

and preventive medicine practices should be listed in the veterinary care standard operating procedures or in the IACUC-approved sentinel animal protocol. In this regard, Great Eastern University is in compliance with the AWA and the *Guide* and is not mandated to list and approve such activities on a researcher protocol.

1. Animal Welfare Act and Regulations. Section 2.40, b, 2.
2. Institute of Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. 105–132 (National Academies Press, Washington, DC, 2011).

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**RESPONSE**

**Approval required, methods may vary**

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Assessing the health status of animals is certainly part of the veterinary program. Many institutions use standard operating procedures to describe the procedures done by the veterinary staff during quarantine. The veterinary staff often carries out diagnostic work that may include monitoring and sample collection to ensure or to confirm the health status of new animals arriving at the facility. Veterinary diagnostic procedures do not typically require coverage under an IACUC-approved protocol, although the IACUC reviews the veterinary program, including these procedures, as part of the semiannual review.

In this case, the guinea pigs are being used as part of the sentinel program, rather than as part of quarantine procedures. The protocol covering the sentinel program should include a description of the veterinary technicians and other personnel who handle animals for this purpose. This protocol should include guinea pigs, along with any other species routinely monitored in the program. If guinea pigs are not included, the sentinel protocol should be amended to include the species,

**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:*

Though well intentioned, Great Eastern University's IACUC has incorrectly assumed that only a protocol is acceptable to OLAW to meet the oversight requirement described in the OLAW Frequently Asked Question (FAQ)<sup>1</sup>. The FAQ cited does not preclude the use of a standard operating procedure (SOP). Concerning animals used as sentinels, breeding stock, etc., the FAQ states "...the IACUC should review protocols and SOPs that involve animals for such purposes"<sup>1</sup>. The use of a sentinel protocol, a research protocol or an SOP is an institutional decision. It may be based on whether there is ongoing sentinel activity covering many different studies with the species. If only one study requires the species, then including the sentinel activity on the research protocol is an option with the principal investigator's concurrence. A third option is to describe the sentinel activity in an SOP reviewed and approved by the IACUC. Including research animals in the SOP should again have the investigator's concurrence. OLAW and USDA suggest that an institution inform investigators that their study animals may be used in this manner and provide a mechanism for them to decline participation with scientific justification.

The Animal Welfare Act Regulations (AWARs) §2.31 (d)(1) outlines the duties of the IACUC in regards to the review and approval of proposed and ongoing activities involving animals<sup>2</sup>. Under §2.31(e) of the AWARs, a proposal to make a significant change to an ongoing activity must contain the following information: (i) the identification of the species and the numbers of animals used; (ii) a rationale for involving animals and for the appropriateness and numbers of animals used; (iii) a complete description of the proposed use of the animals; (iv) a description of the methods used to assure that pain and distress will be limited to that which is unavoidable, along with the provisions for anesthetics, analgesics and tranquilizing agents where appropriate; and (v) a description of euthanasia methods<sup>2</sup>.

In light of the AWARs, an amendment to the current sentinel monitoring protocol to incorporate the use of study animals or an amendment to the research protocol to reflect the sentinel use would be acceptable. Facilities may utilize an SOP instead of an IACUC-approved protocol for the sentinel monitoring program. Although the AWARs do not specifically address SOPs, USDA acknowledges their role in animal care and use programs and therefore deems the use of an SOP acceptable in this instance.

1. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals—Frequently Asked Questions*. Protocol Review, Question No. D.16. (US Department of Health and Human Services, Washington, DC, 2006, revised 2013).
2. Code of Federal Regulations. Title 9, Ch. 1, Part 2, Subpart C.

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procedure descriptions and justification for the number of animals used in the guinea pig surveillance program. IACUC-approved procedures are protocol-specific and species-specific. Because samples are taken from live animals, which requires handling the animals, these procedures must be included in an IACUC-approved protocol. We see two options in this case: (i) the guinea pigs should be transferred to the already established institutional sentinel

protocol for sample collection or (ii) the researcher's protocol should be amended to include the surveillance procedures, in a manner consistent with the institutional IACUC requirements.

The fact that site visitors and inspectors had never made comments about this topic in the past does not mean the institution handled it appropriately. It is unfortunate that it was not identified during the *de novo* review of the sentinel protocol. It sounds as