

A Member by Any Other Name is...an Alternate?

Dr. A. Kahalili was appointed as an alternate scientific member of Great Eastern University (GEU)'s IACUC. GEUs IACUC was fortunate to have an engaged research community and often received requests from faculty who wanted to join the IACUC. Given GEUs robust training program, both voting and alternate members receive the same level

of IACUC member training (new and continuing).

GEU's default review process is Designated Member Review (DMR). Consequently, and well after completing her training, Dr. Kahalili was assigned to serve as the (sole) Designated Reviewer (DR) for Dr. T. Guaio's new protocol. Kahalili had concerns regarding a few aspects of

the protocol and decided the associated proposed animal activities should be discussed as part of the Full Committee Review (FCR) process. Consequently, she called the protocol to FCR.

Guaio, GEUs most 'vocal' Principal Investigator (PI) who recently rotated off GEUs IACUC as a voting member, was screaming on the phone to Dr. Crick, the IACUC Chair, about the fact that his new protocol application was called to FCR. Apparently, the delay in IACUC approval process would also delay the release of his newly awarded grant funds. Crick commiserated with Guaio but stood firm on the regulatory authority given to IACUC members to call for FCR at any time, and for any reason. Guaio quickly rebutted that Kahalili wasn't an IACUC member, but, rather, an alternate member and that alternate members are not defined in the regulations and, thus, have no authority to call for FCR.

Crick, concerned about his conversation with Guaio, brought the discussion to the next convened meeting of a quorum of the IACUC. Crick asked the committee members their opinions as to whether an alternate can even serve as a DR, let alone call for FCR. GEUs IACUC discussed the following points:

1. Can an alternate be appointed as a DR given that 'full' (i.e., voting) members are not necessarily unavailable during the entire review process?
2. When an alternate member is appointed as a DR, do they have the same authority as a full member?
3. When are alternate members considered 'voting' members?
4. Do the regulatory limitations ascribed to alternate members (e.g., only voting when the primary member is unavailable) apply only during a convened meeting of a quorum of the IACUC or, do the limitations also apply (a) when assigning alternate members to serve as a DR and (b) when performing semi-annual facility inspections?

Lauren Danridge[✉] and Bill Greer[✉]
Animal Care & Use Office, University of Michigan, Ann Arbor, Michigan, USA.
[✉]e-mail: danridlm@umich.edu; wgreer@umich.edu

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A WORD FROM OLAW AND USDA

Response from OLAW

In this scenario several questions are raised about how and when alternates are allowed to serve in place of a regular IACUC member. The chair's selection of an alternate member as a designated reviewer (DR) is a common practice supported by OLAW when a qualified regular member is unavailable at the time that the review is needed¹. The alternate, once designated as a DR, has the same authority as a regular member to conduct the Designated Member Review (DMR) and approve, require modifications to secure approval, or request full committee review², even if the regular member becomes available in the interim. To use alternates to conduct DMR as an expansion of the regular membership when regular IACUC members are available is not permitted and would be noncompliant with the PHS Policy¹. If substituting for an unavailable regular member, an alternate member may contribute to a quorum and vote during convened meetings, and may also serve as a DR. For areas housing non-Animal Welfare Act (AWA)-regulated species, there is no IACUC membership requirement for the individual(s) conducting the inspection. The IACUC may use as few as one qualified individual or ad hoc consultant, who need not be an IACUC member or institutional employee¹. An alternate member, regardless of regular IACUC member availability, may conduct the inspection. For areas housing AWA-regulated species, the IACUC must follow USDA Animal and Plant Health Inspection Service guidance³.

Response from USDA

The Animal Welfare Act and Regulations are silent on the use of alternate IACUC members. APHIS concurs with OLAW's

guidance that the CEO, or their designee, may appoint alternate members to the IACUC provided that the alternate meets any specific membership requirements fulfilled by the regular member and that the Chair may designate alternates to perform DMR when the regular member is unavailable¹. In conducting the review, the alternate has the same authority as regular members to approve, require modifications to secure approval, or request full committee review⁴. If an alternate member requests full committee review, and the regular member is present at the full committee review, the alternate may not contribute to the formation of a quorum or vote¹. □

Patricia Brown^{1✉} and Roxanne Mullaney^{2✉}

¹Director, Office of Laboratory Animal Welfare, OER, OD, NIH, HHS, Bethesda, MD, USA. ²Acting Deputy Administrator, Animal Care, APHIS, USDA, Riverdale, MD, USA.

[✉]e-mail: brownp@od.nih.gov; roxanne.c.mullaney@usda.gov

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2. Public Health Service. *PHS Policy on Humane Care and Use of Laboratory Animals*. (U.S. Department of Health and Human Services, National Institutes of Health, Bethesda, MD, 2015). Section IV.C.2. <https://olaw.nih.gov/policies-laws/phs-policy.htm#ReviewofPHS-ConductedorSupportedResearchProjects>
3. National Institutes of Health. *Guidance on Flexibilities for Conducting Semiannual Inspections of Animal Facilities*. Notice NOT-OD-21-164 [online]. (National Institutes of Health, Bethesda, MD, 2 August 2021). <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-164.html>
4. AWR §2.31(d)(2).

Alternate Rights

"Alternates" were introduced and supported by both OLAW and USDA in NOT-OD-01-017 (2001)¹ and again in NOT-OD-11-053

(2011)² as part of a larger effort by NIH to reduce regulatory burden on IACUCs and researchers by helping IACUCs conduct business "more efficiently". The provision

of alternates helps IACUCs meet quorum requirements necessary to conduct official business at convened meetings and to perform other IACUC functions when one or more

COMPLIANCE CONSIDERATIONS

The Protocol Review coordinators offer the following compliance considerations:

1. IACUC Committee membership and alternates

A properly constituted IACUC that adheres to both the AWAR and PHS Policy includes:

- An IACUC Chair
- A Doctor of Veterinary Medicine
- An unaffiliated member
- A practicing scientist experienced in research involving animals
- A non-scientist

In all cases, the Chief Executive Officer (CEO) (or designee) shall appoint the members of the IACUC, in writing.

In 2001, OLAW provided guidance on the use of alternate IACUC members¹ and updated that guidance in 2011²: "Although PHS Policy and the USDA AWRs are silent on the use of alternate IACUC members, OLAW and APHIS agree that alternates may be utilized [when specific conditions are met]". These conditions include that alternates must, in brief:

- a. Be appointed by the CEO;
- b. Be listed on the IACUC rosters (PHS Assurances and annual reports);
- c. Only serve as an alternate for the membership category(s) for which they are appointed and not represent more than one member at any one time³;
- d. Only contribute to a quorum or act in an official IACUC capacity if the regular member for whom they serve as alternate is unavailable to participate in IACUC business; and
- e. Vote their conscience and not represent the position of the regular member for whom they serve.

Prior to 2001's guidance on the use of alternates, IACUC members were only referred to as appointed, voting, and by their membership category. Currently, alternates are also appointed, voting, and assigned to membership category(s).

2. What constitutes "when unavailable"?

The regulatory language on the use of alternates seems to refer to convened meetings²: "An alternate may only contribute...if the regular member... is unable to attend the meeting, has to leave the meeting early or arrive late, or is recused from participating due to a real or potential conflict of interest."

3. Can an "alternate" serve as DMR?

The 2011 guidance² states that "Service by alternate IACUC members offers an effective management practice to ensure timely review and approval of animal activities" and limits the alternates capacity to "...contribute to a quorum and function as an IACUC member [only] if the regular member for whom they serve as alternate is unavailable to participate in IACUC business..."; i.e. there is no specific mention of alternates in the conduct of DMR.

Consequently, the use of alternates in DMR seems appropriate and without limitation, provided that the IACUC chair has designated the alternate as "qualified to conduct the review"⁴.

OLAW has previously indicated⁵ the use of alternates as DMRs only when the Chair could establish that the regular member was, indeed, not available. However, this was based on the 2001 guidance wherein alternates were limited to a 1:1 match with regular members (vs. per membership category). There has been no updated guidance specifically addressing the use of alternates as DMRs.

4. Can an "alternate" perform semi-annual inspections?

No regulatory guidance is available.

5. How might an IACUC interpret and apply current regulatory guidance?

Consider this hypothetical scenario:

Whilst talking with a colleague, Dr. Rowe, the IACUC Chair at Great Western University (GWU), realized that GWU didn't have a clear understanding

of the privileges granted under the regulations to alternate IACUC members. Consequently, Rowe established a subcommittee of GWU's IACUC and charged it with developing an IACUC policy to govern the use of alternate IACUC members. In brief, the subcommittee developed a policy with the following assumptions:

- a. An alternate IACUC member can only serve in an official IACUC voting member capacity when the voting member they are designated to replace is unavailable (e.g., an alternate scientific member can only substitute for a voting scientific member), and
- b. When an alternate member is serving in an official voting member capacity (e.g., substituting for an unavailable voting member), the alternate member's decisions are their own and should not be influenced by the perceived opinions of the voting member for which they substitute.

Given the GWU subcommittee's interpretation of the regulatory expectations (i.e., the above assumptions), the following policy was developed and presented to the IACUC for approval:

- a. Alternate IACUC members are officially appointed to the committee by the Institutional Official (IO), who has delegated authority from the CEO, based on the IACUC position for which they can serve (e.g., a scientific, non-affiliated, non-scientific, veterinarian).
- b. Alternate members can perform official IACUC member duties in their defined positions and replace a voting member (i.e., serve as a voting member of the committee) only when the voting member is unavailable, but are encouraged to verbally contribute during committee activities when not serving as an alternate for official IACUC member duties.

- c. GWU defines official IACUC member duties as: contributing to the quorum of a constituted IACUC meeting, voting on matters requiring IACUC approval during a convened meeting, serving as a DMR, and performing inspections of facilities used to house USDA-regulated species.

The policy was presented to the GWU IACUC by Dr. Rowe and was unanimously approved.

6. What might be the impact of GWUs new policy?

Several months later, GWUs IACUC has realized the impact of the new policy, which includes:

- The IACUC has 6 regular voting members and 10 alternate members.
- Prior to the creation of this policy, all regular and alternate members were serving as DMRs and facility inspectors.

- Implementation of this policy now requires:
 - a. GWU regular IACUC members to:
 - i. Establish their unavailability by email, indicating the day(s) during which they are unavailable; and
 - ii. Perform 66% more protocol and amendment reviews and facility inspections.
 - b. Dr. Rowe to specifically assign an alternate to cover for the regular member for the indicated day(s) of unavailability.
 - c. The IACUC administrator, as designated by Dr. Rowe, to constantly reassign DMRs for ongoing IACUC reviews between regular and alternate members.
- The time to approval has been increased by ≥ 3 weeks due to increased

workload on regular members and all the reassignments. □

Lauren Danridge [✉] and Bill Greer [✉]
Animal Care & Use Office, University of Michigan, Ann Arbor, Michigan, USA.

[✉]e-mail: danridlm@umich.edu;
 wggreer@umich.edu

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3. OLAW/NIH, 2. *May the IACUC have alternate members?* <https://olaw.nih.gov/faqs#guidance/faqs?anchor=50295>
4. OLAW/NIH, *Correct Conduct of Full-Committee and Designated-Member Protocol Reviews.* <https://grants.nih.gov/grants/olaw/references/laba02v31n9.htm>
5. Brown, P & Gipson, C. *Lab Anim* 36, 14 (2007).

regular IACUC members may not be available to participate. This scenario highlights the importance of establishing IACUC guidelines and policies that clarify and define how the IACUC operates in situations where regulations may be silent, including, when an alternate member can serve in place of their “primary” (full-voting) member or be called upon to perform duties that do not require a vote (e.g., DMR, semi-annual reviews and facility inspections, etc.).

Since DMR is GEU’s default protocol review process, we will assume that at a minimum, GEU IACUC members were provided the name of Guaió’s protocol, a description of the research upon request, and an opportunity to request FCR. In the absence of a request, Crick exercised the Chair’s authority to designate one or more qualified IACUC members to conduct the review on the IACUC’s behalf. Since all IACUC members are equally trained, Crick designated IACUC member, Kahalili, an alternate scientific member. While Guaió is correct that the regulations³ (and PHS Policy⁴) are silent on “alternate” IACUC members, he is incorrect in asserting that Kahalili is not an IACUC member; both “primary” members and “alternates”

must be appointed to the IACUC by the Institutional Official (IO), and alternates may serve in place of one or multiple IACUC members who meet the same IACUC membership requirements.

Guaió’s concern that Kahalili is not authorized to call for FCR during DMR is also incorrect. Any DR, whether conducting the review alone or with other DRs, can send the protocol back to FCR for any reason. If Crick designated the review to more than one IACUC member, those reviewers would have to come to consensus on a final version of the protocol or send it back for FCR if unable to achieve consensus. DRs do not vote to approve the protocol.

Once in FCR, Kahalili would be empowered with the vote only in the physical or technical absence of her primary member. Physically unavailable may mean on vacation, sabbatical, sick leave, at a conference, etc. Technically unavailable may mean a conflict of interest with the protocol (e.g., Principal Investigator (PI) or co-PI on the protocol), an affiliation with a competing grant or protocol, a financial conflict, etc. If the intent of the NIH Notices describing alternates is to help IACUCs conduct business more efficiently, it could be more

efficient for the Chair to select a DR with the most expertise in the proposed research or species, including an alternate, even if their primary member is available. Again, clear IACUC guidelines and policies would clarify this for the IACUC and others. □

Mary Lou James^{1✉} and Laura Lewis^{2✉}

¹*Flight IACUC Chair, NASA Headquarters, Washington, D.C., USA.* ²*IACUC Chair, NASA Ames Research Center, Moffett Field, Mountain View, CA, USA.*

[✉]e-mail: marylou.james@nasa.gov;
 laura.lewis@nasa.gov

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