TITLE: PROTOCOL AMENDMENT & MODIFICATION	**Effective Date:** March 14, 2012
IACUC POLICY: 003 **REVISION:** 7	**Last Revised:** August 2026
SCOPE: This policy applies to all approved IACUC protocols	
PURPOSE: To define when protocol modifications are required, how protocol modifications are submitted, reviewed and approved including the use of Veterinary Verification Consultation (VVC).	
KEYWORDS: Protocol modification, Amendment, Full Committee Review (FCR), Designated Member Review (DMR), Veterinary Verification & Consultation (VVC), and/or Administrative Review (AR).	
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1. BACKGROUND

The PHS Policy on Humane Care and Use of Laboratory Animals (Policy) (IV.C.1.) and Animal Welfare Regulations (9 CFR 2.31 (d) (1) (i)- (iv)) define the responsibilities of the Institutional Animal Care and Use Committee (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 provided.

Additionally, IACUCs are responsible for ensuring that changes to approved animal activities meet the requirements described in the PHS Policy IV.C.1.a.-g. According to the PHS 'NOT-OD-14-126,' institutions may establish, and IACUCs may approve, policies governing the conduct of animal activities. The institution is responsible for developing approval mechanisms within the context of USDA and PHS requirements. These policies must be reviewed by the IACUC at appropriate intervals, but no less frequently than once every three years, to ensure they are appropriate and accurate.

2. POLICY

IACUC approval of proposed changes to previously approved animal activities may be granted through Full Committee Review (FCR), Designated Member Review (DMR), Veterinary Verification and Consultation (VVC), or Administrative Review (AR). The IACUC has discretion to use IACUC-reviewed and -approved policies to define what constitutes 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..

A. Changes requiring Principal Investigator (PI) / Project Director (PD) to submit Amendment for review by FCR or DMR include:

- **Changing from non-survival to survival surgery**
- **A change that results in greater pain, distress, or invasiveness** (unless described under section 2.B.)
- **Housing or using animals at a location outside Department of Animal Resources (DAR) facilities** (that has not been inspected by the IACUC within the last 6 months)
- **Changing the animal species**
- **Changing the study objectives**
- **Changing the PI or PD**
- **A change that negatively impacts personnel or animal health and safety**

- Addition of a new procedure, defined by broad categories such as imaging, surgery, specimen collection, test substance administration, etc. (unless conducted under a previously approved terminal anesthesia)
- Using a strain, stock, breed or genetic modification associated with greater pain, distress, or unusual mortality or morbidity at a stage beyond embryonic development
- Increasing approved animal numbers by greater than 15%

B. Veterinary Verification and Consultation (VVC) includes:

Exclusion Note: VVC cannot be used for Department of Defense (DoD) funded protocols as the DOD Animal Care and Use Review Office (ACURO) must approve all changes before they are implemented within a protocol.

Provided they do not affect the list in Section A above, the changes outlined below may be handled administratively 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 compliance with this policy and appropriateness of the proposed change for the animals in the context of the approved protocol. A veterinarian may refer any request to the IACUC for review for any reason and must refer requests that do not meet the parameters below. VVC may be used for any change described below:

Any addition or change that is animal welfare neutral or positive that is not a new procedure (the latter is defined by broad categories such as imaging, surgery, specimen collection, test substance administration, etc.)

Correction of errors and omissions

Veterinary Care-Related Changes

Examples include surgical methods and approaches, peri-operative care and preparation, preventive care, quarantine, analgesia, anesthesia, sedation, anesthesia reversing agents, health surveillance and treatment of disease or injury.

Facility and Management-Related Changes

Examples include, but are not limited to, changing housing, cage type, diet, transportation, enrichment, and/or approved acclimatization period (following the receipt of animals)

Research Substance/Material Changes

- Change in type, dose, method, route, concentration, volume or frequency of administration of drugs or experimental materials. Note: Written verification from Environmental Health & Safety (EHS) is required for substances that may adversely affect human health and safety.
- Changing to pharmaceutical grade materials when non-pharmaceutical grade was previously approved.
- Changing implant size, shape or materials
- Changing neuromuscular blocking agents with specified monitoring
- Change to any complete/balanced diet including those containing drugs or test substances

Activities/Procedures

- **Changing duration, frequency, type, time points or number of previously approved procedures**
- Changing from euthanasia to terminal anesthesia or vice versa

- Any change/addition under previously approved general, terminal anesthesia, including new procedures.

Euthanasia

- **Changing euthanasia to any method considered acceptable in the "AVMA Guidelines for the Euthanasia of Animals"** including conditional methods provided that conditions are met.

C. Changes requiring PI/PD to submit an Amendment that may be Administratively Approved:

- Addition of personnel, other than the PI/PD
- Changing the protocol title
- Changing funding sources, provided that there is no change in objectives or modification of methods or procedures
- Changing procedure location within the animal program overseen by the IACUC
- Increasing holding time in a procedure area for up to 24 hours for non-USDA species and up to 12 hours for USDA species
- Increasing animal numbers by less than 15% of the approved animal numbers

D. Changes that do NOT require PI/PD to submit Amendment for Administrative Approval:

Changes that may be handled administratively without additional PI/PD submission of an amendment, IACUC-approval, vet consultations, or notifications include:

- Correcting typographical errors, grammar
- Updating contact information
- Removing personnel

E. Examples of changes not requiring review or approval:

- Using fewer animals than approved or omission of experiments, experimental procedures or surgeries (this does not include withholding anesthetics, analgesics, sedatives, or other required pain-relieving measures)
- Changing strain, stock, or breed, including genetically modified stocks and strains (not associated with pain or distress or unusual mortality or morbidity at a stage beyond embryonic development or pain or distress)
- Changing to sterile caging
- Changing physical factors that reduce pain, distress, trauma or infection such as using a smaller needle or implant, choosing earlier endpoints, making smaller incisions, using a less traumatic surgical approach, leaving an animal in its familiar environment for a procedure rather than taking it elsewhere, achieving greater tissue apposition during surgery or using sterile gowns for rodent surgery
- Changing factors that increase human safety that do not impact animal welfare or research objectives such as using additional PPE or less of a previously approved toxic or noxious substance
- Changing brand names or sources of identical drugs, sutures, materials or supplies
- Using discarded carcasses, tissues, organs, blood, etc. from animals as described in IACUC Policy
- Replacing animals that die or are euthanized for health reasons before research manipulations occur
- Changing housing, or procedure and surgery rooms within the DAR animal facility

3. PROCEDURE for VETERINARY VERIFICATION AND CONSULTATION (VVC)

A. Mode of Communication and Submission of Requests

Communications described below may be made in person, by phone, or electronically.

B. Requesting VVC

Any researcher on an IACUC-approved protocol may request VVC from any veterinarian authorized by the IACUC. In addition, ORIA may determine that changes received as an amendment or by other modes fall within VVC and may refer the amendment to an IACUC-authorized veterinarian. Authorized veterinarians may also initiate a VVC to prescribe or withdraw standard-of-care veterinary purview items or activities as detailed above.

C. When Changes May Be Initiated by the Laboratory

Changes will be reviewed by ORIA or an IACUC-approved veterinarian to verify that the change requested can be authorized under this policy. Changes may be initiated as soon as either ORIA or an IACUC-approved veterinarian communicates authorization to the researcher.

D. Researcher May Petition for Clarification of Items Not Included in this Policy

For changes or situations not addressed in this document, the researcher may be asked to wait while the veterinarian and ORIA review the proposed change and determine the appropriate review mechanism. This determination may result in the change requiring Full Committee Review (FCR) or Designated Member Review (DMR) The researcher will be informed of each step as soon as it is determined.

E. Documentation

When an authorized veterinarian evaluates a change request that was made directly to them and determines that it fulfills the requirements for a VVC, they produce an email copied to ORIA, the PI and the researcher (if different from the PI). ORIA evaluates the email for consistency with this policy and comprehensibility. If ORIA deems it appropriate, they update the protocol.

F. Summary List of Protocols, Amendments and Administratively Handled Changes

At each meeting the IACUC will be provided with a list of VVC and ORIA administrative changes and protocols and amendments approved by DMR since the last meeting for review and discussion.

Resources

- Animal Welfare Regulations 9 CFR 2.31 (d) (1) (*i*)- (*iv*)
- PHS Policy on Humane Care and Use of Laboratory Animals
- AVMA Guidelines for the Euthanasia of Animals
- Guidance on Significant Changes to Animal Activities: OLAW Special Seminar, August 21, 2014
- Implementing Guidance on Significant Changes: One Institution's Experience: OLAW Online Seminar, September 8, 2016
- NOT-OD-14-126: Guidance on Significant Changes to Animal Activities
- PHS Policy IV. C on review of PHS-Conducted or Supported Research Projects
- PHS Policy IV. D. on Information Required in Applications and Proposals

REVISION HISTORY:

Revision	Summary of Revisions	Revision Date
1	Update links	March 10, 2015
2	Update and add VVC	July 11, 2016
3	Clarifying VVC approved activities	July 23, 2018
4	New OLAW Guidance & Clarifying VVC approved activities	August 26, 2019

5	Removal of old animal facility name (“PRL”)	November 7, 2023
6	Update to Institute formatting, correct links	October 2025
7	Corrections and removal of apparent inconsistencies	August 2026