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Tackling investigator noncompliance

In a never-ending quest for perfection, the Great Eastern University IACUC modified its annual progress report form (used by investigators with ongoing animal research) to include a summary of the past year's activity and a projection of future activity. While reviewing the form submitted by Dr. Steven Wright and comparing it to Wright's IACUC-approved protocol, the reviewer began to suspect that Wright had performed some unapproved procedures. The approved protocol allowed for recovery major surgical procedures in nonhuman primates (NHPs), however, the type of surgery approved by the IACUC and that performed by Wright appeared to be significantly different. A phone call to Wright confirmed the reviewer's suspicion. Wright had indeed performed survival surgery, but not the surgery approved by the IACUC. Wright was apologetic and agreed to submit an amendment to his protocol. Even though all animals were doing well post-surgery, and even though Wright

quickly submitted the amendment, the issue was brought before the full IACUC. A relatively short discussion, with Wright present, confirmed that the surgical procedures were on an entirely different organ system than described in the approved protocol. Although he repeated his apologies, Wright also added that if he could not continue his work, the data already collected would be worthless. In an executive session, the IACUC determined that it had the following options:

1. Process and review the amendment like any other protocol amendment, allowing work to continue, reminding Wright that in the future all research procedures must be conducted as described in the approved protocol;
2. Suspend any additional surgeries until the amendment is reviewed and potentially approved, but allow non-surgical parts of the study to continue;
3. Suspend the entire study for a specified period of time; or

4. Suspend the entire protocol permanently.

It was obvious that Wright would consider the first option ideal under the circumstances, but would possibly agree to the second. Moreover, some IACUC members who were familiar with Wright's work agreed with Wright's position that the third and fourth options would effectively stop valuable research, invalidate the already completed parts of that research (since the nonsurgical aspects of Wright's studies were directly linked to recording post-surgical data), and result in the animals' having needlessly undergone surgery and recovery.

Can the Great Eastern IACUC suspend selected parts of Wright's protocol? Are there other options to consider that are not listed above? How would you manage this problem? Based on your experience, do you think that an IACUC would approach this problem differently if rats were involved rather than NHPs?

RESPONSE

Suspend the surgeries

Kathy Wadsworth, BS

The investigator clearly violated Animal Welfare Act Regulations (AWARs) and the Public Health Service *Policy on Humane Care and Use of Laboratory Animals* (PHS *Policy*) by conducting unapproved surgical procedures. However, the IACUC is correct to consider Wright's concern that complete suspension of his work would invalidate his research, which in turn would mean that animals would have undergone surgical manipulations needlessly.

The AWARs¹ and PHS *Policy*² grant IACUCs the authority to suspend previously approved activities, but are silent as to

whether the IACUC has the authority to suspend selected parts of a previously approved protocol. As such, it can be inferred that an IACUC may suspend portions of a protocol, depending upon the nature and circumstances involved in the noncompliance.

Since the surgical procedures conducted without IACUC approval involved a completely different organ system, the noncompliance would likely be deemed serious, regardless of species. Additionally, many institutions have Assurances with the Office of Laboratory Animal Welfare (OLAW) that apply the same policies and regulations governing the use of USDA-covered species to non-USDA covered species. Therefore, those IACUCs would likely approach any noncompliance in the same manner regardless of species involved.

The third and fourth options described in the scenario are, of course, the most

punitive and conservative approaches to this noncompliance. However, as the investigator appears to be cooperating with the IACUC's investigation, these options may be unnecessarily severe, given the potential loss of valuable research and subsequent need for additional surgery to replace the lost data. The first option would allow the research to continue unimpeded, but does not address the cause of the noncompliance. Given the seriousness of the noncompliance, it is important to take all measures necessary to avoid future violations.

In light of these concerns, I would recommend that the IACUC consider the second option: suspend surgeries until the amendment is reviewed and approved, but allow previously approved nonsurgical portions of the study to continue. In addition, the IACUC should require that the investigator