

FASEB Webinar Series: Animal Research Regulations

Part 2: The Role of IACUC and AAALAC in Animal Research Oversight

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FASEB

Questions from the Audience

1. **Unfortunately, I was unable to attend part 1 last week. Is it possible to get the recording of Part 1.**

FASEB: Yes. The recording for Part 1—as well as the slide deck and Q&A—is now available on the [FASEB website](#).

2. **Are there any specific trainings for the non-scientific, community member?**

IACUC: The non-scientific member should go through all the trainings that the rest of the IACUC goes through. They should also be included in the institutions Occupational Health program.

VA: The VA requires the same training for the Non-Scientific Member (NSM) or the Non-Affiliated Member (NAM) as for any other member of the IACUC. And because the roles of the NSM and NAM are specifically to contribute to the IACUC the perspectives of those who are not scientifically trained or well-versed in the institutional culture and history, VA does not require additional specific training for these roles. VA does encourage all members, including the NSM and NAM, to remember that all roles are equally important on the IACUC: it is essential that all members speak freely, and are respectfully listened to, and that each member exercise thoughtful judgement in evaluating the issues under deliberation. There is a course “IACUC Community Member Course” available on CITI, and probably other similar courses on other training websites, for those who are interested.

3. **Does the traditional role of the attending vet differ if they are a part-time consultant?**

IACUC: The compliance requirements are the same for a part-time consultant as they are for a full-time AV. The roles of the AV vary depending on institution for both full-time and part-time AVs.

VA: The role of the Attending Veterinarian is defined by the USDA Animal Welfare Regulations as

“a person who has graduated from a veterinary school accredited by the American Veterinary Medical Association’s Council on Education, or has a certificate issued by the American Veterinary Medical Association’s Education Commission for Foreign Veterinary Graduates, or has received equivalent formal education as determined by the Administrator; has received training and/or experience in the care and management of

the species being attended; and who has direct or delegated authority for activities involving animals at a facility subject to the jurisdiction of the Secretary”,

and by the PHS Policy as a

“Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program authority and responsibility for activities involving animals at the institution”.

Although this role is frequently assigned to a veterinarian with a full-time position, and such a person may also have personal responsibility for the clinical veterinary needs of the individual animals, VA regards these as really two separable sets of responsibilities, and the role of the Attending Veterinarian can be met by a properly qualified individual with a part-time position.

4. How does the IACUC verify training for veterinary staff for study specific tasks vs. day to day clinical tasks.

IACUC: Like all persons conducting work with animals, the IACUC verifies the training. For the veterinary staff this is really based on their background as a veterinarian and their experience with the animals they intend to work with. For example, most graduate veterinarians will be very competent working with dogs and cats. If they intended to work with primates we would look for training specific to that species.

VA: VA expects the IACUC to verify the training of veterinary staff for study-specific tasks the same way it evaluates the training of other members of the research staff for such tasks. The veterinary staff members are appointed for their expertise in the veterinary care of laboratory animals, and they should not be assumed to be similarly expert in every study-specific procedure that may be developed to make new research possible.

5. What is the best way to train IACUC members to conduct appropriate and consistent semi-annual inspections?

IACUC: There are a number of online resources that help train people to conduct inspections. You cannot overlook the benefit of working with experienced IACUC members who have conducted multiple inspections.

VA: VA does not require any single specific form of training for all IACUC members, for conducting semiannual evaluations (including both the program review and the facility inspection), but emphasizes the need for each member to understand the purpose of the evaluations and to engage actively in the process. The form used by the VA for reporting the results of the semiannual evaluation is intended to guide participants (without requiring specific training) to pay attention to the aspects of the program and facilities that need to be evaluated (the checklist), to consider how best to address shortcomings that are noted (analysis of the deficiencies and determination of appropriate corrective actions), and to integrate the results of the evaluation into a summary of the

condition of the program and facilities as a whole, with recommendations on how to proceed going forward.

About four times each year, VA posts optional training exercises for IACUCs at https://www.research.va.gov/programs/animal_research/required_training.cfm, addressing various matters that IACUCs often must address. Exercise 1-2014 focused specifically on the requirements for signing the report of the semiannual evaluation, and 2-2012 provided the VA forms that had been newly revised at that time. This website is publicly available, and all are welcome to use the exercises.

6. **What are your thoughts on having PI's and their lab technicians being required to take an animal care class? Not just training, but actually passing an animal care class.**

IACUC: These are useful at times, particularly for training people in techniques like sterile surgery as this can impact animal welfare. A balance must be attained between making investigators aware of compliance requirements and how much of their time you require for training. Remember that reports suggest that dealing with the IACUC is a major source of administrative burden.

VA: VA does not require this routinely, but takes the position that the IACUC has the authority and the responsibility to require it as needed, according to the experience, expertise, and duties of individual PIs and their research staff personnel. Some VA programs require in-person orientations for new personnel, covering common animal care issues, and some have regularly scheduled classes to teach proper handling, restraint, and blood collection techniques in commonly used species (e.g., mice and rats). Ultimately, the instruction or training needed will vary by individual, and should be tailored to each individual's needs.

7. **Can you speak about the use of ad hoc consultants to complete semiannual inspections for non-USDA areas?**

IACUC: Ad hoc consultants can be a valuable resource, particularly if they bring expertise that is lacking on the IACUC. I encourage their use.

VA: It is acceptable to OLAW for the semiannual inspections to be conducted by qualified *ad hoc* consultants, and consistent with VA's reliance on PHS Policy, VA accepts the recent OLAW guidance on this issue prompted by concerns about the impacts of COVID-19 on IACUC function https://www.research.va.gov/programs/animal_research/animal-care-FAQ-COV-19.docx. IACUCs should keep in mind that whether *ad hoc* consultants or IACUC members conduct the program review and facility inspection, the entire IACUC is still required to deliberate on a) whether the deficiencies identified are "minor" or "significant", b) on the appropriate corrective actions required and the timeline for completing them, and c) the implications of these observations for the condition of the program as a whole and the need for any changes in practices or procedures going forward.

8. The current Guide is 10 yrs old, when will a new one be published? Thank you for a great seminar!

IACUC: There are lots of conditions to meet to make this happen so I have no idea. It is important to remember that the IACUC can approve protocols that don't meet specific guidance in the Guide. However, it does need to be scientifically justified. We do often find examples where performance standards are generated by an institution and the IACUC approves a practice based on those institution-generated standards.

9. As senior IACUC member, what is their responsibility? To guide, prevent COI, be impartial and why it is recommended they aren't DVM's?

IACUC: Senior IACUC members should do all of these (guide less experienced members, prevent COI, etc). All IACUC members should strive to be impartial, but we are human. I don't understand the comment about the members not being DVMs. There is a requirement for a scientific member, a non-scientific member, a DVM, and a non-affiliated member. It is not unusual for a person to fill 2 roles (eg the non-affiliated member being a non-scientist). At institutions with a Veterinary School it is not uncommon for the committee to have multiple veterinarians on the committee.

VA: VA recognizes the value of experienced, senior individuals who serve on VA IACUCs. They can bring familiarity with the regulatory requirements, insights into what has and has not worked well in the past, awareness of pitfalls previously encountered (such as conflict of interest issues), and perspectives on the research environment, all of which are important guides to the IACUC going forward. These attributes, plus experience in committee management, are particularly important for the member who serves as the Chair and is therefore responsible for conducting committee business efficiently while also ensuring that all voices on the IACUC are heard, for effective and thorough deliberations. The Attending Veterinarian, generally a DVM, is a required member of the IACUC, and may become a senior member in time. For other veterinarians, the only prohibition is against serving as the NSM (for which their scientific training disqualifies them). Although the Attending Veterinarian may occasionally step in to help chair a meeting (when, for example, the Chair must be recused), it is generally recommended that the Attending Veterinarian not serve as the regular appointed Chair, simply because this combines too much of the authority on the committee in a single individual and undermines the principle of oversight by a committee of equals with a diversity of perspectives.

10. How does the IACUC interact with IBC if rDNA vectors are used with animals?

IACUC: Most IACUCs interact closely and often have people who serve on both committees. It is often the case that an IACUC will not give final approval to a protocol until the IBC has approved the use of agents like rDNA vectors.

VA: The review and tracking of recombinant nucleic acids and genetically modified infectious agents in animal studies can be challenging because the expertise of both members on the IACUC

and members on the IBC is needed, and the actions of the two committees must be coordinated. To help ensure good communication and coordination, VA recommends that at least one IACUC member also be a member of the IBC. There are various possible strategies for managing the oversight, but one suggestion is for both committees to ask on the forms that they review, whether recombinant nucleic acids or genetically modified microbes will be administered to animals. The responses to these entries can then be to be cross-checked before final approvals by the two committees are granted. When recombinant infectious agents are used the institution must ensure that such animal studies comply with both of the following:

- Appendix M, Physical and Biological Containment For Recombinant or Synthetic Nucleic Acid Molecule Research Involving Animals, in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules [https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf]
- Section V, Vertebrate Animal Biosafety Level Criteria for Vivarium Research Facilities, in Biosafety in Microbiological and Biomedical Laboratories , 5th Edition [<https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF>]

11. What do you do verify who is and what is proper training? Who does the training?

IACUC: Some training is mandated by compliance agencies and that training often has oversight by a training officer at the institution. It can also be something the IACUC does at smaller institutions and companies. If training is technical in nature, this is often verified by someone with knowledge of the technique. This could be a veterinarian, or it could be someone in the investigator's laboratory who the IACUC recognizes as an expert. The key is that the training be documented.

VA: VA requires all personnel identified as participating in any IACUC-approved protocol to complete general training about IACUC oversight of research with animals, and about general care and handling of the species in the protocol. Beyond that, the VA assigns to the IACUC the responsibility and the authority to determine what training in specific techniques is needed by individual members of the research staff on specific protocols. For some techniques, the local veterinarians may be excellent trainers. For other more specialized techniques, it may be best to invite experts from other institutions to visit and teach, or for the local personnel to travel to other labs to learn. The IACUC must use its judgement to evaluate the proposed training and the qualifications of the proposed trainer. It is important in any case for the completion of the training to be documented for future reference.