Module V: Post-Approval Monitoring, Allegations and Noncompliance, and Other Tasks As Assigned!

Agenda

The Administrator's Role in Managing

1. Post-Approval Monitoring
2. Allegations, Complaints, Noncompliance & Suspensions
3. Documentation and Reporting
4. Other Tasks Not Listed in Your Job Description!

WHERE TO BEGIN?

Help! I need a road map!

marcy.brown@pfizer.com
dfrolich@scripps.edu
Module V: Post-Approval Monitoring, Allegations and Noncompliance, and Other Tasks As Assigned!

Is There a Definition of Post-Approval Monitoring?

Are there Regulations Requiring Post-Approval Monitoring (Why do it)?

What does PHS Policy say about PAM?

marcy.brown@pfizer.com
dfrolich@scripps.edu
Module V: Post-Approval Monitoring, Allegations and Noncompliance, and Other Tasks As Assigned!

What does the USDA say about PAM?

What does the Guide say about PAM?
Module V: Post-Approval Monitoring, Allegations and Noncompliance, and Other Tasks As Assigned!

What does AAALAC say about PAM?

Post-Approval Monitoring – Developing or Improving Your Program

What is your IACUC’s philosophy?

Post-Approval Monitoring – Developing or Improving Your Program

What is your IACUC’s philosophy?
## Module V: Post-Approval Monitoring, Allegations and Noncompliance, and Other Tasks As Assigned!

### Post-Approval Monitoring – Developing or Improving Your Program

<table>
<thead>
<tr>
<th>Who does protocol or program monitoring?</th>
</tr>
</thead>
<tbody>
<tr>
<td>- The IACUC?</td>
</tr>
<tr>
<td>- Or -</td>
</tr>
<tr>
<td>Someone on behalf of the IACUC?</td>
</tr>
</tbody>
</table>

### Who does it? Mechanisms for Monitoring

- One size does NOT fit all –
- Large organizations
  - Animal care and regulatory programs are often separate
- Small companies & institutions
  - One group may serve both animal care and regulatory functions

### If Not a Dedicated Person, Then Who?

<table>
<thead>
<tr>
<th><a href="mailto:marcy.brown@pfizer.com">marcy.brown@pfizer.com</a></th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="mailto:dfrolich@scripps.edu">dfrolich@scripps.edu</a></td>
</tr>
</tbody>
</table>
Module V: Post-Approval Monitoring, Allegations and Noncompliance, and Other Tasks As Assigned!

THE MANY TITLES FOR “PAM PEOPLE”

From the IACUC-Admin List-serve 1/21/2015

- Animal Research Liaison
- Quality Assurance Specialists
- IACUC Liaison
- Protocol Advisors and Liaisons
- Protocol Liaisons
- Compliance Liaisons
- Compliance Coordinator
- PAM Officer
- Training and Compliance Analyst
- Post-Approval Monitoring Coordinator
- Post Approval Monitoring Officer
- Director of Animal Compliance Support
- IACUC Research Liaison
- FiFis

How Might You do it?
Post-Approval Monitoring Approaches

<table>
<thead>
<tr>
<th>Formal Approach</th>
<th>Advantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Ongoing program of observing &amp; review</td>
<td>- Increases awareness</td>
</tr>
<tr>
<td>- Review of specific documents</td>
<td>- Prompt identification and resolution of concerns</td>
</tr>
<tr>
<td>o Onsite interviews with research personnel</td>
<td>- Educational opportunity for training and making refinements</td>
</tr>
<tr>
<td>o Audits of activities</td>
<td></td>
</tr>
</tbody>
</table>

Formal Monitoring Program

Considerations:

- Funding needs to be identified
- Reporting structure needs to be determined
- Qualified personnel are necessary
- Number and distance of facilities and labs need to be considered
- SOP’s need to be developed
Module V: Post-Approval Monitoring, Allegations and Noncompliance, and Other Tasks As Assigned!

How Might You do it?
Post-Approval Monitoring Approaches

<table>
<thead>
<tr>
<th>Informal Approach</th>
<th>Advantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>✔ Semiannual review of program</td>
<td>✔ Works well in a small setting</td>
</tr>
<tr>
<td>✔ Veterinary &amp; animal care staff provide oversight as part of daily routines</td>
<td>✔ Is cost effective</td>
</tr>
<tr>
<td>✔ Protocol review</td>
<td>✔ IACUC may be more engaged in process</td>
</tr>
<tr>
<td>✔ Review of concerns</td>
<td>✔ Other personnel can be trained</td>
</tr>
</tbody>
</table>

Informal Monitoring Program

Considerations:
- IACUC members need additional training
- Education and training of research staff is essential
- Participation and cooperation of veterinary and animal care staff is critical
- Requires an institutional culture of responsibility and commitment to compliance

Common Models of PAM Programs

- Veterinarian
- IACUC
- Compliance
- Hybrid

marcy.brown@pfizer.com
dfrolich@scripps.edu
Module V: Post-Approval Monitoring, Allegations and Noncompliance, and Other Tasks As Assigned!

Thoughts on the Hybrid Model

Making the most of what you already do!

Use Activities You Already Perform to Count for PAM!

Additional Ideas for a Hybrid PAM
Module V: Post-Approval Monitoring, Allegations and Noncompliance, and Other Tasks As Assigned!

Is Your PAM Program S.M.A.R.T.?

- Specific
- Measurable
- Attainable
- Realistic
- Timely

Final Thoughts

- Recognize those who are doing a good job.
- Maintain a culture of openness and partnership with research groups.
- Provide information and solutions to problems.
- Provide positive feedback for corrective actions taken.

Agenda

The Administrator’s Role in Managing

1. Post-Approval Monitoring
2. Allegations, Complaints, Noncompliance & Suspensions
3. Documentation and Reporting
4. Other Tasks Not Listed in Your Job Description!
Module V: Post-Approval Monitoring, Allegations and Noncompliance, and Other Tasks As Assigned!

Managing Allegations, Complaints and Noncompliance

Don't sweep under the rug

Sources of Allegations/Complaints

- Research Staff
- Animal care staff
- Faculty and staff
- Students
- Compliance/QA Audits
- Regulatory agencies
- The public
- Anonymous sources
- Animal rights groups
- Anyone from anywhere

Handling Allegations and Complaints

- Establish a policy for handling allegations & complaints.
- Follow institutional polices and procedures for protection of whistleblower and the accused.
- Take all allegations and complaints seriously and investigate fully.
- Never assume an allegation is true.
- Maintain confidentiality.
- Allegations may involve more than the IACUC.
- Some allegations may involve noncompliance.

marcy.brown@pfizer.com
dfrolich@scripps.edu
Module V: Post-Approval Monitoring, Allegations and Noncompliance, and Other Tasks As Assigned!

Dealing with Noncompliance

- Act Immediately
- Identify the issues and possible causes
  - Lack of awareness/oversight
  - Frequency of occurrence
  - Protocol review/monitoring
- Determine the degree (significant, minor)
  - Adverse effects on animals/personnel
  - Violation of federal regulations
  - IACUC involvement

Resolution of Noncompliance

- Determine actions to be taken
- Develop a plan for corrective actions and a checklist for accomplishing them
- Obtain support and resources to implement plan
- Notify appropriate institutional officials
- Finalize timeline for resolution
  - (in consultation with regulatory agency if applicable)
Module V: Post-Approval Monitoring, Allegations and Noncompliance, and Other Tasks As Assigned!

### Suspensions – Specific Rules

- Require a meeting of a quorum of the IACUC
- Require a vote of a majority of the quorum present
- IO must review the reasons for suspension in consultation with the IACUC

### Sample Policies for Handling Concerns/Complaints

*The Institution MUST develop methods for reporting and investigating animal concerns*


### Common Issues of Noncompliance

<table>
<thead>
<tr>
<th>Issue</th>
<th>OLAW</th>
<th>USDA</th>
<th>AAALAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal Care</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>ắc</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Program Description/Review</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Policies and Procedures</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Personnel Qualifications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Animal Welfare</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Training</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alignment and Accountability</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Program Management</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Institutional Policies and Procedures</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Animal Welfare</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Program Management</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Veterinary Care</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative Care</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postoperative Care</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PISO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research Analysis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data Collection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data Analysis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data Interpretation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data Reporting</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data Submission</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data Validation</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

AAALAC Trends Data 2011 (presented at PRIM&R 2012)
USDA Data from NABR webinar 01/11/11
OLAW Data from Presentation at PRIM&R 2012
Module V: Post-Approval Monitoring, Allegations and Noncompliance, and Other Tasks As Assigned!

Agenda

The Administrator’s Role in Managing

1. Post-Approval Monitoring
2. Allegations, Complaints, Noncompliance & Suspensions
3. Documentation and Reporting
4. Other Tasks Not Listed in Your Job Description!

Documentation

Laboratory and Study Area Visits

- Keep a database of all approved laboratories and housing facilities
- Maintain a program of frequent visits to facilities
- Develop and use checklists
- Target high risk areas

Documentation & Reporting

Allegations, Complaints & Noncompliance

- Indicate how incident was reported/discovered
- Summarize allegation/complaint
- Describe
  - How the investigation was conducted
  - Who participated in the investigation
  - Results of the investigation
  - Actions taken to correct and to prevent recurrence
  - Sanctions put in place (if any)
- Send report to the IO and other appropriate persons and agencies.
### Module V: Post-Approval Monitoring, Allegations and Noncompliance, and Other Tasks As Assigned!

#### Suspensions – Reporting Rules

<table>
<thead>
<tr>
<th>Must report to</th>
</tr>
</thead>
<tbody>
<tr>
<td>OLAW (if PHS assured)</td>
</tr>
<tr>
<td>USDA (if regulated species)</td>
</tr>
<tr>
<td>AAALAC (if accredited)</td>
</tr>
</tbody>
</table>

#### NIH – OLAW Guidance

- **NOT-OD-07-044** – Clarifies that no costs for activities with live vertebrate animals may be charged to NIH if there is not a valid Animal Welfare Assurance and Institutional Animal Care and Use Committee (IACUC) approval. [http://grants.nih.gov/grants/guide/notice-files/not-od-07-044.html](http://grants.nih.gov/grants/guide/notice-files/not-od-07-044.html)
- **NOT-OD-10-081** - Provides additional clarification in reference to Notice NOT-OD-07-044 regarding the grantee’s responsibilities when animal activities have been conducted which do not meet the terms and conditions of grant award. [http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-081.html](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-081.html)
- **NOT-OD-05-034** - This guidance is intended to assist IACUCs and Institutional Officials in determining what, when, and how situations should be reported under IV.F.3 of the Policy, and to promote greater uniformity in reporting. [http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html)

#### NOT-OD-05-034 Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals

- **Examples of reportable situations**
- **Examples of situations not normally required to report**
- **Time Frame for reporting**
- **Information to be reported**
USDA - Animal Welfare Regulations

- If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any Federal agency funding that activity.

9 CFR Ch. 1, 2.31 (d)(7)

AAALAC

"It is AAALAC’s expectation that such reports will be investigated by the appropriate oversight body (e.g., the IACUC or comparable oversight body) and that any necessary corrective actions will be taken. In addition, AAALAC International should be informed of the results of the investigation and any subsequent corrective measures."

AAALAC FAQ C.7

TWO ARTICLES INCLUDED ON PORTAL

(1) J. G. COLLINS
(2) J. R. HAYWOOD AND MOLLY GREENE

http://ilarjournal.oxfordjournals.org.proxy1.athensams.net/content/49/4.toc

marcy.brown@pfizer.com
dfrolich@scripps.edu
Module V: Post-Approval Monitoring, Allegations and Noncompliance, and Other Tasks As Assigned!

References & Acknowledgements

- ILAR Journal, Volume 49, Number 4, 2008
- Animal Use Oversight: Balancing Risk Management with Burden
- OLAW and APHIS: Common Areas of Noncompliance, Lab Animal, May 2000
- Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals, Feb. 2005

Agenda

The Administrator’s Role in Managing

1. Post-Approval Monitoring
2. Allegations, Complaints, Noncompliance & Suspensions
3. Documentation and Reporting
4. Other Tasks Not Listed in Your Job Description!

Other Tasks as Assigned

IACUC Administrators may have responsibilities in:
- Collaborations, sub-contracts, off-site activities
- Comparing grants to protocols
- Managing external visits
- Reporting & recordkeeping
- Making sure it all happens when it is supposed to!
Module V: Post-Approval Monitoring, Allegations and Noncompliance, and Other Tasks As Assigned!

### Other Tasks as Assigned

IACUC Administrators may have responsibilities in:
- Collaborations, sub-contracts, off-site activities
- Comparing grants to protocols
- Managing external visits
- Reporting & recordkeeping
- Making sure it all happens when it is supposed to!

### IACUC Administrator responsibilities

Collaborations, sub-contracts, off-site activities

- What are the issues?
- Have a formal written agreement, contract or MOU
- Check USDA, OLAW, AAALAC status
- Proceed with caution!

### Collaborations, Subcontracts, Off-site Activities

<table>
<thead>
<tr>
<th></th>
<th>USDA</th>
<th>PHS</th>
<th>OLAW</th>
<th>AAALAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who is responsible? Who Owns the Animals?</td>
<td>If more than one facility is involved, USDA places responsibility for the animals being used not only with the institution that is involved in their housing and care, but also with any institution involved in the planning and execution of the study itself.</td>
<td>Jurisdiction is based on the source of support, not ownership. It is imperative that PHS-supported institutions that subcontract or collaborate with other institutions, clearly define respective responsibilities.</td>
<td>When a large group of institutions is involved with a single grant, the prime grantee must take responsibility for all partners and sub-projects, insuring that assurances are in place and IACUC approval has been obtained.</td>
<td>AAALAC follows ownership to determine who is responsible for off-site animals. If an accredited institution does not own the animals, AAALAC does not require oversight by them. However, they should ensure that they are partnering with reputable organizations.</td>
</tr>
</tbody>
</table>
Module V: Post-Approval Monitoring, Allegations and Noncompliance, and Other Tasks As Assigned!

How to avoid confusion

- Develop a policy
- Draft a contract or MOU
- Clearly establish animal ownership
- Establish what monies may be used for
- Identify the level of institutional oversight necessary

Recommended Resources:

Guide for the Care and Use of Laboratory Animals
- Chapter 2

Who’s Responsible for Offsite Animals?
- AAALAC Spring 2003
  at aaalac.org, search for ‘offsite’

Contracting In Vivo Research: What are the Issues?
- Wendy J Underwood
  JAALAS 46(4):16-19, July 2007

Laboratory animal–based collaborations and contracts beyond the border
- Dennis Stark

Other Tasks as Assigned

IACUC Administrators may have responsibilities in:
- Collaborations, sub-contracts, off-site activities
- Comparing grants to protocols
- Managing external visits
- Reporting & recordkeeping
- Making sure it all happens when it is supposed to!
### What are the Requirements for Congruence?

#### Comparing grants to protocols  PHS IV.D.2

- “Applications or proposals [to any PHS entity] … shall include verification of approval … by the IACUC of those components related to the care and use of animals.”
- “…that the IACUC has reviewed and approved those components of grant applications and contract proposals related to the care and use of animals.”
- “…for ensuring that the information the IACUC reviews and approves is congruent with what is in the application/proposal.”

### What are the Requirement for Congruence?

#### NIH Grants Policy Statement

- It is an institutional responsibility to ensure that the research described in the application is congruent with any corresponding protocols approved by the IACUC.

Part II, A, 4.1.1.2 Verification of IACUC Approval

### Who Should Review for Congruence?

#### Is the IACUC Administrator responsible?

**WHO, ME?**

In OLAW’s FAQs on Protocol Review, see #D10 “Is the IACUC required to review the grant application?”
Module V: Post-Approval Monitoring, Allegations and Noncompliance, and Other Tasks As Assigned!

What parts of the grant are most useful to compare?

1. “Research Strategy” Section (focus on “Approach”)
2. The “Vertebrate Animal Section” (VAS)
3. “Project/Performance Sites” (Primary and Additional)

See [http://grants.nih.gov/grants/forms_updates_faq.htm](http://grants.nih.gov/grants/forms_updates_faq.htm)

The Vertebrate Animal Section

- Simplification of the VAS:

- See the VAS webpage for more information on what’s required. Here you will find a checklist, detailed instructions, plus links to worksheets: [http://grants.nih.gov/grants/olaw/vertebrate_animal_section.htm](http://grants.nih.gov/grants/olaw/vertebrate_animal_section.htm)

Other Tasks as Assigned

IACUC Administrators may have responsibilities in:
- Collaborations, sub-contracts, off-site activities
- Comparing grants to protocols
- Managing external visits
- Reporting & recordkeeping
- Making sure it all happens when it is supposed to!
Module V: Post-Approval Monitoring, Allegations and Noncompliance, and Other Tasks As Assigned!

IACUC Administrator responsibilities

Managing external visits ~ USDA

- Read the inspection guide!
- Unannounced
- Identify Participants in advance
- Facility tour
- Exit interview
- Send report to IACUC and IO
- Follow-up and appeals process, if any

Animal Welfare Inspection Guide

Animal Welfare Inspection Guide

Animal Welfare Inspection Guide

Animal Welfare Inspection Guide

marcy.brown@pfizer.com
dfrolich@scripps.edu
Recommended Resources:

- A Word from USDA (Lab Animal Sep 2007)
- NJABR’s ‘Managing Inspections’ & ‘Dispute Resolution Process’
- USDA’s Dear Licensee or Registrant
- Understanding USDA’s enforcement process (Lab Animal Jan 2013)
- NABR webinar transcript

IACUC Administrator responsibilities

Managing external visits ~ AAALAC

- Announced - Date selection

- Before the Site Visit
  - Prepare Program Description
    - Self-evaluation using AAALAC template
  - Assignment of site visit team, scheduling date of visit, etc.
  - Logistical arrangements for the site visit

- During the Site Visit
  - Entrance briefing for institutional staff including IO, AV, Operations, EHS, OHW, IACUC Chair and IACUC staff
  - Review Program Description in depth
  - Tour facilities: Animal housing, support space, and labs
  - Meet with IACUC members
  - Meet with technical staff
  - Executive session for site visitors
    - Exit briefing
      - Preliminary findings
      - Any clarifications?
  - What the Site Visitors will Recommend to Council
IACUC Administrator responsibilities

Managing external visits ~ AAALAC
- After the Site Visit
  - Immediate corrections, if any
    - Institution provides post site visit communication
    - due in ~2 weeks
  - Draft site visit report is prepared by the AAALAC site visitors
  - Report reviewed by designated Council Members
  - Council deliberates
    - Convened meeting, 3 times per year (January, May and September)
    - Final report after Jan, May, or Sep Council meeting

Managing external visits ~ OLAW
- Types
  - Generally these are announced, but not always
  - Random 'not for cause', assurance monitoring
  - For cause, responding to concerns
- Participants
  - Site visitors - usually peers from similar type institutions
- Agenda
  - Meet w/IO and CEO, IACUC Chair, AV, IACUC & staff
  - Programmatic & facility review
- Exit interview
  - With above individuals
  - Take copious notes
- Follow-up correspondence

Managing external visits ~ Other?
- FDA
- EPA
- DHS
- NIH Program Projects
- State and local agencies?
IACUC Administrators may have responsibilities in:

- Collaborations, sub-contracts, off-site activities
- Comparing grants to protocols
- Managing external visits
- Reporting & recordkeeping
- Making sure it all happens when it is supposed to!

I WISH SOMEONE HAD …

- … given me a list of all the annual reports (USDA, AAALAC, OBA for rDNA, and OLAW) and when they were due.
- A list of periodic reports would have been nice (USDA Annual, OLAW Assurance Statement, AAALAC Program Description).

IACUC Administrator responsibilities

<table>
<thead>
<tr>
<th>Reporting: Annual</th>
<th>PHS</th>
<th>USDA</th>
<th>AAALAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timetable</td>
<td>Due on or before January 31, describing activity during the previous calendar year (January 1 – December 31)</td>
<td>Due on or before December 1, describing activity during fiscal year (October 1 – September 30)</td>
<td>No specific due date. An institution may choose its reporting period (e.g., calendar year, fiscal year, USDA reporting period, etc.) as long as the period covered is continuous with previous reports.</td>
</tr>
<tr>
<td>Submitted to</td>
<td>OLAW</td>
<td>APHIS, AC Regional Director</td>
<td>AAALAC online for institutional reports, email <a href="mailto:annualreport@aaalac.org">annualreport@aaalac.org</a></td>
</tr>
<tr>
<td>Submitted by</td>
<td>IACUC, through the IO</td>
<td>Signed or certified by CEO or IO</td>
<td>AAALAC online for institutional reports</td>
</tr>
<tr>
<td>Form used</td>
<td>PHS Policy 717/1 &amp; 4</td>
<td>APHIS Form 7033</td>
<td>AAALAC online annual report form</td>
</tr>
</tbody>
</table>

Don't forget about institutional reports!
Module V: Post-Approval Monitoring, Allegations and Noncompliance, and Other Tasks As Assigned!

IACUC Administrator responsibilities

**Reporting: Semiannual**

<table>
<thead>
<tr>
<th></th>
<th>PHS</th>
<th>USDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timetable</td>
<td>Every six months; an AAALAC program status evaluation or accreditation site visit may fulfill these requirements</td>
<td>Every six months; an AAALAC program status evaluation or accreditation site visit may fulfill these requirements</td>
</tr>
<tr>
<td>Submitted to</td>
<td>IO</td>
<td>IO</td>
</tr>
<tr>
<td>Submitted by</td>
<td>IACUC, as a Committee action</td>
<td>NA</td>
</tr>
<tr>
<td>Form used</td>
<td>Not specified, may use AAALAC sample form</td>
<td>Not specified</td>
</tr>
<tr>
<td>Contents</td>
<td>- Describe adherence to Guide &amp; PHS Policy and any departures</td>
<td>- Describe adherence to AWRs and any departures</td>
</tr>
<tr>
<td></td>
<td>- Reasons for departures; identify significant and minor deficiencies; include plan/schedule for correction</td>
<td>- Reasons for departures; identify significant and minor deficiencies; include plan/schedule for correction</td>
</tr>
<tr>
<td></td>
<td>- Includes minority views</td>
<td>- Includes minority views</td>
</tr>
<tr>
<td></td>
<td>- Approved by IACUC</td>
<td>- Approved by majority of AAALAC members</td>
</tr>
<tr>
<td></td>
<td>- Maintained by the institution; available to OLAW upon request</td>
<td>- Reviewed and signed by majority of IACUC members</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Maintained by the Research Facility; available to APHIS and funding agency upon request</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Report failure to meet plan for correction through IO to APHIS and funding agency within 15 working days.</td>
</tr>
<tr>
<td>Reference</td>
<td>PHS Policy IV.B.3, IV.E.1.d &amp; IV.F.4</td>
<td>9 CFR Part 2, Subpart C 2.31</td>
</tr>
</tbody>
</table>

**Reporting: Other**

<table>
<thead>
<tr>
<th></th>
<th>PHS Assurance Study Facility Registration</th>
<th>USDA Research Facility Registration</th>
<th>AAALAC Program Description (PD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>When required</td>
<td>To receive PHS support for animal activities</td>
<td>Administrative regulations must be used for regulated purposes</td>
<td>AAALAC’s Program Description form; available in Word™ or PDF versions</td>
</tr>
<tr>
<td></td>
<td>Approved for a period of up to 4 years</td>
<td>Updated every three years</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Submitted to</td>
<td>AAALAC</td>
<td>APHIS &amp; Regional Director</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Electronically to: <a href="mailto:programdescription@aaalac.org">programdescription@aaalac.org</a></td>
<td>Via hard copy to AAALAC, Intl corporate office</td>
<td></td>
</tr>
<tr>
<td>Submitted by</td>
<td>IO</td>
<td>Signed by person with legal authority to bind organization</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Institutional letterhead, may use AAALAC sample format</td>
<td>AAALAC contact correspondent</td>
<td></td>
</tr>
<tr>
<td>Form used</td>
<td>Institutional letterhead, may use AAALAC sample format</td>
<td>AAALAC’s Program Description form; available in Word™ or PDF versions</td>
<td></td>
</tr>
</tbody>
</table>

**Recordkeeping**

<table>
<thead>
<tr>
<th></th>
<th>PHS Policy</th>
<th>AWRs</th>
</tr>
</thead>
<tbody>
<tr>
<td>IACUC Minutes</td>
<td>Records of minutes, IACUC, activities and any applicable regulations</td>
<td>Records of minutes, IACUC, activities and any applicable regulations</td>
</tr>
<tr>
<td></td>
<td>Records of proposed activities</td>
<td>Records of proposed activities</td>
</tr>
<tr>
<td></td>
<td>Records of significant changes</td>
<td>Records of significant changes</td>
</tr>
<tr>
<td></td>
<td>Outcome of IACUC review</td>
<td>Outcome of IACUC review</td>
</tr>
<tr>
<td>Protocols</td>
<td>Records of proposed activities</td>
<td>Records of proposed activities</td>
</tr>
<tr>
<td></td>
<td>Records of significant changes</td>
<td>Records of significant changes</td>
</tr>
<tr>
<td></td>
<td>Outcome of IACUC review</td>
<td>Outcome of IACUC review</td>
</tr>
<tr>
<td>Basic Documents</td>
<td>AAALAC’s reports and recommendations</td>
<td>AAALAC’s reports and recommendations</td>
</tr>
<tr>
<td></td>
<td>Records of minutes, IACUC, activities and any applicable regulations</td>
<td>Records of minutes, IACUC, activities and any applicable regulations</td>
</tr>
<tr>
<td></td>
<td>Records of significant changes</td>
<td>Records of significant changes</td>
</tr>
<tr>
<td>Other Requirements</td>
<td>Records of minutes, IACUC, activities and any applicable regulations</td>
<td>Records of minutes, IACUC, activities and any applicable regulations</td>
</tr>
<tr>
<td></td>
<td>Records of proposed activities</td>
<td>Records of proposed activities</td>
</tr>
<tr>
<td></td>
<td>Records of significant changes</td>
<td>Records of significant changes</td>
</tr>
<tr>
<td></td>
<td>Outcome of IACUC review</td>
<td>Outcome of IACUC review</td>
</tr>
<tr>
<td></td>
<td>Records of minutes, IACUC, activities and any applicable regulations</td>
<td>Records of minutes, IACUC, activities and any applicable regulations</td>
</tr>
<tr>
<td></td>
<td>Records of significant changes</td>
<td>Records of significant changes</td>
</tr>
<tr>
<td></td>
<td>Outcome of IACUC review</td>
<td>Outcome of IACUC review</td>
</tr>
<tr>
<td>Reference</td>
<td>PHS Policy IV.A</td>
<td>9 CFR Part 2, Subpart C 2.20</td>
</tr>
</tbody>
</table>

marcy.brown@pfizer.com
dfrolich@scripps.edu
Other Tasks as Assigned

Perhaps the #1 IACUC Administrator responsibility!
- Collaborations, sub-contracts, off-site activities
- Comparing grants to protocols
- Managing external visits
- Reporting & recordkeeping
- Making sure it all happens when it is supposed to!

IACUC Administrator responsibilities

Making sure it all happens when it is supposed to!
- See Institutional & IACUC Requirements chart
- Reporting and Recordkeeping Tables
- Schedule and coordinate
  - Timeline
    - All monthly meetings
    - Protocol review deadlines
    - Semiannual review dates
    - Inspection dates
    - All annual report due dates
    - Assurance and program description due dates, if and when applicable
    - Open meeting posting dates
  - Whenever possible, share the timeline (& the workload)
Module V: Post-Approval Monitoring, Allegations and Noncompliance, and Other Tasks As Assigned!

**IACUC Administrator responsibilities**

Making sure it all happens when it is supposed to!

Listservs you need to be on:
- OLAW: OLAW-L-subscribe-request@LIST.NIH.GOV
- subscribe OLAW-L your name
- USDA: Stakeholders Registry
  public.govdelivery.com/accounts/USDAAPHIS/subscriber/new

Other recommended listservs:
- IACUC-Admin – IACUC-ADMIN-subscribe-request@list.msu.edu
- AMP News Digest – outreach@ampprogress.org
- FBR Total E-Clips – fresearch.org/media-center/total-e-clips/
- NABR Update (for member institutions) – http://www.nabr.org/nabr-members-only/subscribe-to-the-nabr-update/
- Check your state or local biomedical research organization – many have listservs or newsletters

**HOW CAN YOU DO ALL OF THIS?**

Some tips from our experts —

- “There are very few situations where there is one only or best way to do things - that is the beauty (and the pain) of performance standards.”
- “Standardization of workflow, cross training of staff, internal ticklers and checks” are necessary.
- “There are tons of resources and a very friendly, helpful community of colleagues out there to assist you. Use them all.”