

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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