

Animal Care & Use Regulations: Responding to the Challenges

2013 UC Compliance & Audit Symposium (South)
February 12, 2013

Presenters:

- Melanie Fabian, CPIA
- Jeffrey Goodwin, DVM, Ph.D.
- Vincent Caiozzo, Ph.D.



Who We Are/What We Do:

- Melanie Fabian: IACUC Administrator
- Jeff Goodwin: Attending Veterinarian
- Vince Caiozzo: IACUC Chairman



Animal Welfare Regulations

Start by defining "animal":



"Any live or dead dog, cat, monkey, guinea pig, hamster, rabbit or such other warm-blooded animal...intended for use for research, teaching, testing, experimentation, or exhibition purposes, or as a pet" [USDA]



"Any **live, vertebrate animal** used or intended for use in **research**, research **training**, experimentation, or biological **testing** or for related purposes." [PHS Policy]



Animal Welfare Regulations

Then define "Use":

Research:

- Benchtop studies using harvested tissues *in vitro*
- Development of animal models for disease
- Behavioral studies – how we learn and react
- Pre-clinical drug development

Teaching:

- Undergraduate basic science laboratories
- Teaching future physicians

Testing:

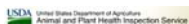
- Cutting edge equipment and devices



Who's in Charge Here?

United States Department of Agriculture:

- Administers the Animal Welfare Act and Regulations
 - 9 CFR Chapter 1, Parts 1-3
 - Not Limited to Research Use
 - Covers warm-blooded animals with a few exceptions



United States Public Health Service

- Extends the AWA/AWR to all vertebrate species
 - Applies only to institutions that receive federal funding



AAALAC Accreditation:

- Association for the Assessment and Accreditation of Laboratory Animal Care, International
- Not a regulatory body, but vital nonetheless
 - Uses the "Guide" as the basis for assessment



"The Guide"



- Eighth Edition released in 2011
- Seventh Edition (1996) had 80 pages, Eighth has 154.
- Office of Laboratory Animal Welfare at NIH has released two notices regarding implementation of new guidelines since December 2011.



The Challenges:

- Remaining in compliance with animal welfare regulations
- Facilitating and supporting cutting-edge research
- Avoiding attention from animal-rights activists
- Doing all of the above with limited resources



Compliance

Most compliance issues result from:

- Absence of leadership from the Principal Investigator
- Breakdowns in communication:
 - Between members of the research team (what's in the approved protocol)
 - Between researchers and veterinarians/husbandry staff
- Lack of appropriate training
- Examples of reportable compliance (must be reported to OLAW):
 - Unapproved Activities
 - Inadequate euthanasia of rodents



Supporting Research



I'll just run this one experiment, and if it works, then I'll modify my approved protocol. After all, it takes SO LONG to get anything approved by that pesky IACUC!

OMB Cost Principles and the NIH Grants Policy Statement (NIHGPS) do not permit charges to grant awards for the conduct of animal activities in the absence of valid IACUC approval of the activity.



“Animal Rights” Activism




nature neuroscience

EDITORIAL

Fighting animal rights terrorism

Some people think the best way to protect animal life is to make scientists fear for theirs.




Things We've Done

- Administratively
 - Extensive Pre-review Process
 - Streamlined procedures for modifications
 - Coming Soon – electronic application and document storage
- The Veterinarian's View
 - Facility Upgrades and Improvements
 - Veterinary Outreach to Researchers
 - Planning for Disaster – new regulatory requirement
- The Chairman's View
 - Faculty investment in the process
 - Fostering a culture of compliance



What we've done – Administratively:

Administrative/Veterinary/Scientific Pre-review:


- Allows researchers one-last-chance to fix the protocol prior to the IACUC's vote at the convened meeting
- Result – more protocols/mods approved at the meeting!

Streamlined Process for Reviewing Pilot Projects:

- New experiments that would normally require full committee review can be performed on a trial basis (limited number of animals) following subcommittee review/approval

Electronic Application and Document Storage

- Coming soon, we hope! (resources needed)

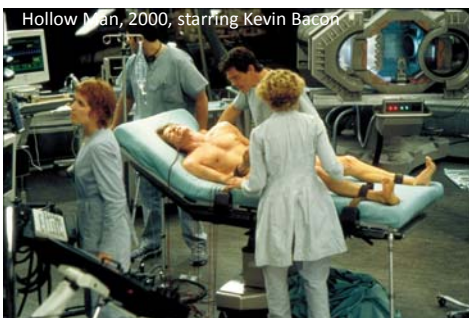


The Veterinarian's Role

- Director of the animal care department (ULAR at UCI):
 - Veterinary care
 - Animal husbandry
 - Health surveillance/biosecurity
 - Animal procurement
 - Facility maintenance
- Works closely with the IACUC on Animal Program oversight, training, post-approval monitoring, compliance issues (reporting)
- Facilitates research



Laboratory animal veterinarian- research facilitator vs. policeman



Current Regulatory Challenges

- Implementing the 8th addition of the Guide
 - Space recommendations for breeding rodents
 - 16" cage height requirements for rabbits
 - Social housing
 - Post-approval monitoring
 - Training/verification of competence
- California Department of Fish and Game reporting requirements for Restricted Species permits
- California Veterinary Practice Act changes- background checks for 'Veterinary Assistants' with access to controlled drugs
- USDA requirement for a written contingency plan
 - Institutions must have a written plan for emergencies by 7/26/13
 - All employees must be trained on the plan by 9/27/13
 - Contingency plans available upon request by APHIS after 9/27/13



From the Chair's Perspective



In Summary

