



# Welcome to OLAW **IACUC Staff** **Online Seminar Series**

June 9, 2011 from 2 to 3 PM (Eastern Time)

## **Writing a Good Assurance**

### Speakers

Eileen Morgan, Director, Division of Assurances, OLAW;  
Kim Taylor, D.V.M., ACLAM, and  
Venita Thornton, D.V.M.,  
Division of Assurances, OLAW

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



*This program is being conducted by the Office of Laboratory Animal Welfare (OLAW), NIH. The views expressed by speakers and moderators do not necessarily reflect the official policies of the Department of HHS; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.*

# Writing a Good Assurance

Eileen M. Morgan  
Director, Division of Assurances

Kim Taylor, D.V.M., DACLAM  
Senior Assurance Officer

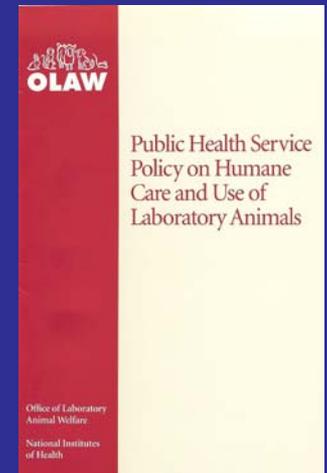
Venita Thornton, D.V.M., M.P.H.  
Senior Assurance Officer

NIH, OER, OLAW  
June 9, 2011



# PHS Policy

- All vertebrate animals
- Animal Welfare Assurance
- Institutional program of animal care and use
- Institutional Animal Care and Use Committee (IACUC)
- Self-regulation by institution
- Reporting requirements
  - Annual
  - Non-compliance



# Animal Welfare Assurances

- Contract with federal government
- Describes animal care and use program
- Documents institutional commitment
- Principal method for compliance oversight



# Types of Assurances

- Domestic
- Foreign
- Interinstitutional



# Foreign Animal Welfare Assurance

- Negotiated when
  - Prime grantee is foreign institution
  - or
  - Domestic grantee conducts animal work at foreign site
- Guided by International Guiding Principles for Biomedical Research Involving Animals (developed by CIOMS)
- Requires list of titles of governing laws, regulations and policies in English
- 5 year period



# Interinstitutional Assurance

- Grantee organization does **not** have animal care and use program (e.g., IACUC or animal facility)
- Animal work conducted at Assured institution
- Good for life of grant only (up to 5 years)



# Domestic Assurance

- Institution owns and operates own animal facilities
- Institution has a complete animal care and use program
  - IO
  - IACUC
  - Veterinarian with program authority and responsibility
- Remain in effect for 4 years and can be renewed



# Sample Domestic Assurance

- This document should not be used by
  - Foreign institutions
  - Institutions that currently do not have their own animal care and use programs
  - When animal activity will be conducted solely at a collaborating institution
- Download sample document from OLAW website  
<http://grants.nih.gov/grants/olaw/sampledoc/assur.htm>
- OLAW website  
<http://olaw.nih.gov>

# Sample Assurance Instructions

- Updated format in 2008
- Text in [brackets] provides guidance
  - [*Italicized text*] = delineates required information
  - Delete bracketed items from final document
- Adherence to sample document facilitates process
  - Concise
  - Provide only requested information



# Sample Assurance Instructions (cont.)

- Attachments
- Provide good points of contact
- Who should write the document?



# Assurance Components

Part I. Applicability

Part II. Institutional Commitment

Part III. Institutional Program for Animal Care and Use

Part IV. Institutional Program Evaluation and Accreditation

Part V. Record Keeping Requirements

Part VI. Reporting Requirements

Part VII. Institutional Endorsement

Attachments



# I. Applicability

- Only list the branches and major components of Institution covered by Assurance
- Any other institutions or locations that are “covered” by Assurance
- “Covered” means the following:
  - PHS funds are used to conduct animal activity at the covered site
  - Responsible for all animal activities
  - IO and IACUC provide oversight
  - Occupational health and safety and personnel training programs

## II. Institutional Commitment

- Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by the Assurance
- Agree to comply with all applicable laws and regulations
- Agrees to be guided by the “U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training”
- Maintain program in accord with the *Guide*



# III. Institutional Program for Animal Care and Use

- A. Lines of authority
- B. Veterinarians associated with program
- C. IACUC composition
- D. IACUC responsibilities and procedures
- E. Occupational health and safety program
- F. Facility and species inventory
- G. Training



## III. A. Lines of Authority

- Lines of communication
- Not supervisory chain
- Diagram or description



## III. B. Veterinarian(s) Associated with Program

- Veterinarian(s)
  - Name
  - Qualifications: degrees and training
  - Authority and responsibility
  - Time contributed to Program
- Veterinarian with program authority and responsibility
- If only one, then describe provisions in place for a back-up veterinarian
- Animal Welfare Act definition of a veterinarian



## III. C. IACUC Membership

- PHS Policy membership requirements
- Must provide name of veterinarian with program authority
- Must provide complete contact information for chairperson
- Sample format included in sample Assurance document
- NIH Guide Notice on alternate members (NOT-OD-11-053)



## III. D. IACUC Responsibilities and Procedures

1. Semiannual program review
2. Semiannual facility inspection
3. Semiannual report to the IO
4. Animal welfare concerns
5. Recommendations to the IO
6. Protocol review procedures
7. Review of proposed significant changes
8. Notification of investigators and IO of IACUC review decisions
9. Continuing reviews
10. Suspension procedures



# III. D. 1. Semiannual Program Review

- Who performs the reviews?
- What items are included or is a checklist used?
- When is the program review conducted?
- OLAW Sample Semiannual Program Review and Facility Inspection Checklist  
<http://grants.nih.gov/grants/olaw/sampledoc/cheklist.htm>



## III. D. 2. Semiannual Facility Inspection

- Who conducts the inspection(s)?
- When do the inspections occur?
- What items are included?
- All members invited?
- OLAW Sample Semiannual Program Review and Facility Inspection Checklist  
<http://grants.nih.gov/grants/olaw/sampledoc/cheklist.htm>



### III. D. 3. Semiannual Report to the Institutional Official (IO)

- IACUC procedures for compiling the report
- Process used to correct any deficiencies noted
- Describe components in report
  - Adherence to *Guide* and PHS Policy
  - IACUC-approved departures
  - Classification of deficiencies
    - Minor or significant
    - Reasonable and specific plan and schedule for correction
- Minority views
- Signed by majority of IACUC members



## III. D. 4. Reporting and Reviewing Concerns

- Mechanisms in place to facilitate/enable individuals to report concerns
- Procedures used to review reported concerns
- Procedures used for reporting the concerns and related IACUC findings and recommendations to the IO



## III. D. 5. Written Recommendations to the IO

- How does the IACUC develop, approve, and submit written recommendations to IO?
- Any aspect of the program, facilities, or personnel training



## III. D. 6. Protocol Review

- Concisely describe protocol review from initial receipt through final decision
- 2 valid methods recognized by PHS Policy
  - Full Committee Review
  - or
  - Designated Member Review
- Outcomes need to be listed for both methods
- “Require modifications (to secure approval)” – See NIH Guide Notice NOT-OD-09-035
- Process after IACUC decision to withhold approval?
- Procedures when more than one designated reviewer?
- Conflict of interest?



## III. D. 7. Proposed Significant Changes

- Review process for proposed significant changes
- Must receive IACUC approval prior to implementing changes



## III. D. 8. Notification of Investigators and Institution

- Written communication
- Withholding approval



## III. D. 9. Continuing Review Activities

- How does the IACUC monitor ongoing activities?
- How does the IACUC conduct triennial reviews?
- USDA covered species and protocol review



## III. D. 10. Suspension of an Approved Activity

- Who may suspend an activity?
- Reasons for suspension?
- How does the IACUC suspend?
- What role does the IO play in suspension?



## III. E. Occupational Health and Safety Program

- Safe work environment Institution's responsibility
- Effective programs require:
  - Administrative support
  - Interactions between several institutional components
- Small institutions may contract with occupational health specialists
- Use the *Guide* as a framework for describing the program
  - Address each major heading in the *Guide*
  - OLAW reviews for basic elements

## III. F. Facility and Species Inventory

- List buildings
- Provide common names for species
- List each species on a separate line
- May code locations
- Sample format in sample assurance

African Clawed Frog (*Xenopus laevis*)

Rhesus macaque (*Macaca mulatta*)



## III. G. Training

- IACUC responsible
- Who needs this training?
- Required training topics
  - Humane animal care and use
  - Methods to:
    - Minimize animal numbers
    - Limit pain and distress
- IACUC member training?



## IV. Institutional Program Evaluation and Accreditation

- Category 1 = AAALAC accredited
  - Do NOT need to submit last Semiannual Report to the IO
- Category 2 = Not AAALAC accredited
  - Must submit last Semiannual Report to the IO



# V. Record Keeping Requirements

- Provides institution with records retention requirements
- Insert name or title of IO where indicated
- Records must be available to OLAW if requested



# VI. Reporting Requirements

- Annual Reports to OLAW
- Prompt reporting to OLAW of reportable events - See NIH Guide Notice NOT-OD-05-034



# Please Send Questions NOW via the Question Box on your Screen

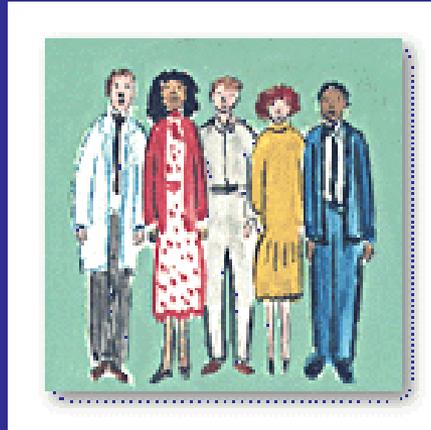
## OLAW Contact Information

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# OLAW Online Seminar Series

## Upcoming Schedule



**September 8, 2011: Occupational Health and Safety Programs**

**December 9, 2011: Grants Policy and Congruence**

