Updates

1. FAQs
2. Guidance to Grantees
3. Recent Commentary
4. Educational Resources

OLAW welcomes comments on any policy guidance http://olaw.nih.gov
Frequently Asked Questions
New FAQs Released in 2010

http://grants.nih.gov/grants/olaw/faqs.htm

- Seven FAQ Topic Sections
  - Applicability of the PHS Policy
  - IACUC Composition, Functions, and Authority
  - Institutional Reporting to OLAW
  - Protocol Review
  - Program Review and Inspection of Facilities
  - Animal Use and Management
  - Institutional Responsibilities

- Search by topic using NEW topic index tool
Is social housing required for nonhuman primates when housed in a research setting?

- Requirement of USDA regulations (9CFR Ch.1, Part 3, Subpart D, 3.81 (a))
- Single housing is the exception
- Exemptions based on strong scientific justification, specific veterinary or behavioral reason
- Lack of caging not acceptable
- Animal Use and Management F14
Should positive reinforcement training be used for nonhuman primates?

- Use when safe and feasible
- Aids in cooperative activities of research or husbandry
- Reduces stress
- Reduces need for chemical restraint
- Animal Use and Management F15
Are laparoscopic procedures considered major surgery?

- IACUC’s authority to determine
- Based on description of procedure and consequences
- Readjust, depending on clinical outcome
- If impairment, must consider major
- Appropriate analgesia, monitoring, etc.
- Animal Use and Management F13
Does OLAW expect the IACUC to notify NIH when there is a change in an animal activity supported by PHS funds?

- Significant change is not necessarily a change in scope
- IACUC is not required to notify OLAW or funding component of significant change
- PI and the Authorized Organizational Official are required to notify Grants Management Officer of change in scope - No less than 30 days prior to change
- IACUC Composition, Functions, and Authority B13
Does the IACUC need to approve research studies that use privately owned animals, such as pets?

- Pets used in research must be covered by an IACUC approved protocol
- Informed consent of owner obtained prior to conduct of research
- Consider legal counsel in development of consent documents
- Applicability of the PHS Policy A7
How can the IACUC determine if animal activities constitute veterinary clinical care or research activities?

- Collection or generation of data for research purposes
- Informed consent of owner
- If PHS funded, Assurance, and IACUC approval required
- Applicability of the PHS Policy A8
Guidance to Grantees

- All notices are posted at OLAW website
- Main webpage under the Guidance section
Instructions for Completion and Peer Review of the Vertebrate Animal Section in NIH Grant Applications and Cooperative Agreements

- Notice NOT-OD-10-027
- Posted April 2010
- Grant Application VAS Worksheet

Notice on VAS - Purpose

- Clarify what information must be in the VAS
- Explain how the VAS is evaluated during peer review and overall scoring
- Distinguish roles of IACUC and SRG
Notice on VAS

- If VAS is lacking or incomplete, may result in deferral or affect impact/priority score
- If coded as SRG concerns, must be resolved prior to award
- NIH staff in the funding program work with PI to reconcile concerns
- OLAW reviews and approves revised VAS
Notice on VAS

SRG role: Evaluate the involvement of animals as part of scientific assessment of the application

IACUC role: Assure the animal care and use protocol conforms to PHS Policy and federal animal welfare requirements

Applicant organization role: Ensure the IACUC protocol is congruent with the proposed use in application
Clarification on the Roles of NIH Scientific Review Groups (SRG) and Institutional Animal Care and Use Committees (IACUC) in Review of Vertebrate Animal Research

- Notice NOT-OD-10-128
- Posted September 2010
Clarification

- If VAS is lacking may result in deferral
- If one or more elements not addressed may affect impact/priority score
- Define vertebrate animal concern and gives examples
- Concerns resolved before award
- Protection of animal welfare in every phase of the grant process
- SRG review does not supersede or replace IACUC
Clarification (cont’d)

- If use “just in time” review by IACUC must support decisions of IACUC
- IACUC may not be pressured to approve a protocol or be overruled on its decision to withhold approval
- Modifications required by the IACUC must be submitted to the NIH with verification of IACUC approval
- Responsibility of institutions to communicate IACUC imposed changes to NIH program officials.
Clarification (cont’d)

- Investigators must convey to the IACUC modifications to project scope and animal usage that result from peer review and award process.

- If investigator does not relay modifications to the IACUC, the institution may choose to require IACUC approval prior to submission of the application.
Update of the *Guide for the Care and Use of Laboratory Animals*

- Notice NOT-OD-10-102
- Notice posted June 2010
Notice on *Guide* Update

- Prepublication copy of 8th edition released
- PDF file available for download at OLAW website
- Until 2010 is published in final form, 1996 edition will remain official *Guide* for PHS Policy implementation
Report on Site Visits to Chimpanzee Facilities and Associated Resources to Aid Grantee Institutions

- Notice NOT-OD-10-121
- Publication August 2010
Site Visits - Chimpanzee Facilities

- July 2010 Summary Report
- Overall in compliance with PHS Policy
- High quality of care and commitment to psychological well-being
Site Visits - Chimpanzee Facilities

- Where safe and feasible, positive reinforcement training to perform cooperative activities
  - Reduce stress
  - Reduce need for chemical restraint
Site Visits - Chimpanzee Facilities

- Greater effort to socially house nonhuman primates – social housing is the default.

- Exemptions:
  - Strong scientific justification
  - Veterinary reason
  - Behavioral reason

- Lack of caging not acceptable
Nonhuman Primate Enrichment

- OLAW web page
- Online seminar recording
  - USDA and OLAW Perspective
- FAQs on social housing issues
- AWIC resources
OLAW Commentary
Commentary in *Lab Animal*

June 2010, Vol. 39, No. 6, pp 165-167
Should the IACUC re-review an approved protocol if concerns about the animal activities arise and when is conflict of interest an issue for IACUC members?

August 2010, Vol. 39, No. 8, pp 233-235
Should an incident involving failure to follow a protocol be reported to OLAW and USDA?
PI Alert and Lab Animal eAlert

May 2010, No. 8
Disaster Planning: How Can I Prepare My Animal-Research Lab for an Earthquake?

July 2010
Was McGill’s “Mouse Pain” Study Compliant with Lab Animal Welfare?
Educational Resources
Educational Resources

 Subscribe through OLAW webpage
  • ListServ
  • OLAW RSS Feed
 Request publications
 Download publications
OLAW USDA and IACUC 101 will sponsor symposium
Animal Welfare & Scientific Research: 1985 - 2010

- October 25-26, 2010 in Bethesda, MD
- Recognizing 25 Years of Improving Animal Welfare, Advancing Science
- Preceded by IACUC 101 and AWIC workshops
- Evening session keynote presentation by Dr. Charles McCarthy, the first director of OPRR
- Early registration extended to September 15th

http://www.awsrsymposium.com
Workshops & Conferences

IACUC 101 Workshop
October 24, Bethesda, MD

AWIC Workshop
October 24, Bethesda, MD

SCAW IACUC Workshops
September 10, Bethesda, MD
September 27, New York, NY
October 21, Chicago, IL

SCAW Winter Conference
December 6 - 7, San Antonio, TX
Upcoming OLAW Online Seminars

December 2010  Protocol Review
March 2011  IACUC Responsibilities Beyond Protocol Review
June 2011  Writing a Good Assurance
September 2011  Occupational Health and Safety Programs
December 2011  Grants Policy and Congruence
Questions? Please Ask!