

Preparing a Small Business Application Involving Vertebrate Animals

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OFFICE OF EXTRAMURAL RESEARCH | OFFICE OF THE DIRECTOR | NATIONAL INSTITUTES OF HEALTH

NIH Mission



*To seek fundamental knowledge about the nature and behavior of living systems and the **application of that knowledge to enhance health, lengthen life, and reduce illness and disability.***

The Small Business Program helps NIH accelerate discoveries from bench to bedside

Congressionally Mandated Programs

\$1.2 Billion Dedicated Funding via Set-aside from NIH's R&D Budget



\$1.1 billion

SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

Set-aside program for small business concerns to engage in federal R&D -- with potential for commercialization

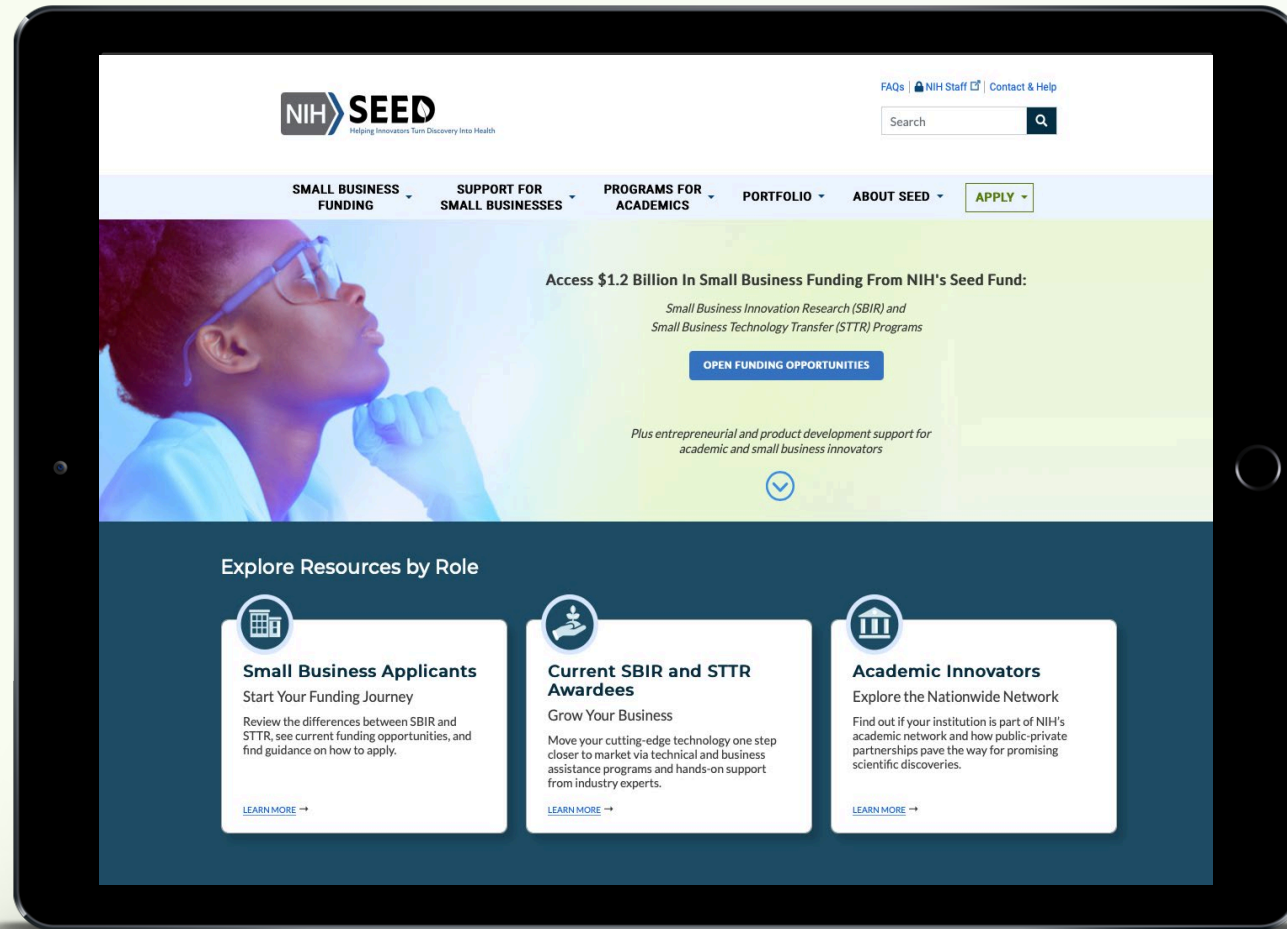


\$150
million

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM

Set-aside program to facilitate cooperative R&D between small business concerns and US research institutions -- with potential for commercialization

Small Business Program Website



<http://seed.nih.gov>

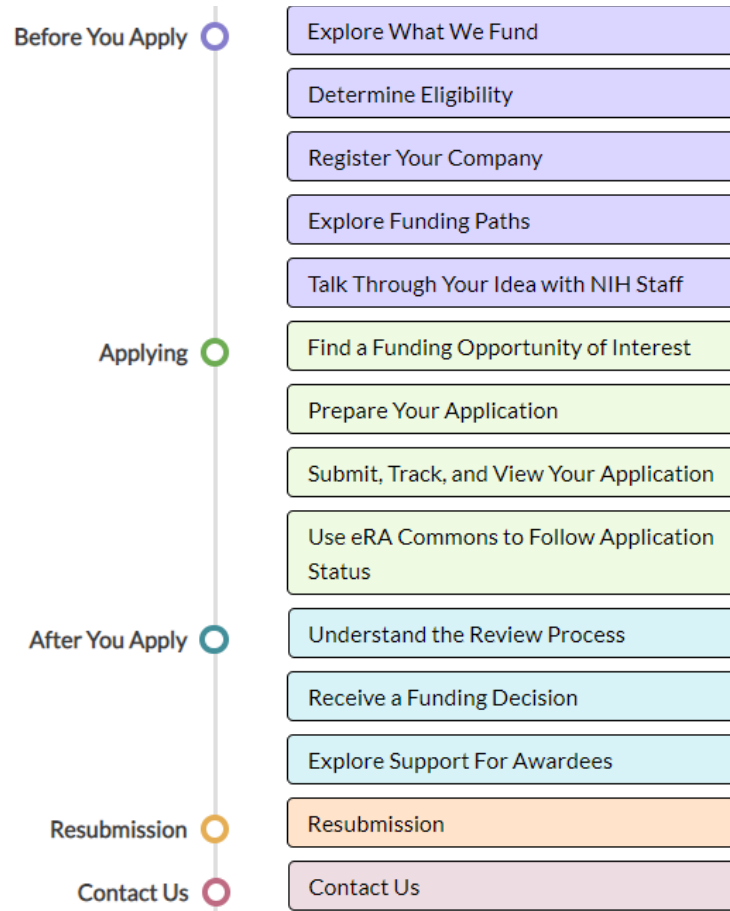
Resources

SMALL BUSINESS FUNDING

HOW TO APPLY

Find step-by-step instructions to apply for SBIR and STTR grants along with contact touchpoints at each step.

<https://seed.nih.gov/small-business-funding/how-to-apply>



Links to:

[Application Instructions](#)

[Annotated Form Set](#)

[Sample Applications](#)

Programs for Applicants:

- **NIH Applicant Assistance Program**
- **Health Disparities Pre-Application (HDPReAPP) Program**

<https://seed.nih.gov/aboutseed/diversify-entrepreneurial-workforce>

Most Important Piece of Advice

NIH SEED
Helping Innovators Turn Discovery Into Health

FAQs | NIH Staff | Contact & Help

Search

SMALL BUSINESS FUNDING | SUPPORT FOR SMALL BUSINESSES | PROGRAMS FOR ACADEMICS | PORTFOLIO | ABOUT SEED | APPLY

Access \$1.2 Billion In Small Business Funding From NIH's Seed Fund:
Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs

OPEN FUNDING OPPORTUNITIES

Plus entrepreneurial and product development support for academic and small business innovators

New to SBIR & STTR?

Learn How to Apply for SBIR or STTR Funding
Find step-by-step instructions on how to apply for more than \$1 billion in funding.

LEARN MORE | READ FAQ

Small Business Research Areas

24 of the NIH's Institutes fund small business R&D projects through the SBIR and STTR Programs.
Select an Institute to learn more about their mission and how they support small businesses.

Select Funding Institute | Learn More

INSTITUTE-SPECIFIC SBIR AND STTR CONTACTS

Talk to a Program Officer at least a month before the application deadline!

List of SBIR Program Managers:
<https://seed.nih.gov>

Not sure who to contact?

Research Portfolio Online Reporting Tools (RePORT): <https://report.nih.gov/>

Email: SEEDinfo@nih.gov



OFFICE OF LABORATORY ANIMAL WELFARE (OLAW): PREPARING A SMALL BUSINESS APPLICATION INVOLVING VERTEBRATE ANIMALS



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Office of Laboratory Animal Welfare (OLAW)
Office of Extramural Research (OER)
National Institutes of Health (NIH)



National Institutes of Health
Office of Laboratory Animal Welfare

LEARNING OBJECTIVES

- ✓ Summarize OLAW's oversight responsibilities
- ✓ Describe the origins and requirements of the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy)
- ✓ Define live vertebrate animal
- ✓ Understand requirements of the Health and Human Services Acquisition Regulations (HHSAR) and National Institutes of Health Grants Statement Policy (NIH GPS)
- ✓ Identify the PHS Policy requirements for an institution receiving funding involving the use of live vertebrate animals
- ✓ Identify the three types of Animal Welfare Assurances
- ✓ Discuss the Vertebrate Animals Section (VAS)
- ✓ Discuss IACUC verification requirements
- ✓ Understand compliance oversight requirements
- ✓ 21st Century Cures Information
- ✓ Additional educational opportunities



OLAW Mission

*The Office of Laboratory Animal Welfare (OLAW) provides guidance and interpretation of Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), supports educational programs, and monitors compliance with the Policy by Assured institutions and PHS funding components to **ensure the humane care and use of animals** in PHS-supported research, testing, and training and thereby contributing to the quality of research.*



OLAW'S RESPONSIBILITIES

Oversee
implementation of
the PHS Policy

Provide
interpretation
and guidance

Negotiate Animal
Welfare
Assurances

Evaluate compliance

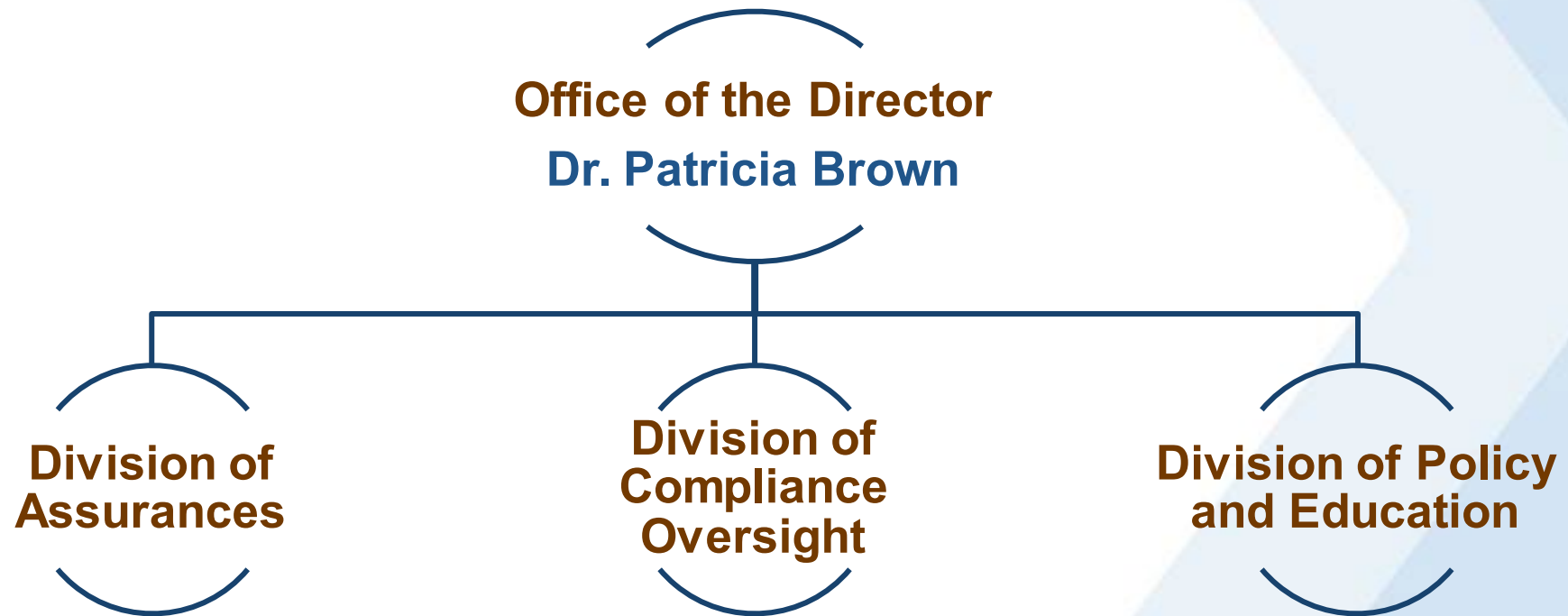
- Institutional self reporting
- Third party allegations
- Whistleblowers

Educational activities

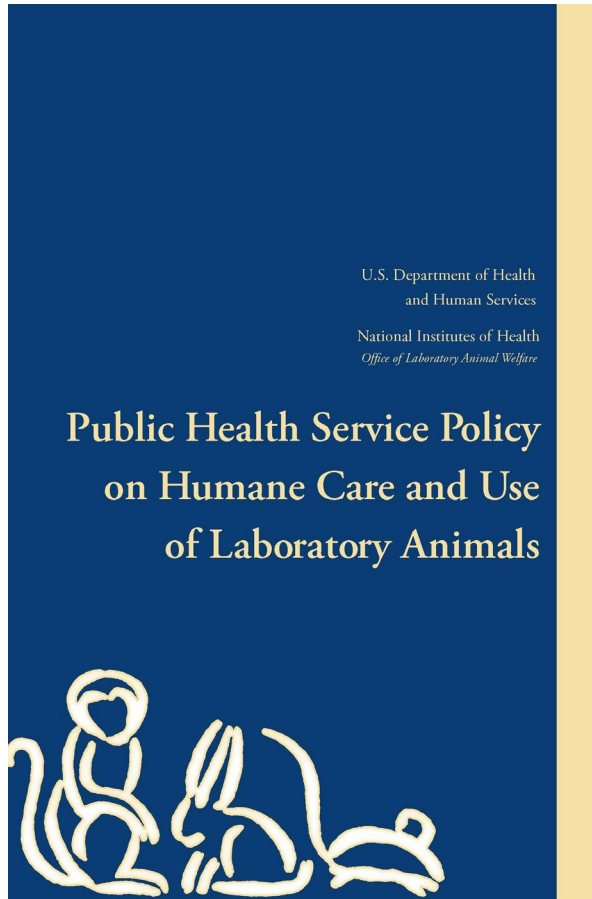
- Workshops/Training
- Resources
- Webinars



OFFICE OF LABORATORY ANIMAL WELFARE (OLAW)



Public Health Service (PHS) Policy: INSTITUTIONAL RESPONSIBILITIES



Animal Welfare Assurance

Functions of the Institutional Animal Care and
Use Committee (IACUC)

Review of PHS-Conducted or Supported
Research Project

Information Required in Applications and
Proposals for Awards Submitted to PHS

Record-keeping requirements

Reporting requirements

THE PHS POLICY APPLIES TO ANIMAL WORK CONDUCTED OR SUPPORTED BY PHS AGENCIES AND...

...agencies that have opted in through
memoranda of understanding with
OLAW.



National Institutes
of Health



National Institutes of Health
Office of Laboratory Animal Welfare

PHS POLICY DEFINITION

Animal defined as:

“any live vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes”.



DOES PHS POLICY APPLY?

Which studies are considered
Vertebrate Animal Use?

- Embryonated egg
- Tadpole
- Zebrafish
- Cow spleen from slaughterhouse
- Custom antibodies from goat
- Chimpanzee behavior study
- Octopus nerve study
- Mosquito malaria study

“Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.”



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Office of Laboratory Animal Welfare

<https://www.wallpaperflare.com/shallow-focus-photography-of-octopus-selective-focus-photo-of-red-octopus-wallpaper-zupqp>

The Institutional Animal Care and Use Committee (IACUC)

The IACUC is responsible for oversight of the animal care and use program and its components as described in the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals ([Policy](#)) and the *Guide for the Care and Use of Laboratory Animals* ([Guide](#)). Its oversight functions include an ongoing assessment of animal care and use.





IACUC Review of PHS-Supported Research Projects (IV.C. 1 a -g)

1. Avoid or minimize pain and distress
2. Appropriate sedation, analgesia, or anesthesia
3. Identification of humane endpoints
4. Appropriate housing that contributes to animals' health
5. Medical care
6. Trained personnel
7. Euthanasia methods consistent with American Veterinary Medical Association Guidelines.

PHS Policy Elements

Information Required in Applications and Proposals for Awards Submitted (IV.D.)

1. Identification of the species and approximate number of animals;
2. The rationale for involving animals, and for the appropriateness of the species and numbers used
3. A complete description of the proposed use of the animals;
4. A description of procedures designed to assure that discomfort and injury to animals is limited, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated;
5. A description of any euthanasia method to be used.



HHS ACQUISITION REGULATIONS

48 CFR CHAPTER 3

- 370.4 Acquisitions Involving the Use of Laboratory Animals

This subpart applies to all research, research training, biological testing, housing and maintenance, and other activities involving live vertebrate animals conducted under contract. Additional information can be found in Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals

- 352.270-5b Care of Live Vertebrate Animals

Before undertaking performance of any contract involving animal-related activities where the species is regulated by the United States Department of Agriculture (USDA), the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR sections 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer



NIH GRANTS POLICY STATEMENT

4.1.1 Animal Welfare Requirements



National Institutes of Health
Office of Extramural Research

NIH GRANTS POLICY STATEMENT

REVISED DECEMBER 2022. This document applies to all NIH grants and cooperative agreements for budget periods beginning on or after October 1, 2022.

You are here: 4 Public Policy Requirements, Objectives and Other Appropriation Mandates > 4.1 Public Policy Requirements and Objectives > 4.1.1 Animal Welfare Requirements

Search NIH Grants Policy Statement

4.1.1 Animal Welfare Requirements

The PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy) requires that an approved Animal Welfare Assurance be on file with the Office of Laboratory Animal Welfare (OLAW) at the time of award for all recipient organizations receiving PHS support for research or related activities using live vertebrate animals. Recipient organizations must establish appropriate policies and procedures to ensure the humane care and use of animals, and bear ultimate responsibility for compliance with the PHS Policy in all PHS supported activities.

The PHS Policy incorporates the U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training, and requires the recipient to maintain an animal care and use program based on the Guide for the Care and Use of Laboratory Animals. An Institutional Animal Care and Use Committee (IACUC) appointed by the Chief Executive Officer or designee, is federally mandated to oversee the institution's animal program, facilities, and procedures (Public Law 99-158, Sec. 495).

The PHS Policy defines "animal" as any live, vertebrate animal used or intended for use in research, research training, experimentation, biological testing or related purposes.

Applications from organizations proposing the use of animals are incomplete if they do not thoroughly address the use of vertebrate animals required in the Research Plan of the application. If the involvement of animals is indefinite at the time of application, the applicant should provide an explanation and indicate when it is anticipated that animals will be used. If an award is made, prior to conducting any animal activities the recipient must submit to the NIH awarding IC for prior approval the detailed information about the use of animals as required in the Research Plan of the application, and meet the Assurance and IACUC approval requirements of the PHS Policy.

Noncompeting and competing awards are prohibited from using NIH funds to procure cats from USDA Class B dealers. The procurement of cats may only be from USDA Class A dealers or other approved legal sources.

NIH funds may not be used to procure or support the use of dogs from Class B dealers. Dogs used in NIH-supported research may only be from USDA Class A dealers or other approved legal sources. Any costs incurred in violation of this policy are unallowable and will be subject to a cost disallowance.

No costs for activities with live vertebrate animals may be charged to NIH if there is not a valid Animal Welfare Assurance and IACUC approval of the activity.

The PHS Policy does not supersede applicable State or local laws or regulations that impose more stringent standards for the care and use of animals in research. All recipient organizations are required to comply, as applicable, with the regulations (9 CFR, Subpart A) issued by the U.S. Department of Agriculture under the Animal Welfare Act, as amended, 7 U.S.C. 2131 et seq., and other Federal statutes and regulations relating to animals.

4.1.1.1 Animal Welfare Assurance Requirements

An Animal Welfare Assurance is the document submitted by an institution assuring institutional compliance with the PHS Policy. OLAW is responsible for requesting, negotiating, approving or disapproving, and, as necessary, restricting or withdrawing approval of Assurances.

When an applicant institution does not have an Animal Welfare Assurance, the Authorized Organization Representative's signature on the application constitutes declaration that the institution will submit an Assurance when requested by OLAW. Upon such request, the institution shall prepare the Assurance as instructed by OLAW and in accordance with the PHS Policy, and the authorized IACUC shall review those components of the application related to the care and use of animals. Except in certain circumstances, the Assurance must be submitted to and approved by OLAW in order for the IC to award the grant. No costs for activities with live vertebrate animals may be charged to NIH grants in the absence of a valid Assurance on file with OLAW.

If the prime recipient does not have an Assurance and the animal activities will be conducted at an Assured institution named as a performance site, the recipient must obtain an Inter-institutional Assurance from OLAW. Under the Inter-institutional Assurance, the recipient and performance site agree that the research will be conducted under the auspices and program of animal care and use of the performance site's Assurance.

4.1.1.2 Verification of IACUC Approval

NIH will delay an award for research involving live vertebrate animals until the recipient organization and all performance sites are operating in accordance with approved Animal Welfare Assurances and the recipient has provided verification of IACUC approval of those sections of the application that involve use of vertebrate animals. IACUC approval must have been granted within three years of the budget period start date to be valid; however, IACUCs may determine that continuing review on a more frequent basis is appropriate.

Verification of IACUC approval may be filed at any time before award in accord with Just-in-Time procedures, unless required earlier by the IC. Therefore, following peer review and notification of impact score/percentile, applicant organizations with approved Assurances may wish to

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 - 4.1.1 Animal Welfare Requirements**
 - 4.1.1.1 Animal Welfare Assurance Requirements
 - 4.1.1.2 Verification of IACUC Approval
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National Institutes of Health
Office of Laboratory Animal Welfare



-content/uploads/2018/03/FullSize_Poster_Mice.jpg

Requirements for research, research training, experimentation or biological testing for related purposes involving live vertebrate animals

1. **Animal Welfare Assurance** for the applicant organization and all performance sites
2. A complete **Vertebrate Animals Section (VAS)**
3. **Verification** that the **IACUC has reviewed and approved** those sections of the application or technical proposal that involve the use of vertebrate animals



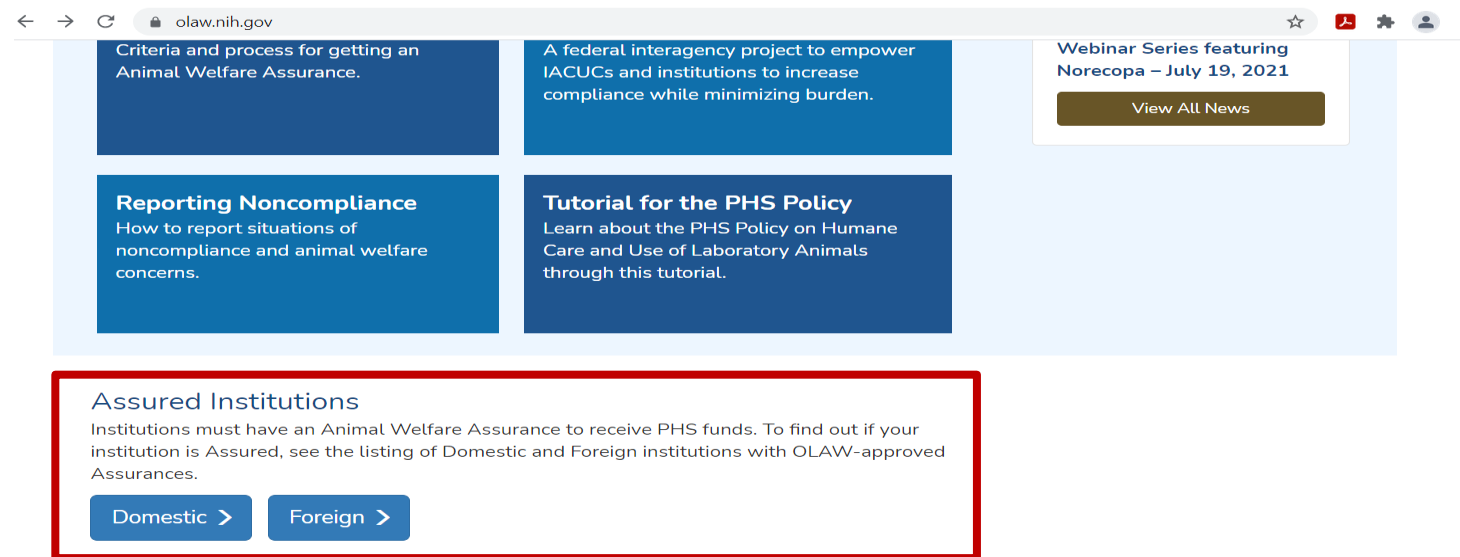
Animal Welfare Assurance

IV.A.1.g. “a synopsis of training or instruction in the humane practice of animal care and use, as well as training or instruction in research or **testing methods that minimize the number of animals required to obtain valid results and minimize animal distress**, offered to scientists, animal technicians, and other personnel involved in animal care, treatment, or use.”



TYPES OF ANIMAL WELFARE ASSURANCES

- Domestic Assurance
- Interinstitutional Assurance
- Foreign Assurance



The screenshot shows the olaw.nih.gov website with several navigation options:

- Criteria and process for getting an Animal Welfare Assurance.
- A federal interagency project to empower IACUCs and institutions to increase compliance while minimizing burden.
- Webinar Series featuring Norecopa – July 19, 2021 (with a View All News button).
- Reporting Noncompliance: How to report situations of noncompliance and animal welfare concerns.
- Tutorial for the PHS Policy: Learn about the PHS Policy on Humane Care and Use of Laboratory Animals through this tutorial.

A red box highlights the "Assured Institutions" section, which includes the text: "Institutions must have an Animal Welfare Assurance to receive PHS funds. To find out if your institution is Assured, see the listing of Domestic and Foreign institutions with OLAW-approved Assurances." Below this text are two buttons: "Domestic >" and "Foreign >".

<https://olaw.nih.gov/guidance/obtaining-an-assurance.htm>



DOMESTIC ASSURANCE



https://www.amprogress.org/wp-content/uploads/2016/06/AMP_Fat-Rat-QR.pdf

- Domestic institution controls their own animal facilities
- Conducts animal research on-site
- Has a complete animal care and use program
 - Institutional Official (IO)
 - IACUC
 - Veterinarian
- Requires PHS, NSF, NASA funding
- Requested by the funding component for negotiation
- Remains in effect for up to 4 years and can be renewed
- Assurance signed by Institutional Official (IO)



INTERINSTITUTIONAL ASSURANCE

- Awardee institution does not have an animal care and use program
- Animal work conducted at Assured Institution
- Valid for the life of the award, up to 5 years (project specific)
- Requires PHS, NSF, NASA funding
- Requested by the funding component for negotiation

FOREIGN ASSURANCE



- Foreign institution controls their own animal facilities
- Conducts animal research on-site
- Has an animal care and use program with institutional signing official
 - Guided by International Guiding Principles for Biomedical Research Involving Animals (CIOMS)
- Follows applicable governing laws, regulations and policies from the country of origin, listed on the Assurance document
- Requires PHS, NSF, or NASA funding
- Requested by the funding component for negotiation
- Remains in effect for up to 5 years and can be renewed
- Assurance signed by Institutional Official (IO)

CONSORTIUM AGREEMENTS: SUB-AWARDS



Photo courtesy of Dr. Cathy Schuppli, DVM, MSc, PhD,
University of British Columbia

- Prime awardee is accountable and must ensure the following for all animal performance sites:
 - Assurance
 - IACUC approval (dated within 3 years)
- Animal welfare requirements apply to all consortium participants and sub-projects



Photo: https://fbresearch.org/wp-content/uploads/2018/03/FullSize_Poster_Mice.jpg

Requirements for research, research training, experimentation or biological testing for related purposes involving live vertebrate animals

1. **Animal Welfare Assurance** for the applicant organization and all performance sites
2. A complete **Vertebrate Animals Section (VAS)**
3. **Verification** that the **IACUC has reviewed and approved** those sections of the application or technical proposal that involve the use of vertebrate animals

VAS TRAINING RESOURCES FOR APPLICANTS

- Notices
- Articles & References
- Commentary
- Frequently Asked Questions
- Topic Index
- Fast Facts**
- Departures from the Guide
- Obtaining an Assurance
- Reporting Noncompliance
- Significant Changes
- Vertebrate Animals Section
- ARENA/OLAW IACUC Guidebook

Fast Facts

- Departures from the Guide
Reporting requirements for deviations from the provisions of the *Guide*
- Obtaining an Assurance
Criteria and process for getting an Animal Welfare Assurance
- Reporting Noncompliance
How to report situations of noncompliance and animal welfare concerns
- Significant Changes
How to handle significant changes to animal activities
- ~~Vertebrate Animals Section~~
VAS requirements, checklist, and detailed instructions for applicants and reviewers

Policies and Laws | Guidance | Education | Resources


Home » Guidance » Vertebrate Animals Section

Vertebrate Animals Section

The following guidance is provided to assist applicants and offerors in preparing the Vertebrate Animals Section (VAS) for submission to the NIH, and to assist reviewers in evaluating the VAS of applications and proposals. Here you will find an overview of the requirements, a checklist for applicants and reviewers, detailed instructions, and responsibilities of applicants, reviewers, and NIH staff.

4/21 VAS in Grant Applications
What is the VAS?

The VAS is the portion of the grant application in which the investigator ensures the animal activity is appropriate for the proposed research and adheres to standards of humane care and use of laboratory animals.



We are pleased to announce the availability of a new [online training module](#) on the Vertebrate Animals Section (VAS) in grant applications.

We want to assist investigators and reviewers in recognizing both the required components of the VAS and the components that are no longer required, with the goals of:

- increasing the number of applications deemed acceptable
- reducing time spent submitting and reviewing extraneous information

This interactive module can be completed in 20 – 30 minutes and includes:

- an overview of the requirements
- a checklist for applicants and reviewers
- detailed instructions

<https://olaw.nih.gov/guidance/vertebrate-animal-section.htm>



Vertebrate Animals Section: 1st Criteria



Photo: https://www.amprogress.org/wp-content/uploads/2016/06/AMP_White-Rat-QR.pdf

1) Description of Procedures

- Provide a concise description of the proposed procedures
- Identify the species, strains, ages, sex and total number of animals by species
- Provide the source of dogs and cats, if used



Photo: <https://fbresearch.org/animal-research/>

Vertebrate Animals Section: 2nd Criteria

2) Justifications

- Provide justification that the species are appropriate for the proposed research
- Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, *in vitro*)



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Office of Laboratory Animal Welfare

Vertebrate Animals Section: 3rd and 4th Criteria



Photo courtesy of Dr. Cathy Schuppli, DVM, MSc, PhD, University of British Columbia

3) Minimization of Pain and Distress

Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury

4) Method of Euthanasia

If investigators are proposing to use a method of euthanasia that is not consistent with AVMA guidelines, they must describe the method and provide a scientific justification.



Photo: https://fbresearch.org/wp-content/uploads/2018/03/FullSize_Poster_Mice.jpg

Requirements for research, research training, experimentation or biological testing for related purposes involving live vertebrate animals

1. **Animal Welfare Assurance** for the applicant organization and all performance sites
2. A complete **Vertebrate Animals Section (VAS)**
3. **Verification** that the **IACUC has reviewed and approved** those sections of the application or technical proposal that involve the use of vertebrate animals

VERIFICATION OF IACUC APPROVAL

- An award for research involving live vertebrate animals will be delayed until the recipient organization and all performance sites have provided **verification** of IACUC approval
 - The date of IACUC approval must not be more than 36 months prior to receiving an award involving animals
- It is an **institutional** responsibility to ensure congruence between the grant or contract and the IACUC approved protocol
 - (HHSAR) solicitation provision [352.270-5a](#) and contract clause [352.270-5b](#)
 - NIH GPS [4.1.1.2](#) Verification of IACUC Approval
- **No costs** for activities with live vertebrate animals may be charged to the grant or contract if there is no Assurance and no valid IACUC approval



What Investigators Need to Know About the Use of Animals



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 (Policy) when using live vertebrate animals. PHS Policy incorporates the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, the *Guide for the Care and Use of Laboratory Animals*, and the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. 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 applies to extramural and intramural activities supported by any PHS agency, including the National Institutes of Health (NIH), the Food and Drug Administration, the Centers for Disease Control and Prevention, and the Department of Health and Human Services. All funding mechanisms, including research and training grants, cooperative agreements, and contracts, conducted at domestic and foreign institutions, are covered by the Policy. Additionally, activities conducted or supported by the Department of Veterans Affairs, the National Aeronautics and Space Administration, and the National Science Foundation are covered by the Policy under memoranda of understanding by these agencies with NIH.

Good animal care and good science go hand in hand.

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 Act and Regulations, 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 NIH Office of Laboratory Animal Welfare (OLAW).

Investigator Responsibilities

Investigators are accountable for the protection of the research animals in their care from the earliest stages of planning until a study is completed, including:

- 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 according to the protocol;
- Complying with institutional policies and procedures;
- Addressing significant changes to the use of animals in progress reports; and
- Addressing changes in the use of animals that may be a potential change in scope, including changes in performance site.

Applying for Funding

The proposed involvement of vertebrate animals is evaluated as part of the peer review process. Applicants must provide the following in grant applications:

1. Concise description of the proposed procedures to be used that involve vertebrate animals, including species, strains, ages, sex, and total number of animals by species to be used.
2. Justification that the species are appropriate for the proposed research and explanation why research goals can't be accomplished using an alternative model.
3. Description of the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.
4. Indication if the euthanasia method is consistent with AVMA Guidelines and a description of the method and scientific justification if it is not.

<https://olaw.nih.gov/sites/default/files/InvestigatorsNeed2Know.pdf>



National Institutes of Health
Office of Laboratory Animal Welfare

COMPLIANCE OVERSIGHT



National Institutes of Health
Office of Laboratory Animal Welfare

REPORTABLE ISSUES DATA ANALYSIS

OLAW opened 5,492 cases from 2016 – 2021

Institutional self-reports

Allegations from employees

Reports from other oversight agencies

OLAW review of Assurance, Annual Report

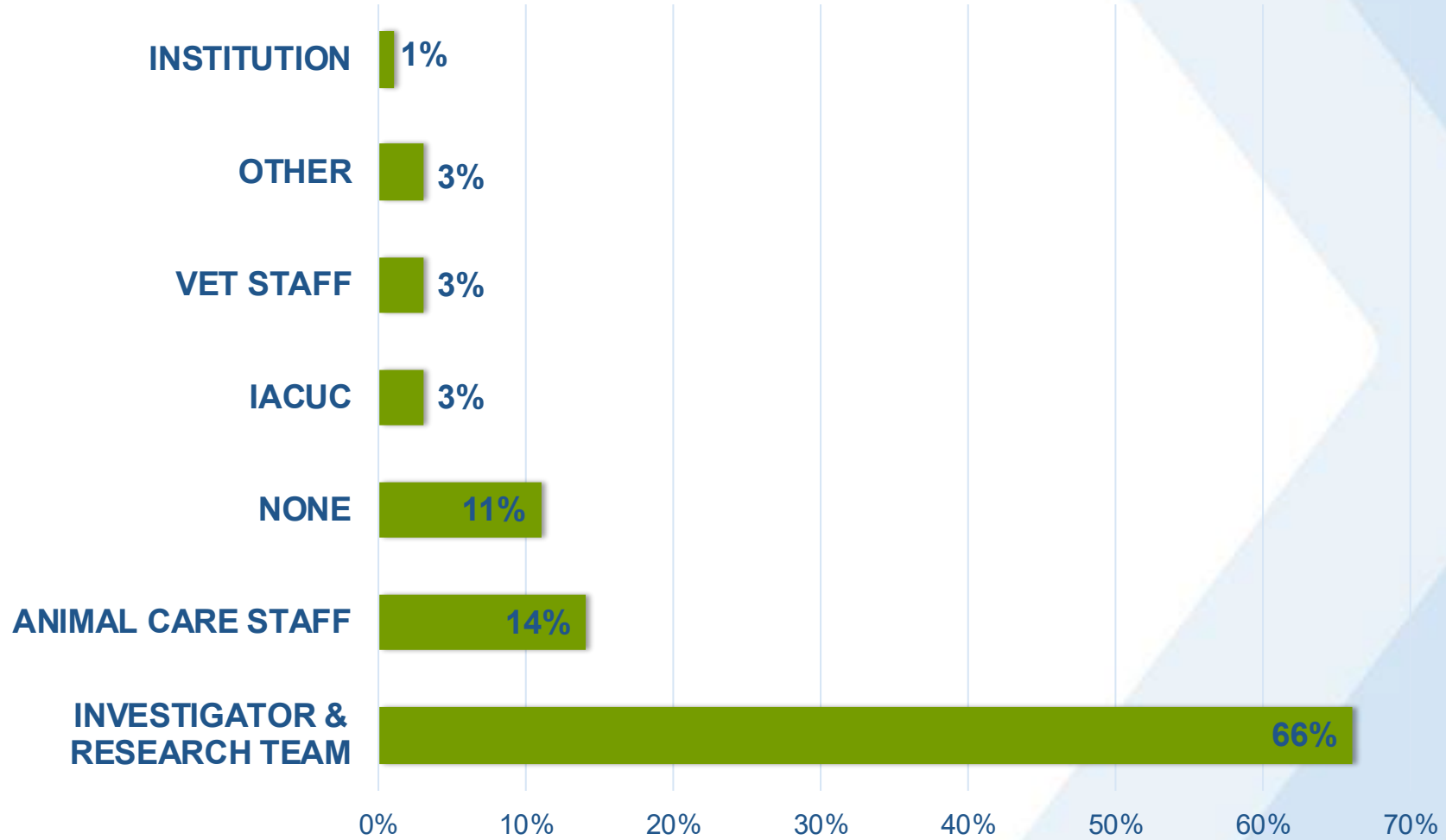
Reports from funding component

Allegations from other sources

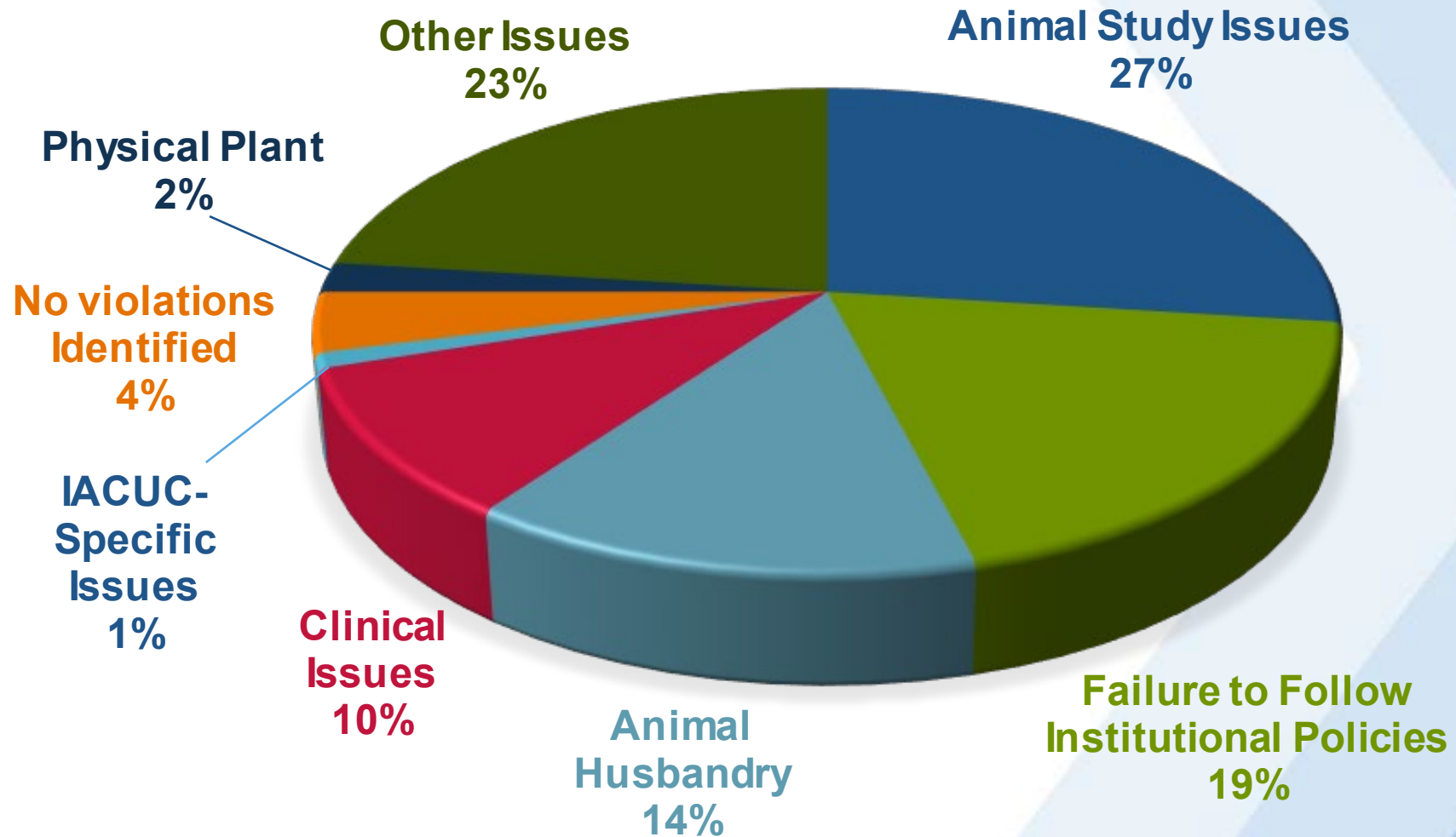
OLAW opened 966 cases in 2021



INDIVIDUALS RESPONSIBLE FOR REPORTABLE ISSUES



TYPES OF REPORTABLE INCIDENTS 2021



PREVENTING AVOIDABLE NONCOMPLIANCE

- Absence of a valid Assurance on file with OLAW
- Absence of valid IACUC approval
 - Failure to obtain IACUC approval for animal activity
 - Failure to obtain IACUC approval for significant changes prior to implementing
 - Continuing animal activities after IACUC approval has expired
 - Continuing animal activities after suspension of IACUC approval



IMPLICATIONS OF NONCOMPLIANCE

- Corrective actions and improved systems
- Restrict / withdraw approval of Assurance
- Special terms and conditions
- **Cost disallowance**
- Suspension / termination of award
- Criminal prosecution





REPORTING IS A COOPERATIVE PROCESS

- ✓OLAW will provide assistance and guidance.
- ✓Institution must demonstrate that corrective actions are being implemented.
- ✓OLAW will evaluate appropriateness of the actions in correcting and preventing the reportable issue.
- ✓Self-reporting is part of enforced self-regulation.

REPORTING NONCOMPLIANCE



Email OLAW, Division of Compliance Oversight at:

- olawdco@mail.nih.gov

Call OLAW, Division of Compliance Oversight at:

- 301-594-2921 or 301-594-2061

Review OLAW's website on reporting noncompliance at:

- olaw.nih.gov/guidance/reporting-noncompliance.htm

<https://grants.nih.gov/grants/guide/notice-files/not-od-05-034.html>



REDUCING REGULATORY BURDEN

21st Century Cures Act



<https://olaw.nih.gov/21st-century-cures-act.htm>



National Institutes of Health
Office of Laboratory Animal Welfare

OLAW EDUCATIONAL RESOURCES

Office of Laboratory Animal Welfare

Policies and Laws ▾ Guidance ▾ Education ▾ Resources ▾

Home » Education

Education

Get information on the OLAW Online Seminars program, webinar recordings & podcasts, and international workshops and conferences.

Workshops & Conferences
IACUC 101 Series
Webinars & Podcasts
ICARE Project & Workshops
Training Modules

Education Resources

- Workshops & Conferences
- IACUC 101 Series
- Webinars & Podcasts

<https://olaw.nih.gov/education>



UPCOMING EDUCATIONAL OPPORTUNITIES

03/08/2023 Virtual	Animal Welfare Information Center (AWIC)	<u>Meeting the Requirements of the Animal Welfare Act Workshop</u>
05/03/2023 - 05/04/2023 Virtual	Animal Welfare Information Center (AWIC)	<u>Meeting the Requirements of the Animal Welfare Act Workshop</u>
06/08/2023 New York, NY	Scientists Center for Animal Welfare (SCAW)	<u>IACUC Training Workshop</u>



TRIVIA TIME!




National Institutes of Health
Office of Laboratory Animal Welfare

SCENARIO 1 – PART 1

Bob's Biotech (BB) will be the awardee for an award involving animal research.

BB does not have their own animal facility but has made preliminary plans with *Lark University* to conduct the animal studies in Lark University's facility.

What are the requirements for the contract to allow the animal activities to proceed?

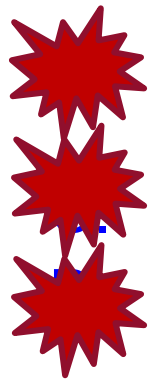
- A. Completed VAS for animal work to be conducted at Lark University
- B. List Lark University as a performance site
- C. Both sites need an Assurance (Lark University needs a Domestic Assurance, Bob's need an IA with Lark University)
- D. IACUC approval from Lark University
-  E. All of the above

SCENARIO 1 – Part 2

Lark University is no longer able to conduct the agreed upon studies so Bob's Biotech identifies BioCorps, a U.S. contract research organization, as the new animal performance site.

What is necessary?

A. Nothing. The funds were already dispersed, and changes happen all the time with science



Bob's Biotech must inform the funding component to obtain approval for a change in animal performance site


BioCorps must have an approved Domestic Assurance

Bob's Biotech must have an approved Interinstitutional Assurance with BioCorps who provides verification of IACUC approval

SCENARIO 2

The PI at *Research Inc.* indicates that she will **not** be performing any animal activities but in the application she indicates she will be obtaining custom rabbit antibodies from *Alpha Omega Enterprises*.

What are the requirements for the grant to allow the animal activities to proceed?

- A. Complete VAS for Research Inc. animal activity
 - B. List Alpha Omega as a performance site
 - C. Both sites need an Assurance (Domestic for Alpha Omega and IA for Research Inc.)
 - D. IACUC approval from Alpha Omega
-  All of the above

SCENARIO 3

Beaker Scientific, Inc. is submitting an application and completed the VAS for a contract for research involving animals. The animal activity will be conducted at **Expert Bio.**, a CRO. Expert Bio has an Assurance on file with OLAW. The PI, Dr. Beaker, says Beaker Scientific has a Memorandum of Understanding (MOU) with Expert Bio in place and he is ready to conduct the research when he receives the award.

What are the requirements for the grant to allow the animal activities to proceed?

A. Dr. Beaker is correct because he has a MOU

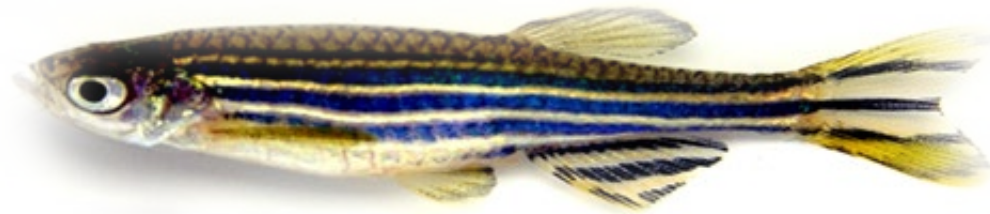
 B. Dr. Beaker will need an Interinstitutional Assurance through OLAW and IACUC approval


C. Dr. Beaker will need IACUC approval with the MOU

D. Dr. Beaker will only need an Interinstitutional Assurance through OLAW

SCENARIO 4

Dr. Rhinder is working on conducted an exciting new study looking at the effect of a chemotherapeutic agent in zebrafish. When submitting the contract application, he is unsure if he should check “yes” or “no” for live vertebrate animal use and he calls you for help. How would you advise him?



-  A. Yes, all zebrafish would be considered vertebrate animals
- B. No, because they are not a “warm-blooded” species
- C. Is this a trick question?

PHS Policy does apply to zebrafish larvae from immediately after hatching (typically 3 days post fertilization [dpf] under optimal conditions)

The PHS Policy, NIH GPS and HHSAR requirements when making an award involving live vertebrate animals include:



- A. Animal Welfare Assurance for the applicant organization and all performance sites
- B. Verification that the IACUC has reviewed and approved those sections of the application that involve the use of live vertebrate animals
- C. A completed Vertebrate Animals Section (VAS) in the application

All of the above

Photo: https://www.amprogress.org/wp-content/uploads/2016/06/AMP_Fat-Rat-QR.pdf

Information Required in Applications and Proposals for Awards Submitted (IV.D.)

1. Identification of the species and approximate number of animals to be used;
2. The rationale for involving animals, and for the appropriateness of the species and numbers used
3. A complete description of the proposed use of the animals;
4. A description of procedures designed to assure that discomfort and injury to animals is limited, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated;
5. A description of any euthanasia method to be used.





Photo courtesy of Dr. Cathy Schuppli, DVM, MSc, PhD, University of British Columbia

Is the submitted VAS acceptable?

1. Description of procedures (describe animals and their use):

Pharmacokinetic studies and surgical procedures will be performed on mice at a Contract Research Organization (CRO) that is yet to be determined. 100 mice will be used in total.

2. Justifications (describe choice of species and lack of alternative model):

Mice are inexpensive and are one of the least sentient laboratory animals.

3. Minimization of Pain and Distress (describe interventions):

Moribund mice will be examined by the veterinarian and decisions on disposition will be made at that time.





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Unacceptable as written

LEARNING OBJECTIVES

- ✓ Summarize OLAW's oversight responsibilities
- ✓ Describe the origins and requirements of the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy)
- ✓ Define live vertebrate animal
- ✓ Understand requirements of the Health and Human Services Acquisition Regulations (HHSAR) and National Institutes of Health Grants Statement Policy (NIH GPS)
- ✓ Identify the PHS Policy requirements for an institution receiving funding involving the use of live vertebrate animals
- ✓ Identify the three types of Animal Welfare Assurances
- ✓ Discuss the Vertebrate Animal Section (VAS)
- ✓ Discuss IACUC verification requirements
- ✓ Understand compliance oversight requirements
- ✓ 21st Century Cures Information
- ✓ Additional educational opportunities



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Q&A Session

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