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## IACUC approval of SOPs

There is a burning desire within the hearts of some animal facility managers to have the IACUC approve each of the facility's Standard Operating Procedures (SOPs), every informal operating policy, every food ration used, and so forth. This is balanced by an equally strong desire of other facility managers to work cordially but at an arm's length from the IACUC. In the latter managers' opinions, the job of the IACUC is to oversee the program of animal care and use as it relates to federal regulations, and nothing more. Not surprisingly, both groups have trouble seeing the other's viewpoint.

At Great Eastern University, the difference in opinion was not among animal facility managers but between the facility director and the IACUC chairman. Dr. Bernard Koul, the animal facility director, believed that the IACUC had an obligation to assure that husbandry and veterinary care for laboratory animals met or exceeded the minimum standards of the *Guide for the Care and Use*

of *Laboratory Animals* (the *Guide*)<sup>1</sup> and the Animal Welfare Act regulations<sup>2</sup>. He had no problem with the IACUC reading the animal facility's SOPs and offering suggestions for improvements, but he did not believe that the IACUC had any authority to approve those SOPs or require changes that went beyond federal regulations. He quoted the section of the Animal Welfare Act regulations that states that an IACUC is to evaluate the care, treatment, housing and use of animals and to certify compliance with the Animal Welfare Act<sup>3</sup>. Koul also said that section 495 of the Health Research Extension Act of 1985 (which requires an IACUC for research funded by the Public Health Service)<sup>4</sup> said nearly the same thing and was focused on compliance with the Act, not on the approval of SOPs by the IACUC.

Dr. Larry Covelli, the IACUC chairman, disagreed with Koul. Covelli said the Health Research Extension Act and the *Guide* required the IACUC to oversee and evaluate animal care and use activities. The Animal

Welfare Act regulations, he said, required a similar review and also referred to animal activities, not just research protocols. In his opinion, approving SOPs that focused on animal activities were well within the scope of the IACUC's responsibility and authority.

Both Koul and Covelli concurred that the IACUC had an oversight and evaluation responsibility for husbandry and veterinary care issues but, using the same documents for their justification, they disagreed on the issue of the IACUC's authority to approve SOPs. What is your opinion and how would you resolve this impasse?

1. Committee for the Update of the Guide for the Care and Use of Laboratory Animals. *Guide for the Care and Use of Laboratory Animals*. 8th edn. (National Research Council, Washington, DC, 2011).
2. Animal Welfare Act. Public Law 89-544. 7 U.S.C. 2131 *et seq.*
3. Animal Welfare Act Regulation. 9 CFR, Part 1. Definitions: *Committee*.
4. Health Research Extension Act of 1985. Public Law 99-158. Sec. 495.

### RESPONSE

#### Review animal welfare SOPs

Cindy Horner, BS, CPIA, CMAR, RLATG & Marie McKeon, MPhil, DABT

Should IACUCs as mandated by the Animal Welfare Act (AWA)<sup>1</sup>, the Public Health Service *Policy on Humans Care and Use of Laboratory Animals* (PHS *Policy*)<sup>2</sup> and the eighth edition of the *Guide for the Care and Use of Laboratory Animals* (the *Guide*)<sup>3</sup> have the authority to approve Standard Operating Procedures (SOPs)? Our IACUC is currently reviewing this question. The IACUC members, fully familiar with federal regulations and the *Guide*, are an institution's subject matter

experts. The IACUC provides regulatory compliance guidance; serves as a resource to facility management on animal welfare issues; provides valuable input to the facility management concerning the interpretation of issues covered in the *Guide*; and provides scientific and ethical knowledge of a range of procedures.

The IACUC has a federal mandate in its function as described in the AWA and PHS *Policy*. Section 2.31 (4)(c)(1) of the AWA states that the IACUC should "review, at least once every six months, the research facility's program for humane care and use of animals..."<sup>1</sup>. Section 495(b)(1) of the PHS *Policy* requires "animal care committees at each entity which conducts biomedical and behavioral research with funds provided under this Act (including the US NIH and the national research institutes) to assure compliance with the

guidelines established..."<sup>2</sup>. The PHS *Policy* goes on to state in section 495(b)(3)(A) that the IACUC should "review the care and treatment of animals in all animal study areas and facilities of the research entity at least semiannually to evaluate compliance with applicable guidelines established..."<sup>2</sup>. In addition, the *Guide* states that "the IACUC is responsible for providing oversight and for evaluating the effectiveness of the training program"<sup>3</sup>.

The review and assurance of compliance of the animal program by the IACUC includes reviewing SOPs during the Semi-Annual Program and Facility Inspection at a minimum, or more often as necessary, as well as reviewing the policies by which an organization affirms its compliance with the AWA and the *Guide* and trains its staff. The IACUC, or at least one designated member (such as the veterinarian),



should be involved in reviewing any SOPs involving euthanasia, animal welfare (such as housing, humane endpoints, blood collection, dosing, handling and restraint), health and safety, facilities (such as environmental and HVAC parameters) and operations (such as cagewash and autoclave operations), areas that are required as part of an animal welfare program.

The *Guide* states twice that the IACUC should approve methods of euthanasia<sup>3</sup>.

To resolve this issue, the IACUC should develop an internal position statement endorsed by the Institutional Official regarding policy and SOP review and approval for the elements of the animal welfare program.

1. Animal Welfare Act. Public Law 89-544. 7 U.S.C. 2131 *et seq.*
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. Committee for the Update of the Guide for the Care and Use of Laboratory Animals. *Guide for the Care and Use of Laboratory Animals*. 8th edn. (National Research Council, Washington, DC, 2011).

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## RESPONSE

### Self-control and institutional culture

**Mario C. Rodriguez, DVM, MS**

Both the Animal Welfare Act (AWA) and its policies<sup>1</sup> and the eighth edition of the *Guide for the Care and Use of Laboratory Animals* (the *Guide*)<sup>2</sup> have the inherent intention for an animal research institution to self-govern and regulate its animal care and use program (Program). An IACUC is, within the scope of federal guidelines and regulations, required to create its own regulations, the Program's regulations. The extent of this self-regulation is determined by the committee, its members and the Institutional Official.

The IACUC, as per AWA and the *Guide*, is not required to approve Standard Operating Procedures (SOPs) in the animal facility. In this respect, Koul's opinion is right. But the IACUC can approve SOPs, if

it decides that this task is part of its duty as the overseer of the Program.

Covelli is correct that the IACUC is responsible for overseeing not just research protocols but the whole Program. The *Guide* defines the Program as "the activities conducted by and at an institution that have a direct impact on the well-being of animals..."<sup>2</sup>. Animal husbandry and any SOPs detailing animal care and management are part of the Program and thus within the scope and responsibilities of the IACUC.

Given the previous information, the IACUC has the authority to create a policy requiring committee approval of any SOP in the animal facility. Koul is wrong and Covelli is right, as long as he has the committee's support. Covelli cannot unilaterally decide that the IACUC is required to approve the SOPs; the whole committee should approve such a policy. It is also true that the IACUC will not be held accountable by regulatory entities such as USDA, OLAW or AAALAC International for approving any SOPs; it is not a written regulation.

On the other hand, I feel it is important for animal research facilities to have an organizational 'culture' that emphasizes animal care and welfare; this goes hand in hand with trusting their hiring process and the animal care professionals they hired. A self-created policy that requires the IACUC to review all facility SOPs before implementation could put animal care and welfare at risk, because of the bureaucracy and time involved with IACUC approval of a modification to an SOP. We know that this happens; a facility manager, veterinarian or other staff member might make decisions that deviate from SOPs in order to assure animal welfare or accommodate an unforeseen situation. There must be a process to allow for such short-term decisions.

The NIH looked into this matter some time ago, concluding that if regulations become excessive, the work culture may change to circumvent the spirit of the law rather than trying to comply with it. This issue plagues larger organizations, resulting in less compliance with increased regulation.

Finally, IACUCs are required to inspect their facilities and review their Program Description at least twice per year; these inspections (adding reports and complaints

from users or care staff) are very good opportunities for the committees to identify adverse situations and reevaluate how things are done, thus triggering SOP reevaluations.

1. Animal Welfare Act. Public Law 89-544. 7 U.S.C. 2131 *et seq.*
2. Committee for the Update of the Guide for the Care and Use of Laboratory Animals. *Guide for the Care and Use of Laboratory Animals*. 8th edn. (National Research Council, Washington, DC, 2011).

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## RESPONSE

### Does approval add value?

**Sai Tummala, DVM, MS, DACLAM, CPIA**

The impasse at Great Eastern University stems from different interpretations of the regulations regarding IACUC approval for all animal facility Standard Operating Procedures (SOPs). Covelli and Koul disagree about the practical implementation of the regulations but share their intent for the IACUC to ensure delivery of quality animal care, regardless of the approval process for SOPs. The quality of animal care and welfare could be best assessed and evaluated by the IACUC either by semiannual review or by periodic evaluation of the program. The performance outcome of animal facility operations, as measured against the benchmarks for the quality of care and animal welfare, should be the standard metric for IACUC to evaluate SOPs and recommend any changes. When the performance in delivery of quality animal care and regulatory compliance is not compromised, then the IACUC requirement for prior approval of or recommendation of changes to the facility SOPs is unwarranted. In this scenario, Covelli should evaluate the program's quality of animal care to determine whether changes to any SOPs are needed; he should not just request prior approval without metrics, which may not add value to the process.

There is great advantage in using benchmarks for quality of animal care as the performance standard for the effectiveness

of operational processes and SOPs. An animal facility is a hotbed of activity where daily operations include inventory and supply chain management, efficient scheduling and use of shared resources, supplier–vendor relations and management of staff and customer relations. Above all, the use of laboratory animals is governed by an interrelated, dynamic system of regulations, policies, guidelines and procedures from different bodies, creating a complex blend of responsibility and authority among different entities at the institution. Regulatory compliance, a critical aspect of animal program management, is shared among the Institutional Official, Attending Veterinarian (AV) and IACUC. There are several paths to achieving the outcome of quality animal care within regulatory compliance. The authority to make decisions based on professional

judgment and knowledge is provided to AVs by the Animal Welfare Act<sup>1</sup> and the *Guide for the Care and Use of Laboratory Animals*<sup>2</sup>. AVs with experience and training in laboratory animal medicine who are Facility Directors should have the authority and flexibility to choose the path that best suits each facility’s situation, without requiring approval from the IACUC. If Koul is the AV, then having the IACUC approve all operational SOPs, as Covelli requests, does not add value to the program, because Koul is the best judge and resource available to the institution for generating and implementing the animal care SOPs. Requiring IACUC approval of SOPs only creates bottlenecks and loop backs, which waste time and money and eliminate nimbleness and operational efficiency in the facility, creating hurdles for delivery of services to customers.

For decades, the process management pendulum has been swinging toward the standardization and control of facility operations due to questionable interpretations of regulations. It’s time to recognize the limits of such processes and consider where judgments based on performance standards, quality of animal care and operational efficiency should be restored or preserved.

1. Animal Welfare Act Regulation. 9 CFR, Ch. 1, 2.31, 2.33.
2. Committee for the Update of the Guide for the Care and Use of Laboratory Animals. *Guide for the Care and Use of Laboratory Animals*. 8th edn. (National Research Council, Washington, DC, 2011).

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## A word from OLAW and USDA

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

The Public Health Service *Policy on Humane Care and Use of Laboratory Animals* (PHS Policy) and Animal Welfare Act Regulations (AWARs) do not specifically identify the review and approval of animal facility Standard Operating Procedures (SOPs) as a requirement for IACUCs. However, SOPs are frequently a component of an animal care and use program because they efficiently define animal husbandry and veterinary care, set standards for equipment maintenance and are used in personnel training and quality assurance assessments. The authority to review SOPs is implied as part of the requirement for semiannual review of the program for humane care and use of animals<sup>1,2</sup>. The eighth edition of the *Guide for the Care and Use of Laboratory Animals* (the *Guide*) comments that “establishing standard operating procedures can assist an institution in complying with regulations, policies, and principles as well as with day-to-day operations and management”<sup>3</sup>. The *Guide* clearly defines the animal care and use program as including SOPs and assigns responsibility for regular review of the program to the IACUC<sup>3</sup>.

The PHS Policy and AWARs allow the IACUC to determine the best means of evaluating the research facility’s programs and facilities<sup>1,2</sup>. The IACUC should approach this responsibility by developing a policy that gives reasonable latitude for changes deemed necessary by the animal facility management and also limits the burden to the committee.

Some research facilities refer to SOPs in their training programs for scientists, research technicians, animal technicians and other personnel involved in animal care and treatment. Such SOPs should be evaluated by the IACUC to ensure that personnel are qualified to carry out their duties<sup>2</sup>. Some IACUCs allow investigators to reference SOPs in their protocols rather than provide a written narrative of common animal use procedures. Such SOPs should be reviewed by the IACUC at appropriate intervals for proposed activity review (at least once every three years according to PHS Policy or semi-annually, if they involve USDA-regulated species) to ensure that they are up-to-date and accurate<sup>2,4</sup>.

1. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986, amended 2002).
2. Code of Federal Regulations, Title 9, Chapter 1, Subchapter A – Animal Welfare: Part 2 Regulations. §2.31(c),(d 1 viii), (d-5), §2.32 (a) (b) (c 1 i-iv).
3. Committee for the Update of the Guide for the Care and Use of Laboratory Animals. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Research Council, Washington, DC, 2011).
4. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals –Frequently Asked Questions*. Protocol Review, Question No. D.14. (US Department of Health and Human Services, Washington, DC, 2006, revised 2010).

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