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FASEB Webinar Series: Animal Research Regulations
Part 2

The Role of IACUC and AAALAC in Animal Research Oversight

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The Role of IACUC and AAALAC in Animal Research Oversight

Part 2 – Animal Research Regulations
Speakers

Gaylen Edwards, DVM, PhD
Chair, Institutional Animal Care and Use Committee (IACUC)
University of Georgia

Alice Huang, PhD
Deputy for IACUC Guidance, Office of the Chief Veterinary Medical Officer, Department of Veterans Affairs

Kathryn Bayne, MS, PhD, DVM, DACLAM, DACAW, CAAB
Chief Executive Officer, Assessment and Accreditation of Laboratory Animal Care (AAALAC)
To Ask A Question

Type your question in the white box and click “Send” (gray button)
IACUC OVERVIEW

◆ Required by Animal Welfare Act (AWA) and Public Health Service (PHS) in United States
  ▪ Similar oversight bodies are required globally

◆ Membership is appointed by the CEO or a person delegated to perform this function.

◆ Membership must include a properly trained veterinarian and a person not affiliated with the institution who doesn’t use laboratory animals.
  ▪ The size of the committee may vary. The AWA requires at least 3 people and the PHS requires 5.
HOT BUTTON ISSUES

◆ Everybody on the proposal is properly trained.

◆ Goals are understandable.
  ■ Well written lay summary

◆ Animal numbers are justified

◆ Alternatives are not available.
  ■ Literature search for USDA species
Techniques that involve animals are clear and easy to follow.

- Infectious diseases/cancer
  - Explain the disease course, if possible

- Surgery
  - Proper technique
  - Anesthesia and analgesia
  - Postoperative monitoring

- Euthanasia
Drug doses are appropriate and consistent throughout document.

- Give yourself ranges of doses
- Use classes of drugs (e.g. alpha$_2$ agonists)

Endpoints for more invasive protocols.

- Provide evidence that the endpoint is appropriate.
- Be willing to increase monitoring when knowledge of disease course is available.
IACUCs NEED SOUND VETERINARY ADVICE

Attending Veterinarian

- OLAW: The veterinarian on the IACUC must have direct or delegated program authority and responsibility for animal-related activities.

- AWA: Title 9 C.F.R., Section 2.33 - Attending Veterinarian and Adequate Veterinary Care
  - (a) Each research facility must have an attending veterinarian who is required to provide adequate veterinary care to the facilities animals (Sect. 2.33(a)).
Is an IACUC member.

May wear many different hats.

In my experience, this person often serves as the liaison between animal care program (including IACUC), institutional official, and regulatory agencies.

May not have direct clinical care duties.
COMMON MISCONCEPTIONS

- The IACUC wants the fewest number of animals.
  - The IACUC wants the right number of animals

- The IACUC wants too many details.
  - Focus on details that impact animal welfare.
  - Remember that this needs to be understandable by the general public.

- The IACUC doesn’t understand my position as a PI.
  - These are your faculty/scientist colleagues on the IACUC.
Role of the IACUC
The IACUC and What It Does

IACUC

NSM (Chair)

NAM

AV

Scientist

Oversight of Animal Research Program

Protocol Review

Addressing Concerns

SOPs

PAM

Per diems

Facilities Mgmt

Vet Care

Semi-annuals

Husbandry

Protocol Review

Addressing Concerns

SOPs
Regulatory Requirements

![Diagram showing Regulatory Requirements]

- USDA Animal Welfare Act &Regs
- AVMA Guidelines
- US Government Principles
- The Guide
- VA Policy
- AAALAC Rules of Accreditation
A Way to Meet Ethical Requirements

Ethical Conduct of Research

- PHS Policy
  - USDA Animal Welfare Act & Regs
  - AVMA Guidelines
  - US Government Principles

- VA Policy
  - AAALAC Rules of Accreditation

The Guide
Regulations Prescribe the IACUC

IACUC
- NSM (Chair)
- NAM
- AV Scientist

Oversight of Animal Research Program
- Protocol Review
- Semi-annuals
- SOPs
- Addressing Concerns
- Per diems
- Vet Care
- Facilities Mgmt
- Husbandry

Ethical Conduct of Research

SPH Policy
- USDA Animal Welfare Act & Regs
- AVMA Guidelines
- PHS Policy

AAALAC Rules of Accreditation
- VA Policy
- US Government Principles

FASB

FASEB
Federation of American Societies for Experimental Biology
IACUC Oversight is the Mechanism for the Ethical Conduct of Research. The Guide, USDA, USDA, PHS Policy, AVMA, USDA, AAALAC Rules, and USDA are involved. The Oversight of Animal Research Program includes Protocol Review, Semi-annually, Per diems, SOPs, PAM, Husbandry, Vet Care, and Facilities Mgmt. The AV Scientist oversees the IACUC, which addresses Concerns. The Ethical Conduct of Research is overseen.
EACH IACUC Member Must...

- Fully engage in deliberations
  - Contribute own perspectives
  - Ask questions for clarification
  - Respect perspectives of others
- Make informed judgements
- Vote your conscience
- Document work
Protocol Review

Ethical Conduct of Research
Protocol Review

Use informed judgement to help the PI …

◆ make sure the proposed protocol meets regulatory and ethical requirements
◆ document that clearly

www.faseb.org
Semiannual Evaluations

Ethical Conduct of Research
Semiannual Reviews -- Why Bother?

- Regulatory requirement
- A useful tool for making sure that ethical requirements continue to be met as things change over time
Evaluation Teams

- ≥ 2 IACUC members
- “Fresh eyes”
- Non-member guests
Semiannual Evaluation Process

- Checklist
- Evaluate findings / determine appropriate corrective actions, using even small failures as indicators of weaknesses to be addressed to prevent larger failures
- Document what these mean for the program
Addressing Concerns

Ethical Conduct of Research

USDA
AWAR
AVMA

PHS Policy

The Guide

AAALAC Rules

US Gov't Prin

VA Policy

AV
Scientist

IACUC

NSM
(Chair)

NAM

PAM

VA

Protocol Review

Addressing Concerns

Oversight of Animal Research Program

Vet
Care

Semi-annuals

Facilities Mgmt

Per diems

Husbandry

SOPs
Transparency is Critical

◆ Trust is difficult to build, easy to lose, and very difficult to re-build.

◆ Worst response: the appearance of a cover-up

◆ To avoid the appearance of a cover-up: promptly self-report non-compliance and corrective actions
Ethical Conduct of Research
The Role of AAALAC International in Animal Research Oversight

Kathryn Bayne, MS, PhD, DVM, DACLAM, DACAW, CAAB
Chief Executive Officer
Oversight and Acronyms

An interdigitated system
IACUC -- AAALAC

**IACUC**
- Local oversight - deep dive
- Oversight of entire program
- Inspects facilities
- Typically every six months
- Authority to suspend protocols, require corrective actions and set timeline for correction

**AAALAC International**
- External assessment - systems, processes - validated by detailed review
- Assessment of entire program
- Reviews facilities
- Typically every 3 years
- Determines accreditation status, institution
- Voluntary
Use of AAALAC Assessment for IACUC’s Semiannual Evaluation

- NOTICE: OD-00-007 (1999)
  - The provision to utilize ad hoc consultants may be invoked by IACUCs to make use of either of the two AAALAC assessment programs (Program Status Evaluation or Accreditation), or the pre-assessment preparation activities, to meet the requirements for an IACUC semiannual program evaluation and subsequent report.
Fundamentals of Accreditation Systems
Accreditation is a highly effective tool for:

- Helping to introduce continuous quality improvement programs to newly accredited or not-yet-accredited organizations;
- Creating new leadership for quality improvement initiatives;
- Increasing social capital by giving staff the opportunity to develop relationships.

Pomey et al. 2010
Accreditation Introduces Organizational Changes

- Promotes organizational learning through the application of accreditation standards
- Helps identify quality improvement initiatives
  - Accreditation aims to benchmark institutional performance against quality standards

Ghareeb 2018
Accreditation Promotes a Strong Institutional Framework

- Roles and responsibilities are clearly delineated
- Policies and procedures are understood
- Educational and training systems are inclusive and well-functioning
- Oversight and information support systems are established/refined
- Assessment systems are established and meaningful
AAALAC’s Oversight Principles

- Rules of Accreditation
  - The institution shall observe any and all statutes and governmental regulations which bear upon animal care and use
  - The Guide shall serve as the basis for the establishment of specific standards for accreditation
- Trust relationship
- Validate with Peer Review
AAALAC Founders

- Recognized that a consistent, high level of research animal care would benefit science
- Recognized as well that input from scientists was needed
AAALAC International

- Nonprofit organization
- Assessors work in the same environment
- Does not establish standards/policies
  - Relies on scientific literature and consensus reports
  - Science is objective, verifiable, and a common language around the globe
AAALAC International Assessment Process
Multilayered Review

- by the AAALAC International Council on Accreditation (COA)
- using a performance approach

Final Deliberation

External Review
Site Visit

Internal Review
Preparing Program Description (PD)
Tiers of Assessment Standards

Three Primary Standards

Scientific Literature, Expert Guidance

Regulations, Laws, Policies
Three Primary Standards

ETS 123 - Appendix A (2006)

8th Edition
ILAR Guide
(2011)

3rd Edition
Ag Guide
(2010)
AAALAC accredits research animal care and use Programs

“…means the policies, procedures, standards, organizational structure, staffing, facilities, and practices put into place by an institution to achieve the humane care and use of animals in the laboratory and throughout the institution.”
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Accreditation Process

1. Download Application Package from AAALAC website
2. Program Description (PD)
   - Self-evaluation
3. Site visit: COA member(s) + ad hoc(s)
   - PD discussion, review animals/facilities/operations, review program documentation, meet with IACUC, interview staff
4. Site Visit Report
5. Council Deliberations
6. Outcome (letter to institution)
AAALAC International Accreditation

- A key element of an interdigitated oversight system
- Shares some features with other mechanisms, but with the added value an accreditation system (for any industry) brings
A commitment to purpose

Accreditation

Education

Assessment

www.aaalac.org

THANK YOU
To Ask A Question

Type your question in the white box and click “Send” (gray button)
Other Questions?

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COVID-19 Resources


- Flexibilities for Assured Institutions for Activities of IACUCs (NOT-OD-20-088)
- Recorded Webinar: “Pandemic Contingency Planning and Its Impact on Animal Care”


- Telework policy – all correspondence (including PD’s) to be sent electronically

- NIH-wide:
  - Coronavirus Disease 2019 (COVID-19): Information for NIH Applicants and Recipients of NIH Funding [updating in real time]