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Of alternate and designated IACUC members

Among the many issues affecting IACUCs, one that continually raises its head is the need for a sufficient number of qualified persons to carry out protocol reviews. To help alleviate this need, both the federal Office of Laboratory Animal Welfare (OLAW) and the USDA's Animal Care division of the Animal and Plant Health Inspection Service (APHIS/AC) permit the use of alternate members on an IACUC. As might be expected, the use of alternate members has led to its own problems, as seen in this case report from Great Eastern University.

It was summertime, and the Great Eastern University IACUC knew it would not have sufficient members to have full committee meetings. Therefore, it was decided that for July and August, all protocols would undergo designated-member reviews only. That way, there would not be a routine need for a quorum of members to vote on a protocol. This idea worked well for the first few protocols, but as summer vacations continued

to deplete the ranks of IACUC members, it became difficult to obtain a sufficient number of designated-member reviewers. It was not that there were no more IACUC members at work; rather, the issue was whether the few remaining members could be expected to shoulder the burden of all of the reviews. Larry Covelli, the IACUC chairman, identified an easy solution: just use the alternate members of the committee. Covelli said, "An alternate member can fill in for an IACUC member who is unavailable, as long as the alternate is that person's specific replacement. Problem resolved! We have at least two specifically designated alternates for every scientist on the IACUC, so we'll just let the alternates do the designated-member reviews for the regular member scientists who are on vacation."

"Well, maybe yes, maybe no, Larry," said Ann Nixon, the IACUC coordinator at Great Eastern. "You're the boss, but I'm pretty sure that this whole thing with

alternate members has to do with alternates for full committee meetings, not designated-member reviews. The problem isn't that we don't have enough regular members available who can do designated-member reviews; it's just that they're busy, so you want some extra people to help with the work load. I don't think you can do that."

"I'm sure I can," Covelli replied. "Where is it written that we can't do what I said?"

"Where is anything written about alternate members?" said Nixon. "The only information about them is in the form of notices and published articles. We constantly have these questions coming up."

"That's true," said Covelli, "but until we hear otherwise, let's just do it my way."

What do you think? Can an IACUC use its alternate members for designated-member reviews while regular members are still available to carry out those reviews? On what documentation do you base your opinion?

RESPONSE

What about full committee reviews?

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The specific use of alternate members of an IACUC is not addressed by the PHS Policy or by the USDA animal welfare regulations. APHIS and OLAW did issue a joint communiqué on February 12, 2001 that specifies the circumstances of their use¹:

"Alternates must be appointed by the CEO of the entity for which the committee is established or by the official to whom the CEO has specifically delegated, in writing, the authority to appoint IACUC members. Alternates should be listed on the IACUC rosters submitted to OLAW with Assurance and annual reports.

There must be a specific one-to-one designation of IACUC members and alternates. This is necessary to ensure that a committee is properly constituted, even when alternates are serving. For example, an alternate for an unaffiliated IACUC member would need to meet the unaffiliated member requirements. Use of a pool of alternates would not be consistent with this requirement.

An IACUC member and his or 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 alternate may only contribute to a quorum and function as an IACUC member if the regular member for whom he or she serves as alternate is unavailable.

Alternates should receive IACUC training or orientation similar or identical to that provided to regular IACUC members.

Alternate members would be expected to 'vote their conscience' as opposed to

representing the position of the regular members for whom they serve."

Beyond the regulatory boundaries on the use of alternate IACUC members, their specific use to carry out designated-member review of protocols may be acceptable for Great Eastern University if the burden on the few remaining members is too great. However, there is another issue that may be important.

Implicit in the designated-member review process is that any member has the right to refer the protocol to the full committee if she or he believes that it is necessary. The Great Eastern University IACUC is treading on thin ice by relying upon the designated review process in the face of insufficient committee membership during the summer months. If a full committee meeting is requested but is not possible during a two-month period, then the institution may hamper its own research mission by not permitting PIs to commence

research in a timely manner. To avoid such a situation, the CEO or the Institutional Official might wish to institute a policy to ensure that a quorum of the membership is available every month.

1. National Institutes of Health. Office of Extramural Research Guidance Regarding Administrative IACUC Issues and Efforts to Reduce Regulatory Burden. NOT-OD-017. (Office of Extramural Research, 12 February 2001).

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RESPONSE

Regulations trump convenience

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There are two issues at work in this scenario from Great Eastern University. The first is alternate members, and the second is their use in designated-member review. Let's address the alternate member issue first. It appears that the alternate members have been properly appointed by the Institutional Official to serve as alternates for specific members. Mr. Covelli, the IACUC chair, has suggested using the alternate member in place of a specifically designated member. Great Eastern has two alternates for every member. Mr. Covelli must take great care to not appoint both of the alternates at the same time for meeting attendance or for protocol review, thereby giving one regular member two votes. He must take care not to assign an alternate to protocol review if the regular member is available¹. I was not able to find any indication that an alternate member may not do a designated review, but it is stated that an alternate may not do the review if the regular member is available. By designating two alternates for each member, the chair is able to assign a designated reviewer to each protocol. It is preferable for someone who is an expert in the field to do the protocol review in the absence of the regular member.

Now we need to address the issue of designated review. Here, I believe Mr. Covelli has overstepped his boundaries and is treading on illegal ground. In order to satisfy the minimum regulatory requirements

A word from OLAW and USDA

In response to the issues raised in this scenario, 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) offer the following clarification and guidance:

First, it is important to note that the IACUC chair's proposal does not meet the requirement of the PHS Policy at IV.3.C.2 and the AWA regulations because it fails to provide a list of research projects; make written descriptions of the research available; and provide an opportunity for members to call for full committee review^{1,2}. It is not acceptable to allow designated reviewers to grant approval without first giving all IACUC members an opportunity to request full committee review. This is described in OLAW's Report of May 21, 1990, and in Part 2, Section 2.31(d)(2) of the Animal Welfare Regulations^{2,3}.

If the workload is too heavy for an IACUC, the institution should evaluate other options for meeting its obligations (such as appointing additional regular members). In this scenario, however, the chair may use alternates for designated-member protocol review if he is very careful to use an alternate for a regular member that is truly unavailable.

NIH Notice OD-01-017 states, "There must be a specific one-to-one designation of IACUC members and alternates. This is necessary to ensure that a Committee is properly constituted, even when alternates are servingUse of a pool of alternates would not be consistent with this requirement"⁴. This section of the notice makes it clear that alternate members are specific substitutes for unavailable members and may not be used as a pool of general IACUC helpers.

1. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* IV.3.C.2. (US Department of Health and Human Services, Washington DC, 1986; amended 2002).
2. 9 CFR, 2.31. Chapter 1, Subchapter A - Animal Welfare: Part 2.
3. National Institutes of Health. OPRR Reports (Office of Extramural Research, 21 May 1990). <http://grants.nih.gov/grants/olaw/references/dc90-1.htm>.
4. National Institutes of Health. Office of Extramural Research Guidance Regarding Administrative IACUC Issues and Efforts to Reduce Regulatory Burden. NOT-OD-01-017. (Office of Extramural Research, 12 February 2001). <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-017.html>.

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of both OLAW and PHS, it is required that "all IACUC members be given a list of protocols to be reviewed and access to the necessary information on the protocol to be reviewed"². Part of the information conveyed to the committee is name of the individual who has been assigned to do the designated review. If any of the members feels that the protocol should go before the full committee, then its review must be deferred until the next properly convened meeting of a quorum³. By predetermining that all protocols submitted in July and August would go to designated review, the IACUC Chair has circumvented the committee and their right to call for full review.

It is difficult to find people to serve on the myriad committees in a university setting,

but we must take care not to violate the regulations or to bend them for our convenience. In my opinion, as long as Mr. Covelli allows for all voting members to have their right to call for a full review of all protocols, and is not giving multiple votes to any one member, he can assign alternate members to complete designated reviews of protocols.

1. PHS Policy IV, C 2; AWAR §2.31, d, 2.
2. Wolff, A. Correct conduct of full-committee and designated-member protocol reviews. *Lab Anim. NY* 31, 28-31 (2002).
3. Silverman, J., Suckow, M.A., Murthy, S. (eds.). *The IACUC Handbook* §9:19-9:24, pp.115-119 (CRC Press; Washington, DC, 2000).

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