

# Guidance on Significant Changes to Animal Activities NOT-OD-14-126

OLAW Special Webinar  
August 21, 2014

- George Babcock, PhD
- Jerry Collins, PhD
- Betty Goldentyer, DVM
- Mary Lou James, BS
- Cyd Gillett, DVM
- Susan Silk, MS



# NOT-OD-14-126: Background

The PHS Policy on Humane Care and Use of Laboratory Animals (Policy) ([IV.C.1.](#)) and Animal Welfare Regulations ([9CFR 2.31 \(d\) \(1\) \(i\)- \(iv\)](#)) define the responsibilities of the IACUC regarding review and approval of proposed significant changes to animal activities. Changes to approved research projects must be conducted in accordance with the institution's Assurance, the United States Department of Agriculture (USDA) Animal Welfare Act and Animal Welfare Regulations and must be consistent with the [Guide](#) unless an acceptable justification for a departure is presented. Additionally, IACUCs are responsible for assuring that the changes to approved animal activities meet the requirements described in the PHS Policy [IV.C.1.a.– g.](#)

# Background

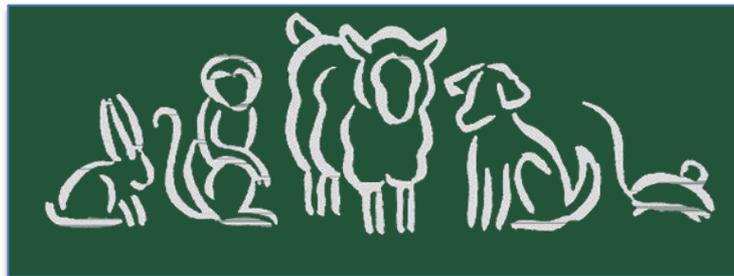
IACUC approval of proposed animal activities or significant changes to previously approved animal activities is granted after full committee review (FCR) or designated member review (DMR). Additionally, institutions may establish and IACUCs may approve policies (e.g., guidance documents, standard operating procedures, drug formularies) for the conduct of animal activities. These policies must be reviewed by the IACUC at appropriate intervals of no less than once every three years to ensure they are appropriate and accurate.

# Significant Changes to Animal Activities Previously Approved by the IACUC

The IACUC has some discretion to use IACUC-reviewed and -approved policies to define what it considers a significant change, or to establish a mechanism for determining significance on a case-by-case basis in accordance with the PHS Policy [IV.C.1.a.-g.](#) It is the IACUC's responsibility to clearly define and communicate its policy for determining significance to investigators.

# Significant Changes to Animal Activities Previously Approved by the IACUC

In brief, significant changes include changes that have, or have the potential to have, a negative impact on animal welfare (see paragraph 1., below). In addition, some activities that may not have a direct impact on animal welfare are also considered to be significant (see paragraphs 2. and 3., below).



# Significant Changes to Animal Activities Previously Approved by the IACUC

In support of the use of performance standards and professional judgment and to reduce regulatory burden, IACUC-reviewed and -approved policies (e.g., guidance documents, standard operating procedures, drug formularies) for the conduct of animal activities may be used for the administrative handling of some significant changes according to the following considerations:

# Paragraph 1.

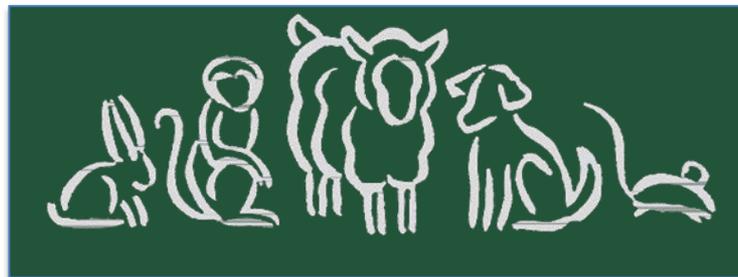
1. Significant changes described in 1.a. – g., below, must be approved by one of the valid IACUC approval methods described in the PHS Policy IV.C.2., that is FCR or DMR, including changes:
  - a. from nonsurvival to survival surgery;
  - b. resulting in greater pain, distress, or degree of invasiveness;
  - c. in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
  - d. in species;
  - e. in study objectives;
  - f. in Principal Investigator (PI); and
  - g. that impact personnel safety.

## Paragraph 2.

2. The specific significant changes described in 2.a.- c., below, may be handled administratively according to IACUC-reviewed and -approved policies in consultation with a veterinarian authorized by the IACUC. The veterinarian is not conducting DMR, but is serving as a subject matter expert to verify that compliance with the IACUC-reviewed and -approved policy is appropriate for the animals in this circumstance. Consultation with the veterinarian must be documented. The veterinarian may refer any request to the IACUC for review for any reason and must refer any request that does not meet the parameters of the IACUC-reviewed and -approved policies. This includes changes in:
  - a. anesthesia, analgesia, sedation, or experimental substances;
  - b. euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals; and
  - c. duration, frequency, type or number of procedures performed on an animal.

## Paragraph 3.

3. A significant change that may be handled administratively according to an existing IACUC-reviewed and -approved policy without additional consultation or notification is an increase in previously approved animal numbers (PHS Policy [IV.D.1.a.](#)).

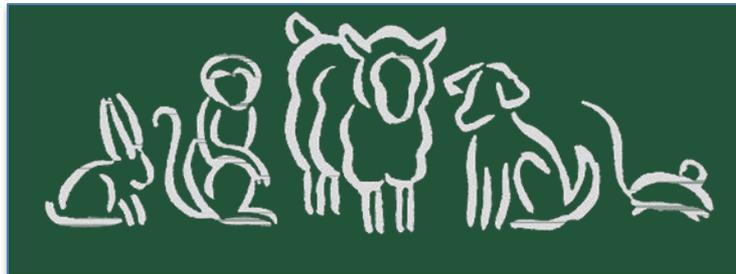


## Other Changes: Paragraph 4.

4. Changes that may be handled administratively without IACUC-approved policies, consultations, or notifications include:
  - a. correction of typographical errors;
  - b. correction of grammar;
  - c. contact information updates; and
  - d. change in personnel, other than the PI. (There must be an administrative review to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in occupational health and safety programs, and meet other criteria as required by the IACUC.)

## Other Changes: Paragraph 5.

5. Investigators may use fewer animals than approved. This does not require IACUC approval, notification, consultation, or administrative handling.



# USDA Concordance

The USDA Animal and Plant Health Inspection Service has reviewed and concurs with the guidance provided in this Notice.



# Inquiries

For questions or further information, contact:

Office of Laboratory Animal Welfare

Office of Extramural Research

National Institutes of Health

6705 Rockledge Drive, Suite 360

Bethesda, MD 20892-7982

Phone: 301-496-7163

Fax: 301-480-3394

Email: [olaw@mail.nih.gov](mailto:olaw@mail.nih.gov)

Web: <http://olaw.nih.gov/>

