

- National Institutes of Health. *Guidance on Significant Changes to Animal Activities*. Notice NOT-OD-14-126. (National Institutes of Health, Washington, DC, 26 August 2014).
- OLAW online seminar (2016, September 8). *Implementing Guidance on Significant Changes: One Institution's Experience*. https://grants.nih.gov/grants/olaw/educational_resources/webinar_09082016.htm

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RESPONSE

Has it been approved?

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In this scenario, Green, the IACUC administrator, is basically correct. According to *Guidance on Significant Changes to Animal Activities*¹, any of the following changes must be approved by one of the valid IACUC approval methods described in the PHS Policy (IV.C.2; ref. 2), that is, by either Full Committee Review, or Designated Member Review:

- “a. from non-survival to survival surgery;
- b. resulting in greater pain, distress, or degree of invasiveness;
- c. in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
- d. in species;
- e. in study objectives;
- f. in Principal Investigator (PI); and
- g. procedures that impact personnel safety.”

Adding either of the procedures described by Green would fit under either situation a, b or e above. As minor as a procedure may be, if it is a new procedure being added to a protocol, according to the Guide, it has to be approved by the IACUC.

The Veterinary Verification and Consultation process (VVC) which Dr. Thorne refers to can be used to make significant changes to animal activities that are already part of a protocol which was previously reviewed and approved.

No matter what classification the amendment is given, the animal's welfare should prevail.

A Word from OLAW

In response to the questions posed in this scenario, the Office of Laboratory Animal Welfare (OLAW) provides the following clarifications.

Veterinary verification and consultation (VVC) is a method for approving significant changes to a previously approved protocol.¹ It may not be used to add a new procedure that was not previously approved on the protocol. Such a change should be reviewed and approved by full committee review (FCR) or designated member review (DMR).

There are two parts to approving a significant change by VVC. The first part is when the IACUC approves a policy, SOP or guidance that describes the significant changes acceptable to the IACUC. The second part is when a veterinarian authorized by the IACUC, in consultation with the research team, verifies that the requested change is in compliance with the IACUC-approved policy and appropriate for the specific situation and animal(s). The veterinarian is not conducting DMR, but is verifying compliance with the IACUC policy and that the change is appropriate for the animals in this circumstance. The consultation with the veterinarian must be documented.¹

An example of when VVC is appropriate is as follows. The IACUC has a VVC policy that describes acceptable parameters of blood collection. The IACUC approved a protocol to use one of the approved methods of blood withdrawal in its policy. The IACUC may use VVC to permit the research team to make a significant change, such as collecting additional samples or changing the location of the blood withdrawal, providing it is within the parameters specified in the policy. However, VVC may not be used to add blood collection for a protocol that was not approved for blood collection.

1. National Institutes of Health. *Guidance on Significant Changes to Animal Activities*. Notice NOT-OD-14-126. (National Institutes of Health, Washington, DC, 26 August 2014).

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- National Institutes of Health. *Guidance on Significant Changes to Animal Activities*. Notice NOT-OD-14-126. (National Institutes of Health, Washington, DC, 26 August 2014).
 - Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
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RESPONSE

New procedure requires IACUC review

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The disagreement between Green and Thorne is not whether the procedure should be approved by the IACUC, but when it should be approved. Green believes

that an additional procedure versus a change in procedure will require FCR or DMR for approval. Thorne believes that Veterinary Verification and Consultation (VVC) is appropriate in this instance. *Guidance of Significant Changes to Animal Activities*¹ states that the VVC may be used for “review and approval of proposed significant changes to animal activities.”

The investigator has requested an additional procedure to the protocol, which was not in the original submission. The VVC guidance was meant to alleviate administrative burden on both the IACUC and the researcher. However, it does not remove the IACUC's responsibility to review procedures added to a protocol, regardless of whether the procedure is being viewed as major or minor. If the investigator wanted to change the method of implant from a small incision to say an injectable method, and the IACUC has an already approved policy for these types of procedures, than the significant change in procedure could be administratively handled via the VVC