

University at Buffalo Institutional Animal Care and Use Program

Policy on Veterinary Verification and Consultation Process

Introduction

In accordance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, all activities with live vertebrate animals must be covered under an active approval by the Institutional Animal Care and Use Committee (IACUC). Federal regulations (USDA Animal Welfare Regulations and PHS Policy) require that the IACUC at each institution “review and approve, required modifications (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities.” The same federal regulations define the responsibilities of the IACUC regarding the review and approval of such changes, a process referred to as amending a protocol. Policies pertaining to the amendment review processes must be IACUC approved before implementation.

For significant changes to animal activities previously approved by the IACUC, the IACUC usually uses a combination of Full Committee Review (FCR) and Designated Member Review (DMR) to review amendments. However, the IACUC has some discretion with this process providing compliance with PHS Policy is maintained. One of the times when discretion may be used is allowing the use of a Veterinary Verification and Consultation (VVC) approval process for specific and defined significant changes.

The UB IACUC has decided to utilize VVC for the following reasons: to increase overall protocol compliance, to expedite making small changes that would positively impact animal welfare after consultation with LAF Veterinarians and to aid PIs with the frustrations of not being able to file amendments for small changes because other protocol amendments are currently under review in the Click system.

Definitions

Full Committee Review (FCR): Per federal mandate, FCR occurs when a quorum of IACUC members meets to discuss and vote on research or teaching protocols/amendments and any related IACUC business. IACUC meetings allowing FCR occur monthly at UB.

Designated Member Review (DMR): Protocol/amendment review is assigned to select IACUC members outside of an official IACUC meeting. At UB, amendments and revisions of protocols already reviewed via FCR are assigned to designated reviewers by the IACUC Chair. Designated reviewers may always recommend FCR if complicated issues are noted.

Veterinary Verification and Consultation (VVC): Special review process allowing select changes to already approved protocols and procedures after consultation with designated veterinarians. IACUCs must first approve VVC policies before implementing them. VVC allows for the most rapid approval of small changes to protocols. Several protocol changes are excluded from VVC.

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Policy

This policy outlines the requirements and steps for making changes to UB IACUC protocols via the VVC process.

1. Veterinary Verification and Consultation (VVC) is **NOT** to be used to make the following types of changes to IACUC protocols:
 - a. Addition of **entirely NEW experiments or procedures**
 - b. Changes that **increase the chances of compromising animal welfare** (increased pain and/or distress and related changes in pain category assignment)
 - c. Changes to the **objectives of a study**
 - d. Changing from **non-survival to survival** surgery
 - e. Changes in the **species**
 - f. Change of **Principal Investigator or key personnel**
 - g. Changes in housing and/or use of animals in a **location that is not part of the animal program** overseen by the IACUC
 - h. Changes that **impact the safety of personnel**

2. Veterinary Verification and Consultation **IS** to be used to make the following changes:
 - a. Changes to an **already approved procedure**
 - i. *Examples:*
 1. **Changing the genotyping procedure** to one that might **cause less pain or discomfort** for the animal particularly taking into consideration the age of the animal (ear punch instead of tail snip).
 2. Changing the **blood collection method** to one that might **cause less pain or discomfort** for the animal (submandibular instead of retro-orbital collection)
 3. Changing the **blood collection volume or frequency** as long as doing so will not increase the chances of compromising animal welfare
 4. Making a **change to a surgical procedure** that is not expected to increase pain or distress (i.e. suture material or pattern)
 - b. Changes in **anesthesia, analgesia or sedation** for **already approved procedures** (as long as changes do not increase pain or distress)
 - c. Changes in **euthanasia** to any method approved in the most current AVMA Guidelines for the Euthanasia of Animals
 - d. Changes in **duration, frequency, type, or number of procedures or their timeline** performed on an animal (but not entirely new procedures). Note: multiple survival surgeries in a single animal may not be approved via VVC.

3. The **procedure for amending an approved protocol through the VVC process** is as follows:
 - a. First, contact either the Attending Veterinarian (AV) or the Clinical Veterinarian (CV) that serves on the IACUC to discuss your proposed changes. They will advise on whether VVC is appropriate. **Please use discretion, saving VVC for those**

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times when it is most appropriate to expedite approval for compliance purposes. It is not intended to replace the standard method in place for amending protocols!

- b. Complete a **VVC Request Form**, and attach it to your IACUC Protocol via a (non-private) comment.
 - c. Send an email to notify the IACUC Office and both veterinarians (AV and CV) that you have submitted a VVC Request Form. Be mindful that after-hours/weekend requests may not be reviewed until the next business day. For absolute emergencies, contact the on-call veterinarian.
 - d. Either the AV or CV will respond via (non-private) comment to approve or disapprove your changes via VVC.
4. Following approval of changes via VVC:
- a. VVC approved changes may begin immediately following AV/CV approval via non-private comment, but an official amendment must follow to reflect those changes in the Click protocol.
 - b. PIs will be given 60 days to file an amendment to add VVC changes.
 - c. Allowance for changes made via VVC expires after 60 days.
 - d. Any changes made through the VVC process will be noted in the next IACUC meeting agenda so that the IACUC is aware of the changes/determinations made.

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Veterinary Verification and Consultation (VVC) Request Form

(Complete form, attach to relevant Click protocol via comment, then notify IACUC Office and veterinarians via email. If urgent, call veterinarian on-call.)

1. A phone consultation with Dr. Peirick/Dr. McCutcheon (**circle**) has taken place on _____ (**date**).
2. IACUC **approved protocol**: _____ (IACUC approved protocol number for which changes are sought).
3. IACUC **approved procedure(s)**: _____ (exact name of approved procedure(s) already in Click for which changes are sought).
4. **Description of changes**:

5. Required Attestations:

- a. I hereby attest that I fully understand that this VVC Request Form must FIRST be reviewed and approved by a veterinarian. Only after official approval notification, may I begin implementation of changes. (Simply submitting this form is not the final step!)
- b. I hereby attest that I also understand that changes approved by VVC will expire within 60 days of veterinary approval UNLESS an official protocol amendment is made and approved.
- c. I have fully reviewed and understand the UB IACUC Policy on VVC.

PI Signature: _____

Date of VVC Request Form Submission: _____

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