Introduction to OLAW

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

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.
“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

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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.
“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.”
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- 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
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. ______________________
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
• “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.)
• 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.
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 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.
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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)
Questions?

“Tilly”
Regulatory Chaos?