

# When Terms and Conditions Are Not Upheld

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# OLAW's Purpose

- How OLAW provides guidance & interpretation of the PHS Policy, supports educational programs, & monitors compliance with the Policy by Assured institutions & PHS funding components to ensure the
- What humane care & use of animals in PHS-supported research, testing, & training, thereby contributing to the quality of
- Why PHS-supported activities.

## ▣ Promoting Compliance

- Facilitating animal welfare: Assurance document describing how institution will comply
- Educating through workshops, online seminars, website content, resources
- Monitoring institutional self-reporting
- Evaluating allegations of noncompliance

# OLAW's Authority: P.L. 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- Funding can be withdrawn if animal care does not meet guidelines

# NIH Guidance to Grantees

- NIH Policy on Allowable Costs for Grant Activities Involving Animals When Terms and Conditions are Not Upheld
- Notice NOT-OD-07-044
- Posted January 2007 with OPERA
- Link from OLAW web site

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-044.html>

# Issues That Prompted Guidance

OMB and NIH Grants Policies **do not permit:**

- Use of a lapsed Inter-institutional Assurance
- Change of performance site without obtaining Assurance
- Conduct of animal research with expired IACUC protocols

# Notice on Allowable Costs

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No costs may be charged for the conduct of animal activities when certain terms and conditions are not upheld:

- Absence of a valid Assurance
- Absence of valid IACUC approval

# Valid Animal Welfare Assurance

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- Domestic
- Foreign
- Inter-institutional

# 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

# Foreign Assurance

- Foreign institutions that are grantees or subaward partners to a domestic grantee
- Agree to comply with the International Guiding Principles for Biomedical Research Involving Animals of the Council of International Organizations of Medical Sciences (CIOMS)
- Laws and regulations of the country in which it is located
- Remain in effect for up to 5 years
- Do not need to submit certification of IACUC approval if receiving a direct award

# Inter-Institutional Assurance

- Prime grantee does not have their own animal program
- Contract the animal work to an Assured institution
- Uses the facilities and IACUC of another institution
- Inter-Institutional Assurance document
  - Contract between grantee institution, Assured performance site and OLAW
  - Agree to conduct the project according to the assurance of the covered organization
- Timeframes are project specific

# Consortium Agreements: Sub-awards

- Prime grantee is accountable to NIH and must confirm:
  - Assurance
  - IACUC approval (dated within 3 years)
    - Required from only 1 Assured entity
- Animal welfare requirements apply to all consortium participants and sub-projects
- For more information see NIH Grants Policy Statement, Part II, Terms and Conditions of NIH Grant Awards, Consortium Agreements

Slide 13 title: Consortium Agreements: Subawards continued

Large bullet: Inter-Institutional Assurance is needed:

Small bullet: Prime grantee has no animal program and animal work is being conducted at an Assured performance site.

Large bullet: Foreign Assurance is needed

Small bullet: Domestic prime grantee with a foreign performance site using animals:

Smaller bullet: Domestic grantee's IACUC approves animal activities performed at foreign site.

# Consortium Agreements: Sub-awards continued

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- 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:
  - Domestic prime grantee with a foreign performance site using animals:
    - Domestic grantee's IACUC approves animal activities performed at foreign site

# Research Without Approval

Absence of IACUC approval:

- Failure to obtain IACUC approval
- Expiration of IACUC-approved Animal Study Protocol
- Suspension of IACUC approval
- Report to OLAW and NIH funding component
  - When work is conducted outside terms and conditions of grant or
  - When study is suspended

# The Right Way to Conduct Animal Research

PI is awarded grant and NIH provides funds

PI conducts IACUC-  
approved research

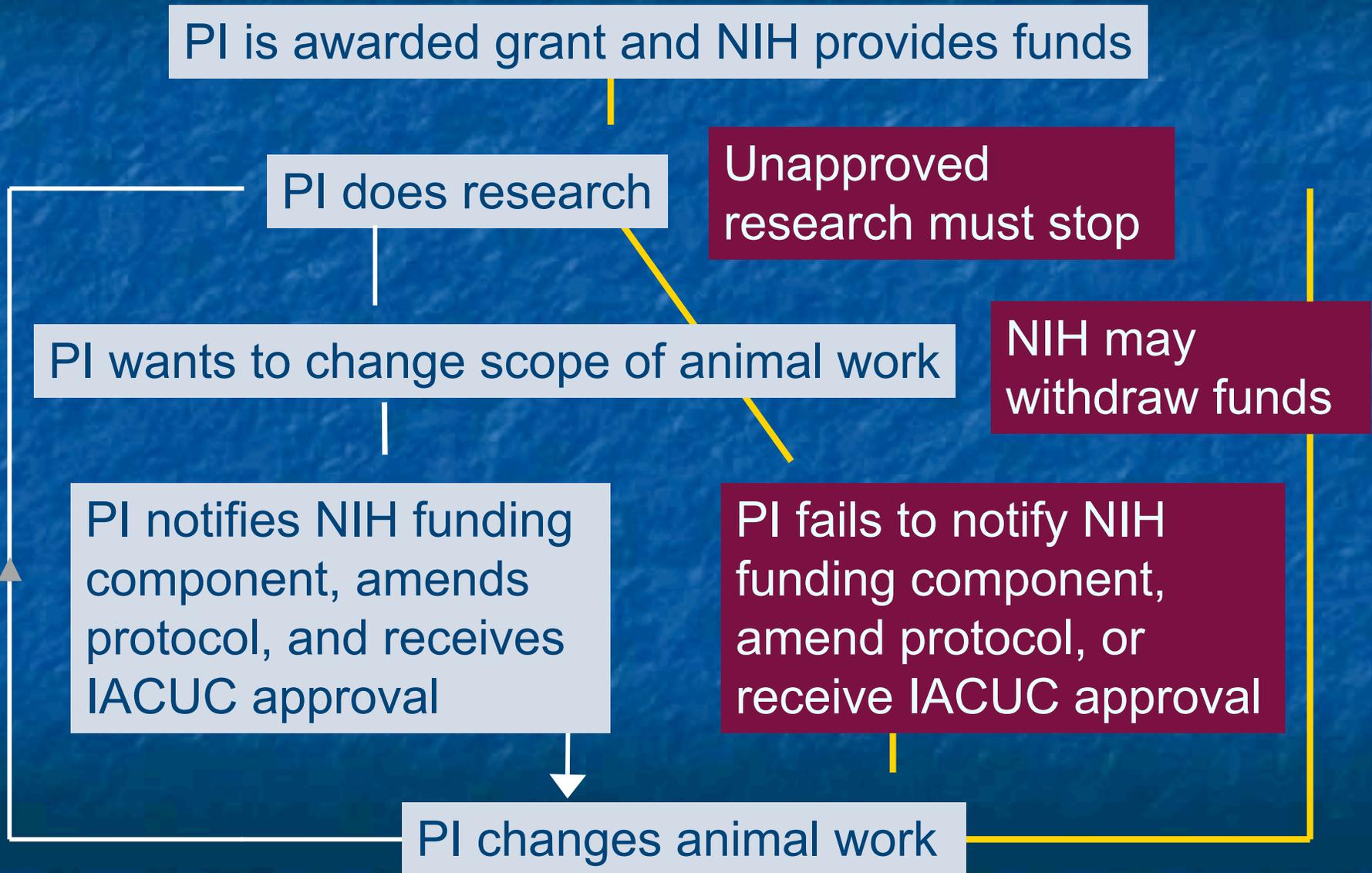
PI wants to change scope of animal work

PI notifies NIH funding component &  
obtains approval, amends protocol,  
and receives IACUC approval

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PI changes animal work

# Failure to Obtain IACUC Approval



Slide 15 is a flow chart showing the right way to conduct animal research. On the first line of the flowchart is a block that says “PI is awarded grant and NIH provides funds.” There is an arrow to a block directly underneath that says “PI conducts IACUC-approved research.” There is an arrow directly down to the next line. That line says “PI wants to change the scope of animal work”. An arrow points directly down from the line to a box that says “PI notifies NIH funding component and obtains approval, amends protocol, and receives IACUC approval.” An arrow goes directly from this box to the next box, that says “PI changes animal work.” An arrow goes from this box along the left side of the slide back up to the box that says “PI conducts IACUC-approved research. This slide shows a loop that can occur repeatedly as the PI conducts IACUC-approved research and seeks approval to make changes in the research protocol.

Slide 16 shows the same boxes and arrows as the previous slide but now additional boxes have been added to show what happens in the case of (title of slide) “Failure to Obtain IACUC Approval.” In this instance, the “PI is awarded grant and NIH provides funds.” As before the “PI does research.” In the next box, the “PI wants to change the scope of animal work.” However “PI fails to notify NIH funding component, amend protocol, or receive IACUC approval.” The “PI changes the animal work.” Additional arrows loop up the right side of the slide. In this instance (when the PI proceeds with unapproved animal work) the “NIH may withdraw funds” and “Unapproved animal work must stop.”

# Expired IACUC Approval

- IACUC **cannot** administratively extend approval
- *De novo* review every 3 years
- If expired:
  - Notify NIH funding component and OLAW if animal work is ongoing
  - Notification after reinstatement is not required
  - Cannot draw grant funds for animals during expired period

# IACUC Protocol Suspension

Animal activity not conducted as approved

IACUC votes for suspension

- Officially convened meeting
- Quorum present
- Simple majority of quorum votes to suspend

Institutional Official with IACUC

- Take corrective action
- Report to OLAW

Institution reports to NIH funding component

OLAW determines if action is adequate

Slide 18 is a simple linear flow chart. The title is "IACUC Protocol Suspension." The first box is red and the text reads "Animal activity not conducted as approved." All subsequent boxes are grey. An arrow leads to a box with the text "IACUC votes for suspension." The 3 bullets beneath the text say "Officially convened meeting," "Quorum present," and "Simple majority of quorum votes to suspend." There is an arrow leading to another grey box. Text reads "Institutional Official with IACUC." Two bullets below this text say "Take corrective action," and "Report to OLAW." An arrows directs the reader to the next box below. The single line of text reads "Institution reports to NIH funding component. A last arrow points to the final box on this slide. The single line of text says "OLAW determines if action is adequate."

# Actions Required After Suspension, IACUC Approval Lapse, Assurance Lapse

- Report the noncompliant situation to OLAW
- Report to the Grants Management Officer of the NIH funding component
- **Do not charge costs during period of noncompliance**
- Continue to maintain and care for animals
- Authorization of funds for maintenance and care of animals is decided on a case-by-case basis by the NIH funding component

# Reporting to OLAW

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- E-mail: [olawdco@mail.nih.gov](mailto:olawdco@mail.nih.gov)
- Phone call: 301-594-2061
- When in doubt, please call
- It is better to ask or report, than not
- Consequences are less desirable if reportable event is withheld and discovered later
- OLAW needs information on serious noncompliance to represent institution to PHS, Congress, & media

# 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

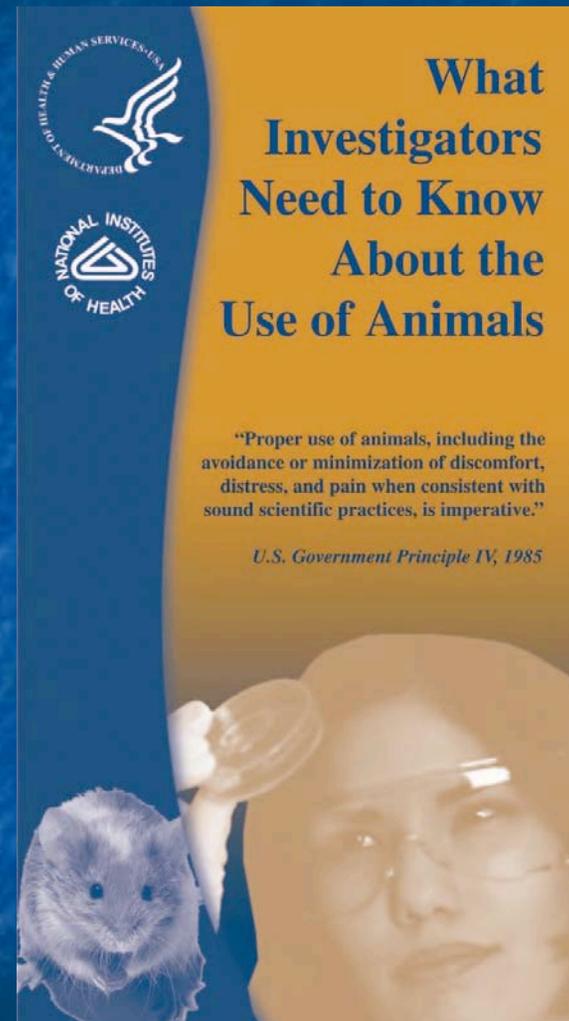


# Questions?

- Questions concerning NIH grants policy:
  - Office of Policy for Extramural Research Administration (OPERA)
  - 301-435-0938 or [grantspolicy@od.nih.gov](mailto:grantspolicy@od.nih.gov)
- Questions about Assurances or IACUC approval:
  - OLAW
  - 301-496-7163 or [olawdoa@od.nih.gov](mailto:olawdoa@od.nih.gov)

# Educational Resource

- Free Brochure
- Targeted to the scientist applying for a grant
- Volume orders OK
- E-mail requests preferred



OLAW web <http://olaw.nih.gov>

Contact OLAW

[olaw@od.nih.gov](mailto:olaw@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)

