

Introduction to OLAW



Paula Knapp, BS, MT, CPIA
Senior Assurance Officer
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health (NIH)

**AWIC Workshop: Meeting the Information Requirements of the Animal Welfare Act
October X, 2022**

Learning Objectives

https://media.wired.com/photos/5926df4f7034dc5f91bece6c/191:100/w_1280,c_limit/GettyImages-95012042.jpg

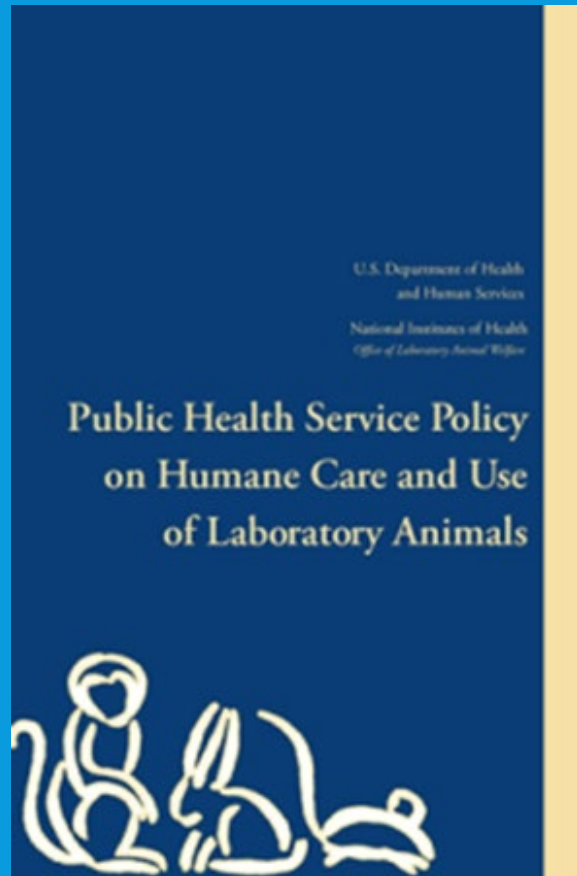


1. Associate the PHS Policy with your institution.
2. Name the office responsible for administering and coordinating the PHS Policy
3. Identify federal funding agencies that comply with the PHS Policy.
4. Apply the PHS Policy definition of a live vertebrate animal.
5. Reflect on key elements of the PHS Policy and how they relate to alternatives to animals and 3Rs.
6. Name the resources that feed the PHS Policy standards and recognize the requirements they have for alternatives to animals and the 3Rs.

Health Research Extension Act (HREA) of 1985

Public Law 99-159 charges NIH Director to establish **guidelines for the proper care and treatment of laboratory animals**

PHS Policy



“It is the Policy of the Public Health Service (PHS) to require institutions to establish and maintain proper measures to ensure the appropriate care and use of all animals involved in research, research training, and biological testing activities conducted or supported by the PHS.” (I. Introduction)

Health Research Extension Act (HREA) of 1985

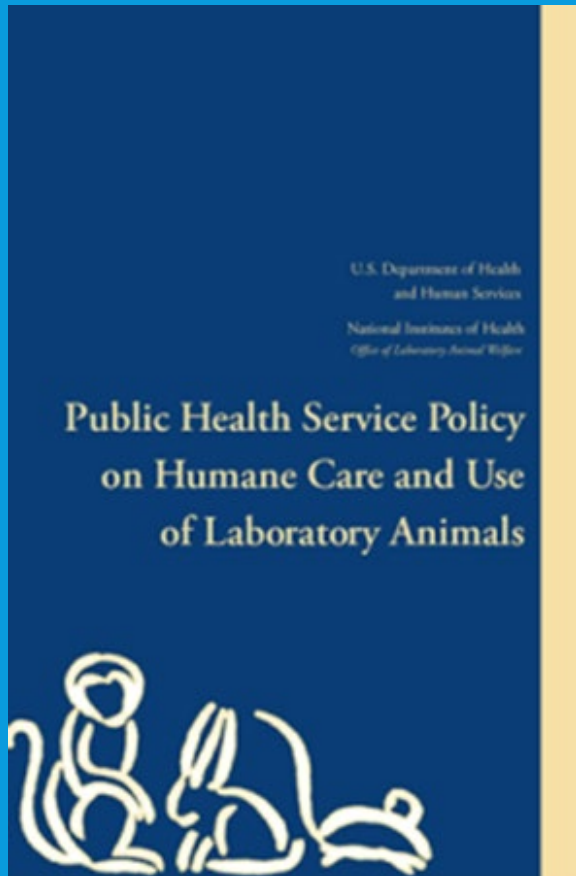
Public Law 99-159 **charges NIH Director** to establish guidelines for the proper care and treatment of laboratory animals

OLAW Mission Statement

The Office of Laboratory Animal Welfare (OLAW) provides guidance and interpretation of the 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, thereby contributing to the quality of PHS-supported activities.



PHS Policy Applicability



“This Policy is applicable to all **PHS-conducted or supported activities involving animals**, whether the activities are performed at a PHS agency, an awardee institution, or any other institution and conducted in the United States, the Commonwealth of Puerto Rico, or any territory or possession of the United States. Institutions in foreign countries receiving PHS support for activities involving animals shall comply with this Policy, or provide evidence to the PHS that acceptable standards for the humane care and use of the animals in PHS-conducted or supported activities will be met. No PHS support for an activity involving animals will be provided to an individual unless that individual is affiliated with or sponsored by an institution which can and does assume responsibility for compliance with this Policy, unless the individual makes other arrangements with the PHS. This Policy does not affect applicable state or local laws or regulations which impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act, and other Federal statutes and regulations relating to animals.” (II. Applicability)

What does “PHS conducted or supported” mean?

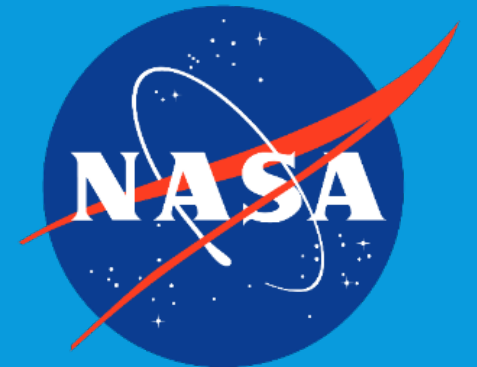
- National Institutes of Health (NIH)
- Centers for Disease Control and Prevention (CDC)
- Federal Drug Administration (FDA)
- Biomedical Advanced Research and Development Authority (BARDA)



What is “PHS conducted or supported” mean?

MOU's with:

- National Science Foundation (NSF)
- Department of Veteran Affairs (VA)
- National Aeronautics and Space Administration (NASA)



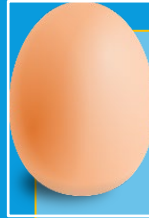
What does “activities involving animals” mean?



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



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



Pre-hatched egg



Tadpole



Zebrafish



Cow spleen from slaughterhouse



Custom goat antibodies



Chimp behavior study



Octopus



Mosquito malaria study

Quick Recap

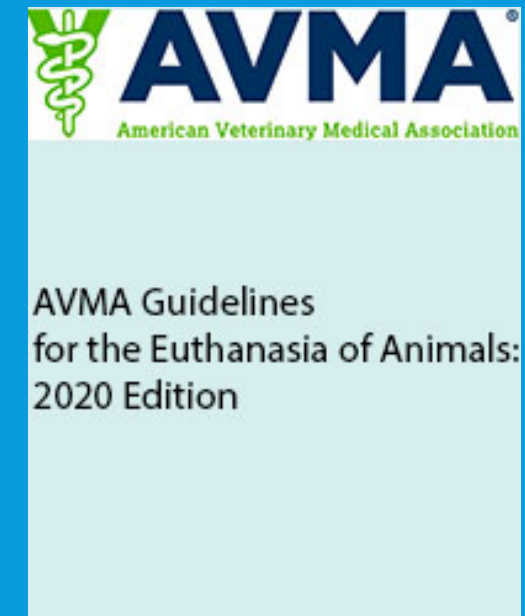
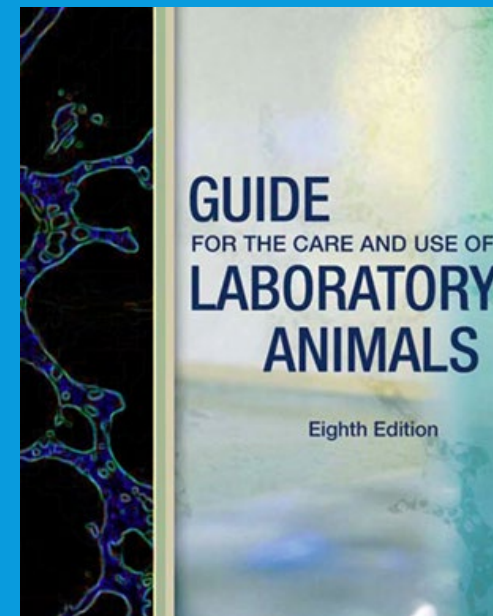
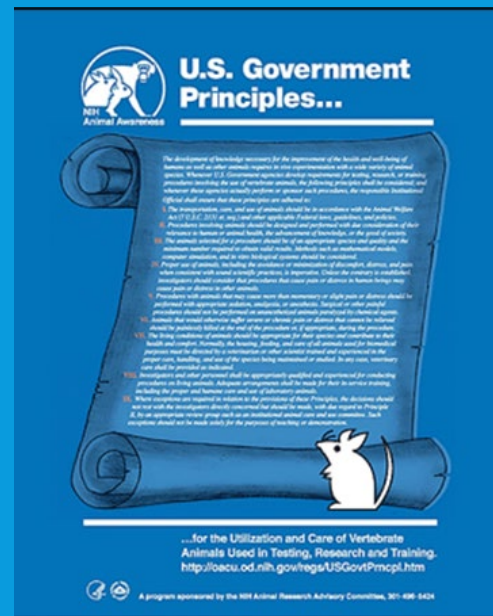
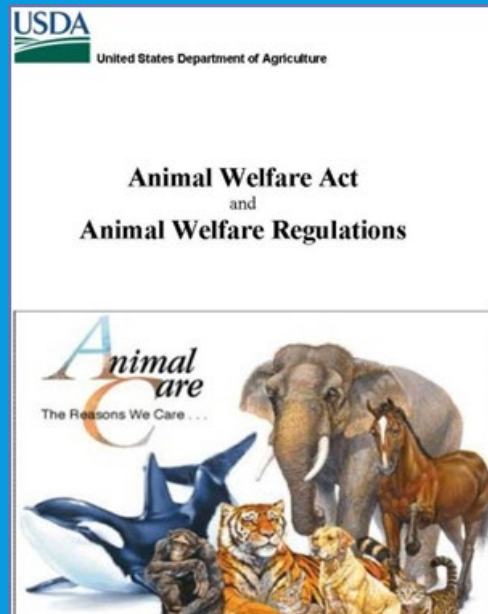
HREA 1985 charges Director of NIH (**OLAW**) to establish guidelines (**PHS Policy**)

for animal activity (**live vertebrate animal used or intended for use in research, research training, experimentation, or biological testing**)

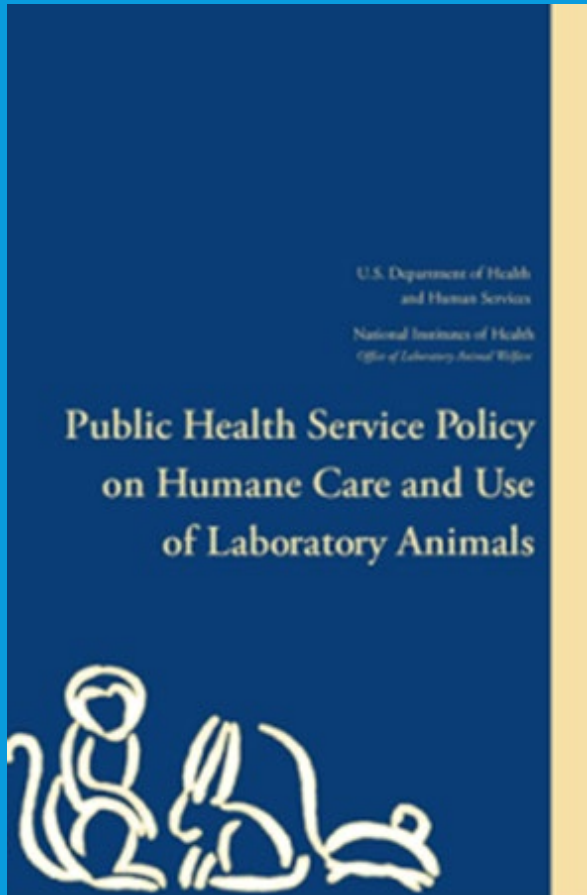
conducted or supported by PHS (**NIH, CDC, FDA, BARDA, VA, NSF, NASA**).



PHS Policy Standards for Animal Care and Use



PHS Policy Key Elements



Animal Welfare Assurance

Functions of the IACUC

Review of PHS conducted or supported research

What is required in proposals for PHS awards

Record keeping and reporting requirements

Reporting requirements

Animal Welfare Assurance



Contract detailing how an institution will implement the requirements of the PHS Policy.

olaw.nih.gov

A screenshot of the NIH Office of Laboratory Animal Welfare (OLAW) website. The header features the NIH logo and the text "National Institutes of Health Office of Laboratory Animal Welfare" and "Office of Laboratory Animal Welfare". A search bar is in the top right. A navigation menu on the left includes "Policies and Law", "Guidance", "Education", and "Resources". Below the menu is an illustration of various animals (dog, cow, monkey, rabbit, mouse). The main content area has a teal banner for the "21st Century Cures Act – Animal Care and Use in Research". Below this are four blue boxes: "Obtaining an Assurance" (circled in red), "ICARE Project & Workshops", "Reporting Noncompliance", and "Tutorial for the PHS Policy". A right sidebar contains "OLAW News" with recent updates. The footer mentions "Assured Institutions" with links for "Domestic" and "Foreign".

NIH National Institutes of Health
Office of Laboratory Animal Welfare

Office of Laboratory Animal Welfare

Search
About OLAW Contact Us

Policies and Law
Guidance
Education
Resources

21st Century Cures Act – Animal Care and Use in Research
Actions to reduce administrative burden on investigators conducting animal activities while maintaining research integrity and the protection of animals.

Obtaining an Assurance
Criteria and process for getting an Animal Welfare Assurance.

ICARE Project & Workshops
A federal interagency project to empower IACUCs and institutions to increase compliance while minimizing burden.

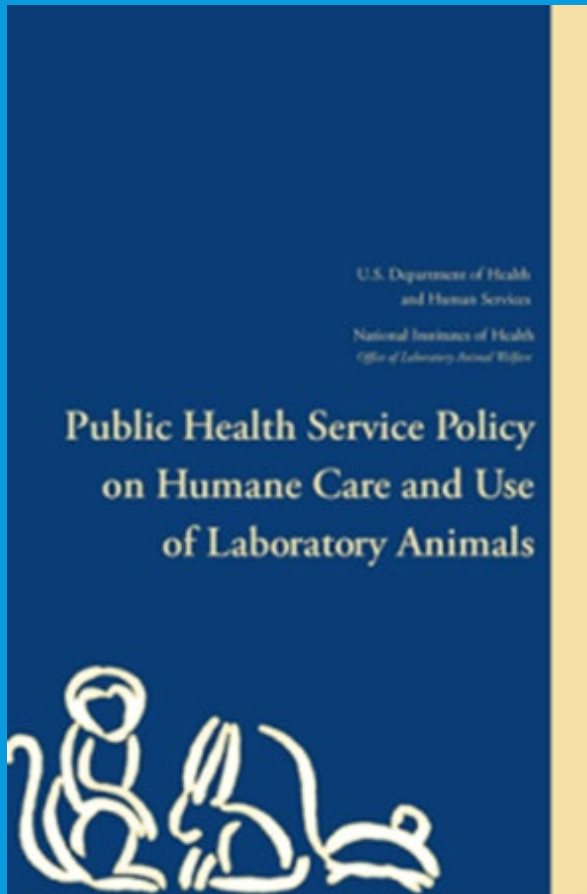
Reporting Noncompliance
How to report situations of noncompliance and animal welfare concerns.

Tutorial for the PHS Policy
Learn about the PHS Policy on Humane Care and Use of Laboratory Animals through this tutorial.

OLAW News
Commentary on Lab Animal Protocol Review Column: October 2022 Issue
Annual Reports to OLAW due December 1, 2022
New Resource Available: NIH's Animals in Research Page
OLAW Welcomes New Staff
View All News

Assured Institutions
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.
Domestic > Foreign >

PHS Policy Key Elements



Animal Welfare Assurance

Functions of the IACUC

Review of PHS conducted or supported research

What is required in proposals for PHS awards

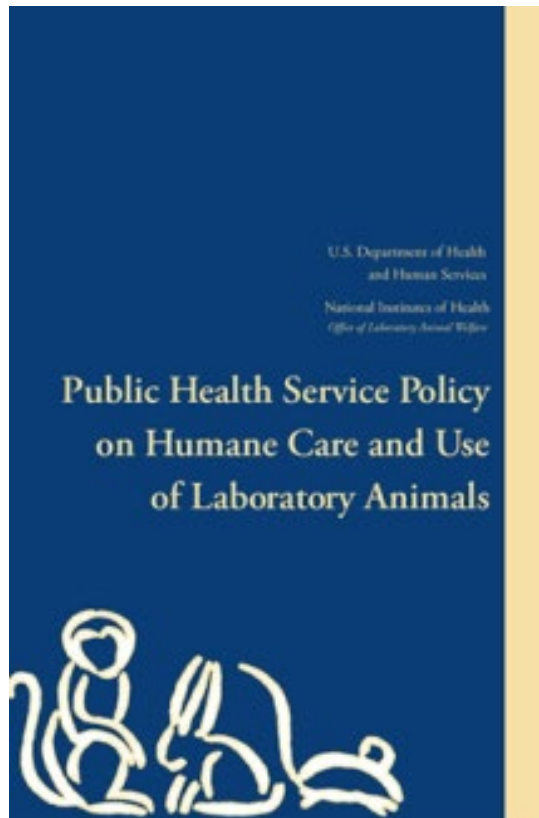
Record keeping and reporting requirements

Reporting requirements

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

- a. Avoid or minimize pain and distress
- b. Appropriate sedation, analgesia, or anesthesia
- c. Identification of humane endpoints
- d. Appropriate housing that contributes to animals' health
- e. Medical care
- f. Trained personnel
- g. Euthanasia methods consistent with American Veterinary Medical Association Guidelines.

Test Your Knowledge



What legislation created the PHS Policy?

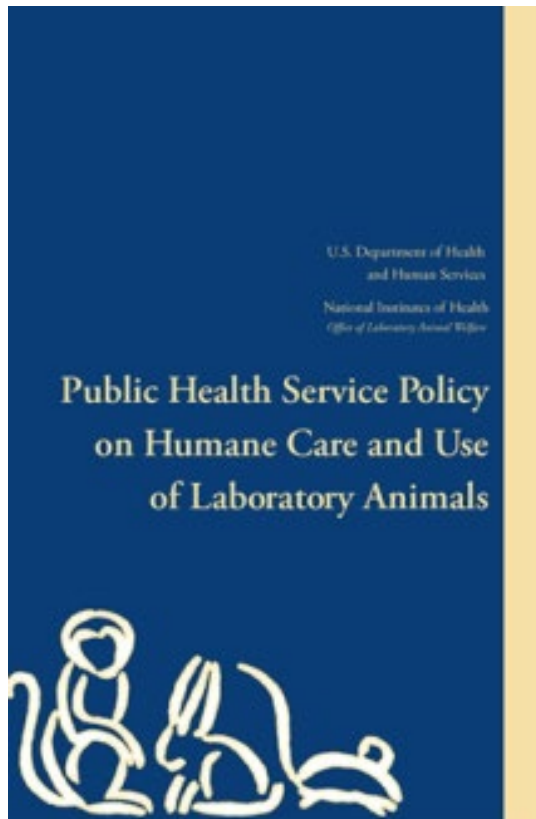
Who is responsible for its implementation?

1.

2.

3.

Test Your Knowledge

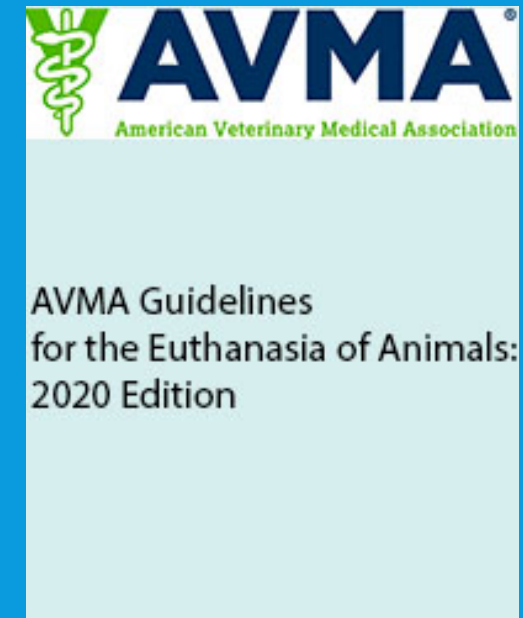
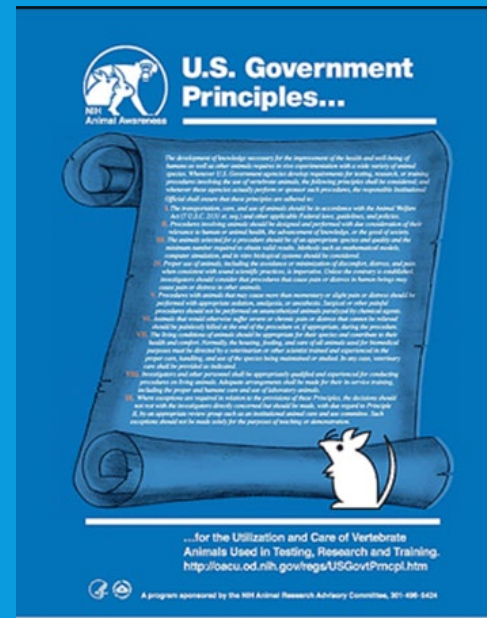
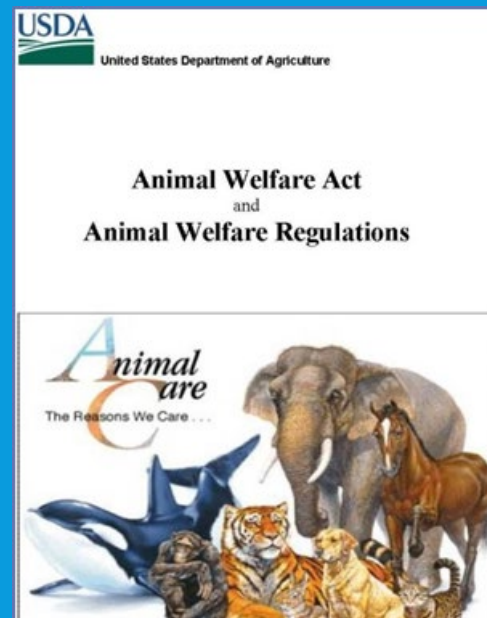
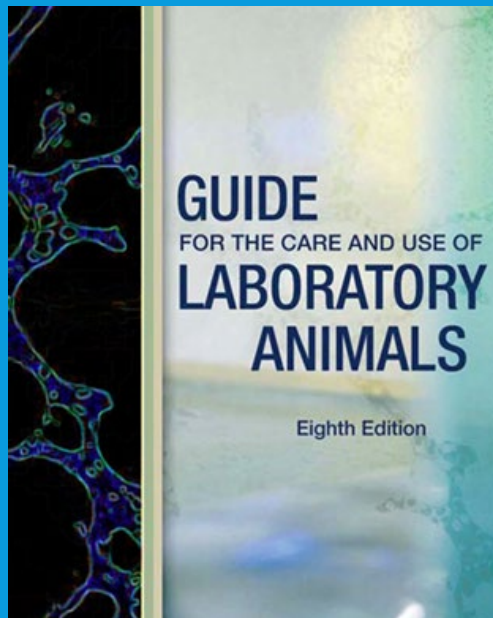


What legislation created the PHS Policy?
[Health Research Extension Act of 1985](#)

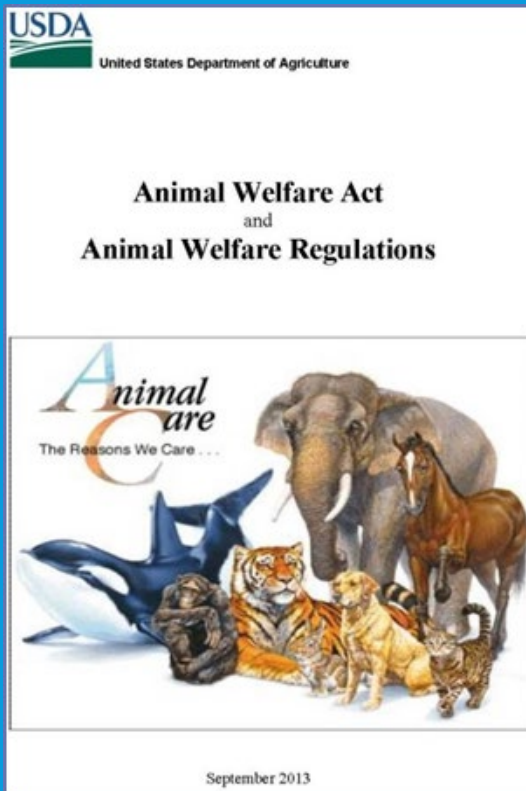
Who is responsible for its implementation?

1. [NIH OLAW](#)
2. [Federal Funding Agencies](#)
3. [Awardee Institutions](#)

PHS Policy Standards for Animal Care and Use

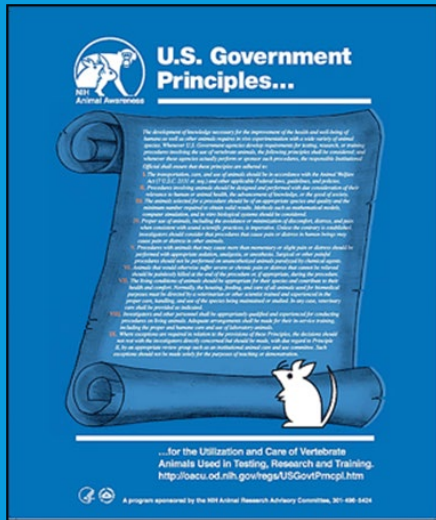


PHS Policy Standards for Animal Care and Use



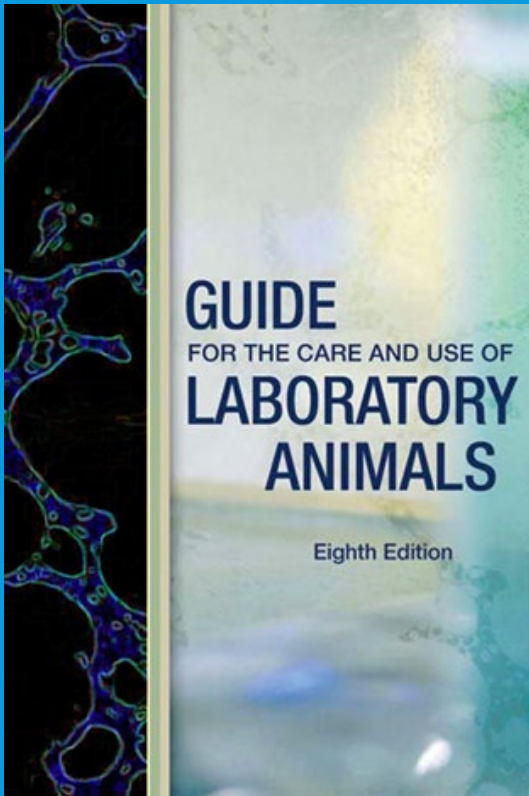
- “All institutions are required to comply, as applicable, with the Animal Welfare Act, and other Federal statutes and regulations relating to animals.” (PHS Policy II.)
- “the IACUC shall confirm that the research project will be conducted in accordance with the Animal Welfare Act insofar as it applies to the research project,” (PHS Policy II.C.1.)

PHS Policy Standards for Animal Care and Use



- The animals should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and *in vitro* biological systems should be considered.
- Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.
- Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.
- Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

PHS Policy Standards for Animal Care and Use



- Endorses the US Government Principles
- Endorses the 3Rs.
- “Institutions and investigators should take all reasonable measures to eliminate pain and distress through refinement....Veterinary consultation **must** occur when pain or distress is beyond the level anticipated in the protocol description or when interventional control is not possible.” (p 5)

PHS Policy Standards for Animal Care and Use



AVMA Guidelines
for the Euthanasia of Animals:
2020 Edition

PHS Policy IV.C.1.g. "Methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator."

- Set criteria for euthanasia
- Assist veterinarians in exercising professional judgement to provide the best methods of euthanasia for different species, and under different conditions.

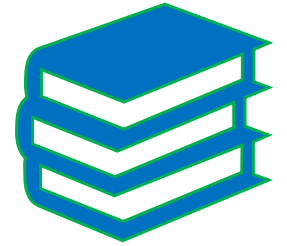
Learning Objectives

https://media.wired.com/photos/5926df4f7034dc5f91bece6c/191:100/w_1280,c_limit/GettyImages-95012042.jpg



1. Associate the PHS Policy with your institution.
2. Name the office responsible for administering and coordinating the PHS Policy
3. Identify federal funding agencies that comply with the PHS Policy.
4. Apply the PHS Policy definition of a live vertebrate animal.
5. Reflect on key elements of the PHS Policy and how they relate to alternatives to animals and 3Rs.
6. Name the resources that feed the PHS Policy standards and recognize the requirements they have for alternatives to animals and the 3Rs.

Education Opportunities



OER Home About Grants Funding Forms & Deadlines Grants Policy eRA News & Events About OER

NIH National Institutes of Health
Office of Laboratory Animal Welfare

Search
About OLAW Contact Us

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, ICARE Project, and educational workshops at

Education Resources

Workshops & Conferences

IACUC 101 Series

Webinars & Podcasts

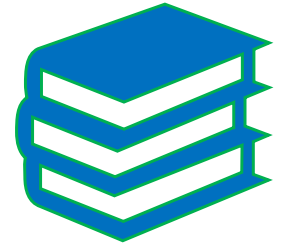
ICARE Project & Workshops
A federal agency project to empower U.S. IACUCs and their institutions to improve animal welfare and increase compliance with federal standards while minimizing regulatory burden.

[Learn More About ICARE](#)

ICARE
Training Modules

Upcoming Events

olaw.nih.gov/education/workshops-conferences.htm



October 23 -27, 2022 **AALAS** (Louisville, KY)

December 5-6, 2022 **SCAW** (San Antonio, TX)

December 12-16, 2022 **PRIM&R Annual Conference** (Virtual)



"Tilly"

Questions?



Regulatory Chaos?