## A word from OLAW

In response to the questions posed in this scenario, the Office of Laboratory Animal Welfare (OLAW) offers the following clarification and guidance, with the assumptions that Great Eastern University has an Animal Welfare Assurance with OLAW and that the study is funded by the Public Health Service.

This column asks whether the IACUC must accept scientific justifications that the committee does not consider adequate. Broadly, the IACUC must determine that investigator-provided scientific justifications are adequate in order to approve the proposed activities. It is the IACUC's responsibility to review the investigator's request in the context of federal requirements and local policies or guidelines.

In the scenario, the attending veterinarian questions the plausibility of the investigator's scientific justification for euthanasia by cervical dislocation. The Public Health Service *Policy on Humane Care and Use of Laboratory Animals* (PHS *Policy*)<sup>1</sup> directs Assured institutions to follow the recommendations of the *AVMA Guidelines for the Euthanasia of Animals: 2013 Edition* (the *AVMA Guidelines*)<sup>2</sup>. The 2013 *AVMA Guidelines* have refined the acceptability of cervical dislocation, stating that "when performed by well-trained individuals on appropriate animals, [it] appears to be humane"<sup>2</sup>. If the IACUC decides to approve the investigator's request, it should ascertain and document demonstrated technical competency by all staff conducting the procedure<sup>2</sup>.

The scenario also questions the legitimacy of the investigator's request to euthanize rodents in his laboratory. This institution requires investigators to provide scientific justification to remove animals from the vivarium. The institution is within its rights to develop and enforce institutional policies, such as a policy requiring investigators to provide scientific justification for conducting animal procedures outside a central animal facility. The following concerns may prompt such a policy: (i) occupational risks to personnel through exposure to animals in the investigator's laboratory; (ii) transportation of live animals through the campus and building corridors to the laboratory; (iii) disposal of animal carcasses after tissue collection; and (iv) aesthetics of the euthanasia method to uninformed observers present in the laboratory<sup>2,3</sup>.

Consideration of the adequacy of scientific justifications is part of the IACUC's overall protocol review responsibility. During protocol review, IACUCs are required to evaluate proposed activities to ensure that they are consistent with the *Guide for the Care and Use of Laboratory Animals*<sup>3</sup>, unless a scientific justification for a departure is presented and is acceptable to the IACUC; that they conform with the institution's Animal Welfare Assurance; that they will be conducted in accordance with the USDA Animal Welfare Regulations<sup>4</sup>, if applicable; and that they meet the requirements of the PHS *Policy* (section IV.C.1; ref. 5). Should a proposal fail to address any of these items to the IACUC's satisfaction, the committee may require modifications to secure its approval.

- 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. American Veterinary Medical Association. AVMA Guidelines for the Euthanasia of Animals: 2013 Edition (AVMA, Schaumburg, IL, 2013).
- Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th ed. 134–135 (National Academies Press, Washington, DC, 2011).
   Code of Federal Regulations. Title 9, Chapter 1, Subchapter A Animal Welfare: Part 2 Regulations. §2.31(d).
- 5. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals—Frequently Asked Questions*. Protocol Review, Question No. D.6. (US Department of Health and Human Services, Washington, DC, 2006, revised 2013).

## Patricia Brown, VMD, MS, DACLAM

Director OLAW, OER, OD, NIH, HHS

very clear about its reasons for originally creating and enforcing these policies. If the policies have been in place without further review for some time, general discussion among the entire IACUC may be beneficial. Information addressing the relevant issues identified by the IACUC could then comprise the comprehensive justification required for approval.

As part of ongoing program review, policies should be regularly reassessed to ensure that they are still relevant and necessary to promote optimal animal care and use. Whereas the *Guide for the Care* and Use of Laboratory Animals<sup>4</sup> (the *Guide*) and IACUC Guidebook<sup>3</sup> focus on review of policies as they relate to provisions of the *Guide*, The IACUC Handbook<sup>5</sup> lists institutional policies separately, emphasizing the effects of local decisions on the conduct of research activities.

It is important to keep in mind that the IACUC has multiple roles. Focus tends to be on the regulatory aspects of the IACUC's responsibilities, which is understandable given the complex regulatory framework. At the same time, there is an obligation to "not only oversee but also support animal users"<sup>4</sup>. Internal policies that place an extra burden on researchers must be carefully evaluated to confirm that they are both reasonable and necessary to meet the overarching goal of ensuring humane care and use of animals while supporting the advancement of scientific knowledge.

- American Veterinary Medical Association. *AVMA Guidelines for the Euthanasia of Animals:*  2013 Edition 38 (AVMA, Schaumburg, IL, 2013). <a href="https://www.avma.org/KB/Policies/Documents/euthanasia.pdf">https://www.avma.org/KB/Policies/Documents/euthanasia.pdf</a>
- American College of Laboratory Animal Medicine. Position on Adequate Veterinary Care. <a href="http://www.aclam.org/Content/files/files/">http://www.aclam.org/Content/files/files/</a> Public/Active/position\_adeqvetcare.pdf>
- ARENA/OLAW. Institutional Animal Care and Use Committee Guidebook 2nd edn. (Office of Laboratory Animal Welfare, Bethesda, MD, 2002).
- Institute for Laboratory Animal Research. *Guide for* the Care and Use of Laboratory Animals 8th edn. 13 (National Academies Press, Washington, DC, 2011).
- Silverman, J., Suckow, M.A. & Murthy, S. *The* IACUC Handbook 2nd edn. 430 (CRC Press, Boca Raton, FL, 2007).

Rosenblatt is IACUC Program Manager at Medical University of South Carolina, Charleston, SC.