NIH Regional Seminar
Research Involving Animal Subjects

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Office of Extramural Research, NIH, DHHS

Office of Laboratory Animal Welfare (OLAW)

- Policy guidance and interpretation
- Animal Welfare Assurance negotiation
- Compliance evaluation
- Education
- Policy waivers
- Advise NIH institutes regarding implementation

PHS Policy on Humane Care and Use of Laboratory Animals, revised August 2002

Health Research Extension Act of 1985
Public Law 99-158
“Animals In Research”
November 20, 1985

Key Elements

- Institutional self-regulation
- Animal Welfare Assurance
- Oversight by Institutional Animal Care and Use Committee (IACUC)
- Record keeping
- Reporting

Guide for the Care and Use of Laboratory Animals

- National Academy of Sciences’ Institute for Laboratory Animal Research
- Performance Standards
  - Published data
  - Expert opinion
  - Scientific principles

Foundation of institutional self-regulation

- Flexibility
- Use of performance standards
- Institutional self-evaluation
- Institutional self-monitoring
- Institutional self-correcting
- Institutional self-reporting

PHS Policy Tutorial at:
US Government Principles

- Transportation
- Relevance
- Species, numbers
- Alternatives
- Pain and distress
- Analgesia, anesthesia
- Humane endpoints, euthanasia
- Living conditions
- Veterinary care
- Trained personnel
- Exceptions

Acceptable methods of euthanasia

- Deviation permitted if
  - scientific justification
  - approved by IACUC

Animal Welfare Assurance

- Condition of grant award
- Description of institution’s program for animal care and use
- Description of IACUC procedures
- Compliance mechanism
  - Annual reporting
  - Self-reporting of noncompliance

Components of an institutional program for animal care and use

- Delineation of authority and responsibility
- Qualified Veterinarian with program authority
- Institutional Animal Care and Use Committee
- Institutional policies and procedures
- Occupational health and safety program
- Training for those involved in animal care/use
- Facilities, animal husbandry
- Veterinary care program

IACUC Membership

- Minimum of five members
  - veterinarian
  - scientist
  - nonscientist
  - nonaffiliated

IACUC Functions

- Oversight of animal care & use program
- Semiannual evaluations and inspections
- Schedule and plan for correcting deficiencies
- Review protocols
- Review concerns
- Advise Institutional Official
- Suspension authority
What does the IACUC approve?

IACUC protocol form?

Grant application?

Do they match? How do you know?

Prompt Reporting

- Institution must promptly report:
  - Serious or continuing noncompliance
  - Serious deviations from standards
  - IACUC suspension
  - Evidence that oversight is effective
  - Usually results in corrective actions and improved systems

OLAW Guidance on prompt reporting, NIH Guide NOT-OD-05-034, 2/24/05

OLAW Compliance Data

- Results of coding 758 cases
- Represents all cases in 2000-2003
- "Case" refers to:
  - Institutional self-reports (96%)
  - Third party allegations (4%)

Type of Noncompliance

<table>
<thead>
<tr>
<th>Noncompliance Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work Before Approval</td>
<td>35%</td>
</tr>
<tr>
<td>Sig Change W/out Approval</td>
<td>13%</td>
</tr>
<tr>
<td>Failure to Follow ASP</td>
<td>9%</td>
</tr>
<tr>
<td>Work Under Expired ASP</td>
<td>7%</td>
</tr>
<tr>
<td>Of failure to follow policies</td>
<td>4%</td>
</tr>
<tr>
<td>Surgical Post Op Failure</td>
<td>3%</td>
</tr>
<tr>
<td>Unauthorized Personnel</td>
<td>9%</td>
</tr>
<tr>
<td>Inadequate Records</td>
<td>5%</td>
</tr>
<tr>
<td>Failed Euthanasia</td>
<td>4%</td>
</tr>
<tr>
<td>OSH</td>
<td>4%</td>
</tr>
<tr>
<td>Other</td>
<td>1%</td>
</tr>
</tbody>
</table>

Responsible Individual(s)

<table>
<thead>
<tr>
<th>Role</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Investigator</td>
<td>66%</td>
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<tr>
<td>Research Tech</td>
<td>7%</td>
</tr>
<tr>
<td>Veterinarian</td>
<td>3%</td>
</tr>
<tr>
<td>Vet Tech</td>
<td>3%</td>
</tr>
<tr>
<td>Animal Caretaker</td>
<td>3%</td>
</tr>
<tr>
<td>Postdoc Student</td>
<td>1%</td>
</tr>
<tr>
<td>Grad Other Student</td>
<td>1%</td>
</tr>
<tr>
<td>IACUC</td>
<td>1%</td>
</tr>
<tr>
<td>Institution Official</td>
<td>1%</td>
</tr>
</tbody>
</table>

Institutional Corrective Action

<table>
<thead>
<tr>
<th>Action</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retraining</td>
<td>25%</td>
</tr>
<tr>
<td>Suspension of ASP</td>
<td>15%</td>
</tr>
<tr>
<td>Inst Policy Modification</td>
<td>14%</td>
</tr>
<tr>
<td>Facility Modification</td>
<td>13%</td>
</tr>
<tr>
<td>Counseling</td>
<td>11%</td>
</tr>
<tr>
<td>Enhanced ASP PI Oversight</td>
<td>7%</td>
</tr>
<tr>
<td>Revise ASP</td>
<td>5%</td>
</tr>
<tr>
<td>Other</td>
<td>10%</td>
</tr>
</tbody>
</table>
To receive an award involving animals….

- Applicant addresses 5 points in the Research Plan of application
- Institutional Animal Welfare Assurance
- Verification of IACUC approval


PHS398 application (Research Plan, 8f) or SF424 PDF attachment 2.

Research Plan #11
Vertebrate Animal Section
- Number and species
- Rationale
- Description of use
- Procedures to minimize pain
- Method of euthanasia

RESPONSIBILITIES

INVESTIGATOR

ACCOUNTABILITY

INSTITUTION

IACUC

Investigator Responsibilities
- Scientific and technical aspects of project
- Comply with IACUC decisions
- Follow institutional policies
- Obtain IACUC approval before introducing significant changes

Institutional Responsibilities
- Appropriate use of funds
- Appropriate performance of activities
- Resources for animal care and use
- IACUC
- Reporting to OLAW

IACUC Responsibilities
- Oversee institutional program
- Protocol review
  - PHS requirement
  - Quality assurance
  - Facilitate humane research
- Identify and correct noncompliance
Success:
- Institutional climate that promotes compliance
- Institutional policies
- Institutional training
- Checks and balances
- Communication, internal and with NIH

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