

funding, animal welfare, etc. for a defined location within a larger, multi-campus organization does not seem to be beyond the spirit of the regulations. Ultimately, it is the CEO's decision to define the scope of the IOs' responsibilities and, therefore, the CEO's responsibility to ensure that each VPR is given sufficient authority to carry out the required oversight of, and provide the required resources for, his or her specific campus.

Another point to consider is the composition of the IACUC. The AVs at Great Eastern appreciate the consistency afforded by using a single IACUC. The regulations do not preclude the use of a single IACUC for four institutions, provided that the IACUC is constituted to satisfy the membership, record-keeping and reporting requirements for each institution. Another option would be to maintain a separate IACUC for each institution, affording each campus the greater local control desired by the VPRs.

If individuals at the various facilities are concerned about consistency among the campuses, the CEO or IOs could implement system-wide policies and procedures, ideally with the input of the officials of the separate campuses. A working group comprised of IOs, AVs, IACUC chairs and other administrators from the various campuses—like UC has—could be helpful.

1. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* Section III, Definition F. (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
2. Animal Welfare Act and Animal Welfare Regulations. 9 CFR §2.30(a)(1-3).

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RESPONSE

Multiple IOs with full authority

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This scenario asks whether there can be more than one Institutional Official (IO) at Great Eastern University. As the IACUC

attending veterinarian (AV) pointed out, the US Department of Agriculture (USDA) and the US National Institutes of Health's Office of Laboratory Welfare (NIH/OLAW) have previously stated that the structure of an organization can vary to accommodate its specific needs¹. The Public Health Service *Policy on Humane Care and Use of Laboratory Animals* (PHS Policy)² and the Animal Welfare Act and regulations (AWARs)³ do not specifically prohibit Great Eastern University from having multiple IOs. But we believe the IACUC Chair was correct in assuming that each IO should have full authority over a designated campus and not just partial authority over the entire university.

In this solution, each of the four campuses of Great Eastern University would have a designated IO along with its previously designated campus AV while retaining their single university IACUC. The logistics of this structure would need to be documented so that all parties understand the expectations, responsibilities and lines of authority. Some of the complicating factors of having a single IACUC and potentially a single PHS Assurance and USDA Registration are indicated below. Most importantly, Great Eastern would need to have a mechanism in place to resolve conflict and maintain programmatic consistency among the four IOs with regard to committing the institution to meet the requirements of the PHS Policy and the AWARs, reporting to regulatory and funding agencies, appointing IACUC members, subjecting protocols to additional review and ensuring personnel training and the availability of training programs.

The IACUC would also need to communicate with all IOs equally regarding semi-annual facility inspection reports, semi-annual program reviews, IACUC suspensions, non-compliance activities and other issues surrounding the animal care and use program. Finally, the IOs would need to reach consensus before communicating decisions with the IACUC to guarantee consistency.

The document described above, detailing the responsibilities and lines of authority for the multiple IOs, should also dictate and outline who has signatory authority for the various regulatory reports (i.e.,

PHS Assurance, USDA Annual Report). Furthermore, that document should be submitted to NIH/OLAW with the institution's PHS Assurance, USDA Registration and Program Description for the Association for Assessment and Accreditation of Laboratory Animal Care International (as applicable) so that the organizational structure, lines of authority and responsibilities are transparent and codified.

1. Brown, P. & Gipson, C. A word from OLAW and USDA. *Lab Anim. (NY)* 38, 113 (2009).
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. Animal Welfare Act and Animal Welfare Regulations. Part 2, Subpart C. Research Facilities.

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RESPONSE

Possible, but prudent?

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The Institutional Official (IO) is the person charged with the responsibility of ensuring that the institution is satisfying regulations set for its animal use and care programs. The Public Health Service *Policy on Humane Care and Use of Laboratory Animals* (PHS Policy) defines the IO as "an individual who signs, and has the authority to sign the institution's Assurance, making a commitment on behalf of the institution that the requirements of this Policy will be met"¹. This is further supported and clarified in the *Guide for the Care and Use of Laboratory Animals*². There, the IO is defined as the person "responsible for resource planning and ensuring the alignment of Program goals and quality animal care and use with the institute mission"². The Animal Welfare Act (AWA) defines the IO as the person who legally commits to ensuring that the terms of the animal welfare regulations are met by the institution³. The PHS Policy and the AWA define the term 'IO' and his or her responsibilities. The AWA and the