

COUNCIL OF PRINCIPAL INVESTIGATORS

APRIL 13, 2016



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Animal Welfare Office

Animal Compliance and Institutional Animal Care and
Use Committee

Presented by
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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



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Third edition
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Institutional Rules and Procedures

- TAMU
 - 15.99.07.M1 Use of Animals in Research, Teaching, and Testing
- 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

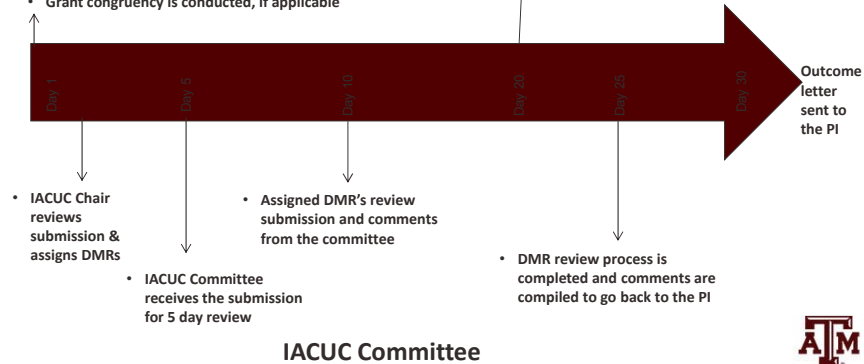
- **Review all animal activities that involve vertebrates used in research, testing, or teaching that occur on Texas A&M University campus within Brazos and Burleson counties and at the branch campus in Galveston**
- **Conduct semi-annual inspections of all animal housing, holding, and surgery areas 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
- CITI Training of AUP participants is verified
- Coordinate with other committees/units to verify issues are resolved or need to be addressed in AUP



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

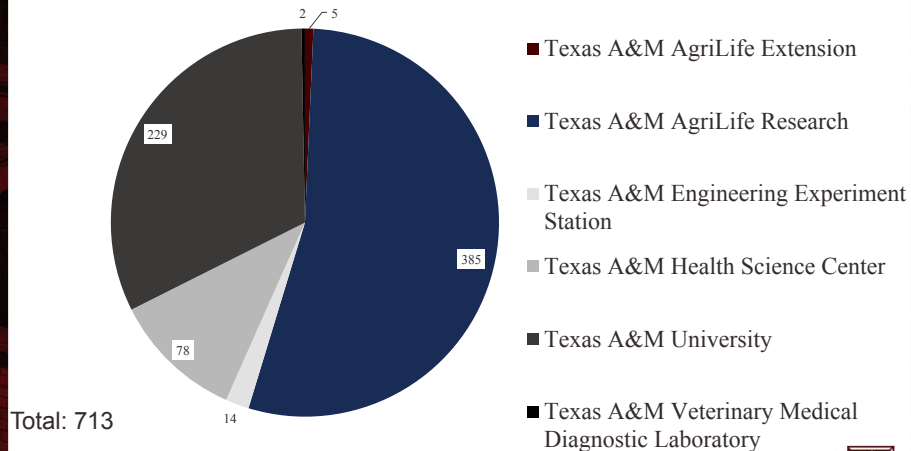


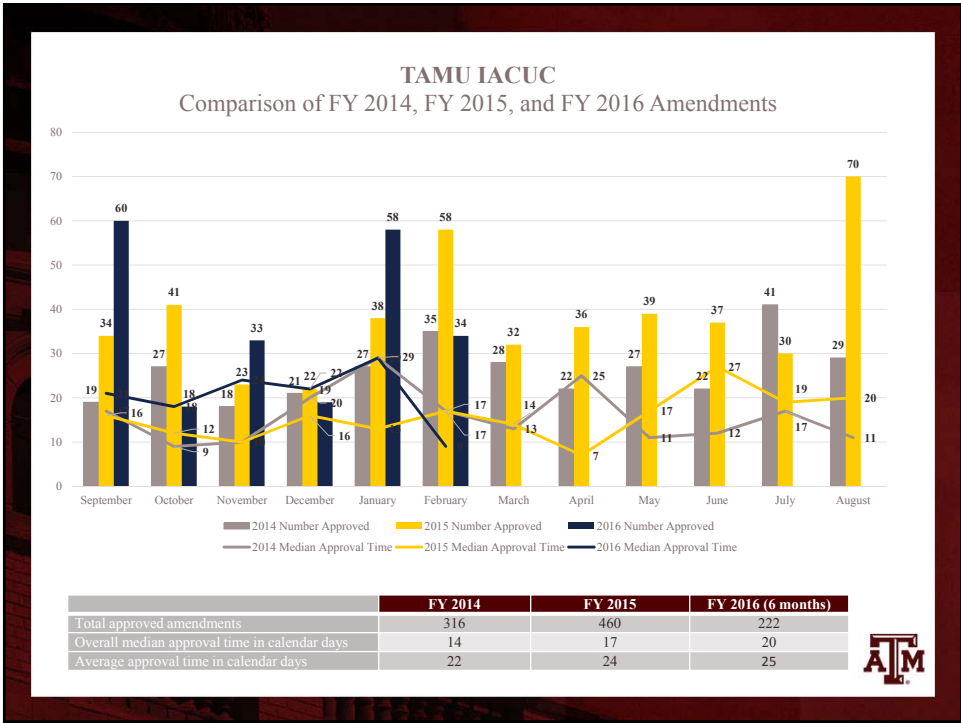
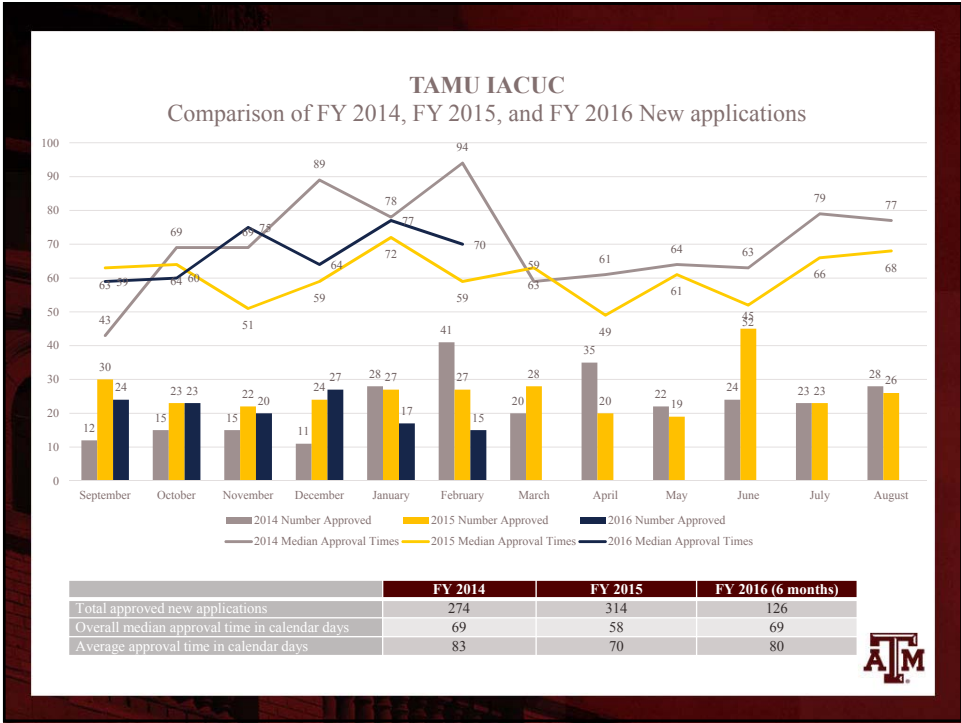
AUP Review Process as Relates to External Funding

- 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





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



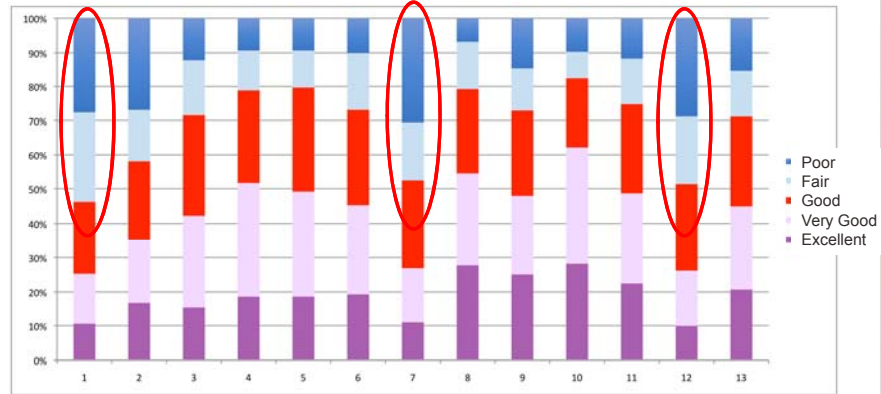
Moving Forward

- 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



2015 CPI Survey: Compliance Ratings

Q67: Animal Care and Use Ratings



- 1 - Turn around (1st)
- 2 - Turn around (amend)
- 3 - Timely interact'n
- 4 - Customer Service

- 5 - Knowledge level
- 6 - Clarity of revisions
- 7 - Billing Accuracy
- 8 - Staff Competence

- 9 - Animal ordering
- 10 - Responsiveness
- 11 - Facilities
- 12 - Interactions between offices
- 13 - Availability



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

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- <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?

