

DePaul University Animal Care and Use Committee SOP		
Veterinary Verification and Consultation (VVC) Process		
Version date: 8/15/2016	IACUC Approved date: 2/15/17	Effective Date: 2/15/17

**Purpose:** The purpose of this SOP is to detail the procedures that will be followed when significant changes to animal activities are reviewed using the Veterinary Verification and Consultation (VVC) process.

**Scope:** All investigators conducting research, research training, teaching, experimentation, biological testing, exhibition, and related activities using live vertebrate animals at DePaul University.

**Background:** In accordance with the *PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy)*, all activities with live vertebrate animals, as described in the *PHS Policy*, must be covered under an active approval by the Institutional Animal Care and Use Committee (IACUC). Federal regulations require that the IACUC at each institution “review and approve, required modifications in (to secure approval), or withhold approval of **proposed significant changes** regarding the use of animals in ongoing activities” (USDA AWRs 2.31 (c)(7), PHS Policy IV.B.7.). The *PHS Policy* (Section IV.C.1.) and the *Animal Welfare Regulations* (9 CFR 2.31 (d) (1) (i)- (iv) define the responsibilities of the IACUC regarding the review and approval of significant changes to animal activities by indicating that when reviewing any “proposed significant changes” the IACUC must “conduct a review of those components related to the care and use of animals and determine that the proposed research projects are in accordance with the PHS Policy.” Changes to approved animal activities must be conducted in accordance with DePaul’s Assurance, the *USDA Animal Welfare Act*, and the *Animal Welfare Regulations* and must be consistent with the *Guide for the Care and Use of Laboratory Animals* and meet the requirements of the *PHS Policy*. Policies pertaining to the review processes must be IACUC approved before implementation.

For significant changes to animal activities previously approved by the IACUC, the IACUC usually uses either a Full Committee Review (FCR) or Designated Member Review (DMR) process. However, 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 what is a significant (major) change or a non-significant (minor) change on a case by case basis, as well as to determine the appropriate review process for significant changes as long as the IACUC is compliant with *PHS Policy* (Section IV.C.1.a-g). One of the times when discretion may be used is allowing the use of a VVC approval process for specific and defined significant changes.

**Procedures:** If a Principal Investigator (PI) has an IACUC approved protocol involving animal activities that was approved via FCR or DMR originally and he/she wants to make a significant change to the animal activity, the significant change may be approved through the VVC process

provided the procedures outlined in this document are followed and the requirements of VVC (as outlined by OLAW) are satisfied. The VVC process may not be used to modify existing procedures, if the modification increases the opportunity for the animals' welfare to be compromised or in instances specifically noted below in agreement with OLAW's guidance (NOT-OD-14-126).

The submission procedure for review of significant (major) changes to an approved protocol through the VVC process is as follows:

- The Office of Research Services staff will receive the protocol amendment from the PI (including revised protocol materials incorporating the change) and send it to the veterinarian along with any supporting documents or materials that may aid in review of the amendment.
- The veterinarian will then review the amendment changes and document the determination.

Note that, under VVC, the veterinarian 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. When this method of review is utilized, the veterinarian consultation will be documented using the “IACUC Veterinary Verification and Consultation (VVC) Review Guide for Documenting Review of Significant Changes.” The veterinarian may make the verification or determine that the change needs to be reviewed by the IACUC via FCR or DMR; because the request does not meet the parameters of the IACUC- reviewed and approved policies for veterinarian consultation.

- Once the review guide is completed, the veterinarian must send the completed review guide to the Office of Research Services (ORS) Staff (usually within 5-7 days of receipt of the amendment).
- The ORS staff will then create an approval letter and send it to the PI (usually within 2-3 business days).
- The PI may initiate the change in the animal activity once he/she has received written approval from ORS on behalf of the IACUC.
- Any changes made though the VVC process will be noted in the next IACUC meeting agenda so that the IACUC is aware of the changes/determinations made.

**Responsibilities:** 1) Principal Investigator (PI) - The PI is responsible for being aware of IACUC policy pertaining to the review of significant changes. The PI must not make a change to his/her already approved animal activity without obtaining written approval through one of the methods noted in DePaul policy. The PI will complete an amendment form and submit the completed form (and any required supporting materials) to the ORS and then wait for written approval before implementing the change.

2) The Institutional Veterinarian –The veterinarian is responsible for ensuring the health and welfare of the animals that are included in the DePaul animal care and use program. The veterinarian must certify that an IACUC policy covers the requested significant change and must determine that the change is appropriate for the specific circumstances when documenting his/her approval on the review guide. The veterinarian may recommend modifications to the PI’s proposed plans, if appropriate, and within the scope of the IACUC’s policies. If necessary, the veterinarian must refer the review of significant changes to the IACUC for FCR or DMR.

3) The IACUC – The IACUC must write, review, and approve of any policies (including guidance documents, SOPs, and formularies) that address significant changes before they are implemented. IACUC policies must be reviewed and approved by consensus at least every three years by one of the following methods:

- FCR or DMR;
- Polling by telephone calls or email; or
- Posting policies in an electronic format for IACUC member review.

The IACUC authorizes the Institutional Veterinarian to handle significant changes through the VVC process by approving this SOP. The IACUC has established the mechanism for documenting the approval of significant changes handled through the VVC process as outlined in this SOP.

**Additional Information:**

In order to accommodate the VVC process, the IACUC has revised policy in the Assurance with OLAW to clearly specify the distinction between Significant (major) changes that may reviewed through the FCR process, the DMR process, and the VVC process and the non-significant (minor) changes that may be reviewed administratively by the Office of Research Services staff.

DePaul University interprets significant (major) changes to mean those that substantially alter or affect the overall study objectives/rationale, specific approved procedures, or the potential for pain, distress, and discomfort in the animals, have a negative impact on animal welfare, or have a direct impact on the health and well-being of the animals.

Examples of significant (major) changes that require FCR and for which the VVC process *cannot* be used, include, but are not limited to:

- Changes to the objectives of a study;
- Changing from non-survival to survival surgery;
- Changes resulting in greater pain, distress, or in a greater degree of invasiveness;
- Changes in the species;
- Change of Principal Investigator or key personnel involved in animal procedures;
- Performing a new procedure;
- Changes in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC; and
- Changes that impact the safety of personnel

Significant changes that impact the health and safety of the animals, but do so to a lesser extent may be reviewed under DMR. Examples of significant (major) changes that may be reviewed under DMR include, but are not limited to:

- An increase of animal numbers, when the additional animals are needed to expand or change the original objective or when the model or experimental design is modified;
- A change in strain within the same species; and
- A change in animal care and /or use procedures that are expected to involve no more than momentary pain or distress (as determined by the IACUC Chair or designee).

Significant changes that *may* be handled administratively in agreement with IACUC reviewed and approved policies and procedures and in consultation with the DePaul Institutional Veterinarian through the Veterinary Verification and Consultation (VVC) process include:

- Changes in anesthesia, analgesia, sedation, or experimental substances;
- Changes in euthanasia to any method approved in the *AVMA Guidelines for the Euthanasia of Animals*; and
- Changes in duration, frequency, type, or number of procedures performed on an animal (but not entirely new procedures)
  - Examples include changing the genotyping procedures utilized, including tail snips, ear punches, and blood collection to one that might cause less pain or discomfort for the animal particularly taking into consideration the age of the animal
  - Making a change to a surgical procedure
  - Changing a drug dose
  - Changing the volume of blood drawn

Non-significant (minor) changes that may be reviewed administratively by the Office of Research Services staff include:

- A change in personnel, other than the Principal Investigator for an existing approved protocol (with administrative review verification that personnel have been appropriately identified, adequately trained, are qualified, and meet other criteria of the IACUC);

- An increase in animal numbers when additional animals are needed for finishing an approved experiment as originally designed and study objectives are not changed (i.e., biological variability was greater than expected, age-related or illness-related loss of animals occurred, or breeding results were poor or not as expected) and the original rationale for the number of animals to be used supports the requested change;
- A change in funding status or source;
- A change in the animal source or vendor;
- Changes in Research Support Facility (RSF) room location or addition of a laboratory space;
- Correction of typographical errors;
- Correction of grammar; and
- Contact information updates

The use of fewer animals than approved does not require handling through IACUC policy, approval, notification, consultation, or administrative handling.

**References:**

1. NIH Notice NOT-OD-14-126
2. OLAW web page about Significant changes:  
[http://grants.nih.gov/grants/olaw/significant\\_changes.htm](http://grants.nih.gov/grants/olaw/significant_changes.htm)
3. OLAW Webinar “Guidance on Significant Changes to Animal Activities,” August 21, 2014: [http://grants.nih.gov/grants/olaw/educational\\_resources/webinar\\_08212014.htm](http://grants.nih.gov/grants/olaw/educational_resources/webinar_08212014.htm)