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Animal care and use programs for multiple campuses

Great Eastern University had one IACUC serving all four of its campuses. There were four attending veterinarians (one for each campus), but only one of them served on the IACUC as the university's attending veterinarian (AV). At first the veterinarians were skeptical about having only one IACUC for four campuses, but over time they recognized some unforeseen value to the arrangement because animal care and use policies and procedures had become more standardized across the campuses. Great Eastern also had four Vice Provosts for Research (one for each campus), but only one served as the university's Institutional Official (IO).

The multiple campuses and animal facilities were becoming a logistical problem. Over time, the Vice Provosts became progressively more uncomfortable with having only one of them wielding the authority to allocate resources that were needed for the animal care and use programs across the campuses. Even with collegial agreements in place, the arrangement gave the IO some *de facto*

authority to allocate funds from another Vice Provost's budget to assure compliance with federal animal care and use regulations. There was no outward animosity, just a desire of the Vice Provosts who were not the IO to have greater authority for the research on their campuses. Eventually, they agreed that because each campus had its own unique personality and research program, each campus should have its own IO.

They asked the IACUC's AV and the IACUC Chair for their opinions on whether there could be more than one IO for the university if each IO had a clearly defined area of responsibility. The AV replied that the US Department of Agriculture (USDA) and the US National Institutes of Health's Office of Laboratory Welfare (NIH/OLAW) had stated that because the size and complexity of institutions vary, no single organizational or administrative structure was compatible with the needs of all institutions¹. It seemed logical to him that if an institution could have multiple AVs, then it should be able to have multiple IOs. The IACUC Chair wasn't as sure. She said that if there would be one

IO for each campus who performed all of the functions of an IO specified in the Public Health Service *Policy on Humane Care and Use of Laboratory Animals*² and the Animal Welfare Act regulations³, then the plan might work. If, however, there would be four IOs, each having only partial authority for what an IO must do (e.g., finances, personnel, infrastructure and research compliance responsibilities) that would, in her opinion, never work or be acceptable to the federal agencies.

What is your opinion? Can there be more than one IO at Great Eastern University? If so, how would you structure their responsibilities to satisfy NIH/OLAW and USDA?

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

Separate institutions

Jennifer Perkins, MA, CPIA

It is understandable that the Vice Provosts for Research (VPRs) of the four Great Eastern campuses want the authority as Institutional Officials (IOs) to allocate resources as they see fit for their individual programs rather than allowing a single IO to represent all campuses. Having one IO per campus can work well as long as each campus maintains a separate Animal Welfare Assurance, registration with the US Department of Agriculture (USDA) and accreditation with the Association for Assessment and Accreditation of

Laboratory Animal Care International (as applicable to their programs).

The real question, then, may be what acceptably counts as an institution requiring an Assurance or USDA registration, noting that the Public Health Service *Policy for the Humane Care and Use of Laboratory Animals*¹ and Animal Welfare Act² offer institutions wide latitude to define and organize themselves. The regulations do not preclude one individual from serving as chief executive officer (CEO) or IO of multiple institutions or prohibit a single campus from being divided into multiple Assured or registered entities, so long as all activities requiring institutional oversight are, in fact, overseen. Designating the four Great Eastern campuses as separate institutions will allow greater local control of their individual programs.

As an example, the University of California (UC) system has ten campuses, each with a stand-alone animal program including an attending veterinarian (AV) and an IACUC that reports to the VPR or IO at that campus. On a regular basis, the UC Office of the President gathers the IOs, AVs and IACUC administrators to discuss common issues. They share best practices and counsel each other on challenging situations, but ultimately, each campus is responsible for its own activities. This works well for UC given the scale of the overall program.

In this scenario, Great Eastern's IACUC Chair was concerned that assigning a defined area of responsibility to each IO would imply that each has only partial authority for what an IO must do. Designating an IO as singly responsible for the personnel, facilities,

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

Gina Prochilo-Cawston, MS, CPIA, PMP & Kathryn Mellouk, MPA

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?

Sheba Churchill, DVM

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

PHS *Policy* do not stipulate explicitly whether this role is to be performed by one individual or by many. The US National Institutes of Health's Office of Laboratory Animal Welfare (NIH/OLAW) in the past has offered guidance on this issue: "...organizations having simple, clear, direct lines of responsibility and corresponding authority function well and are better able to respond quickly and effectively to the requirements of the PHS *Policy*"⁴. In NIH/OLAW's experience, programs that do not support clear communication have failed to be effective⁴.

The advantages of having multiple IOs include knowledge of each individual campus, speed in identifying and addressing campus needs and fair representation of each campus in negotiations. The foreseeable major disadvantages of having multiple IOs are possible miscommunication to regulatory officials, higher costs in paying several individuals instead of one and the potential for budgetary disputes among IOs. The use of one IO for all campuses also has multiple

benefits, such as clear communication with regulatory agencies and uniformity in decision-making, and eliminates most of the disadvantages listed above. If the current Vice Provosts at Great Eastern were willing to continue to assist the IO, then the program would get the best of both worlds.

It is my opinion that the university would be best served by having one individual act as the IO. The underlying problem appears to be the concern over too much authority lying with one Vice Provost. University officials could consider having another qualified individual who has supervisory responsibilities for each of the Vice Provosts, such as a Provost, fulfill the role of IO. They could also rotate each Vice Provost into the IO position for a specific term. The use of a centralized structure of one IO and one IACUC helps to ensure consistent interpretation and administration of regulatory requirements. If university officials instead choose to have multiple IOs, they should consider also creating multiple IACUCs and treating each campus as its own entity. The decision should be

guided by the long-term objectives of the university. University officials should place the needs of the program above those of the individual Vice Provosts, especially if the current system works well for the university. Legally, the university can have multiple IOs but this might not be the prudent choice.

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. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* (National Academies Press, Washington, DC, 2011).
3. Animal Welfare Regulations. Code of Federal Regulations. 9 CFR, Chapter 1, Subchapter A—Animal Welfare, Parts 1–4.
4. Division of Animal Welfare, Office for Protection from Research Risks, National Institutes of Health. Frequently asked questions about the Public Health Service Policy on Humane Care and Use of Laboratory Animals. *ILAR News* 35, 47-49 (1993). <<http://grants.nih.gov/grants/olaw/references/ilar93.htm>>

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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:

May an institution have more than one institutional official (IO) and be compliant with the requirements of the Public Health Service *Policy on Human Care and Use of Laboratory Animals* (PHS *Policy*) and the Animal Welfare Act and Regulations? The PHS *Policy* defines the IO as "an individual", not several individuals¹. OLAW interprets the PHS *Policy* to limit the authority and responsibility of the IO to a single individual, even at very large programs with multiple IACUCs. Institutions may have individuals who are knowledgeable about the animal care and use program and perform some of the daily operations for the IO, but there must be one individual who signs, and has the authority to sign, the institution's Assurance, and commits on behalf of the institution that the requirements of the PHS *Policy* are met¹. OLAW has opined that "direct, clear and straight forward lines of responsibility and corresponding authority function well and allow organizations to respond quickly and effectively when necessary"². Such guidance is applicable in this scenario to maintain a smoothly functioning animal care and use program. In the scenario, the four campuses have the option of having four individual Assurances, which would permit separate IOs for each campus.

The definition of an IO in the Animal Welfare Act and Regulations is "an 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 met"³. As a result, USDA APHIS AC limits the authority and responsibility to a single individual and consequently accepts one IO per registrant.

We note that the head of an institution such as the Chief Executive Officer, President, Provost or Director has the latitude to appoint an individual to serve on his or her behalf as the IO for the animal care and use program.

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. *Policy on Humane Care and Use of Laboratory Animals – Frequently Asked Questions*. Institutional Responsibilities, Question No. G.4. (US Department of Health and Human Services, Washington, DC, 2006, revised 2013).
3. Animal Welfare Act and Regulations. 9 CFR §1.1 Definitions.

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