When Terms and Conditions Are Not Upheld

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December 4, 2008
OLAW Online Seminar
OLAW’s Purpose

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 humane care & use of animals in PHS-supported research, testing, & training, thereby contributing to the quality of PHS-supported activities.

- **How**

- **What**

- **Why**
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- Funding can be withdrawn if animal care does not meet guidelines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

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

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

- 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

- 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

1. PI is awarded grant and NIH provides funds
2. PI conducts IACUC-approved research
3. PI wants to change scope of animal work
4. PI notifies NIH funding component and obtains approval, amends protocol, and receives IACUC approval
5. PI changes animal work
Failure to Obtain IACUC Approval

- PI is awarded grant and NIH provides funds
  - PI does research
    - PI wants to change scope of animal work
      - PI notifies NIH funding component, amends protocol, and receives IACUC approval
        - PI changes animal work
          - Unapproved research must stop
          - NIH may withdraw funds
            - PI fails to notify NIH funding component, amend protocol, or receive 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 IACU-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 arrow 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

- E-mail: 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

- Questions about Assurances or IACUC approval:
  - OLAW
  - 301-496-7163 or olawdoa@od.nih.gov
Educational Resource

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

What Investigators Need to Know About the Use of Animals

“Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative.”

U.S. Government Principle IV, 1985
OLAW web  http://olaw.nih.gov

Contact OLAW
olaw@od.nih.gov

Division of Assurances
olawdoa@mail.nih.gov

Division of Compliance Oversight
olawdco@mail.nih.gov