x [Sample Applications and Summary Statements](#)
- x [CSR](#)
  - o [Roster Index for Regular Standing Study Sections and Continuing SEPs](#)
  - o [Integrated Review Groups](#)

#### Understand Codes on Your Summary Statement

Scientific review officers will code your summary statement to reflect your use of research animals. Such codes can also indicate assurance status, need for IACUC review, missing information, reviewer concerns, or the fact that there are no problems [and the Agency will](#)

If your summary statement lists such a code, contact the program officer listed on your summary statement right away.

Resources

- x [Animals in Research Portal](#)
- x [Bars to Grant Awards SOP](#)
- x [Know What a Summary Statement Means the Strategy for NIH Funding](#)

The Agency Will Send a Just-in-Time Request

After you've cleared initial peer review

Consult your IACUC for guidance. The definition of a "significant change" varies from institution to institution, and your IACUC's actions depend on the nature of your significant change. If you're planning to make a significant change to your ~~project~~, also contact your program





## Noncompliance

### Resources

- x [Animals in Research portal](#)
- x [OLAW](#)
  - o [Annual Report to OLAW](#)
  - o [Examples of Program Changes that Should be Included in an Annual Report](#)

### Keep Your Records Accessible

You must keep your project records accessible for three years after the grant ends. If an issue arises, the Agency must be able to verify the records, which must include all data and fiscal information.

Under PHS policy your institution is required to maintain the following records for a minimum of three years:

- x Assurance approved by OLAW.
- x Minutes of IACUC meetings.
- x Records of IACUC activities and deliberations.
- x Minority IACUC views.
- x Documentation of protocols reviewed by the IACUC, and proposed significant changes to protocols (this documentation must be maintained for an additional three years after completion of animal activities).
- x IACUC semiannual program evaluations and facility inspections, including deficiencies identified and plans for correction.
- x Accrediting body determinations.

Through the [Freedom of Information Act](#) the public can access information about your grant. If someone formally requests nonproprietary information about your application, our FOIA office will provide it.

### Resources

- x [Animals in Research portal](#)
- x [Institutional Reporting to OLAW](#) or [OLAW's Frequently Asked Questions on the PHS Policy on Humane Care and Use of Laboratory Animals](#)
- x [PHS Policy on Humane Care and Use of Laboratory Animals Recordkeeping Requirements](#)
- x [Retention and Access Requirements for Records, 45 CFR Part 74.53](#)