

Confidentiality & conflict: can one member serve two IACUCs?

Rose Rubin, a grant administrator at Great Eastern University, had been serving for many years as a nonscientific member of the school's IACUC. She attended almost all the committee's meetings and had become very familiar with reviewing protocols, inspecting laboratories and animal facilities, and reviewing allegations of protocol noncompliance. Prior to joining Great Eastern, Rubin was a grant administrator at Starling College, a nearby private institution.

Rubin kept in touch with some former colleagues at Starling, including Dr. Melinda Marx, who recently had become the chair of Starling's IACUC. Knowing that

Rubin was currently serving on the Great Eastern IACUC, Marx asked Rubin if she had the time to serve as the nonaffiliated member on the Starling IACUC. Rubin said that she could arrange her time to serve in that position, but she was not sure if her past employment at Starling would be considered as having some form of allegiance to the college even though she did not receive any financial or other benefit from the school after she left. Rubin also wondered if serving on two different IACUCs would raise questions from both IACUCs about maintaining confidentiality of IACUC activities. On the other hand, she reasoned, her knowledge of IACUC operations and her many community

service activities would make her an ideal nonaffiliated member. Marx told her that she would have to sign a confidentiality agreement similar to the one used at Great Eastern, but she believed that Rubin would be an ideal nonaffiliated member on the Starling IACUC.

What is your opinion about Rubin serving on the Starling College's IACUC?

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Finding 'qualified' nonaffiliated members...the struggle is real

The regulatory requirements that should be reviewed are available and reliable to utilize when considering recruitment of qualified nonaffiliated IACUC members. Yet finding the perfect person who aligns to the cookie cutter version of what it means to be a nonaffiliated IACUC member is not an easy task in spite of the resources. Starling College, like many of us, reached out to those we know or have connections with for assistance.

There are a couple of things for both Starling College and Great Eastern University to consider before Rubin gets an appointment to Starling's IACUC. First, as far as I know, there are no regulations that would prohibit someone from serving on more than one IACUC as long as the IACUC organizations are at two different institutions.¹ The issue of leakage of scientific ideas or procedures (proprietary information) may be a concern; however, both institutions should address this armed with proper training in the concerns of confidentiality. In most cases where this is an issue, institutions should follow the protocol of having the individual(s) sign a formal nondisclosure agreement, which would then properly address the issues related to disclosures. Second,

both institutions need to discern the spirit in which the regulations define the term "nonaffiliated."

There are three distinct criterion used by regulatory bodies to define a 'nonaffiliated member': first, the member is not a laboratory animal user or former user; second, they are not affiliated with the institution; and third, they are not an immediate family member of an individual affiliated with the institution^{2,3}. In this scenario, the Starling IACUC would need to deliberate on the perceived conflict of interest by utilizing a former employee to fulfill the nonaffiliated role. In this situation, Rubin is not receiving any financial or other benefits from Starling even though she is a former employee. In addition, she is not serving on any other committee at Starling—her affiliation is strictly with its IACUC. This is an important consideration; because her income comes from Great Eastern University, any opinions or remarks that she may make during a Starling IACUC meeting would not put her at odds with her employer. Opinions also indicate that having someone familiar with the institution could lead to greater participation and a better quality of discussion during meetings.⁴

Rightfully so, utilizing a former employee can certainly be a gray area for some regulatory agencies. Where possible, it would be in the best interest of Starling College to find someone who is *unmistakably nonaffiliated*. If that is not the case, then I would recommend that both the IACUC and Institutional Official meet with Rubin on the record so that she can assure Starling College that she can fulfill the requirements of the nonaffiliated member as noted by the regulations.

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Welcome that community member

This scenario is regarding whether a nonscientific member of the IACUC of one academic institution (Great Eastern University) can serve as

the nonaffiliated (community/public) member of another academic institution (Starling College), of which the person is a former employee.

Assuming Starling College is subject to USDA, OLAW, and AAALAC oversight, the requirements for the nonaffiliated member are:

- Not affiliated with the institution in any other way than as a member of the IACUC¹⁻⁵
- Not in any way obligated to the institution⁵
- Not a member of the immediate family of a person who is affiliated with the institution¹⁻⁵
- Not a current or former laboratory animal user^{1,5} (this restriction only applies if Starling College does not receive PHS funding and is not seeking AAALAC accreditation)

Nonaffiliated IACUC members are meant to represent general community interests in the proper care and treatment of animals²⁻⁵. Both AAALAC and OLAW have advised that appointing someone with no prior ties is preferred, to avoid any ambiguities and overcome the perception of any conflicts of interest; however, appointing a prior employee is not disallowed—as long as the institution can clearly justify their decision. Silverman et al. have actually noted advantages in appointing a prior employee: “fidelity to the institution appeared to engender robust participation, yielding very honest and critical questions, review and commentary.”⁶

According to the AWA, all IACUC members should be made aware that they are obligated to treat material reviewed by the IACUC as privileged or confidential. It should be expected that a member serving on multiple IACUCs would not leak details from one group to the other—or at all⁷.

It is well recognized by research institutions that identifying and retaining an experienced and conscientious community member is difficult. Challenges faced by institutions include identifying individuals that do not pose animal activism risks, are available when needed and possess aptitude for serving on the IACUC. We feel that Rubin would be an ideal community member given that she:

- is well aware of the perceived conflict of interest
- has not received any financial or other benefits from Starling since her departure

A WORD FROM OLAW AND USDA

In response to the issues posed in this scenario, the U.S. Department of Agriculture Animal and Plant Health Inspection Service (USDA-APHIS) and the National Institutes of Health Office of Laboratory Animal Welfare (NIH-OLAW) provide the following clarifications.

Response from NIH-OLAW

In this scenario, a nonscientific member of one research institution's IACUC is asked to serve as the nonaffiliated member of her former employer's IACUC. As noted by other reviewers, such an arrangement is acceptable because the member in question qualifies as a nonscientist and is not currently affiliated in any way other than as the proposed IACUC member¹. In similar circumstances (e.g. an alumnus, former employee or former student), the IACUC should review any potential conflicts of interest due to past affiliation and if determined that no discernable tie or ongoing affiliation exists, recommend the appointment to the Institutional Official and maintain a record of the determination². Institutions with questions about a prospective IACUC member's suitability are encouraged to contact OLAW for guidance or to visit OLAW's website for expanded guidance on PHS Policy requirements for IACUC membership³.

Response from USDA-APHIS

Under the Animal Welfare Act (AWA) and regulations, the IACUC is required to have at least three members consisting of a Chair, the Attending Veterinarian, and a member that is not affiliated in any way with the facility with the intent that the nonaffiliated member represent the public interest regarding the proper care of animals⁴. In this scenario, a non-scientific member of one research institution's IACUC is asked to also serve as the nonaffiliated member on the IACUC of her former employer.

The institution seeking to use the former employee is required to ensure all of the regulatory criteria are met namely, the person is not affiliated with the institution other than being a member of the IACUC, and there are no immediate family member

affiliations⁴. We recommend the institution take into consideration as many factors as possible to ensure there is no element of affiliation. These factors include but are not limited to whether the former employee received certification /degree from the institution, and whether the person continues to receive any type of benefit after the employment ended.

The AWA and regulations are silent regarding a person serving on more than one IACUC concurrently. Should someone elect to serve on more than one IACUC, maintaining confidential information becomes especially important. Under the AWA, it is unlawful for any member of an IACUC to release or wrongfully use confidential information such as trade secrets, processes, identities, data, profits, losses, and expenditures⁵. As a result, the institution should ensure the nonaffiliated member receives instruction that covers responsibilities in accordance with the regulatory requirements for personnel training⁶. Lastly, the Chief Executive Officer of the institution is required to appoint the person to the IACUC⁷. □

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4. Title 9 Chapter 1 Subchapter A § 2.31 (b)(3)
5. United States Code Title 7 Chapter 54 §2157
6. Title 9 Chapter 1 Subchapter A § 2.32 (a)
7. Title 9 Chapter 1 Subchapter A § 2.31 (b)(1)

- is involved in multiple community service activities
- has prior experience serving on an IACUC
- would abide by confidentiality agreements at both institutions

We feel that these qualities outweigh any perception of Rubin's affiliation to Starling College.

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2. Animal Welfare Act (7 USC, Ch. 54, §2143 (b)(1)(B) (p.13 in Blue Book)
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7. Animal Welfare Act (7 USC, Ch. 54, §2157 (p.25 in Blue Book)

Acting professionally and impartially

Nonaffiliated members are an integral part of the IACUC system. Rubin, with her years of experience as an IACUC member (nonscientific) at Great Eastern University, will be an excellent resource for the IACUC at Starling College.

All IACUC members are expected to act professionally and impartially in considering IACUC matters. Rubin would be well aware of this, and she should not have had second thoughts on having concurrent roles in the two IACUCs. Institutions should have established procedures to manage conflict of interests and confidentiality. IACUC members would be required to sign a confidentiality and non-disclosure agreement¹. Rubin's previous employment with Starling College should not be a hindrance to her function as a nonaffiliated IACUC member. Every member should feel free to independently cast their vote in favor or against a motion on the table and abstain as necessary without pressure or undue influence².

It is important to avoid the potential actual or perceived conflicts of interest. Marx could have reassured Rubin by letting her know that there are procedures in place at Starling College with regards to

management of conflict of interests and confidentiality (assuming that these are already in place).

Before signing up with Starling College IACUC as a nonaffiliated member, Rubin must also let Great Eastern University (as her employer) know of her plan to ensure that it is alright for her to join an external committee. Most institutions do encourage and allow their staff to participate in external committees as part of their service to the community.

In New Zealand and Australia, members of the Animal Ethics Committee (AEC)—equivalent of the IACUC—must acknowledge in writing (before appointment) their acceptance of the terms of reference of the AEC, including declaration of interests and any requirements for confidentiality required by the institution³. In New Zealand, the institution's Code of Ethical Conduct for the Use of Animals in Research, Testing and Teaching (CEC) describes how confidentiality and conflicts of interests will be managed⁴.

Institutions should have clear IACUC/AEC policies and guidelines regarding declaration and management of conflict of interests and confidentiality.

These should also include expectations on all committee members (including nonaffiliated members), highlighting the importance of acting professionally and impartially in carrying out their committee role or professional obligations, to ensure fair and unbiased review of IACUC matters.

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