

Veterinary Verification and Consultation (VVC)¹

Background

The PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy) (IV.C.1.) and Animal Welfare Regulations (9 CFR 2.31(d)(1)(i-iv)) define the responsibilities of the IACUC regarding review and approval of proposed significant changes to animal activities. 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.

Purpose

To identify specific significant changes to animal activities that 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 the proposed changes are appropriate for the animals in the circumstance, and are consistent with relevant IACUC approved guidance.

Guideline

Changes not authorized by VVC

- 1. Significant changes described in 1a-g below must be approved by IACUC FCR or DMR, as described in the PHS Policy IV.C.2., that is FCR or DMR. These changes include:
 - a. Non-survival to survival surgery
 - b. Greater pain, distress, or degree of invasiveness
 - c. Housing and or use of animals in a location that is not part of the animal program overseen by the IACUC
 - d. Species
 - e. Study objectives
 - f. Principal Investigator (PI)
 - g. Those which impact personnel safety

Changes authorized by VVC

- 2. The specific significant changes described in 2a-d below may be handled in consultation with a veterinarian authorized by the IACUC. These include changes in:
 - a. Anesthesia, analgesia, sedation, medications, or experimental substances:
 - i. Change of anesthesia, analgesia, sedation, or medications, provided they are approved in the reference formulary
 - ii. Dose of previously approved drug or experimental substance
 - iii. Route of administration
 - iv. Frequency of administration
 - b. Euthanasia to any method approved in the current AVMA Guidelines for the Euthanasia of Animals: 2020 Edition

- c. Duration, frequency, type, or number of procedures performed on an animal. Some examples are:
 - i. Change in the amount, route, and/or frequency of blood collection, while adhering to the IACUC approved guidelines "Multiple Blood Draws"
 - ii. Method of animal identification
 - iii. Biopsy procedure for genotyping
 - iv. Frequency/interval/number of non-invasive procedures such as imaging
 - v. Enrichment provisions
 - vi. Method of restraint (does not include "prolonged restraint")
 - vii. Care during recovery from anesthesia
 - viii. Change from survival to non-survival surgery
 - ix. Use of Elizabethan collar (E-collar)
 - x. Wound closure
- d. Tumor size, growth duration, and/or monitoring

Veterinary responsibility

- 1. Consultation with the veterinarian must be documented by emailing the completed and signed VVC Amendment Request form, available on the ACUC website under Forms, to the ACUC Office (acuc@jhmi.edu).
- 2. The veterinarian may refer any request to the IACUC for review for any reason.
- 3. The veterinarian must refer to the IACUC any request that does not meet the parameters of the items in 2a-d, to be processed as an amendment.

Process: The VVC Request Form is available on the ACUC website under Forms www.jhu.edu/animalcare

- 1. Ways to initiate the VVC process:
 - a. Any amendment submitted to the IACUC through the normal submission process, in which the changes described qualify for VVC, may be assigned administratively to an IACUC approved veterinarian for VVC.
 - b. An IACUC approved veterinarian can initiate a VVC by sending the VVC form to a PI to fill out and send back to the veterinarian for review and signature.
 - c. A PI may download the form from the ACUC website, fill it out, and consult with an approved veterinarian.
- 2. The veterinarian will send the signed document to the IACUC office directly via e-mail. The subject line will contain the letters "VVC," and the Principal Investigator will retain a copy with the protocol for which the change is authorized.
- 3. The IACUC will add the VVC document to the file of the protocol for which the change is authorized.
- 4. The PI will be required to include the amended procedure in subsequent renewal submissions of the affected protocol, if it is to be performed in the future.

References

NIH Guide Notice NOT-OD-14-126 https://grants.nih.gov/grants/guide/notice-files/not-od-14-126.html

AVMA Guidelines for the Euthanasia of Animals-2020 Edition https://www.avma.org/sites/default/files/2020-02/Guidelines-on-Euthanasia-2020.pdf

¹Approved by the JHU Animal Care and Use Committee 8/18/2022, revised 2/2023