Welcome to OLAW IACUC Staff
Online Seminar Series

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

Writing a Good Assurance

Speakers

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Kim Taylor, D.V.M., ACLAM, and
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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

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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
  - 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


- 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

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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