

## 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 question posed in the scenario is whether there is any applicable regulatory guidance for identifying who can serve as the PI for animal activities approved by an IACUC. As the scenario indicates that appropriate contractual agreements were in place to meet NIH requirements, this commentary assumes the following: that the research projects in question were PHS-supported; that the start-up companies are the primary grantees; and that inter-institutional agreements between the grantee institutions, the performance site, Great Eastern, and OLAW have been signed.

The PHS *Policy for Humane Care and Use of Laboratory Animals* (PHS *Policy*) does not contain specific guidance on who can serve as the senior scientist (often called the PI) responsible for research projects involving live vertebrate animals. The only guideline given by the PHS *Policy* is at IV.C.1.f, where it states that “the IACUC shall determine that personnel conducting procedures on the species being studied will be appropriately qualified and trained in those procedures<sup>1</sup>.” Great Eastern requires that the PI for the animal research protocol be “intimately involved with the research,” which is not a PHS *Policy* requirement.

The PHS *Policy* (at II) goes on to state that “no PHS support for an activity involving animals will be provided to an individual unless that individual is affiliated with or sponsored by an institution which can and does assume responsibility for compliance with the *Policy*, unless the individual makes other arrangements with the PHS<sup>1</sup>.” The relationship and details of the affiliation are left undefined, allowing flexibility for cooperative use of resources and facilities among institutions. The IACUC, as part of its oversight of Great Eastern’s program for animal care and use and the institution’s animal facilities, should be included in the development of any sub-granting agreements to ensure that they are consistent with provisions of the PHS *Policy*. The veterinarian also must be aware of her involvement and avoid a conflict of interest when her role blurs from veterinary care provider to scientific collaborator. If she continues to serve a role in the collection of the data, then having another veterinarian affiliated with Great Eastern assigned responsibility for institutional veterinary oversight of animal care and use involving those specific protocols is recommended. If she continues as the PI, she has a “conflicting interest,” according to PHS *Policy* at II.C.2, and cannot participate in IACUC discussions or reviews (except as invited to respond to Committee inquiries) concerning any of the 12 protocols<sup>1</sup>.

The definition cited from the PHS 398 grant application instructions by one of the responders is how the NIH defines who can be named as a PI on a grant application to NIH. This may not necessarily be the same individual listed as the PI on the animal research protocol. As Great Eastern is serving as a sub-grantee (consortium participant) on a PHS-supported award, then the primary grantees (the start-up companies) must have formal written agreements with Great Eastern that address the negotiated arrangements for meeting the scientific, administrative, financial, and reporting requirements, including identification of the PI on each of the grant applications and the individuals responsible for the research activity at Great Eastern, and their roles and responsibilities. Any change in these individuals at Great Eastern is subject to approval by the primary grantee and should be formally acknowledged in the agreements with the primary grantee organization<sup>2,3</sup>.

If the research project involves species regulated by the USDA, then the institution must also comply with the Animal Welfare Act (AWA) and regulations (AWRs). The AWRs define the PI as “an employee of a research facility, or other person associated with a research facility, responsible for a proposal to conduct research and for the design and implementation of research involving animals<sup>4</sup>.” Again, the relationship and detail of the association is left for the institution to define. The IACUC, however, as the responsible entity for compliance with the AWA, must be satisfied with the relationships created by the veterinarian on behalf of Great Eastern and must ensure appropriate oversight of all aspects of the research being conducted at Great Eastern’s facilities by the veterinarian and by researchers from outside institutions.

1. Public Health Service. Policy on Humane Care and Use of Laboratory Animals (US Department of Health and Human Services, Washington, DC, 1986; reprinted 2002).
2. PHS Grants Policy Statement, Part II, Terms and Conditions, Consortium Agreements. [http://grants.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part12.htm#\\_Toc54600259](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part12.htm#_Toc54600259).
3. National Institutes of Health. Office of Extramural Research guidance regarding administrative IACUC issues and efforts to reduce regulatory burden. NOTICE: NOT-OD-01-017 (12 February 2001). <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-017.html>.
4. 9 CFR, Chapter 1, Subchapter A—Animal Welfare, Part 1 Definition of Terms. <http://www.nal.usda.gov/awic/legislat/usdaleg1.htm>.

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