



## OLAW Update

Eileen Morgan  
Office of Laboratory Animal Welfare, OER, NIH  
October 21, 2009  
SRA International 2009



---

---

---

---

---

---

---

---



## OLAW Updates

- Introduction
- Guidance to Grantees
- Educational Resources
- New NIH Initiatives
- OLAW Staff Changes

---

---

---

---

---

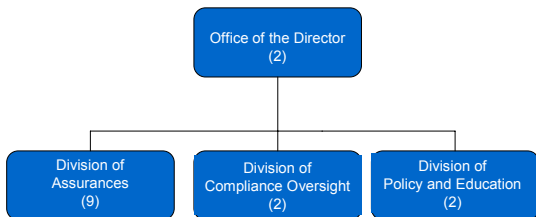
---

---

---



## OLAW organization



---

---

---

---

---

---

---

---



## OLAW's Purpose

OLAW provides guidance & interpretation of the PHS 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.

---

---

---

---

---

---

---

---



## OLAW's Authority: Public Law 99-158

### Health Research Extension Act of 1985

- Director of NIH shall establish guidelines for the proper care and treatment of animals used in biomedical and behavioral research
- Guidelines shall not prescribe methods of research
- Mandates the organization and operation of IACUCs
- Funding can be withdrawn if animal care does not meet guidelines

---

---

---

---

---

---

---

---



## PHS Policy Standards for Animal Use

- PHS Policy for Humane Care & Use of Lab Animals
- Guide for the Care and Use of Laboratory Animals
- U.S. Government Principles
- AVMA Euthanasia Guidelines
- USDA Animal Welfare Regulations

---

---

---

---

---

---

---

---



---

---

---

---

---


---

---

---

---

---

 **OLAW's Philosophy**

“It is far preferable to place primary responsibility for assuring compliance with NIH guidelines on committees within institutions rather than relying on intrusive Federal inspections.”

Congressional committee report accompanying the 1985 Health Research Extension Act

---

---

---

---

---

---

---

---

---

---

 **NIH-Supported Research is a Partnership**

- Collaborative relationship exists between NIH and grantee 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



---

---

---

---

---

---

---

---

---

---



## Who are the Partners?

- Investigator
- Grantee Institution
- IACUC
- NIH
- OLAW

---

---

---

---

---

---

---

---

---

---



## Grant Applicant to Address Vertebrate Animal Use (Electronic Submission)

- SF 424 ~ Research & Related Application
  - Project / Performance Site Location(s)
  - Other Project Information (Section 2 & 2a)
- PHS 398 ~ Research Plan
  - Research Plan Attachments
    - Other Research Plan Sections (11. Vertebrate Animals)
    - PDF format
    - Five Points of Vertebrate Animal Section

---

---

---

---

---

---

---

---

---

---

Close Form
Print Page

**RESEARCH & RELATED Other Project Information**

1. \* Are Human Subjects Involved?  Yes  No

1.a If YES to Human Subjects

Is the IRB review Pending?  Yes  No

IRB Approval Date:

Exemption Number:  1  2  3  4  5  6

Human Subject Assurance Number:

2. \* Are Vertebrate Animals Used?  Yes  No

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending?  Yes  No

IACUC Approval Date:

Animal Welfare Assurance Number

3. \* Is proprietary/privileged information included in the application?  Yes  No

---

---

---

---

---

---

---

---

---

---





### Funding Component (IC) and Review Responsibilities

- Consideration of animal welfare during peer review (may affect score of application)
- If reviewers express concerns about animal care and use, the concerns must be resolved prior to funding
- Ensure that institution has an Assurance
- If no Assurance, the IC requests OLAW to negotiate Assurance
- Verify IACUC approval

---

---

---

---

---

---

---

---

---

---



### Consortium Agreements: Sub-awards

- Prime grantee is accountable to NIH and must confirm:
  - Assurance
  - IACUC approval (dated within 3 years)
    - Only required from one Assured entity
- Animal welfare requirements apply to all consortium participants and sub-projects
- For more information see NIH GPS, Part II, Terms and Conditions of NIH Grant Awards, Consortium Agreements

---

---

---

---

---

---

---

---

---

---



### Consortium Agreements: Sub-awards continued

- **Inter-Institutional Assurance is needed:**
  - Prime grantee has no animal program and animal work is being conducted at an Assured performance site
- **Foreign Assurance is needed:**
  - Direct support to a foreign institution
  - Domestic prime grantee with a foreign performance site using animals:
    - Domestic grantee's IACUC approves animal activities performed at foreign site

---

---

---

---

---

---

---

---

---

---



### Which Study Should Be Checked "Yes" for Vertebrate Animal?

- Embryonated egg
- Tadpole
- Zebrafish
- Cow spleen from slaughterhouse
- Antibodies from goat
- Chimpanzee behavior study
- Octopus nerve study
- Mosquito malaria study (host?)

---

---

---

---

---

---

---

---



### When IACUC Review is Pending

- Application may go to peer review
- Approval date must be received prior to funding

---

---

---

---

---

---

---

---



### Submission of IACUC Review After NIH Receipt of 398/424 (Just in Time)

- Application number
- Title of project
- Principal investigator
- Assurance number
- Date of IACUC approval
- Any changes required by the IACUC

---

---

---

---

---

---

---

---



## Accountability

The institution is accountable for:

- Financial and administrative aspects of the award
- Animal care and use program (IACUC)

The investigator is accountable for:

- Research
- Compliance with the animal care and use program

IACUC, with the Institutional Official, exercises oversight over institutional animal care and use

---

---

---

---

---

---

---

---



## Authorized Organizational Representative

- Designated representative of grantee organization in matters related to the award and administration of NIH grants
- Accountable for appropriate use of funds and performance of activities resulting from application

---

---

---

---

---

---

---

---



## Principal Investigator

- Designated by the grantee as responsible for the scientific and technical aspects of the project
- Member of the grantee team responsible for ensuring compliance with the financial and administrative aspects of the award

---

---

---

---

---

---

---

---



## Language From the Face Page of 398

I certify that the statements herein are true, complete and accurate to the best of my knowledge.

I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

Signature & Assurance  
Principal Investigator / Project Director Assurance

---

---

---

---

---

---

---

---

---

---



## Implications of Noncompliance

- Corrective actions and improved systems
- Restrict / withdraw approval of Assurance
- Special terms and conditions of awards
- Cost disallowance
- Suspension / termination of award
- Criminal prosecution

---

---

---

---

---

---

---

---

---

---



## Stewardship at Your Institution

NIH expects your animal activities to comply with:

- Animal Welfare Assurance
- PHS Policy
- Federal and State regulations
- Institutional requirements

NIH and OLAW are here to help you in the partnership

---

---

---

---

---


---


---

---


---

---

 NIH OFFICE OF EXTRAMURAL RESEARCH



## Guidance to Grantees

 OLAW

---

---

---


---

---

---

---

---

 Guidance to Grantees

Use of Designated Member Review (DMR)  
Subsequent to Full Committee Review (FCR)

- Notice NOT-OD-09-035
- Posted January 2009
- Notices are on OLAW web site

---

---

---


---

---

---

---

---

 Notice on FCR to DMR

What actions can the IACUC take at a convened meeting when substantive information is lacking to approve a protocol?

If **ALL** members **ARE** present – vote to:

- Require modifications to secure approval:
  - Revised protocol to DMR
- OR
- Revised protocol to FCR
- Withhold approval

---

---

---

---

---

---

---

---



## Notice on FCR to DMR

### What actions can the IACUC take...

If ALL members are NOT present?

- If all members have agreed **in advance in writing** to allow the quorum present to decide by unanimous vote to send revised protocol to DMR, DMR can occur

OR

- If no standard procedure is in place, all members must have revised protocol available and opportunity to call for FCR and if none have done so, DMR can occur

---

---

---

---

---

---

---

---

---

---



## Notice on FCR to DMR

### What is the approval date for the revised study?

If the IACUC uses DMR, the approval date is the date the designated member(s) approved the study

### When can the IACUC start using this method?

As soon as all members agree to the process. If the IACUC elects to use the DMR subsequent to FCR review process, inform OLAW in next Annual Report and when renewing Assurance.

---

---

---

---

---

---

---

---

---

---



NIH OFFICE OF EXTRAMURAL RESEARCH

## More Guidance to Grantees



OLAW

---

---

---

---

---

---

---

---

---

---



## New FAQs

OLAW welcomes comments on any of its policy guidance <http://olaw.nih.gov>

### Protocol Review

May an IACUC use DMR subsequent to FCR when modifications are needed to secure approval?

Does the IACUC have to review at the time of grant award if animal research won't occur until year 4 or 5?

---

---

---

---

---

---

---

---

---

---



## Protocol Review

Does the IACUC have to review proposed animal research activities at the time of grant award if the animal research activities will not be conducted until year 4 or 5 of a grant?

- Yes, with rare exception.
- The IACUC must approve the proposed use of animals described in the grant application or contract proposal.
- This is required to comply with the PHS Policy as stated in Section V.B.

---

---

---

---

---

---

---

---

---

---



## Protocol Review, Continued

Does the IACUC have to review proposed animal research activities at the time of grant award if the animal research activities will not be conducted until year 4 or 5 of a grant?

- The IACUC review must be performed prior to the conduct of any PHS-supported animal activity.
- Approval is valid for a maximum of three years.
- Because the scientific enterprise is not static, the need for changes to animal protocols is anticipated and can occur at any time during the life of the protocol.

---

---

---

---

---

---

---

---

---

---



## Protocol Review, Continued

Does the IACUC have to review proposed animal research activities at the time of grant award if the animal research activities will not be conducted until year 4 or 5 of a grant?

- In rare cases, IACUC review of animal activities is conducted later in the life cycle of a grant.
- This occurs if a delayed onset of animal activities is a component of the experimental research design described in the application.
- Notice of Award issued with a special condition indicating that no funds may be drawn from the grant for animal activities until a valid IACUC approval date has been provided.

---

---

---

---

---

---

---

---

---

---



## Commentary in *Lab Animal*

February 2009, Volume 38, No. 2, pp 46-48  
Does a voluntary suspension of an animal activity by a principal investigator need to be reported to USDA and the federal funding agency?

June 2009, Volume 38, No. 6, pp 185-87

When does a clinical evaluation become research, and does the IACUC need to be involved?

---

---

---

---

---

---

---

---

---

---



NIH OFFICE OF EXTRAMURAL RESEARCH



## Educational Resources



OLAW

---

---

---

---

---

---

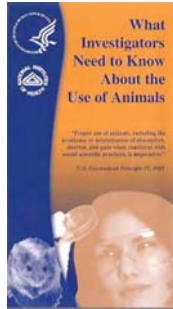
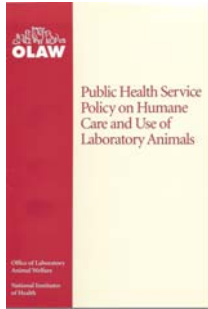
---

---

---

---

- **ListServ:** Subscribe through OLAW webpage for announcements, notices, policy interpretations
- **OLAW RSS Feed:** Available Now!




---

---

---

---

---


---

---

---

---

---

 **Workshops and Conferences**

**IACUC 101/201 Workshops**

- Tentative 2010: February - Lafayette, LA, March - Baltimore, MD, September - Sioux Falls, ID and October - Bethesda, MD

**Scientists Center for Animal Welfare (SCAW) IACUC Training**

- December 7-8, 2009, San Antonio, TX

**Animal Welfare and Scientific Research: 1985-2010**

- Symposium celebrating 25 years of progress in research with animal models
- October 25-26, 2010

---

---

---

---

---


---

---

---

---

---

 **OLAW Online Seminars**

<http://grants.nih.gov/grants/olaw/e-seminars.htm>  
<http://grants.nih.gov/grants/olaw/outreach.htm>

- Targeted for specific audience – IACUC staff, IO
- Online schedule quarterly, next seminar Dec 10
- No cost to participate
- 20 minute presentations with 30 minute Q&A
- Register online – limited to one registration per grantee institution site
- IACUC Staff Seminar recording posted the next day

---

---

---

---

---

---

---

---

---

---



## OLAW Online Seminars

### Upcoming Topics

- December 10, 2009
  - IO: The OLAW Annual Report and More
  - IACUC Staff: The OLAW Annual Report: What You Need to Know

---

---

---

---

---

---

---

---

---

---



NIH OFFICE OF EXTRAMURAL RESEARCH

## New NIH Initiatives



OLAW

---

---

---

---

---

---

---

---

---

---



## Enhancing Peer Review

<http://enhancing-peer-review.nih.gov/>

- Year long review of NIH Peer Review System
- Changes for applications funded in FY2010
- Shorter grant applications, only 1 amendment
- Early stage & new investigator policy
- New 9 point scoring system ↑ reliability
- Enhanced review criteria

---

---

---

---

---

---

---

---

---

---



## RePORT Website and RCDC

### Research Portfolio Online Reporting Tool

- Public site: <http://report.nih.gov>
- Includes ARRA funding, RCDC, Biennial Report,

### RCDC = NIH's research in 215 categories

- Grants, contracts and intramural labs
- Release in spring 2009 on FY08 research

RePORTer = replaces CRISP, beta version up

---

---

---

---

---

---

---

---



## RePORT Portal <http://report.nih.gov>




---

---

---

---

---

---

---

---



## RCDC

- Research, Condition, and Disease Categorization (RCDC) System
- Consistent and transparent information
- NIH's research activities in 360 categories
- Complete list of all NIH-funded projects related to each category
- Grants, contracts and intramural labs
- Release in spring 2009 on FY08 research
- Public web site - view, print and download

---

---

---

---

---

---

---

---



## NIH on Animal Activist Terrorism

"Threats to research with animals threatens the health of the nation. Terrorism of this type is real, life-threatening, and intolerable. 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 animals in research. Animals are critical to the acceleration of biomedical discovery of medicines, therapies, and cures."

Norka Ruiz Bravo, May 2007  
Deputy Director for Extramural Research

---

---

---

---

---

---

---

---

---

---



## Animals in Research Web Site

- NIH Internet site for several audiences
  - General Public (under development)
  - Researchers and Institutions
  - FAQs (under development)
- <http://grants.nih.gov/grants/policy/air/index.htm>

---

---

---

---

---

---

---

---

---

---



## Animals in Research: Resources for Researchers and Institutions

- NIH Internet: assist investigators and institutions to-
  - Understand the regulations and responsibilities of researchers and institutions
  - Prepare for and reduce risk
  - Respond to threats/harassment
  - Communicate to lay audiences about their research

---

---

---

---

---

---

---

---

---

---



## American Recovery and Reinvestment Act (ARRA)

- ARRA Funds to NIH  
<http://www.nih.gov/recovery/>
- \$8.2 B in extramural funding
- Stimulate economy, create/retain jobs, make scientific progress in 2 years
- Targeted supplements to current grants
- NIH Challenge Grant program
- \$1 B to NCRR construction, repairs
- \$300 M for instrumentation/equipment

---

---

---

---

---

---

---

---



## Stewardship Begins at Your Institution

- Know what NIH requires
- Read your Assurance, NIH Grants Policy Statement, Other federal requirements
- Don't forget local institutional requirements

Remember that NIH and OLAW are there to help you in the partnership

---

---

---

---

---

---

---

---



## Questions? Please Ask!

OLAW: 301-496-7163  
[olaw@od.nih.gov](mailto:olaw@od.nih.gov)  
 Division of Policy and Education  
[olawdpe@od.nih.gov](mailto:olawdpe@od.nih.gov)  
 Division of Assurances  
[olawdoa@mail.nih.gov](mailto:olawdoa@mail.nih.gov)  
 Division of Compliance Oversight  
[olawdco@mail.nih.gov](mailto:olawdco@mail.nih.gov)  
 Website: <http://olaw.nih.gov>




---

---

---

---

---

---

---

---