

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 euthanasia³.

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 policies¹ and the eighth edition of the *Guide for the Care and Use of Laboratory Animals* (the *Guide*)² 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..."². 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