

may be an important distinction that gives an IACUC the authority to suspend an un-approved activity. Moreover, just because the IACUC has the authority to suspend a protocol does not mean it must. We believe that suspensions should be reserved for willful and/or egregious noncompliance and/or refusal to cooperate.

- Suspending Wright’s research may cause a loss of valuable data and the need to replicate the experiments (using more animals) or risk invalidating all the previous work, thereby ‘wasting’ the animals already used.

Based on these considerations, we would suggest that the IACUC’s executive committee propose the following recommendations to the full Committee:

- Because of the PI’s willingness to cooperate in a timely manner, a formal suspension of the protocol does not seem warranted. Nevertheless, Wright’s agreement to discontinue all surgeries pending a satisfactory review and approval of the amendment should remain in force.
- Wright must agree in writing with the requirement that all research procedures be conducted as described in the approved protocol unless and until an amendment has been reviewed and approved.
- Wright and his staff must repeat the applicable training requirements.
- An IACUC member and/or representative of the IACUC should conduct post-approval monitoring of Wright’s lab at six-month intervals.
- A note should be sent to all PIs reminding them that all research procedures must be conducted as described in the approved protocol unless a modification is approved in advance for any new procedures. Investigators would be reminded that federal regulations allow for permanent suspension of the use of animals in activities and/or procedures not covered by a protocol approved by the IACUC.
- The executive committee should also recommend that this be the IACUC policy for all future similar infractions regardless of species, funding source, or type of activity (teaching or research); that the IACUC determine if it effectively communicates requirements to the faculty; and that the IACUC deter-

mine if amendments and modifications are reviewed in a timely manner to allow research to move forward.

Finally, it should be noted that if the study is PHS-funded research, the IACUC would be required to send an incident report to OLAW in compliance with its February 2005 directive³. If privately funded (and the protocol is not suspended), notification of either OLAW or USDA is not required.

1. 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).
2. 9 CFR Subchapter A—Animal Welfare, Section 1.1.
3. Office of Laboratory Animal Welfare. NOT-OD-05-034. Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals. (24 February 2005). <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>.

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RESPONSE

Stop and investigate

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The Great Eastern IACUC must send a message to Wright and all other researchers that no animal procedures will be allowed without an approved protocol. While his cooperation after the fact would be considered in his favor, it in no way excuses knowingly embarking on unapproved surgeries. Since IACUC members familiar with Wright’s previous research might be hesitant about stopping his work, we would suggest that the following steps be taken:

- The IACUC immediately report a serious noncompliance to OLAW. The aspects of Wright’s research program that require use of the affected animals will be temporarily suspended. The suspension would remain in effect until Wright prepares a relevant animal protocol proposal and that proposal is approved by the IACUC. Because of the critical nature of his research, the

IACUC would expedite review of this protocol with the expectation that this suspension could be lifted within a few days. Wright would also be placed on probation for a specified amount of time (e.g., one year). During that time, his use of animals would be closely monitored by animal care personnel and the IACUC. If it is discovered during the course of that year that he was again performing unapproved surgeries, his animal-based research would be suspended. A supervised probation would allow Wright to continue his research while at the same time send a clear message that further noncompliance would result in serious consequences.

- The IACUC immediately begin an investigation to determine if students and post-docs working with Wright were aware that the surgeries were not approved. This would emphasize to all that, although Wright (as PI) bears the burden of responsibility for noncompliance, all persons using animals at Great Eastern are responsible for reporting violations of animal care policies. If this investigation determined that Wright instructed those under him to disregard animal use and care policies, the IACUC would have no choice but to suspend his animal-based research until the situation is resolved. If this investigation did not find evidence of intentional violations, then his cooperation with the IACUC and the probationary period would be considered sufficient to prevent recurrence.

If Wright’s research was funded by a grant or contract from an extramural funding source, then the funding agency’s policies governing animal use must also be considered. Those policies might require additional responses by the Great Eastern IACUC.

As far as the IACUC is concerned, the species of animal should make no difference. However, every researcher should be sensitive to how their work would be viewed by the general public. We cannot imagine that public revelation of unapproved surgeries on NHPs would be very favorable for Wright or for Great Eastern University.

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