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An IACUC Chair who isn't a member

Pleasant Gorge College, a small school with big ambitions, was in the process of writing its first research grant requesting Public Health Service (PHS) funding for a project in the college's Department of Biological Sciences that would use common laboratory mice. Although Biological Sciences had a growing research program, the other departments of the school remained focused on teaching, and very few faculty members or administrators were interested in serving on its IACUC. Nevertheless, an IACUC and an approved Assurance were required by the NIH's Office of Laboratory Animal Welfare (OLAW), a part of the PHS, before any PHS financial support could be granted. Eventually, a consulting laboratory

animal veterinarian was employed and appropriate animal housing space was developed. A properly constituted IACUC also was recruited but not without some arm twisting by the school's academic dean. Then another problem arose: none of the IACUC members wanted to be the chairperson of the new committee, claiming that they already had far too much teaching and administrative work to take on another time-consuming responsibility. Frustrated and not wanting to further alienate the faculty, the dean asked the consulting veterinarian if it would be legal and acceptable to OLAW to have a properly constituted IACUC with five voting members but a chairperson who was not a member of the IACUC and did not have

a vote. The veterinarian responded that he had never heard of such an arrangement but, as far as he knew, it would be legal and potentially acceptable to OLAW. With that information, the president of the college appointed the dean as the chairperson of the IACUC.

The dean was pleased with the outcome as she believed that serving as Chair, even if it were for a limited time period, would give her first-hand insights into the operations of the IACUC, experience that would be beneficial as she led the school to further PHS funding opportunities. But do you think that the veterinarian's advice was correct? Can the dean of the school function as the Chair of the IACUC without being an IACUC member and without a vote?

RESPONSE

Chair should be a voting member

Tennille Lamon, DVM, CPIA

The consulting veterinarian is technically correct in that neither the Public Health Service (PHS) *Policy on Humane Care and Use of Laboratory Animals*¹ nor the *Guide for the Care and Use of Laboratory Animals*² requires that the IACUC Chair be a voting member of the IACUC. The Animal Welfare Act and Regulations³ do require that the committee include the Chair, but that requirement would not be applicable unless the research program expanded to include USDA-covered species in addition to the "common laboratory mice" that it currently uses. In any case, the role of the IACUC Chair is vitally important to the success of the committee. The respect of the research community for the Chair, and the IACUC, could be severely diminished if the Chair is not a voting member and does not have a voice in committee decisions.

The IACUC Chair is the spokesperson of the IACUC to the Institutional Official (IO) and the research community. The committee members are generally shielded from public view, whereas the Chair is the visible representative. Since the dean would not be a member, she would not review protocols, determine policies, implement regulations or ensure humane animal care and use, but as Chair, she would need to defend all of the IACUC's decisions to the appropriate stakeholders. That puts the dean into a situation where she, as the leader, would take full responsibility for the IACUC's decisions without having a role in the decision-making process. Her credibility and leadership could be severely damaged in that type of politically precarious position.

The Chair is also responsible for supporting the IACUC members and communicating their needs to the IO. Without serving as a voting member, the dean would not have a clear understanding of the needs of the committee. Serving on an IACUC and bearing the full weight of the responsibility to both the animals and the researchers are necessary to completely understand the challenge of balancing the critical needs of both. Since the dean would

not have that responsibility, she might have a difficult time accurately communicating the IACUC's needs to the upper administration and could lose the respect of the IACUC members. To make matters worse, the IACUC was properly constituted only by the dean pressuring some to serve. With the dean being appointed the Chair without taking on the duties and responsibilities of the voting members, her authority with those on the committee is tenuous at best.

If the dean is truly interested in understanding how an IACUC functions and is looking for future PHS funding opportunities for Pleasant Gorge College, she should serve as a voting member of the IACUC and as the IACUC Chair.

1. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* Section IV.A.3. (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
2. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2011).
3. Animal Welfare Act and Regulations. Code of Federal Regulations. Title 9. Section 2.31.a,b 1-3.

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RESPONSE

Legal, but is it effective?

Carole R. Baskin, DVM, MSc, CPIA & Jana M. Dodge, RVT, LATg, CPIA

Can someone perform the functions of an IACUC Chair as a non-member or as a non-voting member of the committee? From a regulatory standpoint, there is no distinction between a non-member and non-voting IACUC member. The Animal Welfare Act and Regulations¹ state, “The IACUC may invite consultants [...who] may not approve or withhold approval of an activity, and may not vote with the IACUC unless they are also members of the IACUC.” The IACUC may refer to consultants or other experts who are invited to the committee meetings as non-voting members, but there is no regulatory definition of the term. Furthermore, regulations only require that voting members are appointed; therefore, the appointment of the dean as Chair implies, unless otherwise specified, that the dean is a voting member.

Notwithstanding the commentary above, the institution currently needs to abide by only the Public Health Service (PHS) *Policy on Humane Care and Use of Laboratory Animals*², which does not specifically require IACUC membership for the Chair, unless the PHS Assurance was written to also comply with the Animal Welfare Act and Regulations¹. The Chair must also be named on the Assurance document, which implies committee membership, even if this is not explicitly stated. There is little regulatory guidance regarding the Chair’s duties, except for designating members for review¹. Being a non-member would excuse the Chair from voting, performing designated member reviews, calling full committee reviews and signing semi-annual reports. It would not excuse the Chair from the implied (not mandated) obligation of attending all the meetings (in the absence of a Deputy Chair)³. There is also an implied expectation that the Chair will share in the burden of work of the IACUC members, thereby necessitating membership. Moreover, the material reviewed by the IACUC, including

concerns about animal welfare, carries with it a legal obligation of confidentiality; having a Chair who is not a member of the IACUC could be perceived as an attempt to circumvent this requirement³. Finally, it is difficult to fathom how a Chair could perform some of the higher-level functions of the position, including being a spokesperson for the IACUC and the institutional animal care program, without being an IACUC member. If the Chair is not part of the decision-making process, then she cannot be responsible for the decisions, leaving the IACUC with a leader in name only.

Although there are no specific prohibitions against individuals filling more than one role on the IACUC, the Office of Laboratory Animal Welfare strongly recommends against it, in part owing to the appearance of conflict of interest⁴. This would be especially true if functions normally performed by the Chair fell to the consulting veterinarian. A better solution might be to establish a consortium or similar arrangement with nearby organizations⁴ or to hire an experienced IACUC professional. This person could act as trainer, record-keeper, coordinator and counsel to Principal Investigators and to the IACUC on protocol and regulatory issues. Doing so would take most of the administrative burden off the Chair, making it easier for the dean or a senior faculty member to assume an active role on the committee.

1. Animal Welfare Act Regulations. Code of Federal Regulations. Title 9, Chapter 1, Subchapter A, Parts 1–4.
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
3. Office of Laboratory Animal Welfare. *Institutional Animal Care and Use Committee Guidebook* 2nd edn. (US Department of Health and Human Services, Bethesda, MD, 2002).
4. Public Health Service. *Institutional Administrator’s Manual for Laboratory Animal Care and Use* NIH Publication No. 88-2959 (US Department Of Health and Human Services, Bethesda, MD, 1988).

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RESPONSE

Conflict of interest

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The Public Health Service *Policy on Humane Care and Use of Laboratory Animals* (PHS *Policy*)¹ states that the IACUC shall consist of not less than five members but does not specifically include a chairperson as one of those five members. Additionally, the PHS *Policy*¹ requires the Assured institution to “comply with the applicable regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act.” The Animal Welfare Act and Regulations (AWARs)², as stated in §2.31(b)(2), require an IACUC to have at least three members, one of which is a chairperson. In this scenario, however, the AWARs² do not apply because the institution is using only laboratory mice. Furthermore, there is no definition of or guidance on the chairperson’s responsibilities in the PHS *Policy*¹, the AWARs² or the *Guide for the Care and Use of Laboratory Animals*³. The PHS *Policy*¹ also states (in section A.3.b.), “The Assurance must include the names, position titles, and credentials of the IACUC chairperson and the members,” implying that the Chair is not necessarily a member. Therefore, we believe that the veterinarian’s advice was accurate. The dean can serve as the Chair of the IACUC without being a member.

There are several reasons why the president of the college might wish to reconsider the dean’s appointment. The role of Chair typically includes many responsibilities beyond chairing meetings. It is difficult to envision how a person with no experience in animal care and use could make informed decisions when needed. There exists a potential conflict of interest in this scenario as the dean may not be in a position to objectively evaluate the research. The dean’s role at the college includes promoting research funding; therefore, she has a vested interest in the proposed research. The AWARs² (in §2.31(d)(2)) and the PHS *Policy*¹ state that “no member may participate in the IACUC review or approval of a research project in which the member

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has a conflicting interest except to provide information as requested by the IACUC.” Perhaps the dean recognized this conflict of interest and that is why she elected not to be a member. However, even though she is not a member of the IACUC and therefore would not have a vote, she is an authority figure and her presence as IACUC Chair could influence the voting of junior faculty members on the IACUC.

In conclusion, we believe that the dean serving as Chair of the IACUC is not in the best interest of the institution. Although

it technically may be legal for her to do so, the potential for conflict of interest is great and she would likely be unable to fulfill some responsibilities typically assigned to the Chair, such as determining whether a proposed animal use or protocol modification requires IACUC review. If Pleasant Gorge College decided to explore research using USDA-covered species in the future, then the Chair would be required to be a voting member of the IACUC and the institution’s Assurance would need to be amended.

1. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
2. Animal Welfare Act Regulations. Code of Federal Regulations. Title 9, Chapter 1.
3. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2011).

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A word from OLAW and USDA

In response to the questions posed 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 guidance:

The Public Health Service *Policy on Humane Care and Use of Laboratory Animals* (PHS Policy) does not specify whether the Chair must be a member of the Committee. The PHS Policy, in section V.A.4., charges OLAW with “advising...awardee institutions concerning implementation of this Policy”¹. OLAW’s interpretation is that the Chairperson must be a member of the Committee. The Chair is expected to vote unless there is a direct conflict of interest (i.e., involvement in a protocol or another reason to recuse). OLAW’s interpretation is supported by the PHS Policy in section IV.A.3.b., which requires the institution to provide the name, position title and credentials of the Chairperson in the Assurance document¹. Further, in Part VIII of the sample domestic Assurance, the Chairperson is identified as one of the members of the IACUC².

Institutions must have an Assurance on file with OLAW in order to receive PHS funding. If an institution does not have an Assurance, the funding component will ask OLAW to negotiate an Assurance before the grant, contract or cooperative agreement is awarded. OLAW contacts the institution to negotiate an Assurance. (OLAW does not accept or process unsolicited applications.) The institution prepares an Assurance document and submits it to OLAW. OLAW negotiates with the institution until the Assurance document meets the standards of the PHS Policy³. During the negotiation, OLAW advises the institution on the proper constitution of an IACUC. This includes the point that the Chairperson is a voting member of the committee.

Because of the dean’s senior leadership position within the institution, service as Institutional Official (IO) may be more appropriate than appointment as IACUC Chair. The IO is the key person in the organization with the administrative and operational authority to commit institutional resources to ensure that the animal care and use program complies with the requirements of the PHS Policy⁴.

For USDA-registered research facilities, there are several issues in this scenario to be addressed. The first is whether the chair can be a non-voting member. The only non-voting persons involved in IACUC activities are consultants who are not members of the Committee⁵. The Animal Welfare Act Regulations (AWARs) under section 2.31b describe the minimum requirements for IACUC member make-up as a Chair, a veterinarian and a non-affiliated member⁵. By virtue of being a member of the IACUC, the Chair is engaged in the activities of the IACUC as outlined in section 2.31c-e of the AWARs and therefore must vote⁵.

The second issue is whether the Chair needs to be affiliated with the institution. The AWARs are silent on this. A third issue, though not directly stated, is whether the dean is also the IO. Although there is no regulatory prohibition against the IO also being Chair of the IACUC, because of the high potential for a conflict of interest, this dual role is discouraged. Animal Care Policy #15 on Institutional Official and IACUC Membership provides guidance on this matter⁶.

1. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
2. Public Health Service. *Sample Animal Welfare Assurance for Domestic Institutions* (US Department of Health and Human Services, Washington, DC, 2012).
3. Public Health Service. *Obtaining an Assurance* (US Department of Health and Human Services, Washington, DC, 2012).
4. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals—Frequently Asked Questions*. Institutional Responsibilities, Question No. G.5. (US Department of Health and Human Services, Washington, DC, 2013).
5. Code of Federal Regulations. Title 9, Ch. 1, Part 2, Subpart C, §2.31.
6. Animal and Plant Health Inspection Service. *Animal Care Policy Manual*. Policy No. 15: Institutional Official and IACUC Membership. (United States Department of Agriculture, Washington, DC, 2011).

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