

Frequently Asked Questions to OLAW

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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

<http://grants.nih.gov/grants/olaw/VASchecklist.pdf>



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.



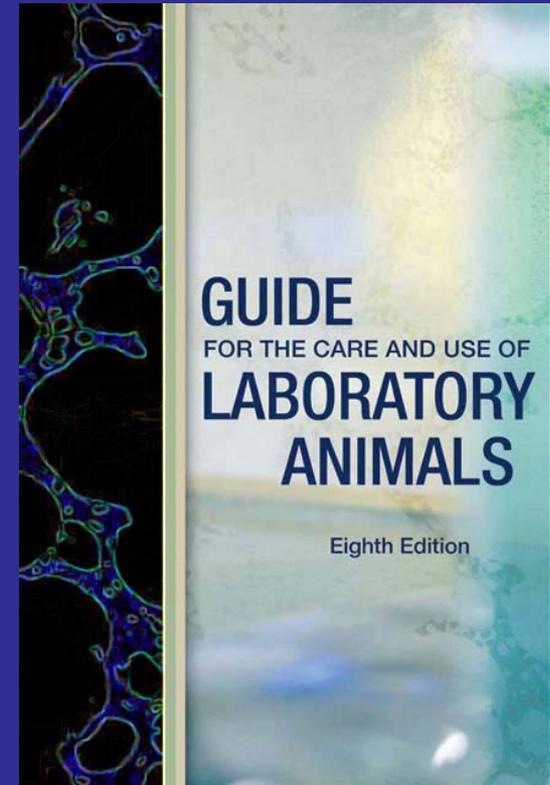
Clarification (cont'd)

- 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 web site
- http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals_Prepub.pdf
- 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
 - http://grants.nih.gov/grants/olaw/primate_enrichment-social_housing.htm
- 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



25
YEARS

ANIMAL
WELFARE

AND SCIENTIFIC
RESEARCH

1985 TO 2010

OCT. 25-26, 2010
MARRIOTT BETHESDA
NORTH HOTEL AND
CONVENTION CENTER
BETHESDA, MD

OCT. 24, 2010
PRE CONFERENCE
IACUC 101 AND
AWIC WORKSHOP

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!

