

her opinions on why she wanted the protocol to go through FCR.

Finally, the Chairman should ensure that the IACUC Staff has documented the revised protocol review system procedures in an approved SOP. All members should be aware of the changes in the review process to fulfill comprehensive protocol reviews.

*St. Joseph's Health Center, Syracuse, New York, USA.*

## RESPONSE

### No harm done, but they can do better

Kim E. Saunders<sup>1</sup> & William E. Dale<sup>2</sup>

It is clear that Great Eastern University is following valid methods of IACUC review as allowed by PHS Policy which are: “(1) full-committee review by a convened quorum of members of the IACUC. Or (2) designated member review by one or more members, employed only after all voting members have been provided an opportunity to call for full-committee review”<sup>1</sup>. The question is whether an alternate member of the IACUC has the authority to call for FCR at a time when it is unclear whether he/she is acting as a voting member. OLAW guidance clarifies that “An IACUC member and his/her alternate may not contribute to a quorum at the same time or act in an official IACUC member capacity at the same time. An alternative member may only contribute to a quorum and function as an IACUC member if the regular member for whom they serve as alternate is unavailable”<sup>2</sup>.

The Great Eastern University IACUC Chair admitted that they did not have a process in place to identify when alternate members would be acting as voting members during the 72 hour review window. We believe that if all voting members were available for review, then the alternate member did not have the authority to request FCR. With that being said, however, we also believe that the Great Eastern University IACUC should encourage full participation by both alternate and voting members, and they were fully justified in providing an FCR of the protocol at the convened meeting. To do otherwise may impose additional administrative burden and further delay the committee's decision.

Moreover, the IACUC is tasked with overseeing the institution's animal program, and if any member has a concern, they should discuss it with the committee.

In the future, the Great Eastern University IACUC should consider adopting a written policy that clearly delineates which members can request FCR. They should also find a method whereby voting members who are unavailable for the 72 hour review are identified, so that alternate members can act in an official IACUC member capacity allowing them to request FCR.

1. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986, revised 2015).
2. National Institutes of Health. NOT-01-017: Guidance regarding administrative IACUC issues and efforts to reduce regulatory burden.

*National Institutes of Health Office of Extramural Research. <https://grants.nih.gov/grants/guide/notice-files/NOT-0D-01-017.html>*

<sup>1</sup> *Department of Comparative Medicine, Oregon Health & Science University, Portland, Oregon, USA.*

<sup>2</sup> *OHSU Research Integrity Office, Oregon Health & Science University, Portland, Oregon, USA.*

## RESPONSE

### FCR and defining the review process

Kimberly Jen & Jason Villano

Both the PHS Policy and the Animal Welfare Act and Regulations indicate that an IACUC may conduct protocol reviews by either FCR or by DMR<sup>1,2</sup>. In this charge, each IACUC member shall be provided with a list of pro-

## A Word from OLAW and the USDA

*In response to the questions posed in this scenario and the reviewers' responses, the Office of Laboratory Animal Welfare (OLAW) and the United States Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care (USDA, APHIS, AC) provide the following clarifications.*

The Animal Welfare Act regulations (AWAR) and the PHS Policy require that prior to DMR, each IACUC member is provided a list of proposed activities to be reviewed and that a written description of activities that involve the care and use of animals is available<sup>1, 2</sup>. IACUC members may read the protocols but there is no requirement to do so. Any IACUC member may obtain upon request, FCR of a proposed activity. If a FCR is not requested, at least one member of the IACUC appointed by the chairperson may conduct DMR with the authority to: approve, require modifications to secure approval, or request a FCR of any of those activities<sup>1, 2</sup>.

Although the AWAR and the PHS Policy are silent on the use of alternate members, OLAW and APHIS have agreed that the use of alternates offers an effective management practice to ensure timely review and approval of animal activities<sup>3, 4</sup>. Past joint guidance states that only when an alternate is serving in place of a regular member due to their unavailability may he or she conduct IACUC business, such as calling for FCR<sup>4</sup>. The IACUC should have a procedure to identify when and which alternate is serving in place of a regular member for DMR, FCR or other IACUC activities. Allowing the alternate member to call for FCR or present the protocol at the FCR may be useful for training, but routine use of alternates when members are available is not an acceptable practice. Likewise, allowing a regular member to request that an alternate serve as a designated reviewer due to the regular member's heavy workload does not meet the intent of the guidance<sup>4</sup>. A typical use of an alternate for DMR is when a regular member is known to be on sabbatical or traveling.

1. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986, revised 2015).
2. 9 CFR Chapter 1 Subchapter A § 2.31(d)(2)
3. 9 CFR Chapter 1 Subchapter A § 2.31(b)
4. National Institutes of Health. NOT-OD-011-053: Guidance to Reduce Regulatory Burden for IACUC Administration Regarding Alternate Members and Approval Dates. National Institutes of Health Office of Extramural Research. <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-053.html>

**Patricia Brown, VMD, MS, DACLAM**

*Director  
OLAW, OER, OD, NIH, HHS*

**Bernadette Juarez**

*Deputy Administrator  
USDA, APHIS, AC*