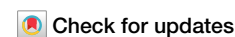


The risk of oversight



A clear organizational reporting structure within the Animal Care and Use Program and a collegial working relationship between the Institutional Official, Attending Veterinarian and Institutional Animal Care and Use Committee are essential to maintain the highest standards of animal wellbeing and research quality. We invited experts from The Feinstein Institutes for Medical Research (Michelle Aparicio) and Rice University (Sarah Viranda and Elyse Ann Orchard), along with USDA and OLAW representatives (Louis DiVincenti and Axel Wolff), to respond to a challenging situation at Great Eastern University.

Great Eastern University (GEU)'s Animal Care and Use Program (ACUP)'s Institutional Official (IO) recently retired and Dr. Opinber, the new IO, asked to meet with Dr. Amoralus, the Attending Veterinarian (AV); Dr. Crick, GEU's IACUC Chair; and Gwen Skladnost, the IACUC Administrator and Director of the IACUC Office.

Opinber, who is new to animal research oversight, was interested in discussing the organizational structure of GEU's ACUP based on her review of prior semi-annual inspection evaluations and an article she discovered by Dr. Van Sluyters¹.

Opinber started the meeting by identifying and questioning the ACUP reporting structure. Specifically, while she understood her responsibilities as the IO, she wanted to confirm that: Amoralus, as the AV, was responsible for ensuring animal health and wellbeing; the IACUC, with leadership from Crick, oversaw the ACUP; and, Skladnost worked hand-in-hand with the IACUC, providing the regulatory expertise needed to ensure the committee could in-fact validate that the ACUP was compliant. Opinber added that Skladnost, who she considered the compliance director, reported to Amoralus. All agreed with her assessment.

Opinber then explained that, as part of her new role, she reviewed past ACUP compliance

records, the official reports and raw data. Needing clarification, she asked why, for example, data in the files she requested from Skladnost didn't align with the findings listed in the semi-annual report to the IO, adding that the IO report seemed to exclude deficiencies discovered in vivarium spaces.

The group collectively explained to Opinber that issues in the vivarium were often resolved prior to drafting the IO report and were subsequently left out of the official document. Opinber asked if that process was also made available to researchers when deficiencies were found and quickly resolved in their areas. Crick and Amoralus responded no, whereupon the meeting ended due to scheduling conflicts. Skladnost, however, stayed behind to explain to Opinber that Amoralus, her supervisor, was persistent that issues identified in the vivarium didn't need to be included in the IO report as long as they were corrected. Skladnost explained that she didn't agree with this process but, as Van Sluyters pointed out¹, programmatic shortcomings are often not addressed as they need to be. She also felt her job security was threatened when she challenged Amoralus' decisions or interpretations of the regulations. Opinber thanked Skladnost for her candidness but could offer no immediate solution.

If you were asked to advise Opinber, what would you tell her?

When the AV is in a position of authority over the IACUC Administrator/compliance office, what are the risks and/or benefits (e.g., potential or real conflict(s) of interest) to the ACUP, and why?

Response from MA

I do not think it is best practice to have the IACUC Administrator report to the AV. That can be a real or a perceived conflict of interest. The IACUC Administrator is a research regulatory compliance professional. That type of ACUP organizational structure is an example of the fox minding the henhouse. While there are no regulations that says the IACUC Administrator/compliance office shouldn't report to the AV, that structure can give the impression that the AV and staff control the program.

The IACUC has the federal mandate for program oversight. No one can subvert the IACUC's authority. The AV is responsible for managing

the Program of Veterinary Care. The IACUC's oversight includes assessing the Program of Veterinary Care. The IACUC Administrator/compliance office typically is responsible for managing the assessment process; therefore, to ensure transparency and complete impartiality, the person responsible for a critical program component like the Program of Veterinary Care should not have any authority over that individual or that process.

The IACUC Administrator felt her job was threatened and informed the IO that the AV was persistent that issues identified in the vivarium didn't need to be included in the IO report as long as they were corrected. One could argue the scenario is a perfect example of why the IACUC Administrator should not report to the AV. However, that would imply all AVs would engage in that type of unethical behavior, which is not fair. The pressure the AV put on the IACUC Administrator demonstrates, in this case, a failure to observe standards, lack of assuming accountability and transparency and a questionable character. No one, especially those in a leadership position, should have the attitude of "rules for thee, but not for me". That behavior only fuels division and contributes to a toxic culture. An ideal program of post-approval monitoring, quality assurance/quality improvement is a positive initiative that results in the collection of actionable data which serves to identify areas in which a program can improve. It is quality control/quality improvement, not criticism. It is an opportunity to evaluate all program components and processes; determine why things are occurring; refine existing processes; or develop new processes, as needed; learn what is needed and strive to improve. There is no need for anyone to take anything personally; no need to hide findings or observations; just learn what you can, and move forward. Visible signs of disorder and misbehavior in an environment encourage further disorder and misbehavior, leading to bigger problems. If you take care of the little things, the big things take care of themselves. Targeting and addressing the little things fosters an atmosphere of order and compliance.

No one individual should be allowed to have an outsized influence on the program. Everyone's role is important to the success of the program and all components should be working collaboratively. It doesn't benefit the culture of program

Box 1 | A Word from OLAW and USDA

In this scenario, a newly designated Institutional Official (IO), learned that the standard Great Eastern University (GEU) procedure excluded deficiencies identified during the semiannual facility inspections, but were resolved prior to drafting the semiannual report. The IO also became aware that within the chain of command in the organizational structure of GEU's Animal Care and Use Program (ACUP), the IACUC Administrator expressed fear of reprisal for questioning the authority of her direct supervisor, the Attending Veterinarian (AV).

Response from OLAW

The Public Health Service (PHS) [Policy](#) on Humane Care and Use of Laboratory Animals IV.B.3 requires that the semiannual report to the IO distinguish significant deficiencies from minor deficiencies and contain a reasonable and specific plan and schedule for correcting each deficiency³. The report must also include a description of the nature and extent of the institution's adherence to the *Guide for the Care and Use of Laboratory Animals* and the PHS Policy. Departures from provision of the *Guide* and the PHS Policy must be identified, along with reasons for each departure. Minority views and identification of facilities that are accredited by AAALAC International must also be included in the report. It is further stated in the *Guide* (page 25) that "After review and inspection, a written report (including any minority views) should be provided to the IO about the status of the Program⁴." GEU's omission of significant and/or minor deficiencies identified during the semiannual facility inspections are considered noncompliant with the requirements of the PHS Policy and may impair the ability for the institution to identify and address programmatic issues.

OLAW and the *Guide* (page 24) require that institutions develop methods for reporting and investigating animal welfare concerns, with procedures or policies

in place for maintaining anonymity, if requested, and protection against reprisal to the individual(s), who in good faith, reports an animal welfare concern⁴. If a robust animal welfare concerns process was in place at GEU, depending on the circumstances, this may have provided the IACUC Administrator the option to anonymously report animal welfare concerns with the omitted deficiencies.

ACUPs managed in accordance with the PHS Policy, *Guide* and the Animal Welfare Regulations (AWRs) function effectively, with clearly defined roles that align responsibility with regulatory and management authority². Although overall program direction should be a shared responsibility among the IO, AV and IACUC, the IO bears ultimate responsibility for the program and is responsible for resource planning and ensuring alignment of program goals with the institution's mission. There should be open and direct lines of communication between the IO, the AV and the IACUC. Practically speaking, the AV is responsible for the health and wellbeing of the animals and the IACUC for ensuring ongoing program compliance through oversight. The IACUC Administrator (i.e., Compliance Specialist) contributes to the IACUC's responsibilities by providing administrative support, regulatory advice, and coordinating communication among the IO, IACUC and AV.

A collegial and effective working relationship between the IO, IACUC and the AV enhances resource efficiency while maintaining the highest standards of animal wellbeing and scientific quality. However, it is equally important that the potential for real or perceived conflicts of interest is circumvented while maintaining this relationship. The IACUC must report directly to the IO and be empowered to perform its duties without undue interference. While there is no prohibition in the PHS Policy for GEU's AV to serve as the

IACUC Administrator's direct supervisor, this practice is strongly discouraged if it presents a conflict of interest that places the IACUC Administrator in an untenable position. To provide the intended checks and balances in the system of self-regulation, it is advisable that GEU's IO reevaluate the current reporting channel(s), while avoiding any potential conflicts of interest and retaliation.

Response from USDA

Under the AWRs, the IACUC is responsible for assessing the research facility's animal program, facilities and procedures⁵, while the AV is responsible for providing adequate veterinary care to the animals at the research facility⁶.

The AWRs require the IACUC, as an agent of the research facility, to inspect all of the research facility's animal facilities, including animal study areas, at least once every six months, using the regulations and standards found in Title 9, Chapter 1, Subchapter A of the Code of Federal Regulations as a basis for the inspection⁵. As a result of this evaluation, the IACUC must prepare a report that contains a description of the nature and extent of the research facility's adherence to the regulations⁵. Additionally, the report must "identify specifically any departures from the [Animal Welfare Regulations] and must state the reasons for each departure⁵." Finally, the report must be submitted to the IO⁵.

All departures from the AWR identified by the IACUC as part of the semiannual inspection process must be included in the report to the IO, regardless of how quickly such departures are subsequently corrected. It is important that the IACUC fully inform the IO about non-compliance at the facility. This information is required for the IO, as the individual who legally commits that the research facility will comply with the AWR, to ensure the entire research facility maintains compliance⁷.

to point fingers and work in silos. Transparency, integrity and collegiality are paramount. The risks associated with the AV being in a position of authority over the IACUC Administrator/compliance office outweigh any benefit. Perceiving a conflict of interest does not make it a conflict of interest. The IACUC Administrator must be

able to manage the overall animal care and use program of compliance without a relationship that directly or indirectly impacts decision-making. An organizational structure with a clear separation of powers serves to insulate and protect the program, prevent encroachment and any appearance of impropriety.

Response from SV and EAO

If you were asked to advise Opinber, what would you tell her?

After review and inspection, OLAW requires a written report to the IO describing facility deficiencies including the vivarium. These findings are either significant (i.e., a threat to animal

health or safety) or minor with a schedule for correction. The report should include input from all program members, including minority views, to ensure any issues, resolutions and preventive measures are included. Where disagreements occur, it is critical to have well-defined institutional policies communicated to members of the animal care program through training. These policies should detail the process of conducting inspections and specify the contents of the final report. Opinger needs to ensure that the concerns raised by Skladnost will be addressed by the IACUC and that concerns for job security are protected under the institutional whistleblower policy. It is important for Opinger to ensure that deficiencies reach the IACUC. Opinger is obligated to ensure effective institutional oversight and whistleblower protections.

When the AV is in a position of authority over the IACUC Administrator/compliance office, what are the risks and/or benefits (e.g., potential or real conflict(s) of interest) to the ACUP, and why?

There is no universally accepted structure of an ACUP. Institutional policies and expectations for the ACUP will mitigate potential risks to animal welfare. There are potential risks and benefits when an AV holds a position of authority over the IACUC Administrator. If the AV is the authority and influences measures taken to address issues before the IACUC reviews them, this arrangement could diminish the ACUP oversight. If conflict arises interpreting regulations and policies, IACUC intervention will provide a comprehensive perspective from committee members. Concerns raised regarding documentation of findings, conflict of interest and perceived retaliation could change the culture to a culture where personnel are afraid to report concerns. If policies allow for the administrator to present these directly to the committee, the IACUC will be allowed to evaluate them.

The benefits of the administrator reporting to the AV is efficient communication and coordination between animal care, veterinary oversight and regulatory compliance. The institution gives the AV authority on animal welfare. The AV, through training and experience, oftentimes is the expert in the management of laboratory animal research programs. This training provides opportunities for collaboration, resulting in the successful and ethical conduct of research that supports the 3Rs (i.e., replacement, reduction, and refinement).

The use of animals in research is a privilege. Personnel involved must adhere to federal, state and humane principles and veterinary care standards. Policies and procedures that define organizational structure and codes of conduct

support collaborative dialogue. The institutional oversight body must provide whistleblower protection for welfare concerns. Training on current information, ethical considerations and awareness of potential conflict of interest at every level of the animal care program is imperative. Everyone must understand their responsibility to uphold ethical animal care and use standards. Regardless of the organizational reporting structure, having clear and transparent policies and guidelines and a guarantee of no retaliation will ensure the prioritization of the ethical treatment of animals in research activities.

Compliance considerations

The Protocol Review coordinators (LD and BG) offer the following compliance considerations:

The use of animals in research, teaching and testing is a unique type of activity; unlike human patients, animals cannot consent. Thus, the federal mandates demand, on behalf of the animals, that animal activities be conducted in compliance with the standards developed to ensure humane and ethical care and use. These standards are not limited, for example, to the appropriate use of anesthesia and analgesia, cage size and sanitization schedules; they also dictate the organizational structure for oversight and administration of the IACUC's functions. Specifically, there are three named components: the IACUC, the IO and the AV.

Since the implementation of the Animal Welfare Act and PHS Policy, ACUPs have evolved with a complexity that was then unimaginable. Along with extraordinary technological advances, the advent of the 'IACUC Administrator' forever changed the face of ACUP administration and oversight (i.e., a label that now describes an individual who is a subject matter expert in the regulations governing animal care and use and compliance, and serves the IACUC, the IO, and the institution in an unbiased manner to ensure compliance and adherence to all federal, state and institutional requirements). Unfortunately, the federal standards have not kept pace; there has been no regulatory reform to officially acknowledge this critical role in ACUPs. Consequently, this lack of evolution in the regulations continues to facilitate improper organizational structures, such as GEU's, wherein the ability of IACUC Administrators (i.e., Compliance Specialists) to satisfy the expectations of this evolved role is compromised by inherent conflicts of interest.

The character, caliber and integrity of any employee enormously impacts the quality of the department, unit, or company – e.g., a poor manager yields unhappy employees, which leads to poor performance and output. As Van Sluyters

points out¹, the same holds true for the IO and AV; but the ethical component of using animals adds even more concern for appropriate organizational structures of ACUPs to eliminate any perceived or actual conflict of interest (e.g., because the AV has "direct or delegated program responsibility to the IACUC"²); it would be difficult for the AV to have authority over the IACUC Administrator who also serves the IACUC and manages a large part of the program's compliance).

The 'elephant in the room' in this scenario often results in the silencing of ACUP members because of power struggles, personalities and politics – e.g., students and post-docs worry about poor recommendations if they speak up about animal welfare concerns; some animal care and use personnel's ability to report animal-related concerns may be impeded by management expectations; and technicians are worried about disciplinary action for not following orders. When IACUC Administrators are deprived of an uninhibited authority to address these (and many other) ethical and morality issues, they themselves are silenced and become less effective in their critical ACUP role.

A Word from OLAW and USDA

Comments from OLAW and USDA can be found in Box 1.

This protocol review was coordinated by Lauren Danridge and Bill Greer.

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Competing interests

The authors declare no competing interests.

Disclaimer

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