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Disagreement between IO and IACUC

During its most recent semiannual inspection, the Great Eastern University IACUC discovered—for the second time—that a satellite rabbit room cared for by a research laboratory had a very high temperature (88 °F) and no auxiliary ventilation. After discussion, the committee voted that this was a repeated significant deficiency that should be reported to the appropriate federal agencies. Michael McGregor, the new Institutional Official (IO) was informed of the committee’s decision, the reason for it and the fact that the IACUC had given the school’s regular animal care staff the authority to immediately move the animals to more appropriate housing. Being new to his position, McGregor initially thought nothing of the incident and verbally agreed with the IACUC. However, he quickly reversed his decision after the well-funded researcher responsible for the rabbits loudly complained about the horrid care his animals had previously received at the Great Eastern central animal facility and described the bad publicity for the school

that would result from any report to federal regulatory oversight agencies.

When Larry Covelli, the IACUC chairman, went to McGregor to voice his dissent about the reversed decision, McGregor downplayed the problem and suggested to him that a report would do more damage to the school’s image and the researcher’s ability to compete for grants than would any minor discomfort experienced by a small number of rabbits. Covelli answered that although there was no known long-term harm caused to the rabbits, covering up such a flagrant disregard for animal welfare and federal animal care standards was contrary to the charge of the IACUC and could lead to even more significant problems. Covelli’s response was not what McGregor had expected. He stood up at his desk, rolled up his sleeves, puffed out his chest and calmly but firmly told Covelli that, in his opinion, the problems that the IACUC found were minor because no harm came to the animals, that the researcher’s job was to do science and not to fix the heating system and that he had no intention of siding

with the IACUC. Rather, he told Covelli to spend whatever money was needed to fix the heat problem and then get on with approving protocols. Covelli tried to have some additional discourse but McGregor was not willing to do so.

Covelli related his meeting with McGregor to the IACUC. He said that he understood he was dealing with a new IO who was trying to gain favor with investigators and that McGregor had to learn more about his IO responsibilities. Nevertheless, he recommended sending a report to USDA/Animal Care and NIH/OLAW, even though the IO would not sign it. Not everybody was in agreement. Some felt that if the IO and the IACUC were not in agreement, a report could not be sent. Others were more pragmatic and said that because the goal was animal welfare, and not fights with the IO, now that they had funding to fix the problem, they should do that and let the disagreement become history.

What is your opinion? How would you resolve the problem facing Great Eastern University?

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RESPONSE

Do not pass go without the IO

Susan A. Iliff, DVM, DACLAM, CPIA & Pam Straeter, MS, RLATG

Covelli and McGregor are at an impasse. We feel the key to resolution of the disagreement is further communication between the IACUC, Institutional Official (IO) and Attending Veterinarian (AV). It is notable that the AV’s involvement is absent in this scenario. The central focus in resolving the conflict should be the standard set forth in the Animal Welfare Act (AWA) governing the use of animals in research. The AWA defines whether a deficiency is significant or minor and addresses the reporting

obligations of organizations that use animals in research. The law defines a significant deficiency as one that “in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals” (§2.31c3)¹. The semiannual report should represent the IACUC’s perspective on whether deficiencies are significant or minor and must include minority views. The regulation requires that the IACUC’s report contain a plan and schedule for correction of each deficiency, whether significant or minor, and requires that a significant deficiency be promptly addressed and remedied.

An ambient temperature of 88 °F without auxiliary ventilation exceeds the threshold of 85 °F set as appropriate for animal health (§3.51b)^{1,2}. This deficiency, observed on more than one occasion, is significant. The most immediate solution would be moving the animals to appropriate housing. Using

available funds to modify the satellite room for appropriate animal housing is an option but does not provide prompt resolution of the problem.

It is unclear what, if any, action was taken when the significant deficiency was first identified during the inspection. If a reasonable and specific plan and schedule for correction of the previously identified deficiency was not followed, this should have been “reported in writing within 15 business days by the IACUC, through the Institutional Official, to APHIS [Animal and Plant Health Inspection Service] and any Federal agency funding that activity” (§2.31c3)¹. The IO’s concern with the potential to damage the school’s image is inappropriate and misplaced. The IO’s role is to uphold the organization’s commitment to animal welfare and animal well-being. The IO needs to understand the gravity

of significant programmatic and facility deficiencies, to resist being bullied by the researcher's complaints and to understand and embrace the value and purpose of the IACUC's role and responsibilities in ensuring animal welfare in research.

The AWA¹ and Public Health Service *Policy on Humane Care and Use of Laboratory Animals*³ are clear in their expectations that reporting of significant deficiencies and serious deviations to USDA/APHIS/Animal Care and other federal funding agencies should be accomplished by the IACUC through the IO. If the scheduled plan to relocate the rabbits to appropriate housing is not followed, this should be reported to APHIS and NIH/OLAW. It is critical that the IACUC and IO communicate with regulators using one voice; thus additional efforts must be expended to align the IO's understanding of the regulation's definition of minor versus significant deficiencies. The IACUC and IO should avail themselves of additional resources (e.g., dean, chancellor, clinical veterinarian, ombudsman) to resolve the conflict.

1. Code of Federal Regulations. Title 9, Chapter 1, Subchapter A – Animal Welfare. Part 2, Regulations.
2. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2010).
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).

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RESPONSE

IACUC must report

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The Great Eastern University IACUC has documented significant deviations from animal housing requirements on two occasions, discussed them in a convened meeting and voted that these findings constitute serious and continuing noncompliance. There is ample justification for this determination. The housing

A word from USDA and OLAW

In response to the questions posed in this scenario, the United States Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care (USDA, APHIS, AC) and the Office of Laboratory Animal Welfare (OLAW) offer the following clarification and guidance:

The Animal Welfare Act Regulations under CFR section 2.31(c)(3) and the Public Health Service (PHS) *Policy on Humane Care and Use of Laboratory Animals (Policy)* in section IV.B.3 indicate that the IACUC semiannual reports must distinguish significant deficiencies from minor deficiencies and provide a specific plan and schedule for correction^{1,2}. Under CFR section 3.51(b), auxiliary ventilation such as exhaust fans, vents or air conditioning shall be provided when the ambient temperature is 85 °F or higher¹. The *Guide for the Care and Use of Laboratory Animals (Guide)* recommends a dry-bulb temperature range for rabbits of 61–72 °F and cautions that ventilation systems should maintain temperatures within 2 °F (ref. 3). Lack of auxiliary ventilation is a clear departure from the regulatory requirement and *Guide* standards, may result in distress and poses a threat to the health and safety of the animals. The semiannual report should therefore indicate the finding as a significant deficiency and include a plan and schedule with dates for correction.

The scenario relays that the IACUC labeled the problem as a “repeated significant deficiency”, but it is unclear whether the original discovery of the problem resulted in the creation of a specific plan and schedule for correction. Under CFR section 2.31(c)(3), USDA/APHIS and the federal funding agency are to be notified in writing and within 15 business days (of detection of the problem) by the IACUC through the Institutional Official (IO) when there is a failure to adhere to a prescribed plan and schedule to correct a significant deficiency¹. The PHS *Policy* in section IV.F.3 requires the IACUC through the IO to promptly report the circumstances and actions taken with respect to any serious or continuing noncompliance with the PHS *Policy* or deviation from the *Guide*². The regulations and PHS *Policy* clearly state that there must be a formal plan in place. A report from the IACUC through the IO to USDA is indicated if this deficiency had not been corrected according to the specific plan and schedule in the semi-annual report. The regulations under CFR section 2.35(f) and the PHS *Policy* in section IV.E require the findings of the semiannual inspections to be documented in the semiannual reports, the deliberations of the IACUC to be recorded in the IACUC minutes, and the records of these activities to be available for inspection by an authorized APHIS or federal funding agency representative^{1,2}. The IACUC must be empowered by the Chief Executive Officer of the institution to perform its duties without undue interference⁴. As signatory on the Animal Welfare Assurance, the IO is held responsible for ensuring compliance with the reporting requirements of the PHS *Policy*.

It is important to note that APHIS/Animal Care is always available for consultation and therefore encourages an open dialogue at any level of the agency in the event an institution is seeking direction on an issue. Likewise, OLAW welcomes reporting inquiries and will provide guidance with regard to specific situations. More detailed guidance on reporting noncompliance can be found on the OLAW Reporting Noncompliance webpage (http://grants.nih.gov/grants/olaw/reporting_noncompliance.htm).

1. Code of Federal Regulations. Title 9, Chapter 1, Subchapter A – Animal Welfare: Part 2 Regulations.
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington DC, 1986; amended 2002).
3. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2010).
4. Office of Laboratory Animal Welfare. *Institutional Animal Care and Use Committee Guidebook* 2nd edn. 32 (US Department of Health and Human Services, Bethesda, MD, 2002).

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conditions fall well outside the parameters of the Animal Welfare Act (AWA)¹ and the *Guide for the Care and Use of Laboratory Animals* (the *Guide*)². High temperatures and poor ventilation pose risks to animal welfare and research variables by rendering animals more susceptible to disease. These conditions create occupational health concerns by exposing workers to high ammonia levels and to animal allergens due to increased shedding at higher temperatures^{3,4}. Finally, the failure to correct the housing conditions after the initial finding is, in and of itself, reportable, as stated in OLAW's *Guidance on Prompt Reporting*⁵. Therefore, the IACUC is obligated to report the deficiency to OLAW and USDA unless the inspection findings themselves are shown to be in error.

Ethics aside, the satellite inspections and meeting minutes are matters of record and are therefore available to any diligent Veterinary Medical Officer or site visitor from the Association for the Assessment and Accreditation of Laboratory Animal Care; their discovery by an outside regulatory or accrediting agency in the absence of corresponding incident reports could raise embarrassing questions about Great Eastern's ability to act in the best interests of the animal care program. Certainly, incident reports should state that corrective action has been taken by moving

the rabbits to more appropriate housing, and funds have been allocated to bring the satellite facility up to code.

The stickier issue is the threat from the Institutional Official (IO) to withhold his signature from the incident reports. Although the IO has ultimate responsibility for the animal care program, he or she does not have authority over the IACUC. The duties of the IO are to ensure that the animal care program follows the requirements of the *Guide* and the AWA, to align the animal care program with the institutional mission and to allocate the resources needed for the program's successful execution^{1,2}. We would argue that the IO has no right to withhold his signature, unless the reports contain factual errors. His refusal could be interpreted as obstruction of the IACUC's business and a betrayal of his fiduciary responsibility to Great Eastern. If the IO is obdurate, the University's IACUC office or Office of Research Risk Management should submit the reports without his signature.

Most compliance problems present opportunities to edify the unenlightened, and this one is no exception. For expertise the IACUC need look no further than their committee members. The Attending Veterinarian can delineate the negative impacts of unstable housing conditions on research variables and animal welfare. The IACUC chair can clarify the roles of the

IACUC and the IO. And the community member can warn of the damage to the public trust that results when undisclosed violations are later discovered by regulators or leaked to the public by whistleblowers. Perhaps a delegation of these individuals can meet with the principal investigator, the IO and the more uncertain committee members to bring everyone to a common understanding of their respective responsibilities to the animal care program.

1. Code of Federal Regulations. Title 9, Chapter 1, Subchapter A. Part 3.51, Facilities, indoor.
2. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2010).
3. National Research Council. Allergens. in *Occupational Health and Safety in the Care and Use of Research Animals* chap. 4 (National Academies Press, Washington, DC, 1997).
4. American Association for Laboratory Animal Science. Rabbits. in *ALAT Training Manual* chap. 23 (AALAS, Cordova, TN, 1998).
5. Office of Laboratory Animal Welfare. *Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals*. Notice NOT-OD-05-034. (National Institutes of Health, Washington, DC, 24 February 2005, updated 15 April 2010). <<http://grants.nih.gov/grants/guide/notice-files/not-od-05-034.html>>

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