Protocol Review & Facility Assessment

Item 5 – Veterinary Verification and Consultation (VVC)

Introduction

The NIH has provided guidance (NOT-OD-14-126) on interpretation of PHS policy concerning the allowance for certain types of significant changes to animal activities previously approved by the IACUC to be administratively approved using Veterinary Verification and Consultation (VVC).

Specifically, 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 that they are appropriate and accurate.

According to PHS policy, this allows the IACUC some discretion to use IACUC-reviewed and approved polices to define what it considers a significant change or to establish a mechanism for determining significance on a case-by-case basis, and define the criteria for VVC approval of significant changes to animal activities previously approved by the IACUC

Policy

The Attending Veterinarian (AV) will determine if a requested change meets the criteria described below for VVC review. If so, the requested change to an IACUC-approved protocol will be reviewed and approved by the AV. The AV 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. The AV will retain the discretion to send any requested change to either Designated Member Review (DMR) or Full Committee Review (FCR) as appropriate. All changes approved by VVC will be reported to the IACUC at the next convened meeting.

VVC Criteria

Significant changes within the following categories **CANNOT** be approved by VVC:

1. from non-survival to survival surgery;
2. resulting in greater pain, distress or degree of invasiveness;
3. in housing or use of animals in locations not overseen by the IACUC;
4. in species;
5. in study objectives;
6. in Principle Investigator (PI) and;
7. that impact personnel safety.

Significant changes within the following categories **MAY** be approved by VVC (providing they meet defined criteria):

- Anesthesia, Analgesia, Sedation, or Experimental Substances

  Changes in agents administered to animals may be approved by VVC provided that:

  1. The change would not violate any of the above restrictions preventing administrative review;
  2. Changes in anesthesia, analgesia and sedation are only to agents and dosages listed on the approved formulary (see attached);
  3. Changes in experimental substance administration are only to substitute equivalent agents at established safe dosages for that species.

- Euthanasia

  Changes in the method of euthanasia may be approved by VVC provided that:

  1. The change would not violate any of the above restrictions preventing administrative review;
  2. The proposed new method of euthanasia is approved by the AVMA Guidelines for the Euthanasia of Animals.

- Experimental Procedures

  Changes in the duration, frequency, type, or number of experimental procedures may be approved by VVC provided that:

  1. The change would not violate any of the above restrictions preventing administrative review;
  2. Changes in experimental procedures are only to substitute procedures that should be equivalent to approved procedures and/or improve animal well-being and/or improve the value of the data collected.

- Additional Animals

  Requests to add additional animals to an approved protocol may be approved by VVC provided that:

  1. The species involved is not regulated by the USDA;
  2. The proposed increase is not an amount greater than 10% of the original number approved and when combined with all previously approved requests for additional animals, does not constitute a greater than 30% increase over the original number approved.

- Housing Location

  Requests to house animals (> 12 hours) in facilities other than DLAR may be approved by VVC provided that:

  1. The change would not violate any of the above restrictions preventing administrative review;
  2. The change does not involve a species regulated by the USDA;
  3. The space meets the minimum requirements for the species as described in the *Guide for the Care and Use of Laboratory Animals*, 8th Ed.

VVC Process

1. IACUC administrator will route the addendum form to the AV who will determine if the proposed change meets the criteria for VVC review.
2. If the AV determines that the addendum **does not meet** the criteria for VVC review, it will be processed for review according to IACUC-approved policy, *Item 4 – Protocol Amendment (Addendum).*
3. If the AV determines that the addendum **meets** the criteria for VVC review, the AV will interact directly with the PI to resolve any questions or concerns.
4. When all questions/concerns have been resolved, the AV will route the approved addendum to the IACUC administrator for final processing.
5. The IACUC administrator will verify personnel training for any added procedures.
6. The IACUC administrator will notify the PI of approval.

Other Changes

The following administrative changes may be approved by IACUC administrative personnel:

1. correction of typographical and formatting errors;
2. correction of grammar (provided the intended meaning does not change);
3. changes in personnel except the PI (provided that all training and occupational health requirements have been met);
4. changes in experimental procedure location (provided that the new area meets standard laboratory criteria, is appropriate for the intended use and is located within space under the authority of the IACUC).

Attachment: *Formulary for Laboratory Animals*, Third Edition

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