

# Animal Protocols: The Who, What and How

Elizabeth M. Bailey and  
Dana F. Glass-Mattie

# Objectives

- The Who: Background of regulations
- The What: What components are needed for a protocol
- The How: How to write a protocol to stay compliant
- Post-Approval Monitoring (PAM)



“So what do we do for dinner?”

# Background

- Several entities exist to help protect/regulate animal use in research
  - Nationally
    - United States Department of Agriculture (USDA)
    - Office of Laboratory Animal Welfare (OLAW)
    - Public Health Service/National Institutes of Health (PHS/NIH)
    - Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALACi)
  - UT
    - Office of Laboratory Animal Care (OLAC)
      - <http://www.vet.utk.edu/olac/>
    - Institutional Animal Care and Use Committee (IACUC)
      - <http://iacuc.tennessee.edu/>

# USDA

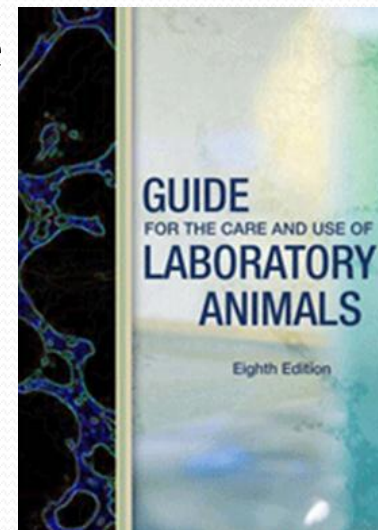
- The Animal Welfare Act (AWA) was enacted by US Congress in 1966.
- The Act applies to all research facilities, public or private, academic or industry-based, whether or not they receive federal funds that use animal species designated (a.k.a “covered”) by the U.S. Secretary of Agriculture
  - guinea pigs, hamsters, gerbils, rabbits, dogs, cats, nonhuman primates, marine mammals, farm animal species when used in biomedical research, and warm-blooded wild animals
  - The AWA specifically excludes rats of the genus *Rattus* and mice of the genus *Mus* bred for use in research, and birds specifically bred for research
  - However, **wild** mice and **wild** birds captured for research activities **ARE** covered by the USDA

# OLAW

- Health Research Extension Act of 1985
  - Federal mandate for governing the use of animals supported by Department of Health and Human Services (DHHS) funds.
  - Legal requirements similar to and consistent with the Animal Welfare Act
  - Apply to all DHHS/NIH-conducted or supported research, research training, and biological testing activities involving the use of all vertebrate animals
  - Defined an animal as **any** live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.
  - Established IACUCs and defined the roles of the IACUC
    - <http://grants.nih.gov/grants/olaw/olaw.htm>

# PHS/NIH

- Umbrella organization in the U.S. Federal Government consisting of eight Health and Human Services health Agencies, the Office of Public Health and Science, and the Commissioned Corps
- The NIH is the largest agency within the PHS
- “The Guide”
  - PHS Institutions required to follow
  - Recommends following Guide for the Care and Use of Agricultural Animals in Research and Teaching (FASS) for agricultural animals
  - Basis for AAALAC International accreditation
  - Covers all aspects of animal care programs and facilities



# AAALACi

- AAALAC International is a private, nonprofit, non-government organization- independent assessment
- UTK has AAALAC accreditation
- Accreditation does not insure award approval
- Site visits occur every 3 years and use “The Guide” as tool



# OLAC- UTK

- Attending veterinarian:
  - Patricia Coan, D.V.M., Ph.D., DACLAM
- Two other veterinarians
  - Dr. William Hill, D.V.M., DACLAM
  - Dr. Joleen Adams, D.V.M.
- Two laboratory animal technologists provide daily medical care
- Provides training on topics including basic handling skills and techniques, animal welfare and husbandry
- Consultation during IACUC protocol preparation
- Species specific technical procedures and support
- Training of individuals or groups on an as-needed basis for specific skills
- Schedule wet-labs
- OLAC website: <http://www.vet.utk.edu/olac/>

# IACUC- UTK

- Committee made of ~20 members that meet to discuss/approve animal use protocols
- Meet 1<sup>st</sup> Tuesday of every month
- Members represent entire university (Ag, Main and Medical Center campuses) and include community members with no direct affiliation with UTK
- IACUC chairman: Robert Donnell
- IACUC coordinator: Betsy Bailey
- Director of Animal Compliance Support: Dana F. Glass-Mattie (not a voting member of the IACUC)
- Website: <http://iacuc.tennessee.edu/>

# IACUC- UTK

- Specific functions including:
  - protocol review and approval
  - biannual inspection of all animal use areas
  - critical self assessment of UTK's animal use program
  - **the ability to suspend an animal activity due to protocol noncompliance following a thorough investigation**

# Animal Protocols

- Protocol must be written for any work to be performed with animals (research and teaching)
- Forms found on-line at UT IACUC home page
- Amendments
  - Procedural
  - Personnel
- Reviews toward approval
  - Administrative
  - Veterinary
  - Biosafety
  - Occupational Health
  - Designated Member or Full Review
- All listed on protocol must complete online training

# Animal Protocol Writing

- More work that goes into writing up front- typically less changes will need to be made
- Way it is written can make it easier to stay compliant
- Non-technical summary
  - Be concise
  - Written in language that 8<sup>th</sup> grader can understand
  - Write out acronyms first time use them
- Flow chart
  - Be concise
  - Logical manner
  - Include every procedure performed on or with a live animal
- Animal welfare
  - Justify why using live animals and if work is duplicated
  - Include all pain/distress procedures

# Animal Protocol Writing

- Searches
  - Ensure work is not being duplicated
  - Perform literature searches of two subject-specific databases
  - Dates searched must say date (not present)
  - Consult with research services librarians for resources
    - Pendergrass Library
  - Use PUBMED, CAB (web of science)
  - Resources
    - Leenaars M, Hooijmans CR, et al. (2011). A step-by-step guide to systematically identify all relevant animal studies. *Laboratory Animal*
    - <http://libguides.library.umkc.edu/content.php?pid=28311&sid=209336>
- Assessment of pain and distress
  - Weight/Body condition scores = large animals
  - Body condition scores = rodents

# Animal Protocol Writing

- Criteria for removal from study
  - Time-point that will allow criteria
- Veterinary Care
  - OLAC, Large or Small Animal Clinical Sciences or Local Practitioner
- Housing
  - Need total number of animals requested- 3 year total
    - Try to over-estimate, not under
    - Explanation on how derived
      - Statistics
      - Biostatistician is good resource
  - Don't use animal room number unless definite
    - Rooms assigned by facility manager in (name of facility)
  - Special requirements
    - Need justification
  - Transport and Disposal

# Animal Protocol Writing

- Personnel Listed
  - Have to have approved training
  - Have to be in or exempt from OHP
  - Make sure all are included!
- Euthanasia
  - section **must** be completed in case something occurs to warrant it.
  - AVMA approved guidelines:  
[http://www.avma.org/issues/animal\\_welfare/euthanasia.pdf](http://www.avma.org/issues/animal_welfare/euthanasia.pdf)



# Animal Protocol Writing

- Appendices
  - Make sure all are checked that apply- should match the flowchart
- Animal Hazard Control Form
  - Filled out by safety official (radiological, biohazard or chemical)
  - If hazard is involved, appropriate signage/cage cards employed and all personnel must be informed (own staff and facility staff)
    - Orange cards must be placed on animal cages/pens with identifying hazard sticker
  - New SOP requires cage-side training

# Animal Protocol Writing

- Avoid pitfalls
  - Better to overestimate # of animals than underestimate but do not be excessive
  - Give ranges of items
  - Use words like: approximately, up to, no more than
  - Put in options (methods of administration/collection)
  - Check all boxes
  - Call or email with questions while writing
  - Don't change form

# Post-Approval Monitoring (PAM)

- PAM= program through which IACUC can ensure and document program integrity, compliance with regulations/guidelines, and adherence to protocol
- Act as positive interaction to help offset negativity often felt with regulations
- Help encourage self-reporting
- If identify non-compliance, help PI find a way to become compliant
- Provide more rigorous review than can be done on semi-annual review
- Be another person out there to help identify potential problems (animals, safety, hazards)
- Act as a facilitator between IACUC and PI
- Ultimately, help protect the University

# What PAM is NOT

- NOT animal police
- NOT trying to get PI or staff in trouble
- NOT a voting member of IACUC
- NOT a replacement for IACUC or OLAC veterinary care
- NOT required, a new regulation or a 'must' in the guide

# How PAM Works

- Protocol selected for PAM observation
- Watches all or parts of the procedure as written
- Checks lab notebook/medical records
- Can look for any obvious safety concerns
- Any steps that appear to be noncompliant will be noted
- PI and/or lab staff will be briefed on findings and discussion on how to fix noncompliance will be suggested
- Follow-up email will be sent out stating the findings
- Monthly report of all PAM observations will be sent to the IACUC for review
- Immediate animal concerns that warrant it- OLAC veterinarians and/or IACUC chair will be informed
- Here to help- better UT finds mistakes than regulatory agency

# Preventing Incompliance

- Self-report: if realize that your procedure or personnel have changed, go ahead and submit amendment
- Ask questions: go to IACUC/OLAC homepage to find contacts for questions
- Communicate: make sure all involved with protocol (including facility staff) are aware of what is going on
- Review: go over protocol often with those involved (and yourself) to ensure still being followed
- Write: write protocol to give yourself some options
- Organization: keep lab records up-to-date



Questions??