

Policy for Dealing with Specific Significant Changes to Animal Activities
Previously Approved by the UH IACUC
Reference: NIH Notice NOT-OD-14-126

IACUC Approved: February 19, 2015	Other Approvals:
Revisions and Approvals: 10/15/15, 11/23/15, 12/3/15, 2/15/18, 6/20/19, 10/17/19	

Policy

Per NIH's guidance document NOT-OD-14-126 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 Public Health Service (PHS) Policy IV.C.1.a-g. This policy accommodates the wide variety of species that are housed and used in association with the University of Hawai'i (UH) Animal Care and Use Program. This policy must be reviewed by the UH IACUC no less than once every three years.

A. Implementation

1. PI will request revisions via the Topaz protocol process.
2. Requests will be evaluated by the UH Animal Welfare Compliance Office (AWCO), who will forward the requests to the appropriate individuals, DMR, or to the IACUC for FCR for their reviews and decisions.
3. The change may be implemented once it is documented in the Topaz protocol.
4. In the event of an emergency situation¹, the change may be implemented immediately after the veterinarian verifies the change (as per OLAW webinar on Significant Changes to Animal Activities, 2016). The change must later be documented in the Topaz protocol.

B. The following significant changes on a previously approved IACUC protocol may be handled administratively through veterinary verification and consultation without full IACUC review if the following conditions are met:

- 1) The veterinarians in the UH Veterinarian's Office, will serve as subject matter experts to verify and consult on the proposed changes listed in 4) a-j are covered by IACUC approved policies that are appropriate for the animals and circumstances.

¹ Example of emergency situation presented by OLAW: During non-business hours a technician drops a test tube of blood and needs to do an additional blood draw on a group of animals. The veterinarian approved to do VVC could authorize the additional blood draw by phone from home, as long as the additional blood draw is within the range approved in the IACUC policies and the veterinarian is familiar with the training and experience of the technician.

- 2) Consultation with the veterinarian from the UH Veterinarian's Office will be documented. The documentation will be forwarded to the UH Animal Welfare Compliance Office.
- 3) The veterinarian may refer any request to the IACUC for review for any reason and must refer any request that does not meet the parameters of the IACUC-reviewed and –approved policies.
- 4) These significant changes include:
 - a. Methods of anesthesia, analgesia, sedation. As long as they conform to the current approved version of the IACUC Policy on Rodent and Rabbit Anesthesia and Analgesia or current version of Plumb's Veterinary Drug Handbook or equivalent veterinary formulary.
 - b. Methods of euthanasia, as long as they are within the acceptable and conditionally acceptable parameters of the most current version of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals listed at <https://www.avma.org/kb/policies/documents/euthanasia.pdf> and conform to the current approved version of the UH IACUC Policy on Euthanasia.
 - c. Experimental substance, as long as these do not involve significant changes that must be approved by one of the valid IACUC methods described in the Public Health Service Policy IV.C.2, listed below under D. Experimental substances may include medications included in the current edition of Plumb's Veterinary Drug Handbook or equivalent veterinary drug formulary. PI must provide written documentation from Environmental Health and Safety and Biosafety Offices that the experimental substance will not impact personnel safety.
 - d. Strains, breeds, or stocks of species or sources, as long as they do not require new or revised permit conditions, Institutional Biosafety Committee review, or housing that involves significant changes (e.g. see D.3 below) that must be approved by one of the valid IACUC methods described in the Public Health Service Policy IV.C.2, listed below under D. The PI must provide written documentation from the UH Biosafety Office that the strain or species does not require Institutional Biosafety review:
 - e. Route of administration of substance, as long as all staff listed on the protocol can provide written proof of demonstrate of proficiency on the new method of administration, prior to working independently.

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- f. Performance of repeat procedures, as long as they conform to the UH Policy on Performance of Repeat Procedures.
- g. Type of housing, as long as it does not require Institutional Biosafety Committee or EHSO review, or housing that involves significant changes (e.g. see D.3 below) that must be approved by one of the valid IACUC methods described in the Public Health Service Policy IV.C.2, listed below under D.
- h. Methods of animal identification except those requiring sedation or conditionally acceptable methods (e.g. toe clipping).
- i. Blood collection route and volume, as long as they conform to UH Policy on Performance of Repeat Procedures.
- j. Changes in housing location within an IACUC approved facility, as long as it does not require new or revised permit conditions, Institutional Biosafety Committee review, or housing that involves significant changes (e.g. see D.3 below) that must be approved by one of the valid IACUC methods described in the Public Health Service Policy IV.C.2, listed below under D. The new location must meet all the requirements of the approved protocol and the management of the new facility must verify that they can accommodate the request.
- k. Transferring animals not previously approved by the IACUC for transfer between approved protocol(s) using the same species.

Receiving Topaz protocol revise in the *Amendment Question - Description of Animal Component Changes* 1) approximate number of animals to be received via transfer each year, 2) the sending PI's protocol number(s). Revise the *Species Section* under *Projected Animal Requirements* to update any changes that the transfer may affect (animal numbers, pain category, housing location). For *Source* add sending PI's protocol number,

Sending Topaz protocol should amend, if necessary, under section *Euthanasia and Disposition of Animals*, *question Description of Disposition of Animals* to include option "allow transfer to other approved IACUC protocols using same species."

- C. The following significant changes on a previously approved IACUC protocol may be handled administratively by the AWCO without full IACUC review, and without additional consultation or notification. The AWCO may refer any request to the IACUC for designated member review (DMR) or full committee review (FCR) for any reason, including requests for more than 25% annual

increase from baseline animal numbers for a particular year. The AWCO will notify the Animal Veterinary Services (AVS) Operations Manager when the change involves animals housed in AVS operated vivaria:

1. Up to a 25% increase in previously approved animal numbers for a particular year.
- D. Other changes, that are not considered significant, that may be handled administratively by the UH Animal Welfare Compliance Office without IACUC-approved policies, consultations, or notifications include:
1. Correction of typographical errors
 2. Correction of grammar
 3. Contact information updates
 4. Change in personnel, other than the Principal Investigator, as long as there is administrative review to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in occupational health and safety programs, and meet other criteria required by the UH IACUC.
- E. Significant changes that must be approved by one of the valid IACUC approved methods described in the PHS Policy IV.C.2, that is full committee review, include the following changes:
1. From non-survival to survival surgery
 2. Resulting in greater pain, distress, or degree of invasiveness
 3. In housing and or use of animals in a location that is not part of the animal program overseen by the UH IACUC
 4. In species
 5. In study objectives
 6. In Principal Investigator (PI).
 7. That impact personnel safety