Welcome!
The University of Pittsburgh
Animal Care and Use Program
IACUC-ECO
Tuesday, February 26th 2013
Today’s Agenda

• Introduction
• Laws and Regulations
• Navigating the IACUC Web-Site
• Protocols and an Introduction to ARO
• Breeding and weaning
• PAMs/SARs
• Controlled drugs
• Compliance Crash Course
• Conclusion
• Animal Welfare Act of 1966 ("the AWA"): 
  
  – Has been expanded considerably through amendments since first passed into law. The AWA creates general standards, as well as specific standards for individual species such as dogs, cats, horses, marine mammals, and primates.

  – Animal protected include Warm-blooded animals (mammals and birds), with certain exceptions. Such as mice, rats, and birds bred for use in research (see Animal Welfare Act Amendments of 2002, below); farm animals used for food or fiber (e.g., sheep's wool); retail sales of ordinary pet animals to consumers; animal shelters and pounds that don't sell to dealers; ordinary pets.
Laws and Regulations

• Animal Welfare Act of 1966 ("the AWA"):

  – Requires each research facility to establish an Institutional Animal Care and Use Committee (IACUC). Each IACUC is required to submit an annual Animal Welfare Assurance, including statistics on animal use at that facility.

  – The AWA is enforced by the Animal and Plant Health Inspection Service of the USDA (APHIS). The Act requires licensing and registration of all affected businesses and research facilities. APHIS performs unannounced inspections at least once a year. APHIS can set civil penalties for infractions, issue cease-and-desist orders, impose fines, and suspend or revoke licenses.
Laws and Regulations

- Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals:
  
  - This policy must be followed by all PHS assured institutions (required to receive federal money).
  
  - Animal protected include all vertebrates.
  
  - Seeks to minimize the number of animals used and the pain and distress inflicted, consistent with scientific necessity. Incorporates the Animal Welfare Act and requires institutions to use the *Guide for the Care and Use of Laboratory Animals (Guide)* as a basis for developing and implementing an institutional program for activities involving animals.
Laws and Regulations

• Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals:
  
  – Requires each research facility to establish an Institutional Animal Care and Use Committee (IACUC). Each IACUC is required to submit an annual Animal Welfare Assurance, including statistics on animal use at that facility.

  – The office of laboratory animal welfare (OLAW) has responsibility for the general administration and coordination of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals.
Laws and Regulations

- Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC):
  
  - AAALAC International is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. Animal protected include all vertebrates.
  - Recognized as the “gold standard” for institutions that achieve excellence in animal care and use.
  - Requires annual reporting and prompt reporting of adverse events.
  - Requires a comprehensive site review every three years by a trained team of AAALAC site visitors. Next visit in 2013.
Navigating the IACUC Web-Site

www.iacuc.pitt.edu
Protocols and an Introduction to ARO

Protocols address and assure:

- Conformity to OLAW, USDA and PHS regulations, guidelines and policies
- Pain/Distress
- Surgery
- Euthanasia
- Housing Conditions
- Alternatives
- Rationale and Methods
- Duplication
- Qualifications of Personnel
Protocols and an Introduction to ARO

What is Required for New Protocol Approval:

• Committee Approval
• IACUC Mandated Training
  - Research Integrity Module
  - Use of Laboratory Animals in Research and Teaching Module
  - Species Specific Modules
• EHS Approval
  - Requires EHS training and AESP registration
• Letter of Scientific Merit*

*Only for research funded by sources that do not conduct a peer-review of research proposals.
Protocols and an Introduction to ARO

No animal experimentation or use is permitted without written approval by the IACUC.

To participate in research on an approved protocol, you must be listed on the protocol. Addition and removal of personnel from a protocol can be initiated by completing the “change of personnel” form for non-ARO protocols. Changes in personnel to an ARO protocol must be completed via a modification request within the ARO system.

Protocol approval is valid for three years

- Protocol must be renewed annually (reminders sent at 90, 60, and 30 days).
- A new protocol must be submitted in the third year to continue the project.
- If not renewed by deadline, your animals may be confiscated by DLAR.
- You will have a 30 day window for approval, then protocol terminates.
Protocols and an Introduction to ARO

Modifications:

• When must I submit a Modification Request?
  • Administrative changes (personnel, funding source, etc...)
  • Anesthetic changes
  • Euthanasia methods
  • Request for additional animals or different strains
  • Procedural changes (surgical or otherwise)
  • Pain/Distress category revisions
  • Adding new test agents
Protocols and an Introduction to ARO

Modifications:

- **When may I not submit a Modification Request?**
  - Species changes
  - Making procedural changes unrelated to specific aims
  - Change in scientific aims of study
  - Change from non-survival to survival surgery
  - Change from single to multiple survival surgeries

To make any of the above changes, a new protocol must be submitted for review.
Protocols and an Introduction to ARO

Modifications, some FYIs:

• Multiple modification requests can not be accepted.
  • Any request submitted while one is already under review will be returned without review.
  • Try to address all anticipated changes on one request form.

• Remember to revise your protocol for submission with your modification.
  • Modifications submitted without a revised protocol can not be reviewed.

• The average time for an ARO modification is 6 days
What does IACUC approval mean?

• Approval letter grants permission to conduct animal-based research as described in the approved protocol.

• PI is responsible for guaranteeing that all animal manipulations are described in the approved protocol.

• PI is responsible for the care and well-being of animals in their research program.

• PI is Responsible for guaranteeing that protocol remains active (appropriately renewed in a timely manner).
Protocols and an Introduction to ARO

What does approval *not* mean?

- Protocol approval does not imply that housing space is available in the approved location.
Protocols and an Introduction to ARO

Who can I contact for assistance in writing my protocol or modifications?

- IACUC Office, iacuc@pitt.edu
- MWRI IACUC Chair, Robert Powers, Ph.D., mjm81@pitt.edu
- PITT IACUC Chair, Frank Jenkins, Ph.D., fjenkins@pitt.edu
- MWRI Veterinarian, Kelly Hopper, DVM, hopperk@mwri.magee.edu
- DLAR Veterinarian, dlar@pitt.edu
- Reference Librarian, Melissa Ratajeski, MLIS, mar@pitt.edu
Protocols and an Introduction to ARO

Animal Research Online (ARO)

- As of 2012, all new protocols must be submitted using ARO. This system has reduced review times and includes a number improvements such as:
  - Protocol applications make use of intelligent branching, so researchers don’t have to answer questions that do not pertain to their own work.
  - Instant access to approval letters and the approved versions of all protocols.
  - Real-time access to all approved personnel listed on a protocol.
  - Automated email reminders.
  - State transparency, meaning that you will always know where your protocol is in the review process.
  - The system is self-contained, and doesn’t require the separate submission of an EHS workbook with every protocol.
  - Because it is internet-based, it is accessible from any computer with an internet connection.
Protocols and an Introduction to ARO

Animal Research Online (ARO)

• Access ARO at: http://www.iacuc.pitt.edu/protocol/aro

• Resources for ARO
  • University of Pittsburgh IACUC ARO users manual
  • ARO FAQs
    • http://www.iacuc.pitt.edu/protocol/aro-faqs

• Live training sessions on the use of ARO occur every Thursday at 2 p.m. in the IACUC Office; room 206 of the Hieber Building (located on Fifth Avenue across from the BST-III; Hieber's pharmacy is located in the same building). **Space is limited; reservations should be arranged through Michael Kessler (kesslermc@upmc.edu).**
Compliance Contact Information:

Denise Capozzi, VMD, DACLAM  
Director, Education & Compliance  
Director, IACUC Office  
Ph: 412-383-2009  
Email: dcapozzi@pitt.edu

Susan Meyers, MS  
Compliance Coordinator, ECO  
Grants Specialist, IACUC  
Ph: 412-383-2002  
Email: meyerssa@upmc.edu

Jeremy DeRicco, MBA  
Training Coordinator, ECO  
Ph: 412-383-1737  
Email: dericcojs@upmc.edu

Tracy Bruno, BS, LATg  
Compliance Coordinator, ECO  
Ph: 412-383-1251  
Email: brunotl@upmc.edu
Breeding and Weaning:
PI Responsibility

Breeding Schemes are described in your protocol

• Pair mating: One female, one male can be kept with litter of pups. Pups must be weaned by day 28, unless otherwise justified on your protocol.

• Harem mating: One male with a breeding group of up to three females. PI or staff must remove female(s) once they are recognized as pregnant and place them in a separate cage to avoid over crowding. Pups must be weaned by day 28, unless otherwise justified in your protocol.
Breeding and Weaning:
PI Responsibility

• No more than one litter of pups may be present in a cage at a given time.

• When females give birth, the PI or lab member must alert the animal care staff so that cage changing can be scheduled to allow the new litters to remain undisturbed for 7 days.

• If a litter is born to a harem breeding cage before the adults are separated, the PI or lab member must remove all mice except the mother and pups to a separate cage.
Cage Cards

**PROTOCOL NUMBER**

*Pl name*

*Personnel*

*Procedures & Treatments*
Documenting Procedures

Yellow Procedure Cards

Research Records

Dates, procedures, observations, initials
Documenting Clinical Issues

Serves as a “red flag” to PI and Veterinary Care and as a form of communication between the two.
Breeding and Weaning: PI Responsibility

Cage Card

When a new litter is born, the card pictured must be filled out.

When the animal are weaned, the PI or lab member must document the number of animals weaned on the weaning log located within the animal housing room. This is essential for tracking animal numbers in your breeding colonies and to ensure you remain within your approved number of animals for each protocol.

When weaned, the maximum cage density should not exceed 4 males or 5 females per cage.
Breeding and Weaning: PI Responsibility

Breeding/Weaning Log

<table>
<thead>
<tr>
<th>DATE</th>
<th>INVESTIGATOR</th>
<th>PROTOCOL #</th>
<th>TOTAL # WEANED</th>
<th># BOXES ADDED</th>
<th>FOOD AND WATER PROVIDED (required)</th>
<th>INITIALS</th>
</tr>
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Food and water must be provided by the investigator at the time of weaning. Please flag boxes with a "Recently Weaned" card.
Breeding and Weaning: PI Responsibility

- Too many animals in a cage
- Double litters
- Over Due weaning
Semi-Annual Reviews

- Animal Facilities (>1200)
- Outside Use Areas (>300)
- Outside Housing (Satellites)
Housing Facilities

• Environmental conditions
  – Temperature, humidity, lighting, ventilation

• Physical Structures
  – Walls, doors, floors, ceiling, vents

• Cleanliness/Husbandry
  – Sanitation schedules, records review
Housing Facilities

• Animals
  – Cage cards/records
  – Population density
  – Health and well-being

• Support Areas
  – Cage wash
  – Surgical Suites
  – Feed/bedding storage
  – Service elevators
  – Transport vehicles
Animal Use Laboratories

- Drug storage, expiration dates
- Sharps disposal
- Anesthetic vaporizers
- Gas cylinders
- Required signage
- Hood certification
- Housekeeping
- Records
Approved Outside Housing Site

- Husbandry Logs
- Cages
- Food Storage/milling dates
- DLAR Notification/Vet Tech Rounds
SAR Report

- A = Acceptable
- M = Minor Deficiency
- S = Significant Deficiency
- CNC = Continued noncompliance
Post Approval Monitoring (PAMs)

• What is it?
• Who?
• Why?
• Frequency?
Controlled Substances

- Authorized Personnel
- Sourcing
- Storage and Control
- Accountability
- Disposal
Focus on Compliance...
Compliance Tips

• Know the rules
• Follow the rules
• Work as a team
We are responsible for

Our own safety
Safety of others
Physical Injuries
Zoonoses

Herpes-B virus

Ringworm

Pasteurella
We are responsible for

Proper handling and disposal of chemicals, bio-hazardous agents, and radioactive waste

We are also responsible for...

- Conducting good science
- Providing stewardship to animals
Before Working with Animal Models...

Animal Exposure Surveillance
Training: IACUC and EHS
Submit the Required Forms

ARO Protocol
Protocol Modifications
Personnel Updates
EHS forms

PENDING
Read and Understand Protocols
Follow Protocols

Post-op Analgesia

Post-op Monitoring
Monitor for Expired Drugs, Fluids & Materials

http://medrepexpress.com
http://www.patientpowernow.org/wp-content/uploads.jpg
Pharmaceutical Grade Agents
Label Secondary Containers
Anesthetic Vaporizers
Transporting Animals & Research Supplies

http://www.johnlund.com/page.asp?ID=1419
Garb
ID Badges

http://www.fotosearch.com/photos-images/id-card.html
Cross-Trafficking Between Facilities
Food and Water
Effective Euthanasia
Housing Animals for >12 hours in a Research Lab
Housekeeping

http://healthcare.spacesaver.com/centralsteril.e.jpg
Working Alone
Speak-up

Ask Questions, Report Concerns
Non-Compliance Notice

University of Pittsburgh
Research Conduct and Compliance Office
Education and Compliance Animal Care and Use Program

Date: September 28, 2010
Subject: Fall 2010 IACUC Semi-Annual Review
         EBST Outside Use Areas

Dear Dr. Investigator:

During the IACUC semi-annual inspections conducted at the EBST on September 27, 2010 a minor non-compliance was cited.

Animal Use Area E111:

Expired Heparin: Two vials of expired heparin were found on the animal procedure bench (March, 2010). IACUC policy states that “no expired drugs or fluids may be administered to animals for any research or instructional purpose, including terminal procedures. All expired drugs, including anesthetics and analgesics must be disposed of properly on or before their date of expiration.” IACUC policy further recommends routine inventory monitoring of all drugs administered to animals to prevent this problem.

Please forward a Corrective Action Plan (CAP) to Ms. Eco at eco5@pitt.edu by October 12, 2010.

Note: The PI is solely responsible for submitting the CAP or any other documents associated with this notice. A CAP submitted by anyone other than the PI will be rejected.

If you require further clarification or assistance, please contact me.

Regards,

Susan Meyers, MS
Education and Compliance Office
meyerss@upmc.edu
Subject to Review

- Internal: Compliance/IACUC
- External: OLAW, USDA, Funding Agencies

Ramifications of NC

- Fines
- Reportable/FOIA
- Suspension
- Funds returned
Working with animal models is a privilege not a right
Animal surgery