Foundations of IACUC and Animal Activities in Research Administration

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EXPERIENCED ANIMAL USERS?
The most important animal-welfare law in America began with a stolen dog.
H.R. 9743 — Pepper's law

• Congressman Rep. Resnick was recruited to Pepper's cause.
• A family found their dog to be missing.
• Eventually, it came out that Pepper had been stolen and sold to a research hospital for investigating a new cardiac pacemaker.
• Seven days after Pepper's death, Resnick introduced a dog-napping bill on the House floor.
• On Aug. 24, 1966, the president signed the [significantly improved] proposal into law: The Animal Welfare Act
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.
Can we define “Animal Welfare”?

• ...refers to the state of the animal; the treatment that an animal receives is covered by other terms such as animal care, animal husbandry, and humane treatment. Protecting an animal's welfare means providing for its physical and mental needs. (American Veterinary Medical Association, AVMA)

Alternatively:

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

How do institutions accomplish adherence?
AWAR: IACUC and AV

• “The Chief Executive Officer of the research facility shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members to assess the research facility’s animal program, facilities, and procedures.”

• “Each research facility shall have an attending veterinarian who shall provide adequate veterinary care to its animals in compliance...”
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)
HEALTH RESEARCH EXTENSION ACT OF 1985

The Federal Law which provides the statutory mandate for implementing the “Public Health Service Policy on Humane Care and Use of Laboratory Animals.”
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
The term “animal” means any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal, as the Secretary may determine is being used, or is intended for use, for research, testing, experimentation, or exhibition purposes, or as a pet; but such term excludes (1) birds, rats of the genus Rattus, and mice of the genus Mus, bred for use in research, (2) horses not used for research purposes, and (3) other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. With respect to a dog, the term means all dogs including those used for hunting, security, or breeding purposes. (AWAR)

Animal – Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes. (PHS)
Implementation of PHS Policy & The *Guide*

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.
### VII. Institutional Endorsement and PHS Approval

#### A. Authorized Institutional Official

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Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.

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#### B. PHS Approving Official *(to be completed by OLAW)*

**Name/Title:**
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6705 Rockledge Drive
RKL1, Suites 360, MSC 7982
Bethesda, MD USA 20892-7982 (FedEx Zip Code 20817)
Phone: +1 (301) 496-7163
Fax: +1 (301) 451-5672

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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
• Review and approve, require modifications in (to secure approval), or withhold approval proposed animal activities and significant changes in ongoing activities.
• 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

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

“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.”
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).”
Other areas requiring IACUC oversight (but it depends!)

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

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