Welcome!

FASEB Webinar Series: Animal Research Regulations
Part 1

Understanding Federal Oversight Mechanisms

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Understanding Federal Oversight Mechanisms

Part 1 – Animal Research Regulations
Speakers

Patricia Brown, VMD, MS
Director, Office of Laboratory Animal Welfare
Office of Extramural Research
Office of the Director
National Institutes of Health

Tanya Tims, DMV
Supervisory Veterinary Medical Officer, Animal and Plant Health Inspection Services - Animal Care, US Department of Agriculture

Alice Huang, PhD
Deputy for IACUC Guidance, Office of the Chief Veterinary Medical Officer, Department of Veterans Affairs
To Ask A Question

Type your question in the white box and click “Send” (gray button)
Animal Research Regulations

Animal Welfare Act (1966)
United States Department of Agriculture
Animal and Plant Health Inspection Service (USDA APHIS)

Health Research Extension Act (1985)
National Institutes of Health
Office of Laboratory Animal Welfare (NIH OLAW)

Institutional Animal Care and Use Committee (IACUC)

Research with Animals

AAALAC

AAALAC
Assuring Animal Welfare in Research

Tanya Tims, DMV
Supervisory Veterinary Medical Officer, Animal and Plant Health Inspection Services (APHIS) - Animal Care
Research Animal Oversight Entities

- USDA, OLAW and AAALAC

- Considerable overlap:
  - Animal care and use committees (IACUC)
  - Attending veterinarian
  - Minimize pain and distress, Humane euthanasia
  - Sanitary, safe animal enclosures
  - Qualified personnel
  - Annual report; reporting of adverse events
### Differences

<table>
<thead>
<tr>
<th>USDA</th>
<th>OLAW</th>
<th>AAALAC</th>
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<tbody>
<tr>
<td>Certain warm-blooded animals</td>
<td>All live vertebrate animals</td>
<td>All vertebrates/invert</td>
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<tr>
<td>All research facilities in US</td>
<td>Receiving PHS funds</td>
<td>Vol. accreditation International</td>
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<td>AWA and regulations</td>
<td>PHS Policy and the “Guide”</td>
<td>The “Guide”</td>
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<td>FOIA</td>
<td>FOIA</td>
<td>Confidential</td>
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<tr>
<td>Unannounced annual on-site inspections</td>
<td>Detailed written Assurance, some site visits</td>
<td>Announced triennial on-site visits</td>
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<tr>
<td>No OS&amp;H regulations</td>
<td>OS&amp;H</td>
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Enforcement of the Animal Welfare Act

- Breeders
- Dealers
- Exhibitors
- Research Facilities
- Transporters and Handlers

Enforcement of the Horse Protection Act

Emergency Response
Fiscal Year 2019

Total Animal Care inspectors = 104 (66 are VMO’s)

920 registered research facilities ("R")
160 registered Federal research facilities

1221 inspections conducted:
- 91% full compliance
- 98% substantial compliance
Animal Welfare Act

1. To ensure that animals intended for use in research facilities or for exhibition or for use as pets are provided humane care and treatment.

2. To assure the humane treatment of animals during transportation in commerce, and....

3. To protect the owners of animals from the theft of their animals by preventing the sale or use of animals which have been stolen.
The ‘Blue Book’

Code of Federal Regulations
Title 9, Chapter 1,
Subchapter A, Parts 1-4
Regulations and Standards

Provides for the humane care and treatment of “animals” in regulated activities.
Research Activities defined

- Research
- Teaching
- Testing
- Experimentation
How did USDA get involved in the first place?

- ...pet theft and public outcry

- Prior to 1966, no federal law addressing laboratory animal welfare
The Animal Welfare Act

◆ The Laboratory Animal Welfare Act passed in 1966

◆ Several amendments made over the years to include more than just laboratory animals…now known as the Animal Welfare Act.

◆ Among these changes was 1989 requirements of the IACUC
Institutional Animal Care and Use Committee

Ensures activities are in accordance with the AWA R&S, unless there is an acceptable justification for departure in writing

- Internal oversight body

- Assesses the facility’s:
  - Program for humane care and use of animals
  - Proposed activities involving animals
  - Animal facilities
So how does AC assure animal welfare at a research facility?

Inspections
- *Oversee the function of the IACUC*
  - Protocol review
  - Required records
  - Veterinary Care requirements
    - Personnel
- Inspect facilities and animals
- Animal handling
- Review animal acquisitions

Education
- Mock Inspections/Courtesy visits
- IACUC training
- Follow up on Non-compliances

Required Reporting
- Annual report
- Protocol Suspensions
- Significant deficiencies not corrected
- MMOPs
AC Inspections

- Based on the AWA Regulations
- Inspections are unannounced
- Frequency of Inspection based on Risk
  - Required by law to inspect RFs at least once/year
- Photographs
- Document non-compliances
- Exit interview
We Inspect:

◆ Animals
◆ Facilities (animal rooms, surgical suites, cage wash, food storage)
◆ Transport and primary enclosures
◆ Husbandry and care practices

◆ Talk with employees (Investigators, Technicians, Caretakers)
We review:

- All required IACUC documents
- Protocols
- All practices Involving Pain and Distress
- SOPs
- Dog Exercise Plan
- Primate Enrichment Plan
- Program of Veterinary Care
- Animal room records
- Personnel training requirements
- Staffing to provide required animal care
- Procurement of animals
- Tracking of animals and numbers
Animal Care Mission

To provide leadership in establishing standards of humane care and treatment of animals, and to achieve compliance with those standards through inspections, education and cooperative efforts.
Sources of Information

Animal Care Ft. Collins Office: 970-494-7478
Animal Care Riverdale Office: 301-851-3751

Animal Care Website:
- Animal Welfare Inspection Guide: Chapter 7

APHIS stakeholder registry (to receive notices and updates):
https://public.govdelivery.com/accounts/USDAAPHIS/subscriber/new
Research Involving...Animals

Patricia Brown, VMD, MS, DACLAM
Director, Office of Laboratory Animal Welfare
National Institutes of Health
Understanding the Dual Nature of NIH

**NIH is an institution** (Intramural Research)
- Approx. 6,000 scientists
- Approx. 10% of NIH’s budget

**NIH supports** institutions & people (Extramural Research)
- >2,500 institutions
- >400,000 scientists & research personnel
- Approx. 70,000 applications and 40,000 awards annually
- Approx. 80% of the NIH budget
OLAW Mission

To ensure the humane care and use of animals in Public Health Service-supported research, testing, and training involving animals and thereby contribute to the quality of research.
Authorizing Legislation - Public Law 99-158
Health Research Extension Act of 1985

- NIH Director to establish guidelines for research funded by NIH and PHS agencies
- Animal Welfare Assurance agreement
- Institutional Animal Care and Use Committee (IACUC) with oversight authority
- Institutional opportunity to correct deficiencies
Key Elements of the PHS Policy

- All vertebrate animals
- Animal Welfare Assurance
- Institutional Animal Care and Use Committee
- Self-regulation by institution
- Requirements for:
  - Record keeping
  - Reporting
OLAW Responsibilities

- Oversee implementation of PHS Policy
- Provide interpretation and guidance
- Negotiate Animal Welfare Assurances
- Evaluate compliance
  - Institutional self reporting
  - Third party allegations
- Educational activities
PHS Policy

**Animal** defined as:

“any live vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.”
(Formerly Report of the AVMA Panel on Euthanasia)
Federally supported scientists are accountable from the time they first plan their research to the time the research is completed to protect the welfare of the animals used in the research.

"Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society."

US Government Principle II
US Government Principle III

“The animals selected for a procedure 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.”
US Government Principle IV

“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.”
US Government Principle V

“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.”
Post-Award Responsibilities

- Obtain IACUC approval prior to using animals or making significant changes
- Ensure research is conducted according to the approved protocol
- Comply with institutional policies and procedures
More Post-Award Responsibilities

- Address significant changes to the use of animals in progress reports to NIH
- Obtain prior permission from NIH for the use of animals involving a change in scope, including changes in performance site
- NIH Grants Policy, Section 8.1.2.5 Change in Scope
Post-Award Miss-steps

- Conducting research in the absence of IACUC approval
- Implementing a significant change without IACUC approval

- Such noncompliance must be reported by the IACUC through the Institutional Official to:
  - OLAW
  - the funding component(s) supporting the award
- Where charges have been made for unauthorized animal activities, appropriate adjustments must be made to remove those charges
NIH-supported research is a partnership

- Collaborative relationship exists between funding agency and awardee institution
- The partners share a mutual need to assure compliance
- Each partner has responsibilities and obligations as stewards of public funds
- Institutional self-governance is the foundation of PHS Policy
Thank You
How Does VA Integrate the Requirements of USDA and OLAW?

Alice Huang, PhD
Deputy for IACUC Guidance
Office of the Chief Veterinary Medical Officer
Veterans Health Administration
Department of Veterans Affairs
VA Policy
Why does VA impose further requirements?

Because of VA’s structure as an organization of 70+ separate research programs

◆ Setting agency-wide standards
◆ Promoting agency-wide coordination and harmonization
Setting Agency-Wide Standards

◆ AAALAC Accreditation

◆ R&D Committee

◆ Protocol Review Requirements
  ■ 2 Reviewers
  ■ Secondary Review

◆ Collaborations
  ■ CVMO approval to accept IACUC approval of Collaborating Institution
  ■ VA representation on IACUCs

◆ Office of Research Oversight
Coordination and Harmonization

◆ Working with others outside of VA
  - FOIA requests
  - Congressional inquiries
  - New legislation
  - CURES Act
  - FDP

◆ Depends on CVMO being well-informed
  - Semiannual reports
  - Alerts about matters of potential public interest
  - Reports to oversight entities
To Ask A Question

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Office of Public Affairs
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COVID-19 Resources


- Recorded Webinar: “Pandemic Contingency Planning and Its Impact on Animal Care”

- OLAW Guidance in Preparing for the Coronavirus Disease 2019 Outbreak

- Flexibilities for Assured Institutions for Activities of IACUCs (NOT-OD-20-088)

- NIH-wide:
  - Coronavirus Disease 2019 (COVID-19): Information for NIH Applicants and Recipients of NIH Funding [updating in real time]