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 All About Grants Tutorials.

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Other Resources

- See our other All About Grants tutorials

Requirements for Grantees Using Research Animals

If you are a principal investigator planning to use live vertebrate animals for research, research training, or biological testing, you must adhere to requirements in the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (referred to as PHS policy in this tutorial) and the Animal Welfare Act and Regulations.
The PHS policy is summarized in the brochure What Investigators Need to Know About the Use of Animals.

PHS's definition of research animal use includes production of custom antibodies and animals obtained for their tissues. Read more at Applicability of the PHS Policy.
Read about NIH animal research, policies, and crisis management at OER Animals in Research.
Peer reviewers will evaluate your application based on your compliance, so it's important to know what's expected of you and your institution.

When you apply for funding, you need to answer all five points in the Vertebrate Animals Section (VAS) of your grant application package. Most grant types, including research grants such as the R01 and Exploratory/Developmental Grant (R21) use electronic application. Find guidance on completing the VAS in the Worksheet for Review of the Vertebrate Animal Section (PDF).
Go to our Strategy for NIH Funding for beginning-to-end, step-by-step information about applying for the most common grant types.

If your application receives a fundable overall impact/priority score, have your animal use protocol reviewed and approved by an institutional animal care and use committee (IACUC), which evaluates your institution's animal research program.

To receive an award, you must have IACUC approval, and your institution must have an Animal Welfare Assurance approved by the NIH Office of Laboratory Animal Welfare (OLAW).
If you have domestic subaward agreements, those organizations also need IACUC approval and an assurance. Read more in the Subawards (Consortium Agreements) for Grants SOP.
For foreign awards and subawards, learn more at IACUC Requirements Vary for Domestic and Foreign Institutions.

To find out if your institution is assured, see OLAW's Domestic Institutions With a PHS Approved Animal Welfare Assurance or Foreign Institutions With a PHS Approved Animal Welfare Assurance. Domestic assurances are valid up to four years, then they must be renewed. Foreign assurances last up to five years and may be renewed only for current or pending awards involving vertebrate animals. Learn more at Is Your Institution Assured by OLAW?

It's also a good idea to find out if your institution has animal facilities accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International.

- AAALAC is a private, nonprofit organization; participation in its accreditation program sends the message that your institution is committed to high-quality animal care and

use.
- OLAW accepts AAALAC accreditation in lieu of some required documentation. Non-accredited institutions are required to provide a copy of their most recent semi-annual report of program review and facility inspection with their assurance.

Resources
- Animals in Research portal
    - Animals in Research SOPs
- The Agency's Application portal
    - Grant Application, Electronic SOP

Research Planning Is a Team Effort

Planning and teamwork are key to preparing a successful application. An animal research application requires a lot of work, so start early, leave time for unanticipated issues, and involve experts in your project from the beginning.
- Ask senior institutional animal care and use committee (IACUC) members to validate your ideas and methods.
- Consult with the attending veterinarian about available facilities, equipment, personnel, and products. For example, the veterinarian may know of a new analgesic that introduces fewer variables into the research.
- The institutional business official who submits your grant application should also be comfortable with your proposal.

These early consultations protect you and your institution. Since NIH allows just-in-time IACUC approval of animal use protocols, a PI can move a research project all the way through NIH initial peer review before an IACUC has a chance to see it.

If your IACUC has last-minute problems with your protocol, e.g., you have no biosafety level 4 facilities for Ebola research, you might not receive funding you otherwise could have received. See the Agency's Strategy for NIH Funding for more tips and advice on organizing and conveying your ideas.

Resources
- Animals in Research portal
- Sample Applications and Summary Statements

Consider Alternatives to Using Animals

When planning your research, consider whether you can achieve your scientific objectives while reducing the number of animals, refining the use of animals by minimizing their pain or distress, using a lower order species, or designing your experiments to avoid using animals at all.
USDA regulations require that investigators search the scientific literature for alternatives. Conduct this search while you plan your experiments. Include the search results in the animal study protocol for your IACUC's approval.

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

- Limit animal involvement by using the minimum number required to obtain valid results.
- Use non-animal methods, such as mathematical models, computer simulation, or *in vitro* biological systems.
- Avoid or minimize animal discomfort, distress, and pain as is consistent with sound scientific practices.
- Use appropriate sedation, analgesia, or anesthesia when your procedures will cause more than momentary pain or distress. Do not perform surgical or other painful procedures on non-anesthetized animals.
- If animals are necessary, select the lowest phylogenetic species appropriate for the experiment.

Resources

- Animals in Research portal
- National Library of Medicine
    - Bibliography: Alternatives to the Use of Live Vertebrates in Biomedical Research and Testing
    - Index Medicus
    - Medline Plus
    - PubMed
- OLAW Useful Links—Alternatives to Animal Testing

Check for Limits on Your Planned Animal Species or Source

As you plan, remember that NIH or HHS policies may affect your choice of species or source of animals. Review existing policy through the OLAW Web site, and for new policies, watch the *NIH Guide* and *Funding News*.

Here's a summary of the latest policies on chimpanzees, dogs, and cats:

Chimpanzees

See the November 18, 2015 NIH Director Statement, "NIH Will No Longer Support Biomedical Research on Chimpanzees." For background and information on the Chimpanzee Research Use Panel, see NIH's Use of Chimpanzees in NIH-Supported Research.

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:

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

For details, see the December 17, 2013, *Guide* notice.

Cats
Awardees must not use NIH funds to get cats from Class B dealers. See the February 8, 2012,*Guide* notice.

Resources

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

Is Your Institution Assured by OLAW
Before the Agency can award your grant, your institution and all performance sites involved in animal work must have an Animal Welfare Assurance on file with OLAW and provide certification of IACUC approval.

There are three types of Animal Welfare Assurances: domestic, interinstitutional, and foreign.

- **Domestic assurances** are for U.S. institutions that control their own facilities, conduct animal research, and have a complete animal care and use program in place, including a veterinarian and IACUC.
    - Domestic assurances typically remain in effect for up to four years and can be renewed.
- **Interinstitutional assurances** are for organizations that do not have their own animal facilities and will conduct animal activity at an assured institution, named as a performance site on the grant or contract.
    - The organizations agree to conduct the project according to the assurance of the covered organization.
    - Timeframes for these assurances are project specific and approved for the life of the project, up to five years. For example, a small business subcontracting animal work to a performance site must apply for a new interinstitutional assurance each time it successfully competes for a grant.
- **Foreign assurances** are for foreign institutions that are grantees or subaward partners to a domestic grantee.

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.

- 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.
- 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.

- If the institution doesn't have an assurance, OLAW will negotiate one with the grantee.
- 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.
- Read more in the Subawards (Consortium Agreements) for Grants SOP.

Resources

- Animals in Research portal
- Animals in Research SOPs
- OLAW—Obtaining an Assurance
- OLAW Topic Index—Animal Welfare Assurances

How to Get an Assurance

If your institution has never had an assurance, don't worry about it when you apply. The Agency grants management or program staff will contact OLAW to negotiate an assurance with your institution if you're likely to be funded based on peer review results, e.g., your percentile or overall impact/priority score is within the Agency's payline.

For that process, OLAW will send your institution an electronic packet that includes a sample assurance and PHS policy information. IACUC members and other experts at your institution should collaborate to draft the assurance, inserting your institution's animal policies and procedures where appropriate. Follow the format shown at OLAW's sample Animal Welfare Assurance for Domestic Institutions, Interinstitutional Assurance, or Animal Welfare Assurance

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 compliance with the PHS Policy and the *Guide for the Care and Use of Laboratory Animals*. Your application is barred from an award until an approved assurance is in place.
When reviewing your institution's animal welfare assurance, OLAW will evaluate several items, including veterinary care, personnel qualifications and training, occupational health and safety, IACUC procedures, and animal facilities and husbandry.

Resources

- Animals in Research portal
- OLAW—Obtaining an Assurance
- OLAW Topic Index—Animal Welfare Assurances

What OLAW Looks For

Veterinary Care

When reviewing your institution's domestic assurance, OLAW will evaluate several items, including applicability, lines of authority, veterinary care, IACUC procedures, personnel qualifications and training, occupational health and safety, and animal facilities and husbandry.
All veterinary programs should provide for the following:

- Access to animals and periodic assessment of their well-being.
- Appropriate facilities, personnel, equipment, and services.
- Treatment of diseases and injuries and the availability of emergency, weekend, and holiday care.
- Guidelines for animal procurement and transportation.
- Preventive medicine.
- Pre-surgical planning, training, monitoring, and post-surgical care.
- Pain relief, including analgesics, anesthetics, and tranquilizers.
- Euthanasia. Follow the *American Veterinary Medical Association Guidelines for the Euthanasia of Animals*.
- Drug storage and control.

The veterinarian must have program authority and responsibility for the institution’s animal care and use program, including access to all animals. He or she must also have the authority to implement the veterinary care program and oversee the adequacy of other aspects of animal care and use, e.g., animal husbandry, nutrition, sanitation practices, and hazard containment.
The size of the veterinary staff depends on the institution and the size and nature of its animal program. Consultant or part-time veterinary services may be appropriate for small programs with limited numbers of animals.
Do not include the veterinarian's resume as an assurance attachment. Instead, describe the veterinarian's qualifications in the assurance documentation. Follow the format shown at OLAW's sample Animal Welfare Assurance for Domestic Institutions.

Resources

- Animals in Research portal
- 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

- Animals in Research portal
- IACUC 101 Series
- OLAW Topic Index—Training of Staff
- OLAW Useful Links—Training and Education

Occupational Health and Safety

OLAW makes sure your institution has an occupational health and safety program for all personnel who work with animals. The program will depend on the facility, research activities, hazards, and animal species involved. Minimally, the program should include the following:

- Control and prevention strategies
- Hazard identification and risk assessment
- Facilities, equipment, and monitoring
- Personnel training
- Personal hygiene
- Animal experimentation involving hazards
- Personal protection
- Medical evaluation and preventive medicine for personnel
- Where appropriate, special precautions for personnel working with nonhuman primates

For guidelines on establishing and maintaining an effective safety program, check out *Occupational Health and Safety in the Care and Use of Research Animals*, published by the National Research Council.

Resources

- Animals in Research portal
- OLAW Topic Index—Occupational Health and Safety

Animal Facilities and Species Inventory

Institutions provide a facility and species inventory as part of their domestic assurance. Follow the format shown at OLAW's sample Animal Welfare Assurance for Domestic Institutions. OLAW uses this information to assess the nature and size of the animal care and use program

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

Resources

- 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's 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 8, IACUCs do the following:

- Review and approve animal use protocols, including significant changes to previously approved protocols.
    - 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.
    - For more information, see OLAW Topic Index—Protocol Review.
- Monitor the animal care and use program, including semiannual program review and facility inspection and report of the IACUC evaluations to the institutional official.
- Review concerns involving the care and use of animals.
- Make recommendations to the institutional official on the institution's animal program, facilities, or personnel training.
- Be authorized to suspend a previously approved protocol in instances of noncompliance.
- Evaluate compliance with institutional policies.
- Report annually and notify OLAW of suspensions and instances of serious noncompliance with PHS policy. See OLAW'sReporting Noncompliance for guidance on what an IACUC should report to OLAW.
- 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.

- **Domestic grantees with no foreign subawards**
    - Follow all the IACUC requirements outlined in this tutorial and by OLAW.
- **Domestic grantees with a foreign subaward**
    - The domestic institution's IACUC reviews and approves the animal activity as described in the application.
    - Both institutions must have an OLAW assurance.
    - The foreign subawardee should also follow the instructions in the next section.

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

Resources

- Subawards (Consortium Agreements) for Grants SOP
- Animals in Research portal
- PHS Policy on Humane Care and Use of Laboratory Animals Frequently Asked Questions—IACUC Composition, Functions, and Authority
- OLAW Topic Index—IACUC Composition, Functions and Authority

How Your IACUC Is Structured

Your IACUC will have at least five members, including people with the following backgrounds.

- A veterinarian with experience in laboratory animal science and medicine, who has direct or delegated authority and responsibility for activities involving animals at the institution.
- A practicing scientist experienced in research with animals.
- A person whose primary concerns are in a nonscientific area, e.g., an ethicist, lawyer, or member of the clergy.
- A person not affiliated with the institution who represents community interests and who is not a laboratory animal user.

Other IACUC members are usually faculty members and fellow researchers who are familiar with the issues you are facing and can serve as resources to help you prepare the best possible application.

Resources

- Animals in Research portal
- PHS Policy on Humane Care and Use of Laboratory Animals FAQs—IACUC Composition, Functions and Authority
    - What are the IACUC membership criteria?
- OLAW Topic Index—IACUC Composition, Functions and Authority

Write Your Protocol

Coordinate writing your application and protocol. Be sure to write and submit your protocol early enough for the IACUC review. When you send your protocol to your IACUC, it is extremely important that the substantive information is consistent with what you proposed in your grant application. Depending on how your IACUC tracks protocols, administrative details like PI name and application title may vary or be omitted.

Most IACUCs require investigators to submit information about proposed animal use on an institutional protocol review form. Before writing your protocol, consult with the attending veterinarian on the latest technologies and procedures that could improve your approach. Also

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

- **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.
- **Justification for using animals.** Describe why an animal model is necessary. If you're studying a human health problem, state its cause, existing therapies, and the potential contribution of your experiments to further its understanding. Use lay language, explaining all medical terms and defining acronyms the first time you use them.
- **Justification for species.** Tell IACUC members why you chose one species over others. You should generally use the most appropriate and least sentient species capable of providing the data you need. The following is a typical hierarchy of sentient animal species.
    1. Non-human primates, such as monkeys, marmosets, and baboons.
    2. Large animals, such as cats, dogs, and pigs.
    3. Rabbits.
    4. Rodents, such as hamsters, rats, and mice.
    5. Non-mammalian vertebrates, such as poultry, reptiles, and fish.

Your rationale for using a species may be size or availability; the existence of previous work or laboratory data that validates the use of a certain animal model; or the availability of reagents.

- **Justification for number of animals.** Request the amount of animals you need and explain why. Use the minimum number needed to yield statistically significant results.
- **Consideration of alternatives.** Convince IACUC members that you have adequately explored alternative methods. Use techniques to minimize pain and distress. These are known as "refinements" to your protocol. List databases you searched and when, citations derived, and the keywords or search strategy. List other sources, such as journal articles, presentations, and colleagues.
- **Description of animal procedures.** Include non-surgical methods, such as injections and sample collections; surgical methods, such as suturing and anesthesia; and other measures, such as pre-anesthetic fasting, drugs, and care during recovery.
- **Assurance that qualified staff will perform work.** Name all personnel who will be working on your study, along with their animal research experience and familiarity with your proposed procedures. If you or someone on your staff does not have the necessary experience, list experts at your institution who can provide training. Your IACUC will have to verify that this training took place before animal work can begin.
- **Endpoint criteria.** Choose endpoints that achieve the aims of the study and avoid unnecessary pain and distress. Include the criteria you will use to decide when to intervene or end animal use in the study, e.g., pain that cannot be controlled with analgesics, tumor size, and stage of disease. Interventions include euthanasia, treatment, or discontinuance of procedure. Many institutions have default criteria, so check with your IACUC for guidance.

Resources

- Animals in Research portal
- ClinicalTrials.gov
- Index Medicus
- Medline Plus
- PubMed
- Sample Animal Study Proposal, OLAW
- 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 SF 424 Application Guide.

Go to Show Resources, Institutional Support in 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's Domestic Institutions With a PHS Approved Animal Welfare Assurance or Foreign Institutions With a PHS Approved Animal Welfare Assurance.

Resources

- Animals in Research portal
- 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 the 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:

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

Follow the instructions for Vertebrate Animals in the SF 424 Application Guide.
NIH's Worksheet for Review of the Vertebrate Animal Section (VAS) (PDF) 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 Just-In-Time in the Strategy for NIH Funding for more advice on drafting your application.

Resources

- Animals in Research portal
- 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 How 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

- Review Criteria SOP
- Animals in Research portal
- Sample Applications and Summary Statements
- CSR
    - Roster Index for Regular Standing Study Sections and Continuing SEPs
    - 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 can issue your award. See Research Animals Involvement Codes for a complete list.
Codes that result in a bar to award must be resolved before the Agency can release your award.

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

Resources

- Animals in Research portal
- Bars to Grant Awards SOP
- Know What a Summary Statement Means in the Strategy for NIH Funding

The Agency Will Send a Just-in-Time Request

After you've cleared initial peer review, we'll send you a request for just-in-time information if your application is in the fundable range.

For animal research, you will need to send in your certification of IACUC approval and resolve any reviewer concerns before the Agency can issue your award. See If You Have Animal Research Documentation and Prepare Your Just-In-Time Information in the Strategy for NIH Funding.

Resources

- Animals in Research portal
- Paylines and Funding
- Sample Request for Just-in-time Information
- When to Contact an Program Officer

Reporting Requirements During Your Award

During the life of your grant, there are several reporting requirements the Agency requires. For example, you'll need to get your certification of IACUC approval at least every three years.

For general reporting requirements, start reading at Your Reporting Requirements in the Strategy for NIH Funding.

Resources

- Animals in Research portal
- Strategy for Your Grant in the Strategy for NIH Funding
- *NIH Grants Policy Statement*
- When to Contact an Program Officer

IACUCs Monitor Your Progress

By signing your application, your institutional official promises the federal government that your institution will comply with all terms and conditions of award, including those covering animal care and use. Monitor your work closely. As PI, you are accountable for all activities involving animals during the project.

Your approved animal use protocol is a contract between you and your IACUC, stipulating that your project will follow all institutional polices and procedures. You must obtain IACUC approval *before* you make any significant changes to the research, including the following:

- Switching from nonsurvival to survival surgery.
- Introducing procedures that result in greater pain, distress, or degree of invasiveness.
- Using different anesthesia, analgesics, sedation, or experimental substances.
- Changing PI, species, study objectives, or methods of euthanasia.

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 signficant change.
If you're planning to make a significant change to your project, also contact your program officer right away. The NIH Grants Policy Statement requires grantees to obtain prior approval from NIH for changes in scope. For a list, see Some Actions Require Our Approval in the Strategy for NIH Funding.
You will also need to get a new IACUC approval every three years; some IACUCs may require it sooner. Institutional officials and IACUCs do not have authority to extend an IACUC approval beyond its expiration date. Conducting research in the absence of a valid IACUC approval constitutes noncompliance with PHS policy and it is reportable to OLAW.

Resources

- Animals in Research portal
- *NIH Grants Policy Statement*
- OLAW—Reporting Noncompliance
- Significant Changes section of the OLAW Topic Index—Protocol Review

You'll Have Semiannual Reviews and Inspections

As part of its semiannual program review and facility inspection, your IACUC will conduct routine assessments of institutional animal activities.
This review covers institutional policies and responsibilities, IACUC membership and functions, and IACUC record keeping and reporting procedures. It also looks at the adequacy and appropriateness of animal environment, housing, and management; veterinary care; staff training; emergency preparedness; and occupational health and safety programs.
A facility review is a physical inspection of buildings, areas, and vehicles (including satellite facilities housing animals for more than 24 hours) used for confinement, transport, maintenance, breeding, or experiments, including surgery.
Your lab may be inspected as part of a facility review, or your IACUC may randomly visit to verify that you are following your protocol.
IACUCs report the results of their program evaluation and facility inspection to the institutional official for animal welfare. These reports describe any deficiencies found and include plans and schedules for correcting each one.
Institutional officials submit semiannual IACUC reports to OLAW only if requested or if the institution is submitting a new or renewal assurance and is not accredited by the Association for Assessment and Accreditation of Laboratory Animal Care.

Resources

- Animals in Research portal
- *Institutional Animal Care and Use Committee Guidebook*
- *NIH Grants Policy Statement*
- Semiannual Program Review and Facility Inspection Checklist
- Semiannual Report to the Institutional Official

Avoid Suspension of Animal Activities

Your IACUC can suspend your project if it finds serious or continuing noncompliance with PHS policy or your institution's assurance or deviations from the approved protocol or the *Guide for the Care and Use of Laboratory Animals*.
If you have a subaward agreement, noncompliance at the subaward organization can also provoke a suspension. See theSubawards (Consortium Agreements) for Grants SOP for more information.
Your IACUC will convey its reasons for a suspension to the institutional official for animal welfare, who will take corrective measures and report the situation to OLAW.
OLAW can withdraw approval of your institution's assurance though this is extremely rare. Should this happen, your institution would become ineligible for spending NIH funds on research activities involving animals, and the Agency may seek to recover its monies. NIH may allow expenditures for the maintenance and care of animals.
OLAW can also place restrictions on an institution's assurance until compliance problems are fully resolved. OLAW always emphasizes corrective rather than punitive actions and will restrict or withdraw approval of an assurance only if an institution's efforts to correct its problems are unsuccessful.

Resources

- Animals in Research portal
- *NIH Grants Policy Statement*
- OLAW—Reporting Noncompliance
- OLAW Topic Index—Suspensions

Know Your IACUC's Reporting Requirements

At least once every 12 months your institution is required to submit a report from your IACUC to OLAW, signed by the institutional official for animal welfare and IACUC chairperson. The report includes the following.

- Changes in the institution's program of animal care and use.
- Change of institutional official or IACUC membership.
- Dates when the IACUC conducted its semiannual program evaluations and facility inspections.
- Minority IACUC views, i.e., dissenting opinions attached to required reports.

Annual reports are due by January 31 for the previous calendar year. Your institution sends the report as a PDF email attachment to olawarp@mail.nih.gov. If you have questions or need assistance, call OLAW at 301-496-7163.
In addition to the annual report, your institutional official for animal welfare must notify OLAW promptly of any of the following:

- Serious or continuing noncompliance with PHS policy.
- Serious departures from the *Guide for the Care and Use of Laboratory Animals*. Note that exceptions listed in the *Guide*are **not** departures.
- IACUC suspensions.

Send preliminary and final reports of noncompliance, deviations, and IACUC suspensions to olawdco@mail.nih.gov.
Learn more about the reporting process and see a sample final report at OLAW's Reporting

Noncompliance.

Resources

- Animals in Research portal
- OLAW
    - Annual Report to OLAW
    - 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:

- Assurance approved by OLAW.
- Minutes of IACUC meetings.
- Records of IACUC activities and deliberations.
- Minority IACUC views.
- 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).
- IACUC semiannual program evaluations and facility inspections, including deficiencies identified and plans for correction.
- Accrediting body determinations.

Through the Freedom of Information Act, the public can access information about your grant. If someone formally requests non-proprietary information about your application, our FOIA office will provide it.

Resources

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

In Conclusion

We hope these pages have helped you. If you're looking for more in-depth information, refer to the Animals in Research portal. If you have questions that weren't answered here, contact OLAW or Communicating With the Agency—How to Get Help.

This site is part of the Agency's outreach to its extramural research community. Let us know how you liked the site and what other information or resources you'd like to see online—email deaweb@niaid.nih.gov.