

Who should request a full committee review?

Jerald Silverman, DVM

The Great Eastern University IACUC normally reviewed all protocols and amendments by designated member review (DMR) unless full committee review (FCR) was requested. As was the usual procedure of the IACUC, an email notice was sent to all regular voting members and all alternates that a new protocol was available for review in the IACUC's secure mailbox. If no request for FCR was received within 72 hours, the protocol would undergo DMR. An alternate member of the IACUC looked at a protocol in the mailbox and requested full committee review. Without any further consideration,

the IACUC office scheduled the protocol to be discussed by FCR at the next full committee meeting. When that meeting occurred all the regular members were present. The chairman, trying to be helpful to a new IACUC member, restated the process that was used to request FCR. The new member then asked if an alternate member could ask for FCR when nobody on the email listserv really knew which regular members were available at the time or even who had looked at the new protocol during the 72 hour review period.

The chairman agreed that was a good question and the IACUC office had always

assumed that if nobody asked for FCR, it was simply assumed that all voting members agreed to have the protocol reviewed by DMR. He also agreed that there was no process in place to verify which voting members had looked at the protocol or if alternates could request FCR during that 72 hour period. But the chairman thought this was more of a technicality than a real problem for the IACUC, so the committee went ahead with a FCR of the protocol.

In your opinion, did Great Eastern do the right thing, legally or ethically, by going ahead with the FCR? What might be done to resolve this issue in the future?

RESPONSE

No tracking, no proof

Kimberly S. Edgar

The old saying, "if something is not documented, it didn't happen", applies perfectly to this scenario. The Chairman was correct in his decision to have the committee do an FCR at the next meeting because it was a technical issue with how the protocol was reviewed through the e-mail system. The Chairman lacked the information to know if it was also a compliance issue because of the technical deficiencies associated with the protocol being available to both members and their alternates at the same time. Based on how the protocol review system was established, the e-mail system lacked the tracking information to know which members had actually reviewed the protocols within the 72 hour period. These procedures raise the question regarding how the IACUC documents that the protocols are actually being reviewed under both PHS and USDA Guidelines. It is conceivable that none of the members could have reviewed the protocol

within the 72 hour period, which resulted in the protocol automatically going to DMR.

The Chairman has the responsibility to ensure that the reviews are complete and each member was aware of and had the opportunity to ask questions regarding specific protocols. The next step that the Chairman should take is to direct the IACUC Staff to establish an effective review system that tracks the protocol throughout its history. The development of an SOP (Standard Operating Procedure) is needed to describe the procedures that the IACUC will follow to review and approve the protocols to reduce the confusion over which members were both aware of and had reviewed the protocol. These procedures reduce the potential for noncompliance among the members and improve the quality of the review process.

The software for the secure e-mailbox should have the account settings to add tracking and out-of-office options for all members. The tracking setting would report to both the IACUC Staff and the Chairman which members had opened a specific protocol for review, so they would know that the review comments by their designated alternate member were not needed for moving

this specific protocol forward. If the member does not open a specific protocol and/or has an out-of-the office setting on their e-mail account, the IACUC Staff would process the reviews by the alternate member.

As the IACUC Staff reviews procedures, they should query the members to determine if the 72 hour review window provides ample time for comprehensive reviews to accommodate the busy schedules of their members. For example, increasing the review time to 120-hour for Category D & E Protocols might result in more thorough reviews. Encouraging members to use the out-of-office account setting when they have schedule conflicts would send protocols in the review queue to go automatically to their designated alternate member.

Another important point this scenario brings up is the Chairman's responsibility to encourage all members and their alternates to vote their own conscience on protocols and to fully participate in IACUC meetings and training activities. In this scenario, the Chairman should encourage the alternate member to attend the next IACUC meeting where the protocol in question will receive an FCR and to share

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.

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RESPONSE

No harm done, but they can do better

Kim E. Saunders¹ & William E. Dale²

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”¹. 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”².

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>

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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^{1,2}. 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^{1, 2}. 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^{1, 2}.

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^{3, 4}. 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 FCR⁴. 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 guidance⁴. 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-0D-11-053.html>

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posed research projects to be reviewed¹. If DMR is employed, at least one member, designated by the chairperson, reviews the protocol¹. Any member, however, may obtain, upon request, an FCR if she or he believes it is necessary¹.

Both PHS Policy and AWR do not address the topic of alternate IACUC members. However, OLAW and APHIS put forth a joint communication in 2001 (ref. 3) and 2011 (ref. 4) to provide guidance on the use of alternate members. In these, alternate members are designated for regular members and must fulfill the same membership requirement as a regular member^{3,4}. Alternate members are expected to ‘vote their conscience’ as opposed to representing the position of the regular members for whom they serve³.

In the case of Great Eastern University, the implementation of DMR and FCR falls within the AWR and PHS policy provisions. Members are given notice that protocols are available for review and, either by concurrence or silent assent, indicate whether to submit a protocol to FCR. However, it is

unclear if the alternate member was acting on the regular member’s behalf when the FCR was requested. Hence, the new member’s question was valid. It was also possible that the IACUC and the regular member have a heavy workload, as such using the alternate member for designated-member protocol review. Thus, an area of improvement for Great Eastern University would be for the IACUC to document the process of protocol reviews, especially indicating the role of alternate members in it. Orientation and training of new members should include institution-specific protocol review process, which is central to the IACUC’s role in the animal care and use program.

Despite the absence of this clearly defined process, the IACUC office certainly did the right thing by sending the protocol to FCR. The requesting alternate member may attend this meeting and even present the protocol to the full committee, as his/her participation in IACUC activities is welcome, even when the regular member is present³. It is important to note, however, that the alternate cannot contribute to the quorum and vote, and act in an

official IACUC capacity at the same time as the regular member. These restrictions stand to ensure that the committee is properly constituted to conduct official business⁴.

The use of alternates was created to help reduce the regulatory burden for institutions regarding IACUC operations. However, we cannot overlook the regulations that govern their use.

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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. Animal Welfare Act Regulations, Subpart C, § 2.31
 3. 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>
 4. National Institutes of Health. NOT-0D-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-0D-11-053.html>

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