

Jerald Silverman, DVM, Column Coordinator

Policy pressure from the Institutional Official

A recent survey reported that 82% of all IACUC members (and only 75% of IACUC veterinarians) believed that their Institutional Officials (IOs) understood their role in the regulatory process¹. The basic responsibility of the IO is to provide assurance that the institution will comply, where required, with the Animal Welfare Act Regulations² and the Public Health Service *Policy on Humane Care and Use of Laboratory Animals*³. In most cases, the IO has a good amount of political clout within the institution, as exemplified by an incident that happened at Great Eastern University.

Dr. Sandy Wright had a strong preventive medicine program at the Great Eastern University animal facility. There was full accreditation from the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC); for many years, there had been no noncompliant items found during inspections by the US Department of Agriculture; there were no significant animal health problems; and the school's investigators were pleased with the service they received. The exception was Dr.

George Church. Church was an established investigator who disliked most regulations and policies concerning laboratory animal care. He considered them obstructions to research. Church was also a good friend of the IO, who was a professor in Church's academic department.

When Church learned that the animal facility, with the support of the IACUC, would not allow him to omit a quarantine period for the transgenic rats he wanted to receive from a colleague at another institution, he complained directly to the IO. His basic arguments were that the sending institution was a highly regarded research university having full AAALAC accreditation, that its online health reports indicated no laboratory animal diseases and that it would be ridiculous to quarantine the animals for a time period that was longer than the pilot surgical and metabolic study for which he planned to use them. On top of that, he would have to pay a *per diem* rate for quarantine that was substantially higher than the regular rate, which would be a waste of federal research dollars.

Responding to a query from the IO, the IACUC and veterinarian explained the rationale for the quarantine of Church's animals. The IO thanked them and suggested that it would be considered a personal favor if they would reconsider their position on the need for quarantine, based on the high quality of the incoming animals, the short study time and the need to save research dollars wherever possible to assure that sufficient funds would be available to purchase the ventilated cages and racks that were requested in the animal facility's budget.

The veiled threat was obvious. How do you think the IACUC and veterinarian should respond?

1. Silverman, J., Baker, S.P. & Lidz, C.W. A self-assessment survey of the Institutional Animal Care and Use Committee, Part 1: animal welfare and protocol compliance. *Lab Anim. (NY)* **41**, 230–235 (2012).
2. Animal Welfare Act Regulations. 9 CFR, Chapter 1, Subchapter A, Parts 1–3.
3. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals*. (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).

RESPONSE

Stand by the policy

Jim Fallon, BS, MBA

The challenge at hand for Great Eastern University is not so much a matter of quarantine policy but one of organizational behavior and institutional culture.

The Institutional Official (IO) has found him or herself in a compromised position, being a faculty colleague and friend of the investigator who wants the quarantine policy bent to accommodate his research. Church should have been advised at the outset that the role of IO is not to set policy but rather to ensure compliance. However, the IO has not only challenged policy but also applied budgetary and political pressure.

In this case, the quarantine policy of the institution is being challenged. The *Guide for the Care and Use of Laboratory Animals*¹ states, "Rodents may not require quarantine if data from the vendor or provider are sufficiently current, complete and reliable to define the health status of the incoming animals and if the potential for exposure to pathogens during transit is considered." The IACUC and veterinary staff would be well within their bounds to modify the policy, but they have reviewed the matter twice and both times concluded that the institution's quarantine protocol should apply.

Great care and effort is expended when developing an IACUC with the goal of maintaining a humane, well-functioning animal research program that is aligned with the goals of the institution and meets the needs of the researchers. In the best cases,

the group achieves a strong track record over time, demonstrated by full accreditation, strong inspection performance and well-served investigators. It appears that the Great Eastern University IACUC has achieved success (with the possible exception of its working relationship with Church). Maintaining this performance is key to the ongoing success of the committee and the animal care program. Dictating a policy exception carries multiple risks. First, it informs the IACUC that a single individual can override its efforts, which risks eroding the dedication of this group. Second, it could be perceived as putting animals inside the barrier at risk, which would be a disservice to the other investigators at the institution. Finally, relenting to Church would signal to him and others that the path around IACUC governance runs through the IO office, which is inappropriate.