

TITLE: PROTOCOL AMENDMENT & MODIFICATION	Effective Date: March 14, 2012
IACUC POLICY: 003 REVISION: 4	Last Revised: March 13, 2021
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), or Administrative Review (AR).	
Policy Owner: Office of Research Integrity Assurance (ORIA) Vice President for Research Development and Operations (VPR-DO)	
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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 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.](#) According to the PHS ‘[NOT-OD-14-126](#),’ institutions may establish and IACUCs may approve policies for conduct of animal activities. The institution is charged with developing the approval mechanisms, within the context of USDA and PHS boundaries. 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.

2. POLICY

IACUC approval of proposed changes to previously approved animal activities is granted after Full Committee Review (FCR), Designated Member Review (DMR), Veterinary Verification & Consultation (VVC), or Administrative Review (AR). 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.](#)

Changes requiring PI to submit Amendment for review by FCR or DMR include:

- **Change from non-survival to survival surgery;**
- **Change resulting in greater pain, distress, or degree of invasiveness;**
- **Housing or use of animals at a location that is not part of the animal program overseen by the IACUC;**
- **Change in species;**
- **Change in study objectives;**
- **Change in Principal Investigator (PI);**
- **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.);
- 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%

Veterinary Verification and Consultation (VVC) includes:

Exclusion Note: VVC cannot be used for DOD funded protocols as the DOD ACURO must approve all changes before they are implemented within a protocol.

Provided they do not affect the list above, changes 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 already approved circumstances. In addition to publically available drug formularies and list of acceptable administration routes, the parameters below may be verified by the authorized veterinarian based on their subject matter expertise, training, experience, professional publications, or anecdotal information from professional meetings or colleagues. 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/addition of activities that are animal welfare neutral or positive such as:

Veterinary Care-Related

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

Facility and Management-Related

- Changes to housing, cage type, diet, transportation or enrichment (e.g. provision of wheels to rodents);
- Change in approved acclimatization period following the receipt of animals.

Research Substances/Materials

- Standard-of-care veterinary purview items such as antibiotics, bandages, aseptic methods, analgesics, sedatives, anesthesia reversal agents and anticoagulants;
- **Anesthesia, analgesia, sedation, or experimental substances;**
- 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.
- Pharmaceutical grade when availability changes;
- Implant size, shape or materials;
- Neuromuscular blocking agents with specified monitoring;
- Change to any complete/balanced diet contain drugs or test substances;

Activities/Procedures

- **Duration, frequency, type, time points or number of procedures;**
 - Change from euthanasia to terminal anesthesia or vice versa;
- Any change/addition under previously approved general, terminal anesthesia.

Euthanasia

- **Euthanasia to any method approved by the “AVMA Guidelines for the Euthanasia of Animals”** including conditional methods provided that conditions are met-

Changes requiring PI to submit an Amendment that may be Administratively Approved:

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

Changes that do NOT require PI to submit Amendment for Administrative Approval:

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

- Correction of typographical errors, grammar;
- Contact information updates;
- Removal of personnel.

Examples of changes not requiring review or approval:

- Use of 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);
- Change in 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);
- Change to sterile caging;
- Physical changes that reduce pain, distress, trauma or infection such as changing to a smaller needle or implant, an earlier endpoint, making a smaller incision, 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;
- Change that increase human safety that do not impact animal welfare or research objectives such as using additional PPE or less of a toxic or noxious substance;
- Change in brand name or source of identical drugs, suture, materials or supplies;
- Use of discarded carcasses, tissues, organs, blood, eggs, etc. from animals as described in IACUC Policies
- Replacement of animals that die or are euthanized for health reasons before research manipulations occur;
- Change in like housing, procedure or surgery rooms within the PRL facility.

3. PROCEDURE for VETERINARY VERIFICATION & CONSULTATION (VVC)

Mode of Communication and Submission of Requests

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

Requesting VVC

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

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 ORIA or an IACUC-approved veterinarian communicates authorization to the laboratory.

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

For areas or examples not included in this document, requestors may be asked to wait for veterinary and ORIA discussion and concurrence that may conclude in the need for FCR or DMR. The requestor will be informed of each step as soon as it is determined.

Documentation

Whenever an authorized veterinarian evaluates a change request, the request and the conclusion shall be communicated with ORIA and updated in the protocol (when appropriate). The authorized veterinarian may request protocol personnel to update the protocol document or she/he may elect to update the protocol.

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