

NIH Regional Seminar on
Program Funding and Grants Administration

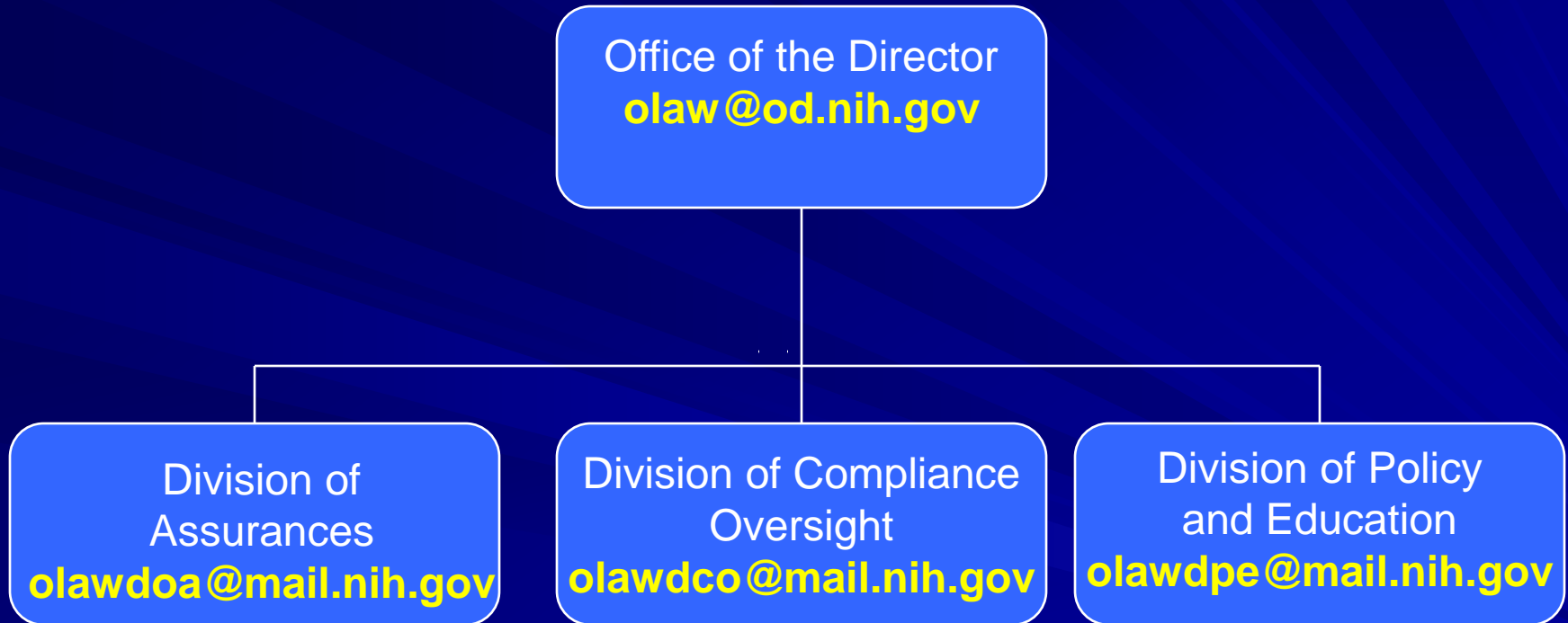


Public Health Service
Policy on Humane Care and Use
of Laboratory Animals



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Office of Laboratory Animal Welfare
Office of Extramural Research
June 25 - 26, 2009

Office of Laboratory Animal Welfare (OLAW)



<http://grants.nih.gov/grants/olaw/contactus.htm>

OLAW org chart
Updated 2/11/09

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

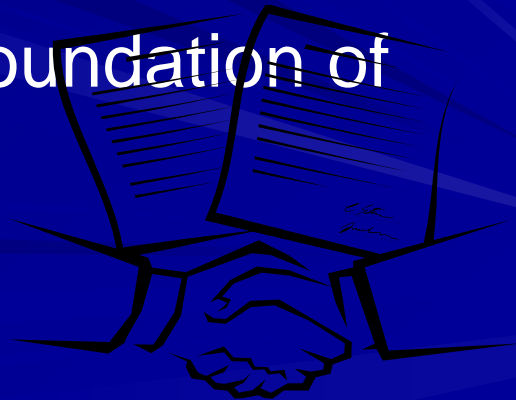
OLAW's Philosophy

“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 Policy on Humane Care and Use of Laboratory Animals

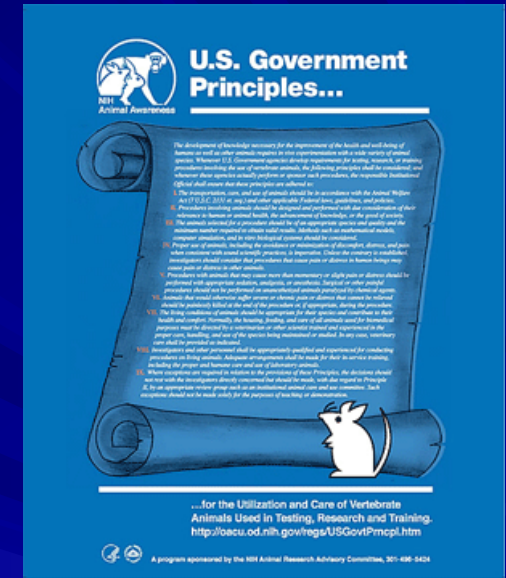
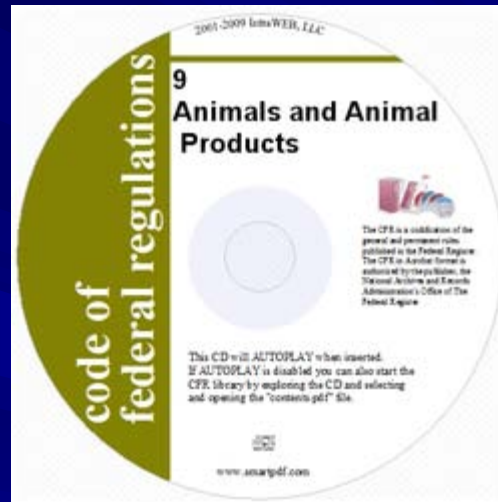
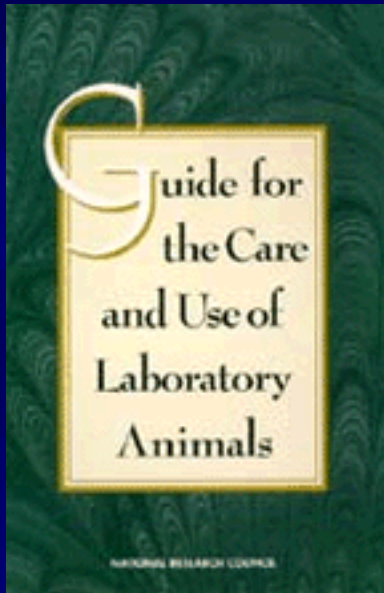
Office of Laboratory
Animal Welfare

National Institutes
of Health

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
- <http://grants.nih.gov/grants/olaw/sampledoc/assur.htm>

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?”

[http://grants.nih.gov/grants/olaw/faqs.htm#proto_18 – Jan.16, 2009]

Prompt Reporting to OLAW

[OLAW-NIH Guide Notice #NOT-OD-05-034- Feb. 24, 2005]

- 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)

RESEARCH & RELATED Project/Performance Site Location(s)

Project/Performance Site Primary Location

Organization Name:

* Street1:

Street2:

* City:

County:

* State:

* ZIP Code:

* Country:

Project/Performance Site Location 1

Organization Name:

* Street1:

Street2:

* City:

County:

* State:

* ZIP Code:

* Country:

Reset Entry

Next Site

Additional Location(s)

Add Attachment

Delete Attachment

View Attachment

OMB 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

SF424

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

**Grantee
Information needs
to be reflected**

3. * Is proprietary/privileged 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.a. * 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

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.

1. Introduction to Application	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
(for RESUBMISSION or REVISION only)				
2. Specific Aims	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
3. Background and Significance	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
4. Preliminary Studies / Progress Report	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
5. Research Design and Methods	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment

Human Subjects Sections

Attachments 6-10 apply only when you have answered "yes" to the question "are human subjects involved" on the R&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.

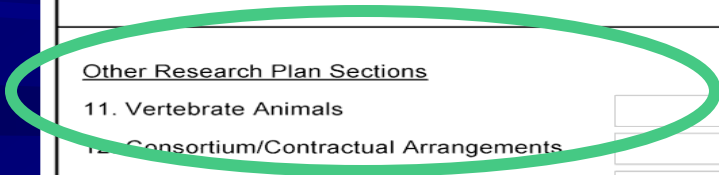
6. Protection of Human Subjects	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
7. Inclusion of Women and Minorities	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
8. Targeted/Planned Enrollment Table	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
9. Inclusion of Children	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
10. Data and Safety Monitoring Plan	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment

Other Research Plan Sections

11. Vertebrate Animals	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
12. Consortium/Contractual Arrangements	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
13. Letters of Support	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
14. Resource Sharing Plan(s)	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment

15. Appendix

Add Attachments Remove Attachments View Attachments



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

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

- 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

Policy on Allowable Costs for Grants Activity Involving Animals

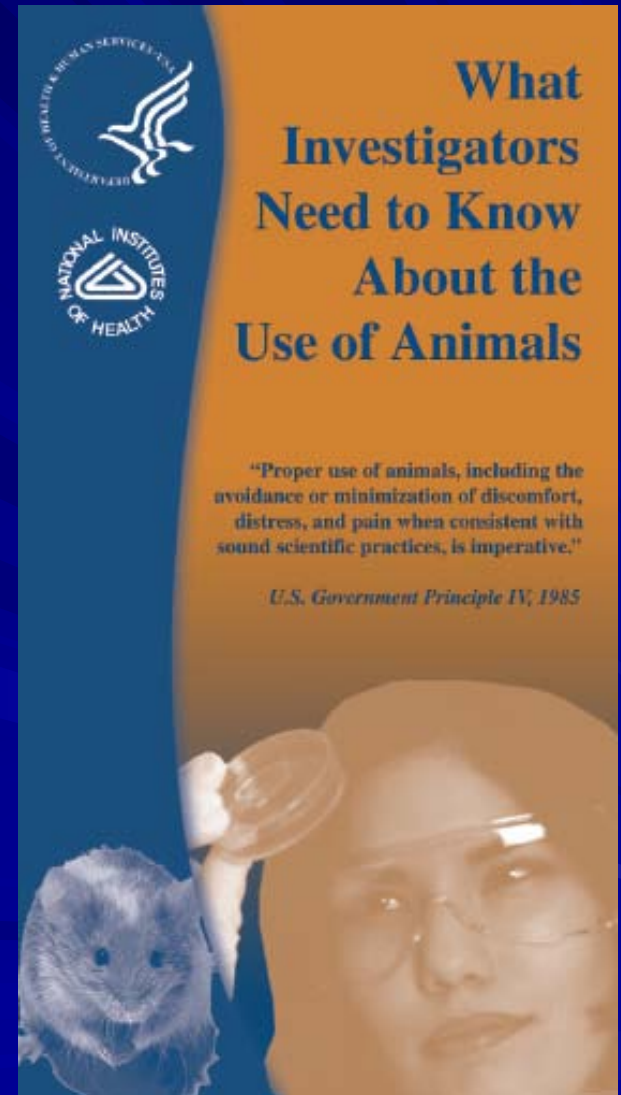
- Institutions are **not** permitted to charge for animal activities when terms and conditions are not upheld
 - Absence of a valid Assurance on file with OLAW
 - Absence of valid IACUC approval
 - ✓ Failure to obtain IACUC approval for animal activity
 - ✓ Failure to obtain IACUC approval for significant 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
[<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-044.html>]

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)

Enhancing Peer Review

- 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

- **R**esearch **P**ortfolio Online Reporting Tool
 - Public site: <http://report.nih.gov>
 - Includes CRISP, RCDC, Biennial Report
- **R**esearch, **C**ondition, and **D**isease **C**ategorization 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
- <http://www.nih.gov/recovery/>
- \$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

**Publications Available from the
Office of Laboratory Animal Welfare**



To request an item send email to olaw@od.nih.gov

Please include the following information:

- title
- format
- number of copies (note limitations for certain items)
- complete name and mailing address

Title	Format	Limit ¹
PHS Policy on Humane Care and Use of Laboratory Animals, 2002	hard copy	none
Guide for the Care and Use of Laboratory Animals, 1996, NRC	CD	none
	hard copy	5 ²
ARENA/OLAW IACUC Guidebook, 2nd Edition, 2002	hard copy	none
What Investigators Need to Know About the Care and Use of Laboratory Animals, NIH Pub No. 06-6009	hard copy brochure	none
Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research, 2003, NRC	hard copy	1 ³
	CD	5
Resource Book for the Design of Animal Exercise Protocols, 2006, APS	hard copy	1 ⁴
Enrichment for Nonhuman Primates, 2005. Series of all 6 booklets, listed below	hard copy	1 ⁵
Enrichment for Nonhuman Primates, 2005 Baboons, NIH Pub No. 05-5745 Capuchins, NIH Pub No. 05-5746 Chimpanzees, NIH Pub No. 05-5748 Macaques, NIH Pub No. 05-5744 Marmosets and Tamarins, NIH Pub No. 05-5747 Squirrel Monkeys, NIH Pub No. 05-5749	hard copy	1
Working Safely with Nonhuman Primates	CD	1
Working with the Laboratory Dog	CD	1
Training in Survival Rodent Surgery	CD	1
Institutional Administrator's Manual for Laboratory Animal Care and Use, 1988, NIH Pub No. 88-2959	hard copy	none

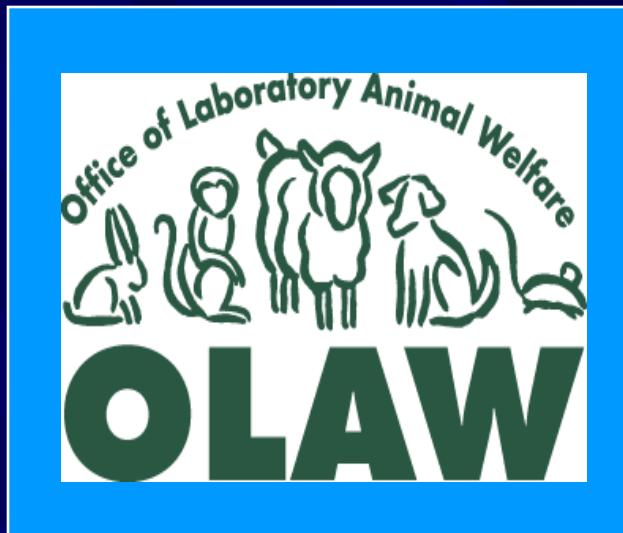
¹ Number of copies you may obtain per request. Contact OLAW at olaw@od.nih.gov to discuss one time exceptions to limitations (e.g., for seminars, classroom use, etc.)

² Additional copies and foreign language versions may be purchased from <http://www.nap.edu> (ISBN:0309053773)

³ Additional copies may be purchased from <http://www.nap.edu> (ISBN:0309089034)

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 ???