IACUC and Research Administration:
Why and when our paths cross and how to improve the journey

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EXPERIENCED ANIMAL USERS?
Overview of Regulations

- Animal Welfare Act Regulations (AWARs) – USDA Covered Species

- PHS Policy & The Guide for the Care and Use of Laboratory Animals ("The Guide") – All vertebrate animals

- Department of Defense Animal Care and Use Review Office (ACURO) - all U.S. Army Medical Research and Development Command (USAMRDC) funded projects
Animal Welfare Act & AWA Regulations (AWAR)

- A series of laws regulating the use of vertebrate animals in research, teaching or testing.
- Violation is punishable under federal law (suspensions, fines and/or imprisonment).
- Applies to all species of warm blooded vertebrates except:
  - Agriculture research using farm animals
  - Rats (Rattus), mice (Mus), birds bred for research
- USDA responsible for enforcing the AWA.
- The Animal and Plant Health Inspection Service (APHIS) is agency within USDA responsible for ensuring this occurs.
AWAR (take home message...the book is 264 pages!)

- Establish standards to govern the humane handling, care, treatment, and transportation
- Minimize animal pain and distress
  - adequate veterinary care
  - appropriate use of anesthetic, analgesic, tranquilizing drugs
  - (or) euthanasia
- Consideration of alternatives to any procedure likely to produce pain to or distress
- Requires an IACUC and an AV
Implementation of AWA/AWAR

Administered by the USDA/APHIS

– At the Institution level:
  • Obtain/maintain USDA Research Registration
  • Annual VMO inspection
  • Annual reports to USDA

– At the PI/Protocol level
  • Annual Review /Annual Renewal (±30 days of approval date)
  • Assignment/reporting of animal use in each Pain & Distress Category (C, D, E)
Public Health Service (PHS) “Policy”

a component of the U.S. Department of Health and Human Services (HHS)

• Public Health Service Policy on Humane Care and Use of Laboratory Animals
  – Broader scope than the Animal Welfare Act
    • all animals involved in activities conducted or supported by PHS
  – Includes the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training
“Government Principles” (for short) – Include:

- consideration of relevance to human or animal health, the advancement of knowledge, or the good of society.
- avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative
- appropriate sedation, analgesia, or anesthesia
- appropriate species and quality and the minimum number required
- living conditions appropriate and contribute to health and comfort
- all personnel shall be appropriately qualified and experienced
- exceptions to the principles require deliberation by the IACUC
The Guide (for short)

• OLAW provides guidance and interpretation of the PHS Policy via The Guide.
• “Must”, “Should”, and “May” statements
• Includes wide range of topics, e.g.,:
  – conduct of certain procedures (aseptic surgery)
  – cage size and density
  – living conditions, care, cleaning
  – occupational health & safety
Implementation of PHS Policy

Office of Laboratory Animal Welfare (OLAW)

– At the Institution level:
  • Obtain/maintain Animal Welfare Assurance
  • Adhere to “The Guide”
  • OLAW inspections – unannounced, for any reason
  • Annual reports to OLAW
  • “Congruency Review”
  • MOUs / IIAs

– At the PI/Protocol level
  • (sometimes) Assignment/reporting of animal use in each Pain & Distress Category (C, D, E)
Institutional Official – An individual who signs, and has the authority to sign, the institution’s Assurance, making a commitment on behalf of the institution that the requirements of this Policy will be met.

Institutional official means the individual at a research facility who is authorized to legally commit on behalf of the research facility that the requirements of 9 CFR parts 1, 2, and 3 will be met.
A private, nonprofit organization that promotes the humane treatment of animals in science through a program of voluntary accreditation.
Questions?

Reviewed:
• AWA / AWARs
• PHS Policy & *The Guide*
• AAALACi

Next topics:
• ACUPs
• IACUCs (purpose, functions)
Animal Care and Use Program (ACUP)

The ACUP encompasses a multitude of roles on our campus that all work together collaboratively to facilitate the ethical conduct of animal research.

- Principal Investigators
- Research Staff
- Administrative Staff
- Veterinarians and Veterinary Technicians
- Husbandry Staff
- Training Core
- Facility Maintenance
- Environmental Health and Safety
- Institutional Biosafety Committee
- Computer support staff
- And many others
Institutional Animal Care and Use Committee

• Ensures that
  – all vertebrate animals receive ethical and humane treatment
  – research is conducted according to all applicable laws, regulations, guidelines and policies

• IACUC
  – properly constituted: Chair, AV, Scientific, Non-Affiliated & Non-Scientific (membership differs AWAR vs PHS Policy)
  – authority to stop work (activity, protocols, suspend people)

• No work with animals can be conducted without an approved animal protocol (includes significant changes to approved protocols)
Functions of the IACUC

- Semi-annual program review and inspections (animal facilities and study area)
- Submit the reports to the IO (semi-annual)
- Make recommendations to the IO regarding any aspect of the program
- Review and investigate concerns involving the care and use of animals
- IACUC Protocol and amendment review (FCR, DMR, VVC, Admin)
- Suspend an activity involving animals (requires a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present)
IACUC Review & Approval

- An animal care and use application (i.e., a protocol)
  - Full Committee Review (FCR)
  - Designated Member Review (DMR)
  - VVC & Admin
- Assigned reviewers
  - Scientific / voting members
  - Veterinarian (pre-review, consultation)
- Additional approvals
  - Training, OHSP (Medical Surveillance)
  - IBC, EHS, IRB
- Approval granted for 3 years; USDA & DoD get annual reviews
DoD & The Animal Care and Use Review Office (ACURO)

- Dual review
  - First: Institution IACUC review and approval
  - Second: Subsequent ACURO review and approval
    - Cannot begin work until ACURO approval is granted
- Double documents
  - IACUC PRO
  - Animal Use Appendix (short or long form?)
- Annual review (same as USDA covered species)
- Inspections (often unannounced) of areas related to DoD awards
Questions?

Reviewed:
• ACUPs
• IACUCs (purpose, functions)

Next topics:
• Award related processes
Award related processes

• e-Systems
• Just in Time & “Congruency Review”
• Funding Letters
• Subcontracts
• Memorandum of Understanding (MOU)
• Inter-institutional Assurance (IIA)
• Others?
ORSP e-Systems?

UNDERSTAND YOU DO NOT?
ASK QUESTIONS YOU SHOULD.
Efficiency & Effectiveness
Just in Time & “Congruency Review”

• “Applications or proposals (competing and noncompeting) covered by [PHS] Policy from institutions that have an approved Assurance on file with OLAW shall include verification of approval (including the date of the most recent approval) by the IACUC of those components related to the care and use of animals.”

• “…the date of IACUC approval of those sections of the application that involve use of vertebrate animals along with any IACUC-imposed changes must be submitted. Pending or out-of-date approvals are not acceptable.”
Verification of Approval by the IACUC

Why?
Just in Time & “Congruency Review”

• RO1, PO1
• T32 (Training Grant)
• UO1/U24 (Cooperative Agreements)
• R41/R42 (STTR)
• Grant Transfers
• DOD (Army)
• Non-NIH funding agencies
• Other?
Funding Letters (sound familiar?)

• PI says Grants Manager needs a letter verifying IACUC approval for their grant, and they need it ASAP, and can I write it for them?
• PI sends me email from Grants Manager for a training grant and it says they need a letter of IACUC approval or a waiver of IACUC review.
• PI wants a letter of IACUC approval that shows only one of the many grants supporting the protocol
• The grant has no vertebrate animal work described, but face page indicates vertebrate animals…can I write a letter of IACUC approval?
Subcontracts

• Money comes from funding agency, to your institution, then out to another entity for animal activities.
  – All of the animal work
  – Some of the animal work
  – Custom made antibodies

• Any federal funds supporting animal activities can only be conducted by entities that hold an approved PHS/Animal welfare assurance.

• No third-party subcontracting allowed!

• What if your institution is the recipient of federal funded subcontract?
“Interinstitutional collaboration has the potential to create ambiguities about responsibility for animal care and use. In cases of such collaboration involving animal use (beyond animal transport), the participating institutions should have a formal written understanding (e.g., a contract, memorandum of understanding, or agreement) that addresses the responsibility for offsite animal care and use, animal ownership, and IACUC review and oversight (AAALAC 2003). In addition, IACUCs from the participating institutions may choose to review protocols for the work being conducted.”
MOU Decision Tree

**FUNDS** are being spent on animal activities that are conducted outside of your institution...are they federal funds?

– Yes
  • Need a Subcontract / agreement (other?)
  • Need an IACUC-MOU

– No (are they internal or external?)
  • Need a Subcontract / agreement (other?)
  • Need an IACUC-MOU
MOU - Ingredients

Federally funded ("like-federal")
- Sub-recipient will need to "own" the animals
- Grant Congruency needs to be completed
- Sub-recipient MUST be PHS Assured
- If USDA covered species are used, sub-recipient must also have USDA Research Registration.
- (Ok if not AAALACi accredited?)

Not-federally funded
- Sub-recipient will need to "own" the animals
- Grant Congruency needs to be completed
- Sub-recipient MUST be PHS Assured
- If USDA covered species are used, sub-recipient must also have USDA Research Registration.
- (Ok if not AAALACi accredited?)
Assured Institutions

Institutions must have an Animal Welfare Assurance to receive PHS funds. To find out if your institution is Assured, see the listing of Domestic and Foreign institutions with OLAW-approved Assurances.

Domestic  Foreign
Office of Laboratory Animal Welfare

Domestic Institutions with a PHS Approved Animal Welfare Assurance

Search by Assurance Number

<table>
<thead>
<tr>
<th>Domestic Institutions</th>
<th>Assurance Number(s)</th>
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<tbody>
<tr>
<td>21st Century Medicine, Inc.</td>
<td>D19-01048 ()</td>
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<tr>
<td>A and G Pharmaceutical, Inc.</td>
<td>D16-00700 (A4404-01)</td>
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<tr>
<td>Aaron Diamond AIDS Research Center</td>
<td>D16-00047 (A3081-01)</td>
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<td>Abcam Burlingame</td>
<td>D16-00550 (A3975-01)</td>
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<td>Abcore, Inc.</td>
<td>D16-00904 (A4713-01)</td>
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<td>D16-00752 (A4497-01)</td>
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<td>Absorption Systems California, LLC - San Diego</td>
<td>D16-00645 (A4282-01)</td>
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<td>Absorption Systems, LP - Exton, PA</td>
<td>D16-00858 (A4653-01)</td>
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<tr>
<td>Accuro Farms, Inc.</td>
<td>D19-01051 ()</td>
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### Foreign Institutions

**Office of Laboratory Animal Welfare**

**Search by Assurance Number**

**Alphabetical Listing**

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<th>United Kingdom</th>
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<td>Argenta Discovery 2009 Limited - United Kingdom</td>
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<td>Barts and The London School of Medicine and Dentistry - United Kingdom</td>
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<td>Charles River Laboratories Edinburgh - United Kingdom</td>
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<td>Covance CRS Ltd.</td>
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<td>Defence Science and Technology Laboratory</td>
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<td>King’s College London</td>
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<td>KWS BioTest, Ltd.</td>
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Inter-institutional Assurance (IIA)

“Institutions must have an OLAW-approved Animal Welfare Assurance before carrying out any activities involving live vertebrate animals. U.S. institutions that receive PHS funds through a grant or contract award are to use the Interinstitutional Assurance when the institution does not have their own:

– animal care and use program
– facilities to house animals
– Institutional Animal Care and Use Committee (IACUC); and
– does not conduct animal research on-site.

In this situation, the awardee institution will conduct the animal activity at an Assured institution (named as a performance site).”
IIA – In other words...

• They get the grant (and do not have a PHS Assurance)
• We do the animal work
• NIH put the regulatory compliance burden on us (uses our PHS assurance)
• Inter-institutional Assurance created for that grant (defined scope of work, defined period of time)
Other areas requiring IACUC oversight (but it depends!)

- Procurement items
- MTAs
- Collaborations (no $$)
- Animal purchases
Questions?

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