

Jerald Silverman, DVM, Column Coordinator

New CEO, new IACUC?

There had been rumors for some time that the Board of Trustees was about to replace Edna Gordon as president of Great Eastern University. It wasn't that Gordon did anything wrong; it was more that she didn't do much of anything at all. The university had languished under her presidency and some board members had been hinting that new blood was needed. Then, unexpectedly, Gordon announced her resignation, saying that she would be leaving in six months to become the president of another academic institution.

None of this raised any eyebrows on Great Eastern's IACUC; the Committee members had seen presidents come and go over the years. For the IACUC, it seemed like business as usual, until one of the newer members raised an unusual issue. Doug Daniels,

who considered himself well-versed in the federal regulations governing IACUCs, asked if there would be any change to the Committee's membership.

"No, I haven't heard anything—but why are you asking?" said Dave Hammill, the IACUC Chairman.

"Well," said Daniels, "the Animal Welfare Act Regulations (AWRs) say that the Chief Executive Officer (CEO) appoints the IACUC, and since the new president will also be our CEO, doesn't the new president have to reappoint the IACUC?"

"I've never heard of anything like that," said Hammill. "In any case, President Gordon appointed Vice-President for Research John O'Connor as the Institutional Official (IO) and you may recall that under the Public Health Service *Policy on Humane*

Care and Use of Laboratory Animals (PHS *Policy*) O'Connor can appoint the IACUC as long as his delegation to do so is specific and in writing."

"Well," said Daniels once again, "that's only under the PHS *Policy*, not under the AWRs. But even under the PHS *Policy*, if the new CEO can delegate the authority to appoint the IACUC to the IO, I'd still like to know if O'Connor will have to be reappointed by the new president when he or she comes on board, and if O'Connor will in turn have to reappoint the IACUC."

What is your opinion on this matter? Will the new CEO (the new president) have to reappoint the IO or the IACUC? Under the AWRs, can the CEO delegate to the IO or someone else the authority to appoint the IACUC?

RESPONSE

New IACUC not needed

Thillai Koothan, DVM, MVSc, PhD & Suzanne Craig, DVM, DACLAM

Great Eastern does not need to reappoint the IO or the IACUC. As it says in 9 CFR 2.31(a), the CEO appoints the IACUC. Once the IACUC is properly appointed by a CEO—either past or present—there is nothing in the regulations that says the IACUC members must be reappointed when the CEO leaves or a new CEO joins an institution.

Senior management changes happen at an institution for many reasons and sometimes there is an interim CEO that precedes the appointment of a new CEO. In that case, should the IACUC get reappointed? Then, when the new CEO takes over from the interim CEO, should the IACUC get reappointed once again? The answer is obviously 'no' in both cases. The need for frequent reappointments would affect the

proper function of the IACUC. CEOs may come and go in an institution, but to maintain continuity and smooth operation, the organizational structure of an institution should not be altered. A CEO may not be familiar with the AWRs, PHS *Policy*, or structure and function of the IACUC. In such cases, it may be prudent to brief the new CEO about the IACUC's role in overseeing animal research.

Moreover, the CEO always retains the authority to change the IO or the composition of the IACUC. The AWRs state that the CEO (or IO) "shall appoint an [IACUC], qualified through experience and expertise of its members to assess the research facility's animal program, facilities, and procedures¹." PHS *Policy* defines the CEO as the "highest operating official of the organization (such as the President of a university)²" and allows the CEO to delegate the authority to appoint the IACUC. The AWRs define the IO as "the individual at a research facility who is authorized to legally commit on behalf of the research facility that the requirements of 9 CFR, Parts 1, 2, and 3 will be met¹." According to

the *Guide for the Care and Use of Laboratory Animals (Guide)*, "the responsible administrative official at each institution must appoint an IACUC³." If this authority is delegated in writing to someone other than the CEO, then that individual should have the ability to appoint the IACUC. In some institutions the CEO delegates the authority for appointing the IACUC to a senior administrator, who also often signs the Animal Welfare Assurance⁴.

1. 9 CFR Subchapter A—Animal Welfare, Parts 1, 2, and 3.
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* A.3.a (US Department of Health and Human Services, Washington, DC, 1986; reprinted 2002).
3. Institute for Laboratory Animal Research, National Research Council. *Guide for the Care and Use of Laboratory Animals* 9 (National Academy Press, Washington, DC, 1996).
4. Silverman, J., Suckow, M.A. & Murthy, S. *The IACUC Handbook* 2nd edn. 20 (CRC Press, Boca Raton, FL, 2007).

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RESPONSE

New policy may be in order

Stephen M. Dempsey, DVM

The regulations are relatively silent on the issue of IACUC reappointment. While the new president of Great Eastern will serve as the CEO, his or her predecessor's appointments to the IACUC do not expire at the end of her term. Great Eastern's duly constituted IACUC does not require reappointment by the new president, unless

that individual specifically wants to make some changes in the Committee's membership.

Under the AWRs, the CEO is authorized to appoint an IO and delegate all or some of the CEO's responsibilities for compliance with the AWRs to that individual. The one caveat is that the person serving as the IO does have to be authorized to legally commit the institution to compliance with requirements of the AWRs. When the new president takes over, it would be prudent for that individual to appoint or re-appoint an IO because of the role

that the IO plays in taking on delegated responsibilities and actions, for which the president/CEO is ultimately responsible. Depending on the institution and president/CEO, the responsibility for appointment of IACUC members can be one of the delegated responsibilities given to the IO.

Although not required under current animal welfare regulations, it would be advisable to consider developing an institutional policy or procedure regarding the appointment of IACUC members, their terms, and the survivability of their appointment

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:

The primary questions posed in the scenario are (1) whether the new Chief Executive Officer (CEO) will have to reappoint the Institutional Official (IO) or the IACUC, and (2) whether under the Animal Welfare Regulations (AWRs), the CEO can delegate authority to appoint the IACUC to the IO or someone else.

The Public Health Service *Policy on Humane Care and Use of Laboratory Animals* (PHS Policy) does not prescribe administrative procedures for appointments of IOs or CEOs, nor does it require that IACUCs appointed by designated IOs be reappointed by successor IOs. Section IV.F.1.b of the PHS Policy, however, does require IACUCs, through their IOs, to report "any change in the description of the program for animal care and use as required by IV.A.1.a.–I. of this Policy¹" in writing to OLAW at least once every twelve months (that is, in the institutional Annual Report). The appointment of a new CEO and/or IO qualifies for reporting because it represents a change in the "lines of authority and responsibility for administering the program and ensuring compliance with this Policy¹" described in the institution's previously approved Assurance and must therefore be re-evaluated by OLAW.

Likewise, in promulgating regulations for the 1985 amendments to the Animal Welfare Act (AWA), it was evident to USDA that rigid administrative requirements would be inappropriate given the diverse nature of research facilities. Rather, institutions should be permitted to develop procedures that satisfy the requirements and correspond to their operations². There is no regulatory requirement for reappointment of IACUC members. The Research Facility Inspection Guide directs inspectors to look for some form of verification of the member's appointment; for example, a periodic letter/memo of reappointment may be appropriate if the institution has defined term limits for its members³.

Guidance previously issued by OLAW states that "the IO signs the Assurance and is the person in the organization

with the administrative and operational authority to commit institutional resources to ensure that the animal care and use program will comply with the requirements of the PHS Policy⁴." It also explains that "the PHS Policy requires the CEO to appoint the IACUC in accord with specified qualifications and membership criteria, although the CEO may delegate this authority in writing," and recognizes that "in some institutions, the IO and the CEO may be one and the same, whereas in other institutions, particularly large ones, the CEO may be further removed from the day-to-day program oversight⁴."

USDA also allows the CEO of the research facility, in accordance with their charter and bylaws, to delegate his or her responsibility under the AWA⁵. This is considered to be an internal institutional matter. The term 'Institutional Official,' as added to the regulations in 1989, can refer to either the CEO or another responsible official authorized to legally bind the facility⁶.

1. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* A.3.a (US Department of Health and Human Services, Washington, DC, 1986; reprinted 2002).
2. USDA APHIS. Final Rules: Animal Welfare; 9 CFR Parts 2 and 3. *Federal Register* **54(168)**, 36123–36163 (31 August 1989).
3. USDA APHIS. Animal Care Resource Guide, Research Manual. <http://www.aphis.usda.gov/ac/researchguide.html>
4. National Institutes of Health, Office of Extramural Research. PHS Policy on Humane Care and Use of Laboratory Animals. Frequently Asked Questions, Institutional Responsibilities, Question No. 5. http://grants.nih.gov/grants/olaw/faqs.htm#instresp_5.
5. USDA APHIS. Proposed Rules: Animal Welfare; 9 CFR Part 2. *Federal Register* **54(49)**, 10835–10954 (15 March 1989).
6. USDA APHIS. Final Rules: Animal Welfare; 9 CFR Part 1. *Federal Register* **54(168)**, 36112–36123 (31 August 1989).

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despite changes of the CEO or the IO. A separate policy for the appointment of the IO should also be developed. That policy should stipulate what responsibilities and actions have been delegated by the CEO and include some statement regarding appointment or reappointment at the discretion of a new or interim CEO. The existence of such policies will help to obviate any questions regarding these appointments.

Finally, it is important to remember that any change to the CEO or IO must be reported to the USDA Animal Care Regional Office within ten days of its occurrence.

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RESPONSE

No change in order

Erin Hutteman, AAS, BS, RLATG

In this scenario, the outgoing CEO of Great Eastern appointed the IO, who then appointed each member of the IACUC. The *Guide* states that “the size of the institution and the nature and extent of research, testing, and education programs will determine the number of members of the committee and their terms of appointment¹.” If the Great Eastern CEO adhered to the regulations and appointed the IO and the IACUC members for certain term periods, then they would not have to be reappointed by the new president of the university. Of course, at the end of their appointed term, the IO and IACUC member could be reappointed if they wished to continue serving.

Daniels is correct that the AWRs state that the CEO appoints the IACUC, but the law does not go into detail as to how an institution handles changes in leadership, except that such changes of operation must be reported to an Animal Care Regional Director. The AWRs defines the IO as someone who is authorized to legally commit on behalf of the research facility. Since the AWRs do not specifically address the CEO or appointment of an IO, one might indeed conclude that the CEO can delegate the appointment of the IACUC to another individual within the institution who can legally commit for the facility.

1. Institute for Laboratory Animal Research, National Research Council. *Guide for the Care and Use of Laboratory Animals* 8 (National Academy Press, Washington, DC, 1996).

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