

submit a corrective action plan detailing procedures to avoid future noncompliance. The IACUC may also wish to initiate a protocol review of the investigator's other approved studies to determine whether the noncompliance is limited to the one protocol or extends to other protocols.

Although the scenario did not mention funding, PHS *Policy* requires IACUC approval of those components of the proposal(s) related to animal care and the use of animals. If Great Eastern's Assurance does not distinguish between federally funded and non-federally funded research, a re-review of the documents would be required to verify consistency between the grant and protocol, regardless of funding. Any inconsistencies would need to be addressed prior to approval of the amendment.

Of course, had the animals not fared as well as they did in the scenario, the IACUC's deliberations would likely be quite different.

1. 9 CFR, 2.31(c)(8).
2. Public Health Service. *Public Health Service Policy on Humane Care and Use of Laboratory Animals* IV.B.8 (US Department of Health and Human Services, Washington, DC, 1986; reprinted 2002).

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RESPONSE

Decide now

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In this scenario, Wright has implemented a significant change to a protocol without prior IACUC approval as required by section IV.B.7 of PHS *Policy*. This is a serious infringement of animal welfare regulations and requires immediate attention from the IACUC and the Institutional Official (IO).

Of the four choices presented, options three and four are permissible under the regulations. Certainly the IACUC has the authority to suspend the protocol, either temporarily or permanently. However, suspension may not be the most appropriate action as it would invalidate the completed work and result in some animals having undergone needless surgery. The first option, allowing additional

surgeries while the amendment undergoes review, is inappropriate. Animal activities must receive IACUC approval before they begin. Option two is the best choice, striking a tenuous balance between good stewardship of the animals and meeting regulatory requirements. Allowing data collection from already operated-upon animals prevents the previously collected data from becoming worthless, circumventing the possibility that the project would need to start over with additional animals. Unfortunately, this option does not meet “the letter of the law,” in that non-IACUC-approved animal procedures would continue until review of the amendment is completed.

To meet both the letter and the spirit of the law, the IACUC should act on the amendment by full review. Although meeting in executive session (*i.e.*, behind closed doors for privacy) the text indicates that the full committee is present. If the IACUC has questions about the amendment as written, Wright could be called back into the meeting to provide answers. Once the committee has all the information it needs, it should act on the amendment by approving or withholding approval. If approval is granted, the project would be back in regulatory compliance. If approval is withheld, all work would cease immediately, and the IACUC should determine what to do with the animals already on study.

The IACUC should also discuss what programmatic lapses allowed this problem to happen in the first place. Does the training program adequately train Principal Investigators (PIs) and their research staff about what changes to previously approved procedures require IACUC approval before implementation? Do the Attending Veterinarian (AV) and his or her staff have adequate oversight of the surgical program? Are they involved in the planning of surgical procedures (or any procedures that might involve more than momentary pain or distress)? If so, how is their involvement coordinated with the IACUC review process? The programmatic issues that allowed the incident to happen should be fixed to prevent it from happening again. Because the incident was a serious violation of PHS *Policy*, the IACUC, through the IO, should promptly provide OLAW with a full explanation of the circumstances related to the problem and the actions taken to resolve it.

As to the last question (about whether the situation should be handled differently if rats are involved instead of NHPs), the answer is no. Although rats are not covered by USDA's animal welfare regulations, they are treated the same according to the *Guide for the Care and Use of Laboratory Animals* and PHS *Policy*.

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RESPONSE

Cooperation counts

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The Great Eastern IACUC's executive committee (Chair, Administrator, and AV) should meet and take the following into consideration in determining a course of action:

- Although off-protocol, the procedures were conducted properly and the PI has no history of non-cooperation or non-compliance. The PI is willing to temporarily discontinue all surgeries, not just the non-compliant portion, while the IACUC reviews his case.
- A major goal of the IACUC is to promote voluntary compliance and cooperation. When this kind of protocol drift happens, it needs to be addressed. Criminalizing the drift and punishing PIs who admit to it would be counterproductive, however; in a case involving a PI who is cooperative and apologetic, a cooperative approach will send a positive message to other faculty that problems can be addressed in a collegial manner for those PIs willing to work with the IACUC. A strong arm approach may be viewed negatively by other faculty and possibly damage the rapport between researchers and the IACUC.
- It is unclear whether the AWARs and PHS *Policy* allow for ‘suspension’ of part of a protocol. PHS *Policy* states that IACUCs are “authorized to suspend an activity involving animals¹,” but the definition of ‘activity’ (“those elements of research, testing, or teaching procedures that involve the care and use of animals²”) does not use the term ‘protocol’. This