RESPONSE

Legal, but is it effective?

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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 nonvoting 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 Animals2, 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 semiannual 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).
- Office of Laboratory Animal Welfare. Institutional Animal Care and Use Committee Guidebook 2nd edn. (US Department of Health and Human Services, Bethesda, MD, 2002).
- 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 Policy¹ 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 Policy¹, the AWARs² or the Guide for the Care and Use of Laboratory Animals³. The PHS Policy¹ 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