NIH Regional Seminar on
Program Funding and Grants Administration

Public Health Service
Policy on Humane Care and Use
of Laboratory Animals

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Office of Extramural Research
June 25 - 26, 2009
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http://grants.nih.gov/grants/olaw/contactus.htm
OLAW provides guidance and interpretation of 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 and thereby contributing to the quality of research.

OLAW Mission Statement, April 2005
OLAW Educational Program

- Partnerships with organizations & institutions
- Workshops, meetings, conferences
- Webinars
- IACUC 101 / 201-Plus training programs
- IACUC Guidebook, 2nd edition
- Web-based tutorial, resources
- Published articles, FAQs, commentary
- Policy interpretations published in NIH Guide for Grants and Contracts
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
Authorizing Legislation
Public Law 99-158 (11/20/85)
Health Research Extension Act

- NIH Director to establish guidelines for research funded by NIH and other PHS agencies
- Animal Welfare Assurance mechanism
- Institutional Animal Care and Use Committee (IACUC) with oversight authority
- Institutional opportunity to correct deficiencies
PHS Policy

- All vertebrate animals
- Animal Welfare Assurance
- Institutional program of animal care and use
- Institutional Animal Care and Use Committee
- Self-regulation by institution
- Requirements
  - Record keeping – program and IACUC records
  - Reporting – annual and non-compliance
Public Health Service Agencies

- National Institutes of Health
- Food and Drug Administration
- Centers for Disease Control and Prevention
- Substance Abuse and Mental Health Services Administration
- Health Resources and Services Administration
- Indian Health Service
PHS Policy:
Standards for Animal Care and Use

AVMA Guidelines on Euthanasia
(Formerly Report of the AVMA Panel on Euthanasia)

June 2007
OLAW Responsibilities

- Oversee implementation of PHS Policy
- Provide interpretation and guidance
- Negotiate Animal Welfare Assurances
- Evaluate compliance
  - Institutional self reporting
  - Third party allegations
- Educational activities
Animal Welfare Assurances

- Contract with federal government
- Documents institutional commitment
- Principal method for compliance oversight
Types of Assurances

- Domestic Full
- Interinstitutional Agreement (AKA Assurance of Compliance)
- Foreign
Domestic Assurance

- Control their own animal facilities
- Have a complete animal care and use program
  - IO
  - IACUC
  - Veterinarian
- Remain in effect for up to 4 years
- Can be renewed
- PHS funding
- Requested by grant management personnel
Domestic Animal Welfare Assurance

- Describes animal care and use program
- Lines of authority and responsibility
- Institutional Animal Care and Use Committee
- Procedures to implement the PHS Policy
- Program of veterinary care
- Occupational safety and health program for personnel
- Training of personnel (investigators, technicians, IACUC)
- Facilities
- Species
Interinstitutional Agreements

- Grantee organization does not have animal care and use program (IACUC, animal facility)
- Animal work conducted at Assured Institute
- Good for life of grant only
- One organization may have multiple IIA numbers
- Requested by grant management personnel
Foreign Animal Welfare Assurance

- Negotiated when
  - Prime grantee is foreign institute OR
  - Domestic grantee conducting 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
- Requires 3 signatures from foreign organization
IACUC Responsibilities

- **Review** animal use protocols (including significant changes to ongoing protocols)
- Inspect facilities every six months
- Review program of animal care and use every six months
- Report to Institutional Official on Animal Welfare every six months
- Review concerns about animal care and use
- Advise Institutional Official
- Authority to **suspend** PHS-supported activity in non-compliance
Criteria for Protocol Review

- PHS Policy, § IV.C.1. (pgs 13 – 14)
- 9 CFR, Chapter 1, § IV. C. 1.
- U.S. Government Principles
- Guide for the Care and Use of Laboratory Animals (pg 10)
Protocol Review

- Minimize discomfort, pain and distress
- Use of appropriate sedation, anesthesia and analgesia
- Humane endpoints
- Living conditions and husbandry appropriate
- Medical care available and provided by qualified veterinarian
- Personnel appropriately qualified and trained
- Euthanasia appropriate and consistent with AVMA Guidelines on Euthanasia (2007)
IACUC Review of Proposed Research Projects

- Institutions are responsible for ensuring that the information in the grant application is congruent with information in the IACUC protocol review form.

- Okay to identify different individuals named as PI on grant and IACUC approved protocol.

- “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?”

Prompt Reporting to OLAW


- Serious or continuing noncompliance with the PHS Policy
- Serious deviations from the *Guide*
- Any suspension of an activity by the IACUC
What Happens When Institutions Report Noncompliance / Suspensions?

- Evidence that oversight is effective
- OLAW provides assistance / advice
- Institution takes corrective actions
- Institutional program is improved
- Research goes forward
- **Rare cases**: institution is unable to take corrective actions and NIH applies sanctions (withdraw or restrict funding)
APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

1. * TYPE OF SUBMISSION
   - Pre-application
   - Application
   - Changed/Corrected Application

2. DATE SUBMITTED

3. DATE RECEIVED BY STATE

4. Federal Identifier

5. APPLICANT INFORMATION
   - * Legal Name: [ ]
   - Department: [ ]
   - * Street1: [ ]
   - * City: [ ]
   - * Country: USA
   - Division: [ ]
   - Street2: [ ]
   - County: [ ]
   - * State: [ ]
   - * ZIP Code: [ ]
   - * Organizational DUNS: [ ]

Person to be contacted on matters involving this application
- Prefix: [ ]
- * First Name: [ ]
- Middle Name: [ ]
- * Last Name: [ ]
- Suffix: [ ]
- * Phone Number: [ ]
- Fax Number: [ ]
- Email: [ ]

6. * EMPLOYER IDENTIFICATION (EIN) or (TIN): [ ]

7. * TYPE OF APPLICANT:
   - Please select one of the following
   - Other (Specify): [ ]
   - Small Business Organization Type
     - Woman Owned [ ]
     - Socially and Economically Disadvantaged [ ]

8. * TYPE OF APPLICATION:
   - New [ ]
   - Resubmission [ ]
   - Renewal [ ]
   - Continuation [ ]
   - Revision [ ]

   If Revision, mark appropriate box(es).
   - A. Increase Award [ ]
   - B. Decrease Award [ ]
   - C. Increase Duration [ ]
   - D. Decrease Duration [ ]
   - E. Other (specify) [ ]

   * Is this application being submitted to other agencies? Yes [ ] No [ ]

   What other Agencies?

9. * NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:

11. * DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. * AREAS AFFECTED BY PROJECT (cities, counties, states, etc.)

13. PROPOSED PROJECT:
   - * Start Date: [ ]
   - * Ending Date: [ ]

14. CONGRESSIONAL DISTRICTS OF:
   - a. * Applicant [ ]
   - b. * Project [ ]

15. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION
   - Prefix: [ ]
   - * First Name: [ ]
   - Middle Name: [ ]
   - * Last Name: [ ]
   - Suffix: [ ]
   - Position/Title: [ ]
   - * Organization Name: [ ]
   - Department: [ ]
   - Division: [ ]
   - * Street1: [ ]
   - Street2: [ ]
   - * City: [ ]
   - County: [ ]
   - * State: [ ]
   - * ZIP Code: [ ]
   - * Country: USA
   - * Phone Number: [ ]
   - Fax Number: [ ]
   - * Email: [ ]

OMIG Number: 4040-0001
Expiration Date: 04/30/2008
Grants Policy Requirements

- Animal Welfare Assurance for the applicant organization and all performance sites.
- Verification that the IACUC has reviewed and approved those sections of the application that involve the use of vertebrate animals.
- Complete Vertebrate Animal Section (VAS)
Grant Applicant Must 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
    - VAS Five Points provided and complete
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 propitious/unprivileged information included in the application?  [ ] Yes  [ ] No

4.a. * Does this project have an actual or potential impact on the environment?  [ ] Yes  [ ] No

4.b. If yes, please explain: ____________________________________________________________

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed?  [ ] Yes  [ ] No

4.d. If yes, please explain: ____________________________________________________________

5. * Does this project involve activities outside the U.S. or partnership with International Collaborators?  [ ] Yes  [ ] No

5.b. If yes, identify countries: ________________________________________________________

5.c. Optional Explanation: __________________________________________________________

6. * Project Summary/Abstract

7. * Project Narrative

8. Bibliography & References Cited

9. Facilities & Other Resources

10. Equipment

11. Other Attachments

Grantee Information needs to be reflected

OMB Number: 4040-0001
Expiration Date: 04/30/2008
**PHS 398 Research Plan**

1. **Application Type:**
   From SF 424 (R&R) Cover Page and PHS398 Checklist. The responses provided on these pages, regarding the type of application being submitted, are repeated for your reference, as you attach the appropriate sections of the research plan.

   *Type of Application:
   - [ ] New
   - [ ] Resubmission
   - [ ] Renewal
   - [ ] Continuation
   - [ ] Revision

2. **Research Plan Attachments:**
   Please attach applicable sections of the research plan, below.

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<th>Add Attachment</th>
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<tr>
<td>1. Introduction to Application</td>
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<td>(for RESUBMISSION or REVISION only)</td>
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<td>2. Specific Aims</td>
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<td>3. Background and Significance</td>
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<td>4. Preliminary Studies / Progress Report</td>
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<td>5. Research Design and Methods</td>
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<td>Human Subjects Sections</td>
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<td>Attachments 6-10 apply only when you have answered &quot;yes&quot; to the question &quot;are human subjects involved&quot; on the R&amp;R Other Project Information Form. In this case, attachments 6-10 may be required, and you are encouraged to consult the Application guide instructions and/or the specific Funding Opportunity Announcement to determine which sections must be submitted with this application.</td>
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<td>7. Inclusion of Women and Minorities</td>
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<td>15. Appendix</td>
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   **Circular Arrow:**
   - Other Research Plan Sections
   - 11. Vertebrate Animals
   - 12. Consortium/Contractual Arrangements
   - 13. Letters of Support
   - 14. Resource Sharing Plan(s)
VAS Five Points

- Describe proposed use and list species, strains, ages, sex, and numbers of animals to be used
- Justify use, species, and numbers
- Veterinary care to include Performance site (separate VAS required for each Performance site)
- Procedures to minimize pain and distress
  - Pain and distress will be limited to *that which is unavoidable*
  - Describe use of analgesics, anesthetics, etc.
- Describe method of euthanasia
  - Reasons for selection of method
  - If not consistent with AVMA Guidelines - provide justification.
VAS Worksheet for Reviewers


- Assist applicants in preparing VAS for submission for peer review
- Guide reviewers in evaluating VAS
- Tools under development
  - Pamphlet for investigators
  - Example VAS
Funding Component (IC) and Peer 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 (Code 44 – Barred from funding)
- Ensure that institution has an Assurance
- If no Assurance, the IC requests that OLAW negotiate Assurance
- Verify IACUC approval – valid date for 3 yrs.
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

- **Inter-Institutional Assurance** is needed:
  - Prime grantee has no animal program (no animal facilities, no IACUC)
  - Animal work must be 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
Institutions are **not** permitted to charge for animal activities when terms and conditions are not upheld

- Absence of a valid Assurance on file with OLAW
- Absence of valid IACUC approval
  - Failure to obtain IACUC approval for animal activity
  - Failure to obtain IACUC approval for significant changes prior to implementing
  - Continuing animal activities after IACUC approval has expired
  - Continuing animal activities after suspension of IACUC approval
Policy on Allowable Costs for Grants Activity Involving Animals

- Institutions are required to report noncompliant situations
  - OLAW (olawdco.mail.nih.gov or 301-594-2061)
  - Institute/Center (IC) supporting the award
- NIH expects grantees to continue to maintain and care for animals during periods of noncompliance
- Funding components may allow expenditure of NIH grant funds for maintenance and care of animals on a case-by-case basis
- NIH Policy on Allowable Costs for Activities with Animals when Terms and Conditions are not Upheld
Educational Resource

- What Investigators Need to Know About the Use of Animals

- > 60,000 already distributed

- Directed at Investigators applying for a grant
New NIH Initiatives

- Enhancing Peer Review
- RePORT Website and RCDC
- ARRA (American Recovery and Reinvestment Act)
Year long review of NIH Peer Review System
Changes being rolled out for applications funded in FY2010
Shorter grant applications, only 1 amendment
Early stage and new investigator policy
New 9 point scoring system - ↑ reliability
Enhanced review criteria

http://enhancing-peer-review.nih.gov/
RePORT Website and RCDC

- **Research Portfolio Online Reporting Tool**
  - Public site: http://report.nih.gov
  - Includes CRISP, RCDC, Biennial Report

- **Research, Condition, and Disease Categorization System**
  - RCDC = NIH’s research in 215 categories
  - Grants, contracts and intramural labs
  - Release in spring 2009 on FY08 research

- RePORTer = replaces CRISP, coming soon
American Recovery and Reinvestment Act

- ARRA Funds to NIH
- $8.2 Billion in extramural funding
- Stimulate economy, create/retain jobs, make scientific progress in 2 years
- Targeted supplements to current grants
- NIH Challenge Grant program
- $1 Billion to NCRR construction, repairs
- $300 Million for instrumentation/equipment
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1 Number of copies you may obtain per request. Contact OLAW at olaw@od.nih.gov to discuss one time exceptions to limitations (e.g., for seminars, classroom use, etc.)
2 Additional copies and foreign language versions may be purchased from http://www.nap.edu (ISBN:0306089573)
3 Additional copies may be purchased from http://www.nap.edu (ISBN:0306089034)
4 Additional copies may be purchased from http://www.the-aps.org/store/
5 Additional sets may be purchased from http://bookstore.gpo.gov (stock No. 017-040-00559-8)
ListServ or RSS Feed: Subscribe through OLAW webpage for current announcements, notices, policy interpretations.

http://grants.nih.gov/grants/olaw/
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ANY QUESTIONS ???