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Note: Text has been edited for clarity.

IACUC Responsibilities Beyond Protocol Review and Facilities Inspection

Speakers: Susan Silk, M.S., Director, Division of Policy and Education, OLAW and Jerry Collins, Ph.D., Division of Policy and Education, OLAW and Yale University.

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http://grants.nih.gov/grants/olaw/Videos/OLAW_IACUC_Staff_Seminar.wmv

(WMP - 42 min). A PDF version of the slides can be accessed at

http://grants.nih.gov/grants/olaw/educational_resources.htm.

Slide 1 (Title Slide)

And now, we will get started with our OLAW online seminar for IACUC staff on March 10th, 2011. Today our seminar is "IACUC Responsibilities Beyond Protocol Review and Facilities Inspection." I am Susan Silk and I am the Director of the Division of Policy and Education in the NIH [Office of Laboratory Animal Welfare](#).

Our seminar today will be presented by Dr. Jerry Collins. Jerry is a professor of Anesthesiology at Yale University School of Medicine, where he studied the pharmacology of the sensation of pain. Jerry has served Yale and the biomedical research community in many capacities. He is a member of the

IACUC 101 faculty. He worked with local, state and national organizations to improve scientific literacy among high school students. He served as a member of the AAALAC International Council on Accreditation. Currently Jerry divides his time between Yale and OLAW. At OLAW, Jerry is a valued consultant to the Division of Policy and Education. At Yale, he continues in his role as an educator and is an advisor to the vice-president for research affairs on IACUC issues. He served for many years as Chair of the Yale IACUC. He's retired from that position now; that's why he had time to develop the reflections that he will share with us today. Jerry, please share with us your expertise about IACUC Responsibilities Beyond Protocol Review and Facilities Inspection.

Thank you, Susan, and thanks to each of you, our participants. We recognize that by the very act of participating in this webinar, you are demonstrating your understanding of the importance of the IACUC process to the success of your animal program. Our goal today is to provide you with additional insights into issues that you, as members of an IACUC staff, should be comfortable with as you interact with your Institutional Animal Care and Use Committee. In [previous webinars](#), we focused on protocol review and facility inspections. Today our focus will be on other IACUC functions that don't always get as much attention.

Slide 2 (Why were IACUC's Developed?)

So why were there – why were the IACUCs developed? Before considering IACUC functions, I want to take a few moments to discuss their creation – since some of their assigned functions make more sense if we appreciate what Congress intended when its members legislated the existence of these committees.

The IACUC process, with which we work today, had its beginnings in the mid-1980s. As a result of increasing pressure from the public, Congress

enacted legislation that led directly to the [Public Health Service \(PHS\) Policy on Humane Care and Use of Laboratory Animals](#) (Policy) and to OLAW's role in the enforcement of that Policy. In addition, separate legislation led to the development of [Federal regulations](#) that are enforced by the [USDA](#). If your institution, in addition to having an Assurance with OLAW, is also registered as a research facility with the USDA, then you are aware of the need to observe both sets of rules.

In October of 2010, OLAW, USDA and IACUC 101 organized a [symposium](#) focused on the past 25 years of animal research oversight. At that symposium, Dr. Nelson Garnett, past Director of OLAW, related a story about how a university administrator described the differences between the PHS Policy and the USDA Regulations. The administrator described the PHS Policy as "being written by ladies and gentlemen for ladies and gentlemen". The administrator then went on to describe the USDA Regulations as having been written for "dog thieves and smugglers". In essence, the USDA enforces federal law, while OLAW works to ensure that the contractual agreement between your institution and the Public Health Service is met.

Of relevance to today's presentation, although there are differences between the PHS Policy and the USDA Regulations – when it comes to IACUC functions – the wording defining those eight functions is almost exactly the same.

"The requirement to establish animal care committees is intended to provide the most constructive assurance that NIH guidelines for the care and treatment of animals are met. It is far preferable to place primary responsibility for assuring compliance with NIH guidelines on committees within institutions rather than relying on intrusive Federal inspections."

This quote was taken from a [1985 Congressional Conference Report](#) resolving Senate and House differences in wording of the Act that mandated

the PHS Policy. It further reflects an important difference between OLAW and USDA. As intended by Congress, local oversight, rather than ongoing federal inspections, is the means by which OLAW implements its responsibilities. Congress knowingly established local oversight as the means of ensuring humane animal care. The IACUC functions were designed to provide the tools that would enable the local committees to meet Congress' expectations.

Slide 3 (IACUC Functions)

The first three functions of an IACUC, as defined in the PHS Policy are (1) to review the animal program, (2) inspect animal facilities and (3) report results of those reviews and inspections to your IO. As my colleagues on the [IACUC 101](#) faculty point out, these three functions constitute the mandated semiannual evaluation of an animal program, something with which you should be quite familiar. In fact for many institutions, these three functions and protocol review account for the majority of an IACUC's time.

Slide 4 (IACUC Functions)

The fourth and fifth functions, review animal care and use concerns and make recommendations to the IO about any aspect of the animal program, facilities, or personnel training, unlike the first three, have no set schedule; and, depending on your program, may occur infrequently. Although we do hope that in the spirit of number five, you have an ongoing dialogue with your IO about the status of your animal program.

Slide 5 (IACUC Functions)

Function six: Review and approve, require modifications in (to secure approval), or withhold approval of proposed animal activities.

Function seven: Review, require modifications to approve, or withhold approval, of proposed significant changes to ongoing animal activities.

Numbers six and seven, typically, are referred to as protocol review and are viewed by many, mistakenly, as the only thing that an IACUC does. Note that six refers to the review of the initial protocol and seven refers to proposed changes to an already approved protocol. In both of these functions, the IACUC is charged with requiring modifications to proposed animal activities, if needed, for approval.

Investigators sometimes question the authority of the IACUC to make such requests.

I also want to point out that there is no mention in the PHS Policy of a "protocol". The IACUC is required to review and approve proposed animal activities. The mechanism is not defined, but the standard of practice has become the use of an institution-specific protocol form that enables each IACUC to address the required items in an orderly fashion. The protocol form came into existence primarily because the forms used to request funds from the PHS do not address all of the issues that an IACUC must consider as it reviews proposed animal activities. [OLAW website provides a [sample protocol form](#) that your institution may choose to use or adapt.]

As you heard in our [December 2010 webinar](#), the *Guide* defines 10 topics that should be addressed when an IACUC reviews a proposed animal activity.

Slide 6 (IACUC Function)

The last IACUC function, number eight, suspend an activity involving animals, is one that we all must take very seriously. Although it is difficult, it is important that each member of the IACUC be willing to vote to suspend an activity when necessary. I encourage you to take a leadership position at your institution to support a "culture of compliance" that will facilitate the IACUC process.

Slide 7 (Not on the List but Essential to Success)

The PHS Policy states "...the IACUC shall conduct continuing review of each previously approved, ongoing activity covered by this policy at appropriate intervals as determined by the IACUC, including complete review... at least once every three years."

Although the PHS Policy defines eight functions, I would like to add a ninth, overarching function. The IACUC must have in place means to get feedback on what happens to the animals after approval for their use has been granted. The IACUC is required to conduct continuing review. When the Policy was first enacted, many institutions interpreted this to mean simply that protocols had to be renewed every three years. While that is true, standard practice has evolved to a process of ongoing review throughout the life of an approved activity, thus providing the IACUC with ongoing feedback.

Slide 8 (Continuing Review)

The need for continuing review has been the focus of much discussion of late and has resulted in the use of the term post-approval monitoring (PAM). The term itself is fine, but post-approval monitoring has taken on a life of its own and has unfortunately become associated with an assumed need to hire personnel who are post-approval experts. While that may be fine for some institutions, please don't assume that the requirement for continuing review means that new staff must be hired. The PHS Policy does require ongoing review, but it does not require a formal PAM process.

Slide 9 (Post-approval Monitoring)

So how do you know if there is ongoing review happening in your institution? If you are registered with the USDA, your IACUC is required to conduct an annual review of all approved protocols that include USDA-regulated species. That is ongoing review. Some institutions apply the requirement to all protocols, not just to ones that involve USDA-regulated species.

Does your husbandry and veterinary staff track unexpected animal death or disease? Health surveillance is essential, but it is also continuing review. Just make sure that the reports are shared with the IACUC.

It is possible that, on occasion, a laboratory has gotten the attention of the IACUC. If there is a concern that members of the lab may not yet fully understand their responsibilities, does your IACUC implement some means of evaluating progress? If so, that's ongoing review.

Does your IACUC receive regular reports about the veterinary health status of your colonies?

Are you reporting noncompliance with the PHS Policy or the [Guide](#) to OLAW? I certainly hope the answer is yes, but think about all of the steps involved in developing those reports. That is continuing review.

It's very likely that your program has ongoing review. As part of that review, it makes sense to examine those processes to determine if the IACUC has a good handle on the status of the animals for which they are responsible.

Slide 10 (1. Review Animal Program)

Function No. 1: Review the animal program. Overseeing the entire animal program is an enormous responsibility, encompassing anything that could have a negative impact on the health or wellbeing of animals and many of the things that could have a negative impact on humans working with those animals. An IACUC must ensure that institutional responsibilities are being met as part of program review; for example, adequate veterinary care and animal housing.

Although we rely on our attending veterinarian for veterinary knowledge, how do we make sure that he or she is applying current standards of care to our animals? A question that your IACUC must consider.

Animal-program relevant occupational health and safety program. It's unlikely that members of your IACUC have training in occupational medicine, but the committee still needs to ask appropriate questions.

For example, it is likely that caustic cleaners are used in some facilities. If they are delivered in large containers and subsequently mixed by staff, what precautions need to be in place? If some of the caustic material splashed into someone's eyes, how close should an emergency eyewash station be?

Does your disaster plan address animals or is it limited to human safety?

If there are sprinkler systems or fire extinguishers in animal housing areas, does the IACUC know if they are checked as required by local code?

These rhetorical questions point out just a few of the myriad areas in which IACUC assessment must occur in order to ensure the health of your animal program.

Slide 11 (1. Review Animal Program)

PHS Policy defines IO as "An individual who signs, and has the authority to sign the institution's Assurance, making a commitment on behalf of the institution that the requirements of this Policy will be met." Is your IO in a position to ensure that your institution's contract with NIH, your Assurance, is met? I know that everyone's time is valuable. The PHS policy, however, is concise and, quite frankly, rather short. If it has not already been done, please ask your Chair to give your IO a copy of the [PHS Policy](#) and then ask him or her to read it if they haven't done so. Think of that suggested activity as your contribution to ongoing review. [You can find information about obtaining copies of the PHS Policy free of charge on the OLAW website. (<http://grants.nih.gov/grants/olaw/references/phspol.htm>)]

Slide 12 (2. Inspect Animal Facilities)

Function No. 2: Inspect animal facilities. PHS Policy directs IACUCs to

inspect, at least once every six months, all of the institution's animal facilities, using the *Guide* as a basis for evaluation.

Has your IO had an opportunity to visit some of your animal facilities? I strongly encourage you help them to do their own mini-inspection and then compare their impression with the most recent report they received from the IACUC about that same location. Hopefully, they will agree with your IACUC's assessment.

Slide 13 (3. Report Semiannual Review Results to the IO)

Function No. 3: Report semiannual review results to the IO. Are your [semiannual reports](#) reviewed and signed by a majority of the IACUC? Do they reflect minority opinions?

What do we mean by minority opinions? This is not the fact that a member voted to not approve a protocol, rather it refers to a committee member not agreeing with some aspect of the semiannual report. For example, the majority of the IACUC feels that things are fine in the animal housing room, but one individual feels that the strong smell of urine means that the ventilation system is in need of repair. You should see that minority opinion reflected in the semiannual report.

Do you and your IO get an accurate sense of your program from each semiannual report? How does your IO follow up on questions or concerns raised in the report? Things work best if there is a partnership between the IO and your IACUC. Does your IO meet on a regular basis with the IACUC Chair or member of the IACUC staff? Many institutions find it helpful to also get input from veterinarians and facility managers.

Slide 14 (Report Semiannual Review Results to the IO)

Do the reports you send to the IO distinguish significant from minor deficiencies? Significant deficiency, in the judgment of the IACUC and the

IO, is or may be a threat to the health or safety of animals or humans. Does your IACUC involve your IO in this determination? If deficiencies are noted, is a reasonable and specific plan and schedule for correcting each deficiency included in the report? Remember that it is up to the IO and the IACUC to determine the seriousness of all noted deficiencies. So how do you accomplish this task? If the IACUC is of the opinion that a deficiency is significant, how long does it take them to inform the IO of the problem?

When evaluating a plan for correction, remember that asking someone else for a plan is not adequate. For example, if floors need to be repaired, it is not enough for the IACUC to ask physical plant for a plan. The report should indicate both how the floors will be repaired and the time line for that repair.

Slide 15 (3. Report Semiannual Review Results to the IO)

The report must contain a description of the nature and extent of the institution's adherence to the *Guide* and the PHS Policy. It must identify any departures from the *Guide* and the PHS Policy. And it must state the reasons for each departure. Notice that a departure is not the same as a deficiency. A strength of the IACUC process is that each committee is permitted to approve procedures that depart from PHS Policy or the *Guide* if that decision is based on sound scientific reasoning. For example, the *Guide* provides details about the maximum number of mice that should be housed together in a given area. If an investigator has designed an experiment to study the effects of overcrowding on mouse reproduction, then a departure from the *Guide*, in the area of housing density, may be approved. That approved departure is not a deficiency, but it should be included in the semiannual report, along with a description of the reason for granting it. At least annually the IACUC should revisit the granting of each departure.

Are you aware of any such departures in your program at present? Have they been included in your semiannual reports to your IO?

Slide 16 (4. Review Animal Care and Use Concerns)

Function No. 4: Review animal care and use concerns. Is your general counsel aware of this federally-mandated IACUC function? How do you maintain anonymity and protect whistleblowers? This is just one reason to make sure that the attorneys are on board.

Remember that the PHS Policy requires that relevant USDA rules must be followed and the USDA requires that individuals who report concerns must be protected from retribution. Although the IACUC is required to review and, if necessary, investigate concerns, they are not in a position to ensure that there will be no retribution.

What will you do if there are human resource issues? For example, can a member of the IACUC question an employee without a union representative being present? Or public relations issues? Is your Office of Public Affairs prepared to respond to questions about alleged animal mistreatment?

Slide 17 (4. Review Animal Care and Use Concerns)

Do you have a policy that encourages everyone to report concerns and identifies individuals to whom concerns should be reported?

It's likely that you do have such a policy, but how is it shared with the community? For example, does a custodian who sees an animal being transported in a hallway know how to raise a concern?

Do persons to whom a report is to be made represent all levels in your organization? For example, do individuals have someone other than their supervisor to whom they may report concerns?

Slide 18 (5. Make Recommendations to IO About any Aspect of Animal Program, Facilities, or Personnel Training)

Function 5: Make recommendations to the IO about any aspect of animal program, facilities or personal training. Don't confuse this with No. 3, the

requirement for a semiannual report of the facility inspection and program review. This is an opportunity to engage the IACUC in consideration of the long-range future of your animal program. As investigators, IACUC members have a vested interest in future success.

Slide 19 (6 and 7. Protocol Review)

Functions 6 and 7. Do you, from time to time, assess protocol forms and procedures to ensure that they are as efficient as possible both for investigators and committee members? Remember that an IACUC can be a real source of apparent regulatory creep.

Slide 20 (8. Suspend an Activity Involving Animals)

Function No. 8: Suspend an activity involving animals. If an IACUC suspends an activity or denies approval of an animal activity, the decision cannot be reversed by an institutional authority. However, institutional leadership may say no to an animal activity that was approved by an IACUC.

Slide 21 (8. Suspend an Activity Involving Animals)

The IACUC may suspend an activity only after review at a convened meeting of a quorum of the IACUC and with a majority of the quorum present voting for suspension.

Slide 22 (8. Suspend an Activity Involving Animals)

If the IACUC suspends an activity involving animals, the IO, in consultation with the IACUC, shall review the reasons for the suspension, take appropriate corrective action and report the action with a full explanation to OLAW. Notice that this is one of two IACUC functions that involve both the IO and the IACUC. The other is when together they determine if a deficiency is significant.

Notice also that it is the responsibility of the IACUC to suspend an activity. That does not mean, however, that they are the only ones with the authority

to halt an activity. For example, the IO may also do so and it is very important that everyone understand that veterinarians have a similar authority to halt an activity if it is to protect the health or safety of animals.

The institution must also inform the funding agency of a suspension of an activity. If a PHS-funded animal activity is suspended, the institution, not the IACUC, is required to inform the funding agency.

Slide 23 (IACUC's are Important Because:)

IACUC's are important because "...their presence will create an ongoing discussion within the nation's research institutions of sensitivity to the care and treatment of research animals. This ongoing process recognizes that such sensitivity cannot be captured in any set of rules, that standards of care will change in the future as science advances, and that the value of medical research requires such judgments to be professionally and scientifically sound."

This quote, also from the 1985 Congressional Conference Report resolving Senate and House differences in the wording of the Act that mandated the PHS Policy, reflects the essence of an IACUC: A group of individuals using sound professional and scientific judgment to resolve challenging questions about the care and treatment of research animals. The IACUC functions are their tools.

Slide 24 (Thank you!)

Thank you. Thank you for participating in this webinar. Thank you for overseeing essential work that contributes to human and animal health. And thank you for helping your institution ensure that self-regulation promotes ethical treatment of animals used in research, teaching, and testing.

Slide 25 (Questions? Please Ask!)

Susan and I are now going to swap roles. I will turn into the moderator and

Susan will do her very best to answer your questions. We do have some questions that we received earlier on, so we're going to be working on those.

And I will remind you that you can submit questions to us by using the attendee box at the bottom there, type in your question and send it off to us, and we'll do our best. Easy for me to say because Susan is the one answering the questions. [Questions can be submitted during the live broadcast of the webinar; you may not submit questions to the recorded webinar. However, you are always welcome to submit questions to OLAW at olawdpe@od.nih.gov.)]

1. Susan, our first question. How soon after the IACUC has completed its program review and facility inspections are we expected to provide the report to the IO? As soon as you can. The IACUC should send the report to the IO as soon as possible, as soon as it has been written and signed by a majority of the members. Semiannual program evaluation and facility inspection must be conducted at least every six months. You definitely don't want to get into a situation where another semi has been conducted before the IO receives the report on the previous one.

2. Our next question. Is the institution required to protect an employee from retribution if the employee knowingly submits a false claim of animal mistreatment? Well, the PHS Policy does not explicitly have a whistleblower protection clause, but OLAW expects that employees submitting a concern about animal welfare in good faith are to be protected, whether the allegation turns out to be well-founded or not. Protection of someone who knowingly submits a false claim would not fall under OLAW's jurisdiction but may be addressed by institutional or local policies.

3. How will we know if the level of ongoing review is adequate at our institution? Well, you should never be surprised. If outside inspections,

such as by USDA or [AAALAC International](#), or your own post-approval monitoring are finding problems that the IACUC didn't detect in its semiannual program review and facility inspection, then you have a problem.

4. Next question, Susan. How can we assess the quality of our veterinary services? Well, I can think of several ways. Bad clinical outcomes, including unexplained or unexpected deaths without veterinary intervention. Nonresponsiveness on the part of the veterinarian to animal health concerns. And complaints. Complaints from investigators and animal facility personnel, including complaints that the veterinarian is not spending adequate time in the animal facility.

I would add another possible one to that. And that is – clearly – just as in human medicine, veterinarian medicine has advanced. So you also want to check and make sure that your veterinarians are, in fact, participating in national meetings or getting journals or are provided with the educational opportunities to make sure that they can stay current in their field.

5. Question No. 5. We have implemented a PAM process within our quality improvement process. But the post-approval monitoring personnel do not report directly to our IACUC. Is that okay? Yes, that's okay. I will remind everybody that PAM stands for post-approval monitoring. The PHS Policy does not specify the means by which institutions achieve compliance with the Policy. Formal post-approval monitoring is not a requirement of the Policy. [If you choose to have] PAM personnel [they] do not have to report to the IACUC, but there should certainly be a mechanism to inform the IACUC when noncompliance is discovered, because the IACUC is responsible for oversight of the institutional animal care and use program and also, with the IO, for submitting reportable events to OLAW.

6. Next question, Susan. If the PHS Policy is focused on animal wellbeing, why should our IACUC be concerned about occupational health and safety issues? Well, the IACUC doesn't have to run the occupational health program itself, but they are responsible for assessing whether the program is functioning as it should, that is to prevent occupational illness and injury of individuals and also providing a safe environment for individuals who work with animals in the facilities or who have frequent contact with the animals. This is stated in the Public Health Service Policy section [IV.A.1.F.](#)

7. What kinds of animal issues should our disaster plan focus on? A disaster plan that takes into account both animals and personnel should be developed. Animal program personnel, such as the vet or facility manager, should be included in organizational planning. Plans should include consideration of immediate animal care and relocation, saving valuable research, humane disposition of animals – should that become necessary, and preservation of valuable strains through cryopreservation.

8. This is a fairly long question here, Susan. Our IO sometimes seems to find our plan and schedule to correct deficiencies unreasonable. We understand that it's hard to find the resources to solve these problems; however, we are expected to make sure the deficiencies are corrected. We have been trying to resolve an ongoing issue with deteriorating floors in one of our housing areas. What should we do? The IACUC is responsible for establishing a reasonable plan and schedule to correct deficiencies. If resources are not available, consider an interim plan. In this case of the floor, this might mean patching rather than replacing the floor. This could be a problem with other high-cost facility improvements. Institutions may need to use interim plans to meet the replacement schedule for HVAC units, for example. But I think that reasonable people trying to work together can find a solution.

9. Next question, Susan. Since our IACUC lacks the required expertise, our general counsel insists that their office, not the IACUC, investigate any reported concerns about our animal program.

Could this be a problem? Yes, I think this could be a problem. Because the lawyers may lack some of the necessary expertise that the IACUC has and [because] it is the IACUC's responsibility to review concerns involving the care and use of animals at the institution. This is according to the PHS Policy at [IV.3.B.4](#). So the IACUC cannot relinquish its responsibility. If the offices work cooperatively, the institution would have the benefit of the expertise of both the general counsel and the IACUC.

10. We are a small institution that is not registered with the USDA. If our IACUC does not approve a protocol, can the IO reverse the IACUC action if she doesn't agree?

Well, the Policy states directly in [Section IV.C.8](#) ... "officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC." In Section [IV.C.4](#), the Policy says the IACUC has the authority to withhold approval of proposed animal activities and goes on to say that the IACUC must notify the PI and the institution of its decision to withhold approval. A statement of the reason for its decision must be included and the investigator must have an opportunity to respond. In my experience, IACUCs work hard to facilitate science and will respond favorably to a request to work with the scientist to develop a modification to the proposal so that it can be approved.

11. Can an IACUC suspend an activity without the agreement of the IO?

The IACUC has the authority to suspend an activity involving animals. The Policy at [IV.C.7](#) directs that after the suspension has taken place, the IO, in consultation with the IACUC, must review the reasons for the suspension and take corrective action. That corrective action must be reported to the IACUC and to OLAW and USDA.

Susan this is an interesting question, in some ways it's a bit off topic, but I think it's one that's important for us to ask and allow you to share with the community.

12. Do you observe any common features in excellent animal care and use programs? Well, I see many things in common, but one of the really important ones is a strong commitment to education. Jerry, you mentioned a culture of compliance. Education is essential in the formation of a culture of compliance at an institution. Training of investigators, research staff, animal facility personnel and IACUC members is essential. When everyone that works with animals understands the system and understands what is expected of them, they can all contribute to an effective, robust program. The system of oversight described by the PHS Policy and overseen by OLAW is based on self-monitoring. Education is an essential component of the system.

13. Our next question. Have IACUC investigations ever been declared noncompliant because questions of interviewees have been found out of bounds by legal or HR staff? Well, if the IACUC ventures into an area, where the jurisdiction really is under another entity, there would be a need to bring in the appropriate office into the matter. An example of that would be asking medical questions of a staff member and in that case I think that you would need to bring in the occupational health folks.

14. Our next question. Wasn't there a PHS Policy on Humane Care in Use of Laboratory Animals prior to 1985? Oh, I love the history of this. And, yes, the PHS Policy as we know it today evolved from the 1971 Policy on Care and Treatment of Laboratory Animals. We just had that out in the historical files yesterday and were looking at it. It allowed for an institution to show, either through its accreditation by AAALAC or that it had an animal care committee, to carry out the assurance of acceptable animal care. The PHS Policy then evolved from an NIH policy, and it was the 1985 revision

that requires the IACUC and its appointment by the C.E.O. of the institution and the eight required responsibilities covered today in our – in Jerry's presentation.

15. Susan, we have a question now about program review. Should the IACUC review the safety record for the facility as part of its program review? Yes, that would be appropriate for them to review the safety records of the animal area.

16. What are the expectations in terms of depth and details for annual protocol reviews? Well, this is up to the needs of the institution. And it's a decision to be made by the local IACUC. Usually these address such areas as any problems with the studies and any proposed changes. OLAW accepts the annual reviews performed to meet USDA Animal Welfare Act requirements.

17. Susan, can you provide a real-life example of where the IO stepped in and suspended research? Well, we have an example where an IO reassigned the PI to another assignment and stopped the protocol. And that was not due to animal concerns, but rather it was due to a personnel decision.

I can think of another situation where the IACUC approved some animal work to be done and then a member of the university administration made a decision that, in fact, they didn't want to have that kind of work done at their institution.

18. Next question. Do minority opinions on the program review need to be signed by the person with minority opinion? As an employee of the facility, they may feel reprisal from the head of the facility. No, no, they do not need to sign the minority opinion. The semiannual reviews only need to be signed by a majority of the committee members. The

minority opinions do not need to be signed by that person and there should be no reprisal for raising animal welfare concerns.

19. Our next question. Before doing any major changes such as refurbishing a floor in a rabbit vivarium where animals will be moved, should this action be put before your attending vet before IACUC approves the action? If there is a concern that animal health or wellbeing may be impacted, then the veterinarian needs to be involved. It doesn't ever seem wrong to include people that would have expertise in the areas that you are working on, so I think it would be a good idea. And it must be done if there's a concern for the animal health or welfare.

Keep in mind the attending veterinarian, by definition, is also a member of the committee, so we would assume that under those circumstances, he or she would be engaged in the discussions as part of the committee.

20. Our next question. What is the difference in the IACUC's opinion between isolation and quarantine? Well, that's a little bit down in the weeds. And OLAW doesn't give the IACUC's opinion. But I can tell you that I think that quarantine usually has a defined SOP regarding the conducting tests, sampling and a defined period of time. Isolation would be maybe due to a contagious disease and a need to separate a colony or perhaps for study requirements.

21. This next question is an interesting one. What do you do if you feel that an IO approves of the IACUC cutting corners? Certainly when I read this question, one of my questions is – who is the you that they're talking about? Unfortunately, the questioner doesn't tell us that. So what does somebody do if they feel that the IO approves of the IACUC cutting corners? Well, OLAW will always accept an anonymous report. If there are activities that are occurring that you think are cutting corners; I think you should call us.

Now, do we have more questions coming in? We've come to the –

We're checking briefly with our staff here to see if there are any additional questions that they are going to be bringing in to us. In the meantime, we would like to again emphasize the importance of this last point. And that is that anybody at an institution that feels that the normal channels are not working effectively certainly has the opportunity to report, anonymously if they choose to do so, to the OLAW their concerns, and that's something that certainly will be taken quite seriously.

Yes, we will take that seriously. So we're waiting here to see if you have any more questions because we do have a few more minutes left in our time. That banging around you hear is us.

Okay. It seems like maybe we've answered all of your questions today.

Thank you so much for joining us. And everybody, have a good day.

Additional Submitted Questions Not Addressed During the Webinar

22. If there are non-voting members of the IACUC that have a minority opinion during the semiannual, should it be listed on the report as a minority opinion? No. Annual reports must represent the consensus of the Committee, and include any minority views filed by members of the IACUC. A person who attends IACUC meetings or participates with the IACUC in some way, but does not vote, is not technically a member of the IACUC. It would not be necessary to include this minority opinion in the annual report. PHS Policy [IV.B.3.](#) and OLAW [FAQ C1](#) provide information about the annual report to OLAW. The IACUC has a responsibility to investigate concerns involving the care and use of animals

at the institution. (PHS Policy [IV.B.4](#)) The IACUC would be charged with investigating the matter of concern that the individual raises.

23. Can semiannual reports be signed digitally? Yes.

24. What exactly constitutes an institution's program review? Is there a good resource available (other than the *Guide*)? At this time we go over a checklist that lists all the program components from the *Guide* but it really seems like a paper exercise with little value.

OLAW has developed a [Semiannual Program and Facility Review Checklist](#).

You can download a version of the checklist that can be customized to aid in your organization's review. Section B.1. of the [Institutional Animal Care and Use Guidebook](#), [available from OLAW](#), has a description of program and facility review starting on page 37 that may be helpful.

25. It was noted that safety records could be reviewed during the semiannual inspection. What about HIPAA laws? To further clarify, the IACUC should verify that each individual who has contact with animals is appropriately participating in the institution's occupational health and safety program. The IACUC should not have access to individual medical records.

26. The webinar suggested that the AV be a member of the IACUC. The IACUC Handbook states that the AV does not necessarily have to be a member of the IACUC and sometimes it would be best if they are not an IACUC member. Would you clarify OLAW's position on this issue? The IACUC must consist of at least 5 members who are qualified, through experience and expertise, to provide oversight for the institution's animal programs, facilities, and procedures. One of these members must be a veterinarian 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. ([PHS Policy IV.A.3.b.](#) and [FAQ B1](#)) OLAW recommends, but does not require, that the veterinarian not

be the chair of the IACUC to avoid a conflict of interest because he or she has direct or delegated program authority.

The IACUC Handbook, Second Edition, Silverman, Suckow and Murthy, section 5:26, observes that the AWAR (2.33,a,3) state, "The attending veterinarian shall be a voting member of the IACUC; provided, however, that a research facility with more than one Doctor of Veterinary Medicine (DVM) may appoint to the IACUC another DVM with delegated program responsibility for animal activities." In the opinion section, the authors note that "some institutions have deliberately avoided placing the AV or the veterinary program director on the IACUC, to dissociate the overall program of veterinary care and its associated scientific interactions with investigators from the monitoring and policing functions inherent in IACUC activities."

27. In Jerry's list of 5 things that are considered continuing review, he listed review of veterinary reports. How often is the IACUC supposed to receive veterinary reports? What items should the veterinary report contain? Is this for all animals (holding, breeding, quarantine, and research) or just the ones participating in research?

Dr. Collins was suggesting that one way for the IACUC to monitor the organization's animal care and use program is to be aware of the data in the veterinary reports. This was not intended to imply that OLAW requires specific review of veterinary reports by the IACUC. The IACUC may develop methods and procedures that work for their organization. For example, the IACUC may ask the responsible veterinarian to inform the committee of any unexpected animal health monitoring results found during regular monitoring of the animal facilities or procedure areas.

28. Jerry mentioned that one of the two things the IACUC does in conjunction with the IO is determine significant deficiencies. Did I hear that correctly? I thought the IACUC was supposed to provide

the classification of deficiencies to the IO. Is there supposed to be a consultation for the determination or does the “working in conjunction” come into play for the resolution of the deficiency. The PHS Policy [IV.B.3](#) states, “A significant deficiency is one which, consistent with this Policy, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals.” Also, please see question 29.

29. You stated that the IO and the IACUC determine whether deficiencies are major or minor. In the event of a disagreement, who is the final arbiter? The PHS Policy [IV.B.3](#) states, “A significant deficiency is one which, consistent with this Policy, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals.” Contact OLAW (301-496-4371) if the IO and the IACUC cannot reach agreement.

30. Should departures from the *Guide* be reported on every report to the IO (every 6 months) or just on their initial occurrence?

Departures from the *Guide* should be reported during every semiannual period in which they occur.

31. Can the IACUC approve a permanent facility deviation (such as not requiring a shelter in a pasture for agricultural animals) and report it to the IO only upon the initial approval of the deviation?

Departures from the *Guide* whether approved by the IACUC as a temporary or permanent deviation should appear in the semiannual report to the IO during every semiannual period in which they occur.

32. Are funding agencies notified if there is a noncompliant report sent to OLAW that had not resulted in suspension? Not necessarily. If terms and conditions were violated, then “Institutions are required to report such situations to the Institute/Center (IC) supporting the award. NIH

expects grantees to continue to maintain and care for animals during the periods described above. Funding components may allow expenditure of NIH grant funds for maintenance and care of animals on a case-by-case basis.” ([NOT-OD-07-044](#)) If the terms and conditions of the grant were not violated, a report to the funding agency is not required.

33. Do conflict of interest issues pertain when the IO wishes to attend IACUC meetings or if the IO is an animal user? Although not prohibited by the PHS Policy, having the Institutional Official (IO) as a member of the IACUC is not in keeping with the intent of the PHS Policy and may be interpreted as “undue influence”. It is important that the IACUC’s authority to approve protocols is independent of the IO (and the CEO) who may not overrule an IACUC decision to withhold approval of a protocol. In addition, the IACUC serves in an advisory role to the IO and reports to the IO. Having the CEO and/or the IO serve on the Committee creates a potential conflict of interest.

There is nothing to prohibit an IO from attending IACUC meetings as long as his/her presence is not seen as influencing a protocol determination. If the IO is an animal user and attended an IACUC meeting where his/her protocol was being reviewed this may be viewed as a potential conflict of interest.

34. When a protocol indicates that hematocrit or circulating blood volume will be monitored in animals where blood collection exceeds the limits in the Standard Operating Procedure or Guidelines, what type of follow up should the IACUC be doing? One way to follow would be to have a veterinarian or other qualified individual associated with the animal care and use program check that the monitoring is being performed.

35. When species-specific training is provided to graduate students by their faculty mentor, is the IACUC required to have proof of the

training? What type of documentation suffices? Is a statement from the faculty member? All personnel involved with the care and use of animals must be adequately educated, trained and/or qualified in the basic principles of laboratory animal science. The Institution has flexibility to determine the mechanism by which training is documented. The IACUC is responsible for providing oversight and for evaluating the effectiveness of the training program. Some form of individual training records should be accessible to the IACUC to allow the committee and any external oversight authority, such as OLAW, USDA, or AAALAC to review and evaluate the effectiveness of the institutional training program.

36. When should a dissenting comment by an IACUC member be included as a minority report in the semiannual report to the IO? An IACUC member's opinion should be included if the member identifies the opinion as one he or she wishes to have submitted to the IO or OLAW. "Any IACUC member may submit a minority view to OLAW addressing any aspect of the institution's animal program, facilities, or personnel training. Whether OLAW receives a minority view as part of an annual report, renewal Assurance document materials, or directly from the dissenting IACUC member, it carefully reviews the information provided in accordance with requirements of the PHS Policy and provisions of the *Guide*." ([FAQ C6](#))