

IACUC Review of Proposed Animal Activities

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Issues To Be Addressed

- Authority of an IACUC to review proposed research projects
- Topics that must be considered by an IACUC when reviewing proposed research projects
- Proposal review procedures
- Q & A



IACUC Authority to Review Proposed Animal Activities: HREA

The Health Research Extension Act of 1985 (HREA), Public Law 99 -158, required that guidelines be established for:

- 1) The proper care of animals to be used in biomedical and behavioral research.
- 2) The proper treatment of animals to be used in such research.



IACUC Authority To Review Proposed Animal Activities: PHS Policy

- Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) promulgates the requirements of Public Law 99 -158.
- PHS Policy IV.B. defines eight functions of an IACUC, two of which relate to the review of proposed animal activities.



PHS Policy IV.B.

“As an agent of the institution, the IACUC shall...

- review and approve, require modifications in (to secure approval) or withhold approval of those components of PHS-conducted or supported activities related to the care and use of animals...
- review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities...”

PHS Policy IV.C.1.

- “...the IACUC shall confirm that the research project will be conducted in accordance with the Animal Welfare Act insofar as it applies to the research project, and
- that the research project is consistent with the *Guide** unless acceptable justification for a departure is presented.”
- “⁹...The *Guide* may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of the PHS Policy.”



PHS Policy IV.C.1.

- a. “...avoid or minimize discomfort, distress, and pain to the animals...”
- b. ...appropriate sedation, analgesia, or anesthesia
- c. Animals that would otherwise experience... severe or chronic pain or distress that cannot be relieved will be painlessly killed...
- d. ...living conditions of animals will be appropriate for their species...”

PHS Policy IV.C.1.

- e. “Medical care...provided...by a qualified veterinarian.
- f. Personnel...will be appropriately qualified and trained...
- g. Methods of euthanasia used will be consistent with the AVMA Guidelines on Euthanasia...”

Guide Topics for Protocol Review

- “Rationale and purpose of the proposed use of animals.
- Justification of the species and number of animals requested. Whenever possible, the number of animals requested should be justified statistically.
- Availability or appropriateness of the use of less-invasive procedures, other species, isolated organ preparation, cell or tissue culture, or computer simulation...”

Guide Topics for Protocol Review

- “Adequacy of training and experience of personnel in the procedures used.
- Unusual housing and husbandry requirements.
- Appropriate sedation, analgesia and anesthesia...
- Unnecessary duplication of experiments.
- Conduct of multiple major operative procedures.”

Guide Topics for Protocol Review

- “Criteria and process for timely intervention, removal of animals from a study, or euthanasia if painful or stressful outcomes are anticipated.
- Post-procedure care.
- Method of euthanasia or disposition of animal.
- Safety of working environment for personnel.”

Guide Topics for Protocol Review

- Physical Restraint
“Prolonged restraint, including chaining of nonhuman primates, should be avoided...”
- Food or Fluid Restriction
“...scientifically justified...monitor physiologic or behavioral indexes...”

USDA

- If your institution is registered as a research facility with the USDA and USDA covered species are used in research, testing, or teaching - there are additional topics that an IACUC must include in its review of proposed animal activities.
- Those topics are listed in 9 CFR 2.31(d).



Methods of Proposal Review

There are only two recognized methods of review of animal activities by an IACUC:

1. Full Committee Review (FCR)
 - Convened meeting of a quorum of members is required.
2. Designated Member Review (DMR)
 - Conducted by one or more members designated by the Chair.

Full Committee Review

There are three possible outcomes of FCR. As described in the PHS Policy, they are:

1. Approval
2. Modifications required in (to secure approval)
3. Withhold approval



Designated Member Review

There are also three possible outcomes for DMR. As described in the PHS Policy, they are:

1. Approval
2. Modifications required in (to secure approval)
3. Request FCR



Modifications Required In (To Secure Approval)

- This category is used when the proposal lacks substantive information.
- Substantive information is the information the IACUC needs to evaluate the proposal in accordance with:
 - Requirements of the PHS Policy
 - Adherence to the *Guide*
 - Institution's Animal Welfare Assurance

OLAW FAQ D19



Proposed Changes

- Proposed significant changes in ongoing animal activities must be reviewed and approved by the IACUC prior to implementation.
- IACUC approval must be by one of the two approved methods - either FCR or DMR.



Examples of Significant Changes

Changes*

- in the objectives of a study;
- from non survival to survival surgery;
- resulting in greater discomfort or in a greater degree of invasiveness;
- in the species or in approximate number of animals used;

OLAW FAQ D9

*Significant changes include, but are not limited to, these examples.



Examples of Significant Changes

Changes* in

- Principal Investigator;
- anesthetic agent(s) or the use or withholding of analgesics;
- method of euthanasia; and
- duration, frequency, or number of procedures performed on an animal.

OLAW FAQ D9.

*Significant changes include, but are not limited to, these examples.



Notification Procedures

The investigator and the institution shall be notified in writing of the committee's decision relative to a research proposal.



Proposal Review Procedures

The PHS Policy requires that the IACUC conduct a complete continuing review of animal activities at time intervals as determined by the IACUC - at least once every three years.



IACUC Authority

Proposals approved by the IACUC may be subject to further review by officials at an institution. However, those officials may not approve an animal activity that has not been approved by the IACUC.



Humane Animal Care

- NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability.
- Animals are critical to acceleration of biomedical discovery.
- Thank you for your contribution to the humane care and use of laboratory animals at your institution.



Educational Resources



Proposed 2011 Workshops & Conferences

March 30, Chicago IL **IACUC 101**

March 31 – April 1, Chicago, IL **PRIM&R**

May 11-12, Philadelphia, PA **IACUC 101/201Plus**

June TBD, Boston, MA **IACUC 101**

August 11, Des Moines, IA **IACUC 101**

Sept. 14 – 15 Houston, TX **IACUC 101/201Plus**

Oct. 19 Albuquerque, NM **IACUC 101(wildlife focus)**



2011 OLAW Online Seminars

March IACUC Responsibilities Beyond Protocol Review

June Writing a Good Assurance

Sept. Occupational Health and Safety Programs

Dec. Grants Policy and Congruence



Questions? Please Ask!

