

Jerald Silverman, DVM, Column Coordinator

## Conference wet lab: is an IACUC needed?

For many years the Eastern Veterinary Conference took place in a convention center located about 5 miles from the veterinary school of Great Eastern University. One of the most popular features of the conference was a wet lab on small ruminant (e.g., sheep, goats) anesthesia and analgesia. The lab, which was held on the premises of the University, focused on the training needs of private-practice veterinary technicians, although some Great Eastern research and veterinary technicians periodically attended. The school acted as a sponsor and overseer of the training lab, and the Great Eastern IACUC routinely reviewed and approved the training activity.

SOCRATES (Students Opposed to Cruel Animal Testing) was a campus group opposed to research and teaching using live

animals. It was also opposed to the wet labs. Originally viewed as little more than a nuisance to the veterinary school, over the years the group continued to petition and demonstrate to stop the wet labs. Eventually, the University administration decided that its time could be better spent on other matters and told the conference organizers to hold the labs elsewhere. This was not easy to do because there were no other animal-using institutions available. In desperation, the organizers decided to hold the wet lab within the convention center. “Why not?” said Bill Henry, the conference’s chairman, “There are live animal demonstrations and teaching at fairs, circuses, and other meetings. We can do the same thing.”

“And do they need IACUCs for these demonstrations?” asked Anne Goode, a member

of the organizing committee?

“I don’t know” Henry responded, “but I can find out. My guess is that none of them have IACUCs, because none of them use research animals. We’re pretty much in the same boat, just teaching folks how to work with small ruminants.”

“OK,” said Goode, “but I’ll bet we do need an IACUC, and if we do, I can envision all kinds of problems getting this plan to work. Let me know what you find out and we’ll take it from there.”

Does the Eastern Veterinary Conference even need an IACUC and IACUC approval to hold its live animal wet lab at the convention center? If it does, what are the critical hurdles to implementation that face Henry and his committee? How might they overcome them?

### RESPONSE

#### Agriculture exemption

Nirah H Shomer, DVM, PhD, DACLAM

There are three types of institutions that require an IACUC:

1. Institutions receiving Public Health Service (PHS) funds because PHS *Policy on Humane Care and Use of Laboratory Animals* (PHS *Policy*) requires adherence to the *Guide for Care and Use of Laboratory Animals* (*Guide*) and the *Guide for Care and Use of Agricultural Animals in Agricultural Research and Teaching* (*Ag Guide*), and both of these documents mandate an IACUC.

2. Institutions accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (because AAALAC generally uses the *Guide* as a basis of accreditation for institutions based in the United States).

3. Institutions that require an IACUC under the Animal Welfare Regulations (AWA).

The first two institutional types are evi-

dently not applicable, although the Eastern Veterinary Conference should carefully scrutinize their funding sources to ensure they are not receiving funds from any agency of the PHS. However, the AWA does need to be considered here. In researching this answer, I used the document “Licensing and Registration Under the Animal Welfare Act—Guidelines for Dealers, Exhibitors, Transporters, and Researchers<sup>1</sup>.”

The AWA covers a variety of activities with animals. The regulations may mandate licensing or registration, but an IACUC is a requirement only for institutions using animals in research, teaching, or testing. The United States Department of Agriculture (USDA) recognizes four major areas of activity: dealer, transporter, exhibitor, and researcher. The Eastern Veterinary Conference would not have the status of a ‘dealer’, unless it plans to sell the animals or give them away as prizes after the demonstration. The conference would not have the status of an animal ‘transporter’, although they should take care that the carrier they use is properly licensed. The wet lab is arguably an ‘exhibition’. There is an exemption for farm animal exhibits,

but this exemption does not apply if the animals are not being used for agricultural purposes; thus I believe this exemption does not apply because it is a hands-on teaching lab. Therefore, it appears that the organizers must obtain an exhibitor’s license for the wet lab. The wet lab does not have a fixed, year-round location, so it would have to follow the rules for a traveling animal show and provide an itinerary that would allow the USDA to inspect it on location.

Finally, the really relevant question is whether this usage would fall under the regulations for research, teaching, and testing. Although these animals are used for teaching, the regulations exempt agricultural research institutions. The guidelines state that “[r]esearch institutions that perform work involving food, fiber, or agriculture and that use horses and domestic farm animals, including rabbits, are exempt by regulation and do not have to be registered<sup>1</sup>.”

Does this wet lab meet the criteria for exemption? For further clarification, USDA Policy #26 (ref. 2) states that: “Farm animals, such as domestic cattle, horses, sheep, swine, and goats that are used for traditional, pro-

duction agricultural purposes are exempt from coverage by the AWA. Traditional production agricultural purposes includes use as food and fiber, for improvement of animal nutrition, breeding, management, or production efficiency, or for improvement of the quality of food or fiber.”

The wet lab subjects are agricultural species, and the wet lab itself is on medical management of these species (*i.e.*, rather than using them as models, the wet lab’s goal is to teach the proper methods of anesthetizing a farm animal). Consequently, this usage is ‘agricultural’ and thus exempt from the regulations that would require IACUC approval.

Was it appropriate in previous years, when the wet lab was held at the veterinary school, for the conference not to have been licensed as an exhibitor? In that case, because the activity was not open to the public I think it did not qualify as an exhibit. At a large teaching institution with an associated agricultural or veterinary school, there could be two IACUCs—one for biomedical research, constituted as outlined in the *Guide*, and one for agricultural research, constituted as outlined in the *Ag Guide*. If that was the case, then the latter should have reviewed this protocol.

I believe that the Eastern Veterinary Conference does not require an IACUC but does require an exhibitor’s license, held either by the conference or by the person(s) owning the animals and providing the wet lab. Other licenses may also be necessary; for example, if there is to be use of controlled substances it is important that they be handled by or under the direction of a veterinarian licensed by both the Drug Enforcement Administration (DEA) and the state equivalent. This might be a problem if the planned instructor is from out of state.

The conference would definitely need IACUC approval to conduct wet labs in non-agricultural species such as dogs, cats, and pocket pets. If they plan to conduct future meetings in the same geographic location and would like to expand their wet lab repertoire, it would be possible (but difficult) to form their own IACUC. An easier path would be to try to find an institutional partner (such as the veterinary school) to sponsor the event (off-site at the convention center if necessary) and provide IACUC oversight and review.

1. USDA. Licensing and Registration Under the Animal Welfare Act: Guidelines for Dealers, Exhibitors,

Transporters, and Researchers.  
2. USDA APHIS AC. Animal Care Policy #26. Regulation of Agricultural Animals (17 November 1998).

*Shomer is Director, Laboratory Animal Resources, Merck Research Labs, Boston, MA.*

## RESPONSE

### Convene a committee

**Tamara Goodman-Kuhel, RVT, RLATG**

One can assume that Great Eastern ceased sponsoring the Eastern Veterinary Conference. Therefore, the PHS *Policy* would not apply to this situation, because the funds most likely come from registration fees and private donations. One can also assume that the wet lab trainees are veterinary technicians who have graduated from an accredited college.

The AWA does regulate the use of ruminant species for teaching and research, and the use of regulated live animals for teaching beyond a secondary-school level qualifies as teaching or research. Therefore, the conference center must register with the USDA as a ‘research facility’, and the Institutional Official (IO) must appoint an IACUC to oversee the use of regulated species in the wet labs. Ideally, the Great Eastern IACUC could serve as their IACUC of record. If the school would rather avoid this choice because of the scrutiny of the animal rights activists, the IO must appoint another IACUC. The AWA regulations require only three members: a Chair and two additional members. Of the three members, one must be a veterinarian with training or experience in laboratory animal medicine and responsibility for the animal activities. Another member must be unaffiliated with the conference center or organizers of the conference. Henry could serve as the third member and Chair. Educating the IACUC to ensure compliance with AWA regulations could be a challenge, so Henry would be wise to find a well-experienced laboratory animal medicine veterinarian. Using an experienced consultant from the Great Eastern’s IACUC would be beneficial as well.

Once the Committee members have been appointed, they should inspect the areas in which live ruminants will be held or used,

and submit their report to the IO. Henry may encounter great difficulties identifying appropriate and compliant facilities in a conference center. He would have more flexibility with facility requirements if the animals are not housed and major survival surgery is not performed, both of which can be avoided in an anesthesia and analgesia wet lab.

Those conducting the wet lab should identify a Principal Investigator (PI) to complete a study proposal. The IACUC would then need to approve the proposal before animal use and also verify all wet lab staff are appropriately trained. The PI will hopefully be a veterinarian with a DEA license for the anesthetics and analgesics used in the wet lab.

Time may be the greatest hurdle for Henry and the IACUC. This entire process is new for him and the other organizers. He will have greater difficulties if he cannot use Great Eastern’s IACUC or find an experienced veterinarian and consultant. He must also allow time to research his state’s regulations, because there may be specific requirements for this scenario. Beginning the process as soon as possible is critical to compliant implementation.

*Goodman-Kuhel is IACUC Program Director, University of Cincinnati, Cincinnati, OH.*

## RESPONSE

### Satellite situation

**Amy J. Funk, DVM & Tiffani Rogers, DVM, DACLAM**

Whether the Eastern Veterinary Conference should form an IACUC for the sole purpose of the wet labs or should depend on the Great Eastern IACUC to provide oversight is negotiable. However, the Eastern Veterinary Conference does need an IACUC and subsequent IACUC approval to hold its live animal wet lab at the convention center.

The AWA defines an animal as any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warm-blooded animal, which is used, or is intended for use for research, teaching, testing, or exhibition purposes, or as a pet<sup>1</sup>. The AWA definition excludes birds; rats of the genus *Rattus* and mice of the genus *Mus* bred for use in research; horses not used for research

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purposes and other farm animals, such as, but not limited to livestock or poultry used or intended for use as food or fiber, or for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber<sup>1</sup>. Clearly, the farm animals proposed for use in this teaching lab meet the criteria for the definition of an ‘animal’. Federal regulations and commonly accepted guidelines that include the AWA, the PHS *Policy*, and the *Guide*, respectively, would be applicable<sup>1-3</sup>. (Implicit is the assumption that Great Eastern receives PHS funding.) Therefore, there is a mandate that the conference organizers have IACUC oversight. The AWA defines a housing facility to mean “any land, premises, shed, barn, building, trailer, or other structure or area housing or intended to house animals<sup>1</sup>”. PHS *Policy* defines an animal facility as, “any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours<sup>2</sup>.” The convention center would serve as a housing facility and procedure area for animals waiting to be used in the wet labs. The convention center’s ability to accommodate the environmental (temperature, humidity, lighting, etc.) and husbandry requirements and/or recommendations of the animals as stated in the AWA, and the *Guide*, respectively, would require compliance. The origin of the small ruminants that will be used for the wet lab is unclear from the scenario. Whether conference organizers acquired them from the veterinary school or purchased them from a commercial farm, responsibility for the animals occurs at the point of custody of the animals, and transportation, health, and husbandry standards must be satisfied in accordance with federal regulations<sup>4</sup>.

The conference organizers should consider whether the animals are going to be used in survival or nonsurvival procedures. If procedures are survivable, then the organizers will have to consider anesthesia, postprocedural analgesics and monitoring, as well as the number of procedures per animal, etc. The organizers should consider the method of transport of the animals to and from loca-

tions via suitable vehicles with controlled temperatures. Appropriate transportation crates or pens that provide adequate ventilation, as well as food and water requirements, as stated in the AWA, should also receive consideration. An animal protocol would provide detailed information for review by the IACUC to ensure that the animals are used appropriately for teaching purposes without sacrificing humane standards of animal welfare and care.

The Eastern Veterinary Conference organizers could ask for an exemption from the AWA as determined by the Administrator, especially if the number of animals used would not be substantial<sup>1</sup>. This may seem to be the easiest avenue for the organizers, but it is not the most prudent. It is not likely that an exemption would be granted, because to do so would vitiate the Act itself and set a precedent that the USDA would not want to promote for this type of activity<sup>1</sup>. Historically there is awareness and scrutiny of animals being used in this teaching lab by an animal rights group. It would be wise and manda-

tory for the organizers to have an IACUC-approved protocol to ensure oversight on animal care and welfare issues.

To initiate an IACUC solely because of the wet lab is not very practical; a better way to involve an IACUC is to have the convention center become a satellite facility of Great Eastern. This would create a balance between the University administration’s concern with avoiding public scrutiny and maintaining training opportunities through practical hands-on experiences.

1. Animal Welfare Act (7 USC 2131–2156).
2. Public Health Service. *Public Health Service Policy on Humane Care and Use of Laboratory Animals III* (US Department of Health and Human Services, Washington, DC, 1986; reprinted 2002).
3. Institute for Laboratory Animal Research, National Research Council. *Guide for the Care and Use of Laboratory Animals* (National Academy Press, Washington, DC, 1996).
4. Huerkamp, M.J. & Archer, D.R. in *The IACUC Handbook 197–198* (eds. Silverman, J., Suckow, M.A. & Murthy, S.) (CRC Press, Boca Raton, FL, 2000).

*Funk is Clinical Staff Veterinarian and Rogers is Clinical Staff Veterinarian, St. Jude Children’s Research Hospital, Memphis, TN.*

## 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 activities described in this scenario would require registration the USDA APHIS AC, as well as review and approval of the proposed animal activity by an IACUC. The training being conducted is considered to be biomedical, rather than agricultural, research (teaching). Agricultural teaching is conducted to improve farm or ranch management and includes such practices as hoof trimming and shearing. Biomedical teaching involves the training of human or veterinary medical personnel (e.g., veterinary technicians) in medical practices and methods (e.g., surgery, diagnostic techniques, anesthesia, and analgesia). When used for such teaching purposes, farm animals are considered to be regulated animals under the Animal Welfare Act.

In addition, as one respondent noted, if the Eastern Veterinary Conference sells the animals (or otherwise receives compensation in disposing of them), it may need to be licensed as a dealer. The conference would not be considered an exhibitor, because the compensation they receive is for providing medical training to the veterinary technicians, not for display of the animals.

If the Eastern Veterinary Conference was supported by the PHS, an appropriate Animal Welfare Assurance and IACUC review in accord with PHS *Policy* would be required.

Options regarding responsibility for IACUC review and oversight of the wet labs are aptly explored in the respondents’ replies.

### **Chester Gipson, DVM**

*Deputy Administrator, USDA, APHIS, AC*

### **Carol Wigglesworth**

*Acting Director*

*Office of Laboratory Animal Welfare, OER, OD, NIH, HHS*