COUNCIL OF PRINCIPAL INVESTIGATORS

APRIL 13, 2016

Animal Welfare Office
Animal Compliance and Institutional Animal Care and Use Committee

Presented by
Tennille Lamon, DVM, MS, CPIA
AWO Director
Regulations For Animal Research

- Animal research is a privilege afforded to us through public trust.

- Animal research is regulated by:
  - The Animal Welfare Act and the Animal Welfare Act Regulations
  - Public Health Service Policy on Humane Care and Use of Laboratory Animals (National Institutes of Health)
  - Health Research Extension Act of 1985
  - U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training
  - The Guide for the Care and Use of Laboratory Animals
  - Guide for the Care and Use of Agricultural Animals in Research and Teaching
  - United States Department of Agricultural Animal Care Policies

Laws and Regulations

- USDA
  - AWA, AWAR, Animal Care Policies
  - Most warm-blooded animals
    - except lab rats/mice, birds, and agricultural production animals

- PHS
  - The Guide, PHS Policy, ILAR Guidebook
  - All vertebrates

- Ag Guide – farm animals for food or fiber studies

- AAALAC
  - Voluntary accreditation – “gold standard”
  - Requires USDA and PHS standards
Institutional Rules and Procedures

- TAMU

- System
  - 15.99.07 Use of Vertebrate Animals

USDA Inspection Process

- Unannounced inspections annually
- Only look at covered species
- Three day inspection with one day dedicated to reviewing IACUC records
  - All category E protocols
  - Percentage of all the rest
  - All minutes, adverse events, annual reports
- Can use our own records to identify non-compliances
- Repeat findings – same infraction, different labs/areas for 3 years (ie expired drugs)
- Age of enforcement – fines, increased inspection frequency
- 6 citations on inspection in June 2015
- No citations on inspection in March 2016
AAALAC Site Visits

- Conducted every three years
  - Last site visit: July 2015
- Peer review
- Not regulatory agency
- Received Probationary Status for 6 months
  - Must address concerns and improve processes
  - Maintain “Accredited Status” to all outside inquiries

Animal Research at Texas A&M University

- Institutional Animal Care and Use Committee (IACUC) must approve all animal activities involving the use of vertebrates in research, testing, or teaching prior to initiation of work.
- Animal activities require an Animal Use Protocol (AUP) to be submitted through iRIS for review by the IACUC.
- Principal investigators must be faculty members and cannot be students.
  - Graduate students are participants.
Institutional Animal Care and Use Committees

- Required by Federal Law - Animal Welfare Act & Public Health Service/OLAW
- Composition mandated by law & institutional policy
- Appointed by & report to Institutional Official (IO)
  - Currently have 25 members
  - Composed of:
    - 15 faculty members representing all colleges in which animal research is conducted
    - 2 facility managers
    - 7 staff members (EHS, Biosafety, CMP, AWO)
    - 1 community member

IACUC Duties

- Review all animal activities that involve vertebrates used in research, testing, or teaching that occur on Texas A&M University campus within Brazos and Burleson counties and at the branch campus in Galveston
- Conduct semi-annual inspections of all animal housing, holding, and surgery areas associated with those activities
  - 972 locations inspected every 6 months
- Investigate all animal welfare concerns
  - 16 subcommittee investigations in FY 15
Submission Process

Animal Welfare Office

- Pre-Review by the IACUC Office for completion
- BOHP & EHS assigned to review
- Attending Veterinarian assigned if Category D or E
- Biosafety assigned to review, if applicable
- CRRC assigned to review, if applicable
- Grant congruency is conducted, if applicable

Day 1

- IACUC Chair reviews submission & assigns DMRs
- IACUC Committee receives the submission for 5 day review

Day 30

- IACUC Chair reviews submission & assigns DMRs
- Assigned DMR’s review submission and comments from the committee
- DMR review process is completed and comments are compiled to go back to the PI

Outcome letter sent to the PI

AUP Review Process

- Two review processes:
  - Designated member reviewer (DMR)
    - Two committee members are named DMR for each protocol
    - All committee members can review and comment on the protocol
    - The DMRs are responsible for approving the protocol or requesting modifications to gain approval
  - Full Committee Review (FCR)
    - The committee discusses the protocol at a convened meeting
    - The committee votes to approve, request modifications to gain approval, table, or withhold approval

Day 5

- Assigned DMR’s review submission and comments from the committee

Day 10

- Assigned DMR’s review submission and comments from the committee

Day 20

- CITI Training of AUP participants is verified
- Coordinate with other committees/units to verify issues are resolved or need to be addressed in AUP

Day 25

- AUP Review Process

Day 40

- DMR review process is completed and comments are compiled to go back to the PI

Outcome letter sent to the PI
AUP Review Process as Relates to External Funding

- Externally funded protocols require a grant/scope of work congruency check prior to approval
- Investigators are required to provide a copy of the grant or proposal at the time of AUP submission
- Any discrepancies between the grant and AUP must be reconciled prior to approval

AWO/IACUC Active Protocols by Institution FY15

- Texas A&M AgriLife Extension: 229
- Texas A&M AgriLife Research: 229
- Texas A&M Engineering Experiment Station: 14
- Texas A&M Health Science Center: 14
- Texas A&M University: 116
- Texas A&M Veterinary Medical Diagnostic Laboratory: 2

Total: 713
TAMU IACUC
Comparison of FY 2014, FY 2015, and FY 2016 New applications

<table>
<thead>
<tr>
<th>FY 2014</th>
<th>FY 2015</th>
<th>FY 2016 (6 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total approved new applications</td>
<td>274</td>
<td>314</td>
</tr>
<tr>
<td>Overall median approval time in calendar days</td>
<td>69</td>
<td>58</td>
</tr>
<tr>
<td>Average approval time in calendar days</td>
<td>83</td>
<td>70</td>
</tr>
</tbody>
</table>

TAMU IACUC
Comparison of FY 2014, FY 2015, and FY 2016 Amendments

<table>
<thead>
<tr>
<th>FY 2014</th>
<th>FY 2015</th>
<th>FY 2016 (6 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total approved amendments</td>
<td>316</td>
<td>460</td>
</tr>
<tr>
<td>Overall median approval time in calendar days</td>
<td>14</td>
<td>17</td>
</tr>
<tr>
<td>Average approval time in calendar days</td>
<td>22</td>
<td>24</td>
</tr>
</tbody>
</table>
Programmatic Changes

• Streamlined the AUP to better reflect information required in protocol and eliminate redundancy
• Simplified CITI training requirements for AUP participants
• Changed the personnel addition process
• Increased the size of the IACUC to decrease the protocol review times
• VVC = Veterinary Verification and Consultation
  – AV can approve certain changes in drugs, anesthesia and euthanasia w/o amendment

Moving Forward

• Ensure that TAMU continues to maintain a high quality program incorporating AAALAC best practices
• Enhancing post-approval monitoring functions
• Continue to evaluate IACUC composition, structure, and expertise
• Continue to review processes and procedures for opportunities to enhance efficiencies and effectiveness and ease administrative burdens on researchers
Q67: Animal Care and Use Ratings

1 - Turn around (1st) 5 - Knowledge level
2 - Turn around (amend) 6 - Clarity of revisions
3 - Timely interact’n 7 - Billing Accuracy
4 - Customer Service 8 - Staff Competence
9 - Animal ordering 10 - Responsiveness
11 - Facilities
12 - Interactions between offices
13 - Availability

2015 CPI Survey: Compliance Ratings

Animal Welfare Office (AWO)

- Liaison between the research community and the IACUC
- Protect TAMU and researchers by assuring compliance to the laws and regulations
- Investigate/follow up on reports of animal welfare concerns & inspection deficiencies
- Review all graduate student proposals for congruency with compliance regulations
- Provide compliance interface with other offices (SRS; OGAPS; MTA; EHS; HRPP; OHP; Biosafety)
AWO Contacts

- Email: animalcompliance@tamu.edu
- Phone: 845-1828
- Fax: 862-3176
- http://rcb.tamu.edu

- AWO Director: Dr. Tennille Lamon
- Research Compliance Coordinators:
  Mr. Ken Gillenwater, Ms. Lauren Douglas,
  & Dr. Gina Lungu
- Post Approval Liaison: Dr. Melanie Landis

Questions?