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Note: Text has been edited for clarity.

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 Additional Questions

OLAW Online Office Hour

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Slides 1-2 (OLAW Online Office Hour)

>>*Brown:* Hello everyone. Welcome to the Office of Laboratory Animal Welfare's first **Online Office Hour**.

Slide 3 (OLAW Office Hour)

I am Dr. Patricia Brown, the director of OLAW. The speakers for our officer hour today will be Eileen Morgan, who is the Director of the OLAW Division of Assurances, and Dr. Axel Wolff, who is the Director of the OLAW Division of Compliance Oversight.

Thanks to everyone who sent in questions to our first OLAW Online Office Hour. Your questions were thoughtful and well written, and many came in ahead of the deadline. That gave us a little extra time to prepare the webinar, which we appreciate. We have rewritten some of your questions for clarity and to merge them into a cohesive presentation. However, we have tried to represent your inquiries accurately. We will not be accepting live questions during our webinar. If you have a follow-up question about one of the topics we discuss today, please email it to the OLAW Division of Policy and Education at olawdpe@mail.nih.gov. Our first series of questions will be about the composition of an IACUC.

Slide 4 (Question 1: Nonaffiliated Member?)

Question 1: We are very concerned about the new guidance on the nonaffiliated member. The guidance seems to be so broad that even a college humanities major, who took a zoology class to fulfill a science requirement, wouldn't be eligible. We just wasted a lot of work recruiting and training a nonaffiliated member who is now not qualified to be

nonaffiliated because he had past scientific training. Why did OLAW start requiring the nonaffiliated member to be a non-scientist?

Slide 5 (Answer 1: Nonaffiliated Member)

>> *Wolff*: IACUCs were increasingly selecting individuals that did not meet the intent of the PHS Policy [[Public Health Service Policy on Humane Care and use of Laboratory Animals](#)] and the *Guide* [[Guide for the Care and use of Laboratory Animals](#)] to serve as the nonscientist and nonaffiliated members. Therefore, OLAW issued [Guide Notice NOT-OD-15-109](#) to clarify the qualifications of those membership roles.

Slide 6 (Guidance on Qualifications of IACUC Nonscientific and Nonaffiliated Members)

This is OLAW's guidance on Qualifications of IACUC Nonscientific and Nonaffiliated Members. Guide Notice NOT-OD-15-109 was released in June 2015. You can find a copy in the Guidance section of the OLAW website under the bullet – "Notices". The URL for the Guide Notice is shown on the slide. [[NOT-OD-15-109](#)]

Slide 7 (Nonaffiliated Member)

Let's review the guidance from OLAW's reference documents. The PHS Policy describes the nonaffiliated member as an "individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution." [[PHS Policy IV.A.3.b\(4\)](#)]

The *Guide* describes the nonaffiliated member as a public member "to represent general community interests in the proper care and use of animals and should not be a laboratory animal user." [[Guide p24](#)]

Slide 8 (Nonaffiliated Qualifications)

There are several names for the nonaffiliated member, including the unaffiliated, community, or public member. The nonaffiliated member must be independent of the institution and must represent general community interests. The nonaffiliated member may not be a current or former laboratory animal user.

The only IACUC member that is inherently or always affiliated with the institution is the veterinarian, whether he or she is an employee, a consultant, or a volunteer. This is because the veterinarian has direct or delegated program authority and responsibility for activities involving animals at the institution. Other IACUC members may – or may not – be from within the institution.

Slide 9 (Nonscientist Qualifications)

The Policy and *Guide* also require that the committee have a nonscientist member. This person may not be a scientist. The nonscientist may have an affiliation with the institution or may be from outside the institution.

Slide 10 (Nonscientist Nonaffiliated Qualifications)

IACUCs may choose to have one individual meet the criteria of both the nonaffiliated and

the nonscientist member. This person may fulfill the membership requirements of both positions. Alternatively, an IACUC may choose to have separate individuals fill these two membership criteria.

Slide 11 (Question 1 con't: Nonaffiliated Member?)

>>*Brown*: Question 1 goes on to ask: Why is the nonaffiliated member required to be a non-scientist?

Slide 12 (Answer 1 con't: Nonaffiliated)

>>*Wolff*: The nonaffiliated member is not required to be a nonscientist. The nonaffiliated member may not be a laboratory animal user or a former laboratory animal user. As OLAW explained in our Guide Notice, the PHS Policy is very specific about the composition of the IACUC so that a diversity of perspectives will be represented in the membership of the committee.

Slide 13 (Policy IACUC Membership Requirements)

The PHS Policy requires that an IACUC have a minimum of five members, of course many IACUCs have more than that. Let's look in more detail at the requirements for the composition of the IACUC. The PHS Policy specifies that the committee include a veterinarian with training or experience in lab animal medicine and program authority, a practicing scientist experienced in research involving animals, a nonscientist, and a nonaffiliated member.

We can see that – in these brief definitions – the Policy and the *Guide* are requiring a very diverse committee. We have two required members who have a sophisticated understanding of the use of animals in research. The first is the veterinarian who has extensive training in clinical care of animals and the second is the scientist who has knowledge and experience about the use of animal models in biomedical research. And we have a required nonscientific member who brings a naïve perspective about science – not just lab animal science, but hypothesis based scientific inquiry. And then we have the nonaffiliated member who brings a different perspective to the review of animal research activities, as he or she is not currently, and has never been, a laboratory animal user. The nonaffiliated member contributes an additional quality to the committee, that is, independence from the institution. Both the nonscientist and the nonaffiliated member are intended to balance the opinions of the members who are lab animal experts by providing community values perspectives.

Slide 14 (Question 1 con't: Nonaffiliated)

>>*Brown*: Question 1 stated: Guide Notice NOT-OD-15-109 seems to be so broad that even a college humanities major who took a zoology class to fulfill a science requirement wouldn't be eligible. Who is qualified to serve as a nonaffiliated member?

Slide 15 (Answer 1 con't: Nonaffiliated)

>>*Wolff*: A person who took a zoology class would be qualified to serve as a nonaffiliated

member. Some examples of nonaffiliated members are members of the clergy, nurses, police, fire fighters, bankers, teachers, librarians, clinical medical doctors, veterinarians from the local veterinary practice (but not involved in research), insurance adjusters, just about anyone can be a nonaffiliated member if they are not affiliated with the institution and are not, or have never been, an animal user.

To meet the intent of the Policy, the nonaffiliated member must represent the general community interests in the proper care and use of animals. The nonaffiliated member must not be a laboratory animal user or former user, must not be affiliated with the institution, or an immediate family member of an individual affiliated with the institution. Immediate family includes parent, spouse, child, and sibling.

In evaluating the qualifications of an individual to serve as a nonaffiliated member, the CEO should confirm the appointee has no discernible ties or ongoing affiliation with the institution. Real or perceived conflicts of interest must be avoided to ensure the IACUC's and the institution's integrity. Appointment of an individual who is unambiguously unaffiliated is the most effective way to fulfill the intent of the Policy.

Slide 16 (Question 1 con't: Nonscientist?)

>>*Brown*: Who is qualified to serve as a nonscientific member?

Slide 17 (Answer 1 con't: Nonscientist)

>>*Wolff*: Examples of individuals that are qualified to serve as nonscientist member of the IACUC include ethicists, lawyers, members of the clergy, librarians, those working in business or finance, instructors in English, history, or other liberal arts disciplines, secretaries, barbers, tradespersons, and artisans.

In evaluating the qualifications of an individual to serve as a nonscientist member, the CEO should consider appointing someone with a naive attitude with regard to science and scientific activities. A person without scientific training meets the Policy's intent. The nonscientist may be affiliated with the institution but is not required to be. When the rationale for categorizing an individual as a nonscientist is not apparent based on their occupation and training, the institution should maintain written documentation of the reason for the categorization. You may contact your OLAW Assurance officer for further clarification.

Slide 18 (Answer 1 con't: Nonscientist)

The following individuals would not meet the definition of the non-scientist: those with an animal science or veterinary technical degree, individuals working as veterinary technicians, laboratory research assistants that works with animals, or IACUC administrators.

Slide 19 (Question 2: Nonscientist Criteria?)

>>*Brown*: Question 2 asks specifically: Would the following fulfill the criteria of

nonscientist?

- First, a reverend with a BA in theology that took six undergraduate courses in sciences including biology, chemistry, and physics.
- A lawyer who in high school took science classes every year (including education on the scientific method). She won a prize during high school for a science project. The lawyer is currently not involved in scientific litigation or anything related to science, nor did she take science classes in college.
- And third, a business manager who oversees the budget for a non-profit organization. The non-profit organization applies for grants, using scientific processes for justification of their proposal. He contributes to the budget section and is aware of the scientific process for writing grants but really does not know science very well and has had no scientific training.

Slide 20 (Answer 2: Nonscientist Criteria)

>>*Wolff*: When making a difficult determination, the IACUC should evaluate the criteria of the proposed nonscientist. He or she should have a different perspective than that of someone with experience in science. Undergraduate science requirements contribute to a well-educated person but do not qualify the person as having a science background.

Similarly, high school science classes do not provide the person with a science background. This is a nuanced concept and must be decided on a case-by-case basis. For example, an individual with a 2-year degree in animal science would be someone with a science background, while someone studying pre-law who took undergraduate biology would not have a scientific background. The business manager's focus is on the budget. All of these individuals meet the criteria to serve as nonscientists.

Slide 21 (Question 3: IACUC Role?)

>>*Brown*: Question 3 is also about IACUC composition and has two parts. The first part asks: Does each member of the committee have to be designated as a veterinarian, scientist, nonscientist, or nonaffiliated member?

Slide 22 (Answer 3: IACUC Role)

>>*Morgan*: No, each member of the committee is not required to be designated as one of the four PHS Policy required membership roles, that is – veterinarian, scientist, nonscientific member, nonaffiliated member. These roles must be filled to have a duly constituted committee. If an IACUC member fulfills the qualifications of the PHS Policy roles, then it is best to designate the member as fulfilling that role.

Individuals who do not meet the qualifications to fill one of the required roles may be designated simply as "member" and may serve on the committee. These members may vote and do contribute to the quorum.

OLAW Assures approximately 1000 domestic institutions. Typically, committees at these institutions range in size from the minimum five members up to 15 or more. Additional

members can have any qualifications that the institution thinks are valuable to the committee. We see many committees that include a variety of scientific members, often with expertise in different areas of science or medicine. Committees also include statisticians, librarians, occupational health and biosafety specialists, and others, too. Additional individuals may qualify to fill required PHS Policy membership roles. Or they may bring other expertise to the committee and may be designated simply as “member.”

Slide 23 (Question 3 con’t: IACUC Membership Requirements?)

>>*Brown*: Part 2 of Question 3 goes on to explain: We have been designating individuals such as vet techs or environmental health and safety specialists as nonscientists because they don’t fit the definition of a practicing scientist that uses animals. But now, according to OLAW’s Guide Notice, we don’t think nonscientist is correct, either. To stop appointing these individuals would be a serious loss to our committee. How do we describe their positions in our Assurance?

Slide 24 (Answer 3 con’t: IACUC Membership Requirements)

>>*Morgan*: These individuals should be listed on the IACUC roster as “members,” as I just described.

There was an important statement in Question 2: “To stop appointing these individuals to our committee would be a serious loss.” This statement demonstrates that this institution understands the intent of the PHS Policy and the *Guide* because they value these members who contribute expertise beyond the designated roles. The Policy says that the IACUC must be qualified through experience and expertise to oversee the institution’s program, facilities, and procedures and supports the inclusion of valued expertise on the committee. [[PHS Policy IV.A.3.a.](#)]

Slide 25 (Question 4: IACUC Alternates?)

>>*Brown*: Question 4: May our committee designate a veterinarian who works in the compliance office as an alternate for a scientific member?

Slide 26 (Answer 4: Alternates)

>>*Wolff*: Yes, a veterinarian may serve as the alternate for a scientific member. The PHS Policy defines a scientist as a “practicing scientist experienced in research involving animals.” In this specific situation, the veterinarian has had scientific training and as such can serve as the alternate for a scientific member, but could also be an alternate for the veterinarian, although not concurrently. [[PHS Policy IV.A.3.b.\(2\)](#)]

Slide 27 (Answer 4 con’t: Alternates)

Let’s review the OLAW guidance on alternates. The CEO, or designee, must appoint alternates to the IACUC in writing. Alternates may only serve as an alternate in the membership role for which they are qualified. If the regular member fulfills a specific membership role, his or her alternate must also fulfill that same role. One alternate may be appointed to serve for multiple regular members provided the alternate fulfills the

specific membership role of the members for whom he or she is substituting. However, an alternate may not represent more than one member at any one time. Multiple alternates may be appointed as alternates for one regular member. [[NOT-OD-11-053](#)]

Slide 28 (Question 5: Unqualified Alternates?)

>>*Brown*: Question 5: If an alternate serves on the IACUC in a role for which they are not qualified, is the IACUC appropriately constituted? If this alternate's presence is needed to form a quorum, is the official business in which they voted rendered invalid? And what should be reported to OLAW?

Slide 29 (Answer 5: Unqualified Alternates)

>>*Wolff*: If an alternate serves on the IACUC in a role for which they are not qualified, the IACUC is not appropriately constituted. If the inappropriately appointed alternate's presence is needed to achieve a quorum, official business that the committee voted on would be invalid and the vote would need to be repeated. This is a noncompliant situation that must be reported to OLAW.

Slide 30 (Question 6: NSF-funded PHS-Assured?)

>>*Brown*: Now we have some questions about the relationship between the National Science Foundation [NSF] and OLAW. Question 6: Our university has a current PHS Animal Welfare Assurance. As of October 2015, the PHS Assures National Science Foundation animal activities. However, if I understand correctly, the PHS does not recognize taxon specific guidelines (e.g., *Guidelines to the Use of Wild Birds in Research*) as standards for animal welfare compliance, but the National Science Foundation does recognize taxon specific guidelines. Should we comply with the *Guide* or the taxon specific guidelines for our NSF-funded research which is now Assured by OLAW?

Slide 31 (Notice of Memorandum of Understanding Between NIH and NSF Concerning Laboratory Animal Welfare)

>>*Morgan*: In August 2015, OLAW released a Guide Notice announcing a Memorandum of Understanding between NIH and NSF Concerning Laboratory Animal Welfare. Under the terms of the MOU, OLAW began Assuring NSF funded research, effective October 1, 2015. [[NOT-OD-15-139](#)]

Slide 32 (Answer 6: NSF-funded PHS-Assured)

To be in compliance with the PHS Policy, your NSF funded research must adhere to the standards of the [PHS] Policy, the *Guide for the Care and Use of Laboratory Animals*, and the AVMA Guidelines for the Euthanasia of Animals. The taxon specific guidelines may be used as supplemental references as long as they do not conflict with the PHS Policy, the *Guide*, or the AVMA Guidelines. The IACUC must also ensure compliance with the regulations and permit requirements of local, state, national, or international wildlife regulations.

Slide 33 (Question 7: Impact of MOU?)

>>*Brown*: Question 7: How will the relationship described in the MOU between National Science Foundation and OLAW impact my institution?

Slide 34 (Answer 7: Impact of MOU)

>>*Morgan*: Effective October 1, 2015, if an institution is receiving NSF funding, the institution must have an approved Animal Welfare Assurance with OLAW. If the institution does not have a PHS Assurance, NSF will request that OLAW negotiate one. If your institution has an Assurance, because your institution has PHS funding in addition to NSF funding, you must add NSF to the Applicability section of the Assurance.

Slide 35 (Answer 7 con't: Impact of MOU)

>>*Wolff*: Note that – as you would for PHS funded activities – you are responsible to report any incidents of noncompliance or adverse events involving animal activities funded by NSF to the OLAW Division of Compliance Oversight.

Slide 36 (Question 8: Other Agencies?)

>>*Brown*: Question 8: What impact does the PHS Policy have on animal research funded by other federal agencies (for example, the US Fish and Wildlife Service)?

Slide 37 (Answer 8: Other Agencies)

>>*Morgan*: The PHS Policy applies to animal activities funded by the PHS and to programs Assured by the PHS. The PHS Policy does not apply to research funded or regulated by the US Fish & Wildlife Service. To expand on this question, PHS Policy states, "This Policy does not affect applicable state or local laws or regulations which impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act and with other Federal statutes and regulations relating to animals." Therefore, the IACUC at PHS Assured institutions must ensure compliance with the regulations and permit requirements of local, state, national, and international wildlife regulations. [[PHS Policy II.](#)]

Slide 38 (Question 9: Taxon Specific Guidelines?)

>>*Brown*: Question 9: What is the role of taxon specific guidelines in IACUC review of PHS Assured NSF-funded research?

Slide 39 (Answer 9: Taxon Specific Guidelines)

>>*Morgan*: As stated earlier, investigators may propose and IACUCs may consider taxon specific guidelines as supplemental resources. When capture, handling, confinement, transportation, anesthesia, euthanasia, or invasive procedures are involved, the IACUC must ensure that the studies are conducted in accordance with the *Guide* as the primary standard. The methods of euthanasia must be consistent with the recommendations of AVMA Guidelines for the Euthanasia of Animals. Any departures from either the *Guide* or the AVMA Guidelines must be justified for scientific reasons by the investigator in writing and reviewed and approved by the IACUC.

Investigators and IACUCs are encouraged to consult relevant professional societies, available guidelines, such as taxon specific guidelines, wildlife biologists, and veterinarians, as applicable, in the design of field studies.

Slide 40 (Important Action Alert from the Ornithological Council for Wildlife Researchers, IACUC Administrators and Institutional Officials)

>>*Brown*: The last several questions were based on issues raised in a seven page document called *Important Action Alert from the Ornithological Council for Wildlife Researchers, IACUC Administrators and Institutional Officials* [Distributed by the Ornithological Council]. The Action Alert was released in November 2015. OLAW has also had telephone and email inquiries about the Action Alert. There are misleading and inaccurate statements in the document that we will review and clarify for the community.

Slide 41 (OC Action Alert Inaccuracy 1)

I am going to quickly read from the Alert, exactly as it was written and then OLAW will comment on each statement. The first misleading statement in the Action Alert is about the scope of Assurances with OLAW. It says, "The Animal Welfare Assurance is an agreement between a research institution that receives PHS support for research and the PHS, as mandated by the federal law known as the Health Research Extension Act (HERA) of 1985 [[Health Research Extension Act of 1985 "Animals in Research"](#)]... Although the HERA does not apply to the NSF [National Science Foundation], NSF also requires an assurance. The NSF Grant Proposal Guide states "Any project proposing the use of vertebrate animals... the organization must have a current PHS Approved Assurance." As PHS will not accept an assurance agreement from an institution that does not receive PHS funding, the NSF developed its own assurance process for institutions that receive NSF but not PHS funding."

Slide 42 (OLAW Comments)

>>*Morgan*: It is an inaccurate statement that "PHS will not accept an Assurance agreement from an institution that does not receive PHS funding." OLAW Assures institutions that conduct research involving animals funded by the NIH, the Department of Health and Human Services, Biomedical Advanced Research Development Authority (BARDA), and the PHS agencies – CDC and FDA. In addition, OLAW Assures animal activities funded by the VA, NASA, and NSF.

Slide 43 (OC Action Alert Inaccuracy 2)

>>*Brown*: Next, the Ornithological Council Action Alert says, "This new agreement between PHS and NSF creates a problem because the two organizations differ as to the animal welfare standards that must be followed. The NSF Grant Procedure Guide directs that the taxon-specific guidelines, such as the [Guidelines for the Use of Wild Birds in Research](#), [3rd ed., 2010] be followed for wildlife research funded by NSF. In contrast, the PHS requires that research funded by PHS adhere to the [ILAR Guide for the Care and Use of Laboratory Animals](#) [8th ed., 2011].

Slide 44 (OLAW Comments)

>>*Morgan*: The NSF Grant Procedure Guide is being updated to reference the PHS Policy, the *Guide for the Care and Use of Laboratory Animals*, and the AVMA Guidelines for the Euthanasia of Animals as the primary standards for NSF-funded research. Institutions must comply with the PHS Policy and adhere to the *Guide* and AVMA Guidelines. Taxon-specific guidelines may be used in a supplementary role as long as they do not conflict with the primary standards.

Examples of appropriate taxon-specific guidelines include:

- [*Guidelines to the Use of Wild Birds in Research*](#)
- [*Guidelines of the American Society of Mammalogists for the Use of Wild Mammals in Research*](#)
- [*Guidelines for the Use of Fishes in Research*](#)

Slide 45 (OC Action Alert Inaccuracy 3)

>>*Brown*: The Ornithological Council Action Alert goes on to say, "Of greater concern is a "must" (i.e., mandatory) requirement in the *Guide* that "Veterinarians providing clinical and/or Program oversight and support must have the experience, training, and expertise necessary to appropriately evaluate the health and wellbeing of the species used in the context of the animal use at the institution. ...Most veterinarians at research institutions have no training in wildlife research or veterinary care of wildlife in captivity or in the wildlife. ...Lacking a veterinarian who has "experience, training, and expertise" would mean that every PHS-assured institution would be out of compliance with PHS Policy even if the project was not PHS-funded." Axel, would you like to comment?

Slide 46 (OLAW Comments)

>>*Wolff*: Sure, the basic tenets of appropriate veterinary care such as pain relief, appropriate animal handling, avoidance of distress, humane euthanasia, trauma repair, and other veterinary procedures apply to all species.

Therefore, a wildlife veterinarian is not the only practitioner that would be qualified to evaluate the health and wellbeing of the species used at an institution.

A skilled laboratory animal practitioner, a skilled zoo practitioner, an exotic small animal veterinarian, or a general practitioner with additional training would all be acceptable as having experience, training, and expertise to oversee wildlife work. A consulting or part-time veterinarian with such expertise would also be acceptable. [[Guide p105-124](#)]

Slide 47 (OC Action Alert Inaccuracy 4)

>> *Brown*: The Action Alert goes on to say, "unless the veterinarian accompanies the researcher on each day field work is conducted (including remote locations and locations outside the U.S.), the veterinarian has no opportunity to evaluate the health and wellbeing of the species... used in the context of animal use at the institution."

Slide 48 (OLAW Comments)

>> *Wolff*: OLAW does not interpret the *Guide* as requiring a veterinarian to be onsite during field research. The *Guide* states, "Some aspects of the veterinary care program can be conducted by persons other than a veterinarian, but a mechanism for direct and frequent communication should be established to ensure that timely and accurate information is conveyed to the responsible veterinarian about issues associated with animal health, behavior, and well-being, and that appropriate treatment or euthanasia is administered." This would apply to both laboratory and field research. [[Guide p106](#)]

Slide 49 (OLAW Comments)

If the IACUC approved protocol is being followed and the objectives of the study are being met, routine communication between researcher and veterinarian may not be required. Unexpected outcomes that affect the animals' well-being would be important to communicate. Communication could be by phone, email, or Skype and is not required to be conducted face-to-face.

The *Guide* does not limit the investigator or the IACUC to seek advice only from wildlife veterinarians and states "IACUCs engaged in the review of field studies are encouraged to consult with a qualified wildlife biologist." [[Guide p32](#)]

Slide 50 (Important Action Alert from the Ornithological Council for Wildlife Researchers, IACUC Administrators and Institutional Officials)

>> *Brown*: In summary, the Ornithological Council Action Alert is a document that contains inaccuracies and OLAW recommends that it be disregarded by the community.

Slide 51 (Question 10: Reporting Noncompliance to OLAW?)

Moving on. Question 10: Our institution is PHS Assured but our Assurance does not state that all noncompliance, regardless of funding source, will be reported to OLAW. When should noncompliance involving research that is not funded by the PHS be reported to OLAW, if ever?

Slide 52 (Answer 10: Reporting Noncompliance to OLAW)

>> *Wolff*: Noncompliance involving animal activities not funded by PHS must be reported to OLAW if there is a potential or actual effect on PHS funded activities. Noncompliance that occurs in a functional, programmatic, or physical area that could affect PHS funded activities or those covered by a memorandum of understanding, must be reported to OLAW. Examples include an inadequate program of veterinary care, training of technical or husbandry staff, occupational health, inadequate sanitation due to malfunctioning cage washer, or room temperature extremes due to HVAC failure.

As we noted earlier, after October 1st, 2015, noncompliance involving NSF funded activities must be promptly reported to the OLAW Division of Compliance Oversight.

Slide 53 (Question 11: Exempt Review Process?)

>>*Brown*: Now we have a number of questions about IACUC review of animal activities, also referred to as animal study proposals or protocols. Here is Question 11: My institution has developed a requirement for a process that we call "IACUC Exempt Review." We require this process when students review secondary data that involves animals. It is similar to the process used by IRBs in human subjects research reviews. What should be included in an exempt application? Can the IACUC designate the IACUC administrator to make these types of exempt determinations?

Slide 54 (Answer 11: Exempt Review Process)

>>*Morgan*: The PHS Policy does not require such a review. Therefore, we do not have any advice on what to include. The institution should determine what information is required to meet needs that the review was developed to address. It would be up to the institution to determine who could address the administration of their process.

The question mentioned that the institution's process is similar to one applied to human subjects research. Human subjects regulation differs from animal research oversight. Even though there are similarities between the human and animal side, it would be a mistake to assume the same rules and regulations apply to both.

We have a saying at OLAW – the PHS Policy is a floor not a ceiling. That means that the PHS Policy is the standard that institutions must meet. Institutions may exceed the requirements of the Policy – if they so choose. When we get complaints from institutions about excessive regulation, we find that the regulatory burden is often self-imposed. Institutions should be careful not to impose restrictions on themselves unnecessarily. Another way of saying that is – we encourage institutions to make sure they receive appropriate benefit from self-imposed burdens.

Slide 55 (Question 12: IACUC Responsibility?)

>>*Brown*: Question 12: What are the IACUC's responsibilities in these two situations? The first one: tissue samples collected from vertebrate animals by a PI at another institution and sent to a PI at our institution to be analyzed (for example, population genetic research). And number two: analysis of archival data (for example, video-taped behavior) gathered on vertebrate subjects.

Slide 56 (Answer 12: IACUC Responsibility)

>>*Wolff*: When tissue is collected from live animals, IACUC review and approval is required. When that tissue is subsequently analyzed at another institution, further IACUC review is not required. The reasoning for this guidance is similar to the reasoning about obtaining off-the-shelf tissues from a repository or commercial source. No review is required. Similarly, no review is required for analysis of archived data such as videotaped behavior.

Slide 57 (Question 13: Signatures?)

>>*Brown*: Question 13: We are not required to obtain signatures on approved animal study proposals.

- May we rely on meeting minutes to confirm that relevant approvals were obtained?
- How should we confirm approval of proposals that were reviewed by the Designated Member Review [DMR] process?

Slide 58 (Answer 13: Signatures)

>>*Morgan*: You are correct that there is no Federal regulation that requires signatures on approved animal study proposals. The PHS Policy allows institutions the latitude to develop business practices that meet their needs. Yes, you may rely on meeting minutes to confirm that relevant approvals were obtained. This may also apply to review and approval conducted by designated member review.

Slide 59 (Question 14: DMR Reassignment?)

>>*Brown*: Question 14: Occasionally our IACUC Chair will appoint someone for DMR, but the designated reviewer cannot complete the protocol review on time for unexpected reasons, such as illness, family emergency, or lack of time. In such situations, can the Chair reassign the DMR to another member? If this is allowed, can OLAW suggest an acceptable process for such a reassignment?

Slide 60 (Answer 14: DMR Reassignment)

>>*Morgan*: Yes, it is perfectly acceptable for the Chair to reassign the designated member review to another qualified reviewer. The IACUC is free to determine a process that works for their program. It is important to document the reassignment. The PHS Policy requires that the designated member be qualified and appointed by the IACUC Chair. It is not necessary to contact the IACUC members as they have previously consented to DMR for protocol review.

Slide 61 (Question 15: SOPs?)

>>*Brown*: Question 15: Our IACUC would like to allow investigators to use IACUC approved SOPs [standard operating procedures] as part of a protocol submission. Can SOPs be referenced by number or is it necessary to include an actual copy of each SOP in the protocol? Do you have suggestions on best practice or advice on what pitfalls to avoid?

Slide 62 (Answer 15: SOPs)

>>*Wolff*: Yes, IACUC approved SOPs can be referenced for inclusion in a protocol. The SOP can be referenced by title or number. The most important consideration is that laboratory staff, IACUC members, and animal program personnel must have access to the content of the SOP to ensure appropriate conduct of the animal activity.

The most likely pitfall is that the SOP content is not familiar to the laboratory staff or that a different SOP is used than intended. SOPs should be reviewed by the IACUC every three

years to ensure that they are accurate and up to date. Or more often if the industry dictates a change or refinement of current methodology.

Slide 63 (Question 16: Refinement?)

>>*Brown*: Question 16: Can the IACUC withhold IACUC approval based on refinement issues? For example, if the IACUC believes that there is a blood collection or surgical technique that is less stressful to the animal than the one proposed by the investigator, can the IACUC require the investigator to use the procedure it prefers?

Slide 64 (Answer 16: Refinement)

>>*Wolff*: It is the IACUC's responsibility to work with the investigator so that the most effective technique is used to safeguard animal welfare and accomplish the aims of the study. In this example, the IACUC might ask the investigator, why he or she chose this particular method and suggest the use of an alternative.

Slide 65 (Question 17: Euthanasia?)

>>*Brown*: Question 17: What level of detail about euthanasia should be included in an animal study proposal?

Slide 66 (Answer 17: Euthanasia)

>>*Wolff*: The IACUC should determine the information needed to meet its responsibility to ensure that the procedure will minimize pain and distress to the animal, consistent with sound research design and will be in compliance with the [AVMA Guidelines for the Euthanasia of Animals](#).

OLAW has an optional sample Animal Study Proposal [ASP] form on our website. The URL is provided on the slide. [[OLAW sample ASP](#)] In this form, we suggest that the IACUC request the following information: Indicate the proposed method of euthanasia. If a chemical agent is used, specify the dosage range and route of administration. If the methods of euthanasia include those not recommended by the AVMA Guidelines, provide scientific justification as to why such methods must be used. Indicate the method of carcass disposal.

Slide 67 (Question 18: Pain Category?)

>>*Brown*: Question 18: Recently a PI submitted a protocol to our IACUC in which they will be using Freund's complete adjuvant in mice. They listed the pain category as C (momentary pain or distress). They also submitted a pain management plan, if pain or distress is noted in the mouse. Our IACUC discussed if this would be the proper pain category. Discussion was tabled until more guidance could be provided. Any help on this issue would be greatly appreciated.

Slide 68 (Answer 18: Pain Category)

>>*Wolff*: Pain categorization is required for the use of USDA regulated species. The PHS Policy does not require pain categories, but it does require that "procedures with animals

will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.” [[PHS Policy IV.C.1.a.](#)]

OLAW recognizes that some institutions choose to assign USDA pain categories to species that are not USDA regulated as part of their process to meet the PHS Policy requirement to minimize pain and distress. If unsure about the potential for pain caused by the procedure, the IACUC could ask the investigator to provide additional information or could consult a subject matter expert.

Slide 69 (Question 19: Departures?)

>>*Brown*: The next questions are about responsibility. Question 19: The first time the IACUC approves a departure, it must be reported in the next semiannual report to the Institutional Official [IO]. A record of the departure must be maintained for as long as the departure is active and approved. If the animal use protocol containing the same departure is renewed as a *de novo* protocol after a third year review, would I need to report the exemption to the IO again? Or is the one time report, regardless of how long the exemption exists, sufficient?

Slide 70 (Answer 19: Departures)

>>*Morgan*: Departures from the *Guide*, including the reason for the departure, should be provided in the next semiannual report to the Institutional Official after the initial review and approval by the IACUC. A mechanism for listing all active approved departures should be retained for review and tracking. Relevant personnel, including the IO, IACUC members and staff, should be able to access the list. The departure should be maintained on the list as long as it is active.

Slide 71 (Guidance on Significant Changes to Animal Activities)

>>*Brown*: In August 2014, OLAW released a Guide Notice on Significant Changes to Animal Activities [[NOT-OD-14-126](#)] to help IACUCs reduce regulatory burden while meeting the PHS Policy requirements. The next questions are about the Veterinary Verification and Consultation [VVC] process described in that Guide Notice.

Slide 72 (Question 20: VVC?)

Question 20: Can Veterinary Verification and Consultation be used if an investigator realizes, months after protocol approval, that there is a need for a one time tail vein blood withdrawal? The approved protocol does not mention any blood withdrawal. The IACUC has an approved VVC policy and has an approved policy for tail vein blood collection that defines allowable volume per draw and frequency. The investigator’s request for approval of the one-time withdrawal meets all of the requirements of the approved policy.

Slide 73 (Answer 20: VVC)

>>*Wolff*: To answer this question, let’s first review OLAW’s [Veterinary Verification and Consultation guidance](#). Specific significant changes may be handled administratively according to IACUC-reviewed and -approved policies in consultation with a veterinarian

authorized by the IACUC. The veterinarian is not conducting DMR, but is serving as a subject matter expert to verify that compliance with the IACUC-reviewed and -approved policy is appropriate for the animals in this circumstance.

Consultation with the veterinarian must be documented. The veterinarian may refer any request to the IACUC for review for any reason and must refer any request that does not meet the parameters of the IACUC-reviewed and -approved policies. This includes changes in:

- anesthesia, analgesia, sedation, or experimental substances;
- euthanasia to any method approved in the AVMA Guidelines; and
- duration, frequency, type, or number of procedures performed on an animal.

Slide 74 (Answer 20 con't: VVC)

The question tells us that the approved protocol does not mention any blood draws. Even though this procedure falls within the parameters of the IACUCs approved blood collection policy, the VVC process may not be used to add a new procedure to a previously approved protocol. The blood draw would need to be added to the protocol by full committee or designated member review.

Slide 75 (Question 21: VVC?)

>>*Brown*: Here's another question on VVC: Can VVC be used if an investigator realizes that an additional cardiac procedure is needed (in this case, it includes anesthesia, venous cut-down, cardiac catheterization, closure and recovery) after the protocol has been approved? The approved protocol specifies four procedures and the PI requests a 5th. The IACUC has an approved policy that permits VVC. They also have an approved policy that permits up to six catheterizations.

Slide 76 (Answer 21: VVC)

>>*Wolff*: Yes, the VVC process can be used to administratively handle this significant change to this protocol for the following reasons:

- The IACUC has approved policies in place.
- The request is a significant change to an already approved procedure.
- The veterinarian confirms that the policies are being applied appropriately.

Slide 77 (Question 22: Contract Congruence?)

>>*Brown*: Question 22: Is there a requirement for congruence between contracts and IACUC protocols, similar to the requirement for grant protocol congruence? Since contracts are often undergoing negotiations right up until the time of award, completing an accurate comparison can be challenging.

Slide 78 (Answer 22: Contract Congruence)

>>*Morgan*: Yes, verifying congruence between the description of the animal activity in the contract proposal and that in the IACUC approved protocol is required for contracts in the same manner as it is required for grants.

Slide 79 (Question 23: Animal Ownership?)

>>*Brown*: Question 23: How does OLAW define animal ownership? Should animal ownership be addressed in a memorandum of understanding?

Slide 80 (Answer 23: Animal Ownership)

>>*Morgan*: OLAW considers that animals are the responsibility of the Assured institution that houses them. The *Guide* states, in the section on Collaborations, "...the participating institutions should have a formal written understanding (e.g., a contract, memorandum of understanding or agreement) that addresses the responsibility for offsite animal care and use, animal ownership, and IACUC review and oversight." [[Guide p15](#)]

Slide 81 (Question 24: Verification of IACUC Approval?)

>>*Brown*: Question 24: Our IACUC is often notified by investigators about a pending grant award with a very short turn around (in some cases, days) for IACUC review and approval. What can the IACUC do to meet the requirements for the grant process? And, is the investigator at risk of losing their award?

Slide 82 (Answer 24 con't: Verification of IACUC Approval)

>>*Morgan*: The PHS Policy [[IV.D.2-3](#)] requires that verification of IACUC approval be provided before an award is made. Under no circumstances may an IACUC be pressured to approve a protocol or be overruled on its decision to withhold approval. The Policy requires that modifications required by the IACUC be submitted to the NIH with the verification of IACUC approval. It is the responsibility of institutions to communicate any IACUC-imposed changes to NIH grants management staff.

Slide 83 (Question 24 con't: Verification of IACUC Approval?)

>>*Brown*: Is the investigator at risk of losing their award, Eileen?

Slide 84 (Answer 24 con't: Verification of IACUC Approval)

>>*Morgan*: Typically the answer is no, but it depends on the time in the Federal fiscal year and the intent to make an award as communicated to the PI by the NIH grants management staff. NIH Institutes and Centers vary in their funding practices. OLAW recommends that the investigator discuss the situation with the IACUC as early as possible. It is beneficial to provide the anticipated IACUC approval date to NIH grants management.

Slide 85 (Answer 24 con't: Verification of IACUC Approval)

At the end of the fiscal year (Federal fiscal year; that's July, August, or September), NIH grants managements may make awards but restrict the draw-down of funds to the portion of the grant that does not include the use of animals until valid IACUC approval is obtained. This is called a restricted award.

Slide 86 (Reminder: Annual Reports to the Office of Laboratory Animal Welfare due January 31, 2016)

Now I'd like to add a reminder regarding the 2015 Annual Report due to OLAW by January 31st, 2016. As with previous annual reports, the information to be reported consists of any change in the institution's animal care and use program, any change in the Institutional Official or IACUC membership, the dates that the IACUC conducted its semiannual evaluations of the program and facilities, and any minority view by an IACUC member. [[NOT-OD-16-022](#)]

Slide 87 (OLAW Comment: Annual Report)

Remember to include any program changes in response to recent OLAW policy updates:

- If your IACUC established policies for administrative handling of some significant changes, indicate that you have a program change and list what these policies are. You do not need to attach or provide copies of the policies. [See [NOT-OD-14-126](#)]
- Include an updated IACUC roster if you've had membership changes such as changes to comply with the guidance on the qualifications of nonscientific and nonaffiliated members. [See [NOT-OD-15-109](#)]
- For institutions with NSF-supported animal activities – Indicate that you have a program change and attach page one of your Assurance (Part I. Applicability) so that it reads: "I. Applicability of Assurance. This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS and NSF. This Assurance covers only those facilities and components listed below." When your Assurance is renewed during your regular renewal cycle, the Assurance document will be updated and submitted to include NSF, as applicable. [See [NOT-OD-15-139](#)]

Slide 88 (Upcoming OLAW Online Seminars)

>>*Brown*: We have come to the end of our webinar. Your questions spanned a broad range of topics, but there is an underlying theme in our answers. The PHS Policy and OLAW guidance support the use of professional judgment by IACUC members and staff. IACUCs have the responsibility and the authority to exercise professional judgment in the humane care and use of research animals, and to reduce burden to the IACUC and to the investigators. Thanks to all of you for participating in this webinar, particularly those who sent in questions.

As mentioned at the start of the webinar, we have recorded the webinar and will post a transcript. So if you would like to review any of the content, you can find it on the OLAW website. [[Education Resources](#)] We anticipate posting that material next week. We'd like to repeat this Office Hour webinar on a periodic basis, if this has been helpful to you, so let us know.

The next OLAW webinar will be on March 3, 2016 when we will discuss the changes in NIH grant application requirements for the use of vertebrate animals. We will especially focus

on how these changes impact congruence review between grant applications and IACUC protocols. We look forward to an exciting 2016 webinar series. So send your topic ideas for upcoming webinars to olawdpe@mail.nih.gov. Good-bye, everyone.

Additional Submitted Questions Not Addressed During the Webinar

[Question 25] Our nonaffiliated member is an anatomy and physiology, microbiology and genetics professor at the local college. He is not affiliated with our institution or any other institution we currently have an MOU with. He did some lab animal work for his Master's thesis in 1972, but has not done lab animal work since. Can he still be our nonaffiliated member?

>> No, the individual that you describe has been an animal user and therefore would not meet the qualifications for the nonaffiliated member. He can still serve on the IACUC as a scientist or he can be listed on the IACUC roster as "member."

The nonaffiliated member must represent the general community interests in the proper care and use of animals. The nonaffiliated member must not be (1) a laboratory animal user or former user, (2) affiliated with the institution, or (3) an immediate family member of an individual affiliated with the institution. Immediate family includes parent, spouse, child, and sibling. In evaluating the qualifications of an individual to serve as a nonaffiliated member, the CEO should confirm the appointee has no discernible ties or ongoing affiliation with the institution.

[Question 26] We have a nonaffiliated member that has received a Bachelor of Science in Geology and a Master's of Education. He has never done lab animal work. He is a Geology professor at the local college. Can he be considered a nonscientist?

>> No, this individual cannot serve as a nonscientist since he has a science degree and is working in a scientific field. He does meet the qualifications of a nonaffiliated member, as described above [Question 25]. Note that the nonaffiliated member and the nonscientist member do not have to be one individual. Rather these roles may be designated to two different individuals.

[Question 27] Does a scientist member of the IACUC have to have a PhD or MD and/or be a Principal Investigator, or would a study staff member with 30+ years of experience conducting animal research (but no advanced college degree) qualify?

>> A person with experience in research using animals would qualify to be a scientific member. A PhD or MD is not required to be a scientific member. It is not a requirement that a scientific member be a PI.

[Question 28] Please define "minority views" and explain when they should be included in (1) the Semiannual Report to the IO, and (2) Meeting Minutes.

>> Minority views can be related to any issue that the IACUC is responsible for; they are not restricted to any specific issue or time period. Minority views are those found in semiannual IACUC reports concerning findings during program review and facility inspections. Minority views may also be included in recommendations to the IO regarding any aspect of the institution's animal program, facilities, or personnel training that were submitted at any time during the reporting year. Minority views involving noncompliance reports may be included in the meeting minutes or in the reports to the IO. All of these examples of minority views must be included in the annual report to OLAW.

Some IACUCs have expressed confusion about the difference between a minority view and a dissenting vote. Both protocol approval and suspension of animal study protocols by the IACUC require a majority vote of a quorum of the IACUC. Although an IACUC member's dissenting vote on these issues must be recorded in the minutes, this does not constitute a minority view for reporting purposes (unless the IACUC member chooses to submit a minority view regarding their dissenting vote). In addition, 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, we carefully review the information provided according to the requirements of the PHS Policy and provisions of the *Guide*.

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