Having trouble with your IACUC?

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Director, Animal Care and Quality Assurance
University of Missouri-Columbia
Objectives

A. Identify regulatory oversight for animal use programs and IACUCs.
B. Point out some variations in regulatory oversight that can cause confusion or regulatory burden in institutions
C. Provide some talking points that we can all take back to our institutions to help minimize regulatory burden on investigators and institutions while maintaining compliance.
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<tr>
<th>Principles</th>
<th>NIH</th>
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<td>U.S. Government Principles for the Utilization and Care of Vertebrate Animals: Used in Testing, Research and Training</td>
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<td>International Guiding Principles for Biomedical Research Involving Animals (Council for International Organizations of Medical Sciences and International Council for Laboratory Animal Science)</td>
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<td>Public Law 99-544; Care and Use of Animals in the Conduct of NASA Activities; 42 USC Sect 2451; 14 CFR, Part 1332</td>
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<td>Guidelines for the Euthanasia of Animals (American Veterinary Medical Association)</td>
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<td>NSF Grant Policy</td>
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## Major sources of regulation for most

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<td>Animal Welfare Regulations</td>
<td>Public Health Service (PHS) Policy</td>
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Honorable mention: Department of Defense (DoD)  
Veterans Administration (VA)
Animal Welfare Act (August, 1966) AWA

Gave USDA regulatory authority over all warm-blooded vertebrates.

Exceptions:
- mice of the genus Mus bred for research
- rats of the genus Rattus bred for research
- birds
- farm animals used in agricultural research
Health Research Extension Act of 1985
(Public Health Service – PHS Policy)

A. Includes oversight of all vertebrates (including rats, mice, horses, farm animals, birds, and fish)

B. Applies only to PHS-sponsored research (CDC, FDA, NIH)

And now….NSF.
Office of Laboratory Animal Welfare (OLAW) administrates PHS Policy

Must meet the standards of AWA (as applicable) and the Guide and Ag Guide
PHS Policy

Institutions must file an Animal Welfare Assurance statement to OLAW every 4 years.

This Assurance defines how you will operate your animal program.

Required to receive NIH Funds
## Animal Welfare Act vs. PHS Policy

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<td>Unannounced annual inspections by USDA Veterinary Medical Officers</td>
<td>Self-regulation, self-evaluation, and self-reporting; although site visits are possible (OLAW)</td>
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1985- Enter the Institutional Animal Care and Use Committee (IACUC)

Mandated by an update to the Animal Welfare Act and the newly released Public Health Service (PHS) Policy
## Animal Welfare Act vs. PHS Policy

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<td>Requires 3 members on IACUC (minimum)</td>
<td>Requires 5 members on IACUC (minimum)</td>
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<tr>
<td>Chair</td>
<td>Attending Vet.</td>
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<td>Attending Vet.</td>
<td>Scientist</td>
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<tr>
<td>Non-affiliated member</td>
<td>Non-scientist</td>
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<td>Non-affiliated member</td>
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Responsibilities of an IACUC

A. Review and approve or disapprove animal use activities
B. Review entire animal use program every 6 months
C. Inspect animal use facilities every 6 months
D. Prepare reports for OLAW/USDA
E. Make recommendations to IO on any aspect of program
F. Review concerns of faculty, staff, public
G. Oversee/Assure training of personnel
H. Establish and maintain an Occupational Health & Safety Program for animal workers
I. Suspend activities or take corrective action when necessary
J. Confirm congruency checks of grants and animal use protocols
Animal Welfare Act vs. PHS Policy

Animal Welfare Act

Requires annual review of animal use protocols

PHS Policy

Requires de novo review of animal use protocols triennially
Reducing Regulatory Burden

Animal Welfare Act vs. PHS policy

Many institutions do annual review of all protocols, regardless of the species involved.
Animal Welfare Act (August, 1966) AWA

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Animal Welfare Act vs. PHS policy

Annual reviews are only required on animal use protocols involving USDA-covered species.

If your institution is doing annual reviews of all protocols, regardless of species, weigh the benefit gained from the information that is gathered vs. the burden of having to do the review.
Reducing Regulatory Burden

Animal Welfare Act vs. PHS policy

Don’t forget to assess the burden on all parties:

- Researchers
- IACUC
- IACUC administrators
Animal Welfare Act vs. PHS Policy

**Animal Welfare Act**

Requires consideration of alternatives from 2 sources plus a written narrative.

**PHS Policy**

Requires that PIs demonstrate that alternatives have been considered, animal numbers are minimal, and pain and distress are minimized.
2.31 (d)(1)(ii) The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources, e.g., the Animal Welfare Information Center, used to determine that alternatives were not available;
Animal Welfare Act

Policy 12 “…APHIS continues to recommend a database search as the most effective and efficient method for demonstrating compliance with the requirement to consider alternatives to painful/distressful procedures.”

“(due to the variation in subject coverage and sources used, one database is seldom adequate)”
Major sources of regulation for most


Animal Welfare Regulations | Public Health Service (PHS) Policy

Policies- 18 policies | National Institutes of Health (NIH)/Office of Laboratory Animal Welfare (OLAW)

United States Department Of Agriculture (USDA)
Animal Welfare Act (August, 1966) AWA

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Exceptions:
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Reducing Regulatory Burden

Animal Welfare Act

Action-
Perform literature searches (2 sources) and write narratives for animal use protocols involving USDA covered species AND potentially painful or distressful procedures.

No such search is needed for non-USDA covered species.

Caveat-
Still have to demonstrate that the PI has considered alternatives to animal use, animal numbers, and minimizing pain and distress on protocols using non-USDA covered species if your institutions receives PHS funds.
Animal Welfare Act

Solution for caveat:

Have PI give a brief description of how the 3 R’s have been considered in protocols that do not involve USDA-covered species. (3 R’s = reduction, replacement, and refinement)

Check your forms. Many IACUC forms already ask for justification of animal numbers and use of animals (reduction and replacement). Then perhaps a simple statement of consideration of refinements.
Reducing Regulatory Burden

A Somewhat Rare Event

In August of 2014, the NIH released new guidance for making significant changes to animal use protocols. The USDA supported and accepted the new guidance.

The mechanism for by which some significant changes can be made is now called Veterinary Verification and Consultation or VVC.
Reducing Regulatory Burden

VVC

Advantages

• Permits research team to immediately apply some significant changes to all animals under the protocol.

• Avoids delays associated with writing and submitting an amendment for IACUC review and approval and reduces the risk of compromising an ongoing research activity.
Examples of what changes can be made by VVC

- Anesthesia, analgesia, sedation, or experimental substances
- Euthanasia to any AVMA approved method including those approved with conditions as long as the conditions are met
- Duration, frequency, type, or number of procedures performed on an animal.
VVC- Regulatory agency expectations

- IACUC policies that address significant changes must be written, reviewed, and approved before they are implemented.

- These policies must be approved by Full Committee Review or Designated Member Review at least every 3 years.

- IACUC members are expected to understand and be familiar with their policies.

- IACUC must authorize veterinarians to administratively handle changes made by VVC.

- IACUC must establish a mechanism for documenting significant changes by VVC.
Reducing Regulatory Burden VVC

Scenario

Dog is sedated and ready for anesthesia when a technician drops your only bottle of isofluorane, the only anesthesia listed in your protocol.

With VVC, and proper IACUC approved policy in place, an authorized vet can be called and the vet can verify the change to a different anesthesia without modification of protocol.
Regulatory Oversight of Animals Used in Research

USDA (United States Department Of Agriculture)

APHIS (Animal and Health Plant Inspection Services)

AAALAC, International

PHS (Public Health Services)

NIH (National Institute Of Health)

OLAW (Office of Laboratory Animal Welfare)

AWA (Animal Welfare Act)

“The Guide” (The Guide for the Care and Use of Laboratory Animals)

VA

IACUC

DoD

Veterinarian- Animal Care

Animal Protocol

Investigator

Veterinarian- Protocols
Regulatory Agencies

Investigator

Institution
Reducing Regulatory Burden VVC

Conclusions:

There are many regulations that institutions must follow.

Many of these regulations overlap and, at times, contradict each another sometimes causing confusion for IACUCs and institutions.

Talk to your IACUC, compliance offices, and even IO about simple changes that can reduce burden (like VVC) on the PIs, the IACUC, and the institution.

Educate yourself about your institution’s Assurance with OLAW.