

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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