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Research Using Agricultural Animal Species

Speakers:

- Debbie Cunningham, DVM, Oklahoma State University
- Louis DiVincenti, DVM, MS, DAACLAM, DACAW, USDA, APHIS, Animal Care
- Susan B. Harper, DVM, MS, DAACLAM, DACVPM, RBP (ABSA), NIH (representing AAALAC International)

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Slide 1: Research Using Agricultural Animal Species

>>Nicolette Petervary Good afternoon, everyone. I'm Dr. Nicolette Petervary, part of the NIH Office of Laboratory Animal Welfare. Today is Thursday, March 21st, 2024, and I'm pleased to welcome you and our speakers to our webinar today on research using agricultural animal species. There are just a few housekeeping details before we get started. If you have questions throughout the webinar, please enter them in the Q&A box. The Q&A box does allow questions to be submitted anonymously, and the chat will also be enabled for this webinar. We will be taking questions at the end of the webinar, and if we run out of time or if the question is a little more nuanced or context-specific, we'll forward the questions to the presenters after the webinar, and then we'll append the questions and answers to the end of the transcript. We'll monitor the chat as best we can, and we encourage you to use it to interact with us and with other participants. The slides, transcript and webinar recording will be available after the webinar on our website, but they do need to be processed for 508 compliance compatibility before posting, and this can take a few weeks, so please bear with us.

I'll start with an introduction for our speakers in the order that they will present. Dr. Louis DiVincenti graduated from the Louisiana State University School of Veterinary Medicine in 2010, completed a residency in comparative medicine at the University of Rochester and Seneca Park Zoo in 2012, and earned a Master of Science degree in clinical translational research in 2014. He was board certified by the American College of Laboratory Animal Medicine in 2013, and the American College of Animal Welfare in 2015. Dr. DiVincenti has held positions as clinical and Attending Veterinarian at academic and contract research organizations, zoos, and private and corporate practice. In 2023, Dr. DiVincenti joined USDA as the Senior Veterinary Medical Officer for Research on Animal Care's national policy staff.

Dr. Susan Harper received her DVM from Louisiana State University and worked in large animal practice for several years before enrolling in a postdoctoral residency and master's degree program in comparative medicine at the Penn State University College of Medicine. She served on the Penn State faculty for two years following graduation before accepting a position with the U.S. federal government. She has worked at several different departments and agencies throughout her career, and currently

serves as the Deputy Director for the Office of Animal Care and Use (OACU) at the National Institutes of Health in Bethesda, Maryland. She is a member of the AAALAC International Council, a diplomate in the American College of Laboratory Animal Medicine and the American College of Veterinary Preventive Medicine, a registered biosafety professional through the American Biological Safety Association, and an active member of numerous professional and veterinary safety organizations.

Dr. Debbie Cunningham is Assistant Vice President for Research at Oklahoma State University in the Office of University Research Compliance. This office supervises all university research compliance programs including IACUC, IRB, IBC, Conflict of Interest, RCR, radiation, laser, biosafety, and Select Agents. Dr. Cunningham holds a BS in microbiology and a DVM degree from Oklahoma State University and is currently completing a residency program in the American College of Animal Welfare.

I'll begin by providing a brief overview of OLAW guidance, followed by Dr. DiVincenti presenting USDA requirements, Dr. Harper presenting the views of AAALAC International, and Dr. Cunningham presenting her perspectives as Assistant Vice President for Research at an institution that utilizes agricultural species.

Slide 2: Office of Laboratory Animal Welfare (OLAW) Resources on Research Using Agricultural Animal Species

OLAW does have some guidance on the use of agricultural species.

Slide 3: Public Health Service (PHS) Policy Definition of Animal

And let's start with the PHS Policy definition of an animal, which is “any live vertebrate animal used or intended for use in research, research, training, experimentation, or biological testing, or for related purposes.”

Slide 4: Where the PHS Policy Applies

Activities are subject to the PHS Policy when animal activities are funded by the PHS and HHS, but it also applies to the funding entities that have memoranda of understanding with OLAW that include the National Science Foundation, the Department of Veterans Affairs, and the National Aeronautics and Space Administration.

Slide 5: Animal Welfare Assurances

Wherever the PHS Policy applies, an animal welfare Assurance is required for all performance sites conducting animal activities. The Assurance is a contract with the federal government that provides a description of the institution's animal care and use program, and documents institutional commitment to follow the Assurance as written. And this means you will be held to what is described in your assurance, even if the Assurance exceeds regulatory requirements, such as covering animals that are not subject to the PHS Policy.

Slide 6: What About Animals Not Subject to the PHS Policy or Covered by the Assurance?

So what about animals that aren't subject to the PHS Policy? Well, institutions need to consider how activities involving these animals may impact those that are covered. OLAW FAQ A.1. states that institutions must ensure that any standards that might not be consistent with PHS policy do not affect or pose risks to PHS supported activities, and you can read more by visiting [the URL on this slide](#).

Slide 7: Guide for the Care and Use of Laboratory Animals (1)

The *Guide for the Care and Use of Laboratory Animals* does not address agricultural animals used for agricultural research in detail, but it does include agricultural species in its definition of animal, and it establishes general principles and ethical considerations that are also applicable to these species and situations.

Slide 8: Guide for the Care and Use of Laboratory Animals (2)

The *Guide* has a section on special considerations for IACUC review that includes a discussion of agricultural animals. It states that classification of research as agricultural or biomedical research is not always straightforward. However, agricultural species are subject to the same ethical considerations as for other animals in research, whether classified as biomedical or agricultural research. Institutions are expected to provide oversight of all research animals and ensure that pain and distress are minimized.

Slide 9: Guide for the Care and Use of Laboratory Animals (3)

It goes on to state that the protocol, rather than the category of research, should determine whether a farm or laboratory setting is appropriate. It clarifies that the *Guide* applies to agricultural animals used in biomedical research, including those maintained in typical farm settings, and adds that for farm settings, the *Guide for the Care and Use of Agricultural Animals in Research and Teaching*, otherwise known as the *Ag Guide*, as well as the use of subject matter experts, may be helpful as resources that are in addition to the *Guide*.

Slide 10: Agricultural Animal Species are Also Addressed in Other Guide Sections

Agricultural species are referenced throughout the *Guide*, and I summarized where they're discussed in the table on this slide. And you can see that they're discussed in terms of restraint, housing, environment, space, and facilities.

Slide 11: Other Resources

Finally, [OLAW FAQ G.7](#) clarifies that Assured institutions may use the *Ag Guide* only as a supplement to the *Guide for the Care and Use of Laboratory Animals*, and not as the primary guidance document when farm animals are used or intended for use in biomedical or behavioral research, research training, biological testing, or related purposes. And you can read more in the URL on the slide. We also have some lab animal protocol review scenarios that discuss agricultural species that are referenced on this slide, but please be aware that commentary is provided in response to specific scenarios and may not be generalizable to your situation, so always contact OLAW directly if you have compliance questions relating to a circumstance at your institution. And now Dr. DiVincenti will discuss agricultural species and activities from a USDA perspective.

Slide 12: Horses and Other Farm Animals and the Animal Welfare Act

>>*Louis DiVincenti*: Thanks Nicolette. I'm Louis DiVincenti, and I'm going to talk about USDA's stance on some of this and what's covered in the Animal Welfare Act. And this is really timely for us because I have been getting a lot of questions about this recently. So hopefully this is clarifying for a lot of people as we move through this.

Slide 13: "Animal" Under the Animal Welfare Act (AWA)

So under the Animal Welfare Act, the term "animal" excludes birds, rats and mice bred for use in research, which we know, [and] it also excludes horses not used for research— horses *not* used for

research. That means horses *used for research* are included. So we'll break that down. And then it also excludes other farm animals used or intended for food or fiber or for improving food or fiber type things. And so generally we refer to that as agricultural uses. So farm animals that are used for agriculture (food or fiber production) or research that's agricultural are excluded from the Animal Welfare Act. Next.

Slide 14: Any “Animal” Here?

Under the Animal Welfare Act, are there any “animals” here [on this slide]? Racehorse, pigs and cattle on feedlots and [in] gestation crates, a sheep being shorn. No, there are no “animals” here. These are all not “animals” under the [definition in the] Animal Welfare Act.

Slide 15: Regulation of Horses and Other Farm Animals Used for Biomedical or Non-Agricultural Research

Congress gave USDA the authority to regulate warm-blooded animals— all warm-blooded animals— with the 1970 Animal Welfare Act amendments. But as a matter of policy, we chose not to regulate those animals until 1990. And so in our in our Notice of Intent to regulate those animals (horses and other farm animals) that's where we clarify that horses and farm animals used for biomedical and non-agricultural research are covered.

So we'll break that down little bit more. Again, there is a distinction in the Animal Welfare Act between horses and other farm animals. So that's important to recognize as we move through some of this.

Slide 16: Horses Used for Research Are Covered

So horses used for research are covered. Any time horses are used for *any* research, even agricultural under the Animal Welfare Act, they are covered. That's a distinction that Congress made distinguishing them from other farm animals. So horses are... should be a little bit easier. Any time they're used for research they're covered. Any time they're not used for research they're not covered. And when they are covered, compliance with all the regulations and the standards that are in subpart F of the Animal Welfare Act Regulations are required.

****POST-WEBINAR CLARIFICATION FROM USDA:**** As of 5/16/24, USDA is clarifying its position on regulation of horses and other farm animals as presented in this webinar. Although USDA has statutory authority to regulate horses used for research and other farm animals used for biomedical and non-agricultural research, we are not changing our current inspection procedures and regulatory oversight of horses and other farm animals at this time. USDA's regulation of horses and other farm animals remains limited to farm animals being used as models for diseases of humans. Should any changes occur in the future, adequate notice will be provided to the regulated community.

Slide 17: Exceptions

Of course we all know that there are always exceptions to the Animal Welfare Act and then exceptions to the exceptions, right? Any time there are the animals are client owned (so they're patients or involved in a clinical trial under a veterinarian-client-patient-relationship) those are excluded. Even if they're being used in a teaching setting. So if this horse [pictured on slide] is getting a PET scan as part of its diagnostics at a veterinary school, then that's not covered. But if this is a veterinary school owned horse

and this this clinician is trying to develop normal PET scan parameters for a horse limb, then that would be covered so that the ownership of the animal [and] the intent of the use is all taken into account there.

Slide 18: Farm Animals Used for Agriculture are Not Covered

Now, on the other hand, farm animals. So other farm animals (besides horses), [that are] used for agriculture, are not covered. So that includes food and fiber production or research that is improving animal nutrition, breeding management, or production efficiency. So when I think of agricultural things, kind of the distinguishing factor that I use is things that happen on a farm or that a farmer would be involved in. And so obviously farmers are involved in nutrition, they're involved in breeding, they're involved in in different types of managing the animals. They care a lot about production efficiency and feed conversion and that sort of thing, and the quality of the meat that that's being produced or the fiber that's being produced or feathers for some of the bird species that we cover— those are the things that are agricultural in nature and are not covered.

Slide 19: Biomedical and Non-Agricultural Research / Teaching are Covered

On the other hand, biomedical and *nonagricultural research or teaching* is covered. So under the Animal Welfare Act teaching and research are equivalent, right? So biomedical research or teaching is covered under the Animal Welfare Act. And we think of biomedical research where what we're talking about is the study of processes of life and the prevention and treatment of diseases, with the ultimate goal of developing treatments and cures for those diseases. And so it's not necessarily translational research. So animal-targeted or animal-centered medical research is biomedical research as well. So all biomedical research, whether or not it has a human application, is covered under the Animal Welfare Act.

Slide 20: Any “Animals” Here? (1)

So are there any “animals” [under the Animal Welfare Act] here [pictured on the slide]? So this is a horse being used for diphtheria testing or vaccine development, a pig having some neurophysiological or neuroanatomy procedure being done, and a sheep post-op from a [research] cardiovascular procedure. Let's say this is a university-owned cow being used to teach veterinary students ultrasound skills. So these are all animals under the Animal Welfare Act.

Slide 21: Any “Animals” Here? (2)

It can be complicated though. So these are bison [pictured on the slide]. They're being used to develop a vaccine for Malignant Catarrhal Fever, which is an animal disease of cattle— that cattle get. These animals are being used to develop a vaccine for cattle, so it will...never improve human medicine [and] will never affect humans. It's not translatable at all. But it's still biomedical. It's still targeting a disease process and with the idea of preventing that disease process. It's not something a farmer is doing. So that's not agricultural research that would be exempt. So these are “animals” under the Animal Welfare Act.

Slide 22: It Can Be Complicated

And it can be complicated. We do recognize that. So let's say this sheep [pictured on the slide] is in this metabolic chamber for a pharmacodynamic study on a deworming medication. That's biomedical. That's not agricultural. A farmer is not interested in pharmacodynamics. So that's covered. Now, let's say the same sheep is in this metabolic chamber and they're studying feed conversion efficiency as the result of that same deworming drug. Then that would be agricultural and not covered. And so there are some really specific nuances, and these can be very situational. And so it's, it's again, going back to the intent of what's agricultural and what's not and kind of parsing that is what we're looking at.

Slide 23: The Purpose of the Activity Matters

And then again, the purpose of the activity matters. These are two students [pictured on the slide] learning how to palpate a cow. This one on the left is not an “animal” [because] that's an animal science student. The one on the right is a veterinary student indicated by her stethoscope. But...

Let's do one more click Nicolette.

I'm sorry. Do one more click.

>>*Nicolette Petervary*: Got it.

>>*Louis DiVincenti*: So this is a veterinary student learning how to palpate a cow: that's biomedical. And [the] animal science student: that's agricultural. And so obviously we recognize that to the cow, it doesn't matter who's palpating it, but it matters to Congress. That's... they made the distinction between agricultural and nonagricultural, and so that's where we are with that making that distinction. Next slide.

Slide 24: When in Doubt, Ask!

Again, we recognize that there are a lot of nuances, and these are really situationally specific sometimes. And so if there's a doubt, ask and we will [assist]. Reach out to me, reach out to your inspector, and we'll be happy to walk you through the thought process of that specific situation. Next slide.

Slide 25: USDA Contact Information

I think that's it. Yeah. So again, feel free to reach out if you have any questions, either to me or to your local inspector and they'll help. Thank you.

>>*Nicolette Petervary*: Thank you, Dr. DiVincenti. And now we'll go on to Dr. Harper.

Slide 26: Research Using Agricultural Animal Species (AAALAC)

>>*Susan Harper*: Okay. Before I start, I want to thank Dr. Petervary and OLAW for the opportunity to participate in today's webinar. Next slide.

Slide 27: Disclaimer

I have a short disclaimer that although I am employed by the NIH intramural program, I also serve on AAALAC International Council in my personal capacity. And I want to clarify to the audience that I'm participating in today's webinar as a member of the AAALAC Council [on Accreditation] and not as an NIH or government employee. Next slide.

Slide 28: What is AAALAC International

There may be some of you in the audience who are not completely familiar with AAALAC, so we'll start off by briefly going over what AAALAC International is and what it does. AAALAC, as the name implies, is an international, private, nonprofit organization that promotes the humane and ethical treatment of all types of animals used in science and education. And the way it accomplishes this goal is through a voluntary assessment and accreditation program.

There are many reasons why an institution might decide to become accredited. Some use accreditation as a symbol of quality, because it's a way of showing colleagues that their institution is serious about setting, achieving, and maintaining high standards for the care and use of animals used in research, testing, and teaching. Another benefit is that it helps to promote and harmonize best practices among the many different programs that have elected to go the accreditation route. AAALAC accreditation also

helps to improve the quality, validity, and scientific integrity of data gained through animal studies, because good animal care and good science go hand in hand. Animals that are healthy and receiving superior care are more likely to yield reliable results. And perhaps most importantly, accreditation demonstrates to the public that an institution is fully committed to the responsible use and treatment of research animals and as part of that commitment is willing to go above and beyond the minimum standards that are required by law. All of these are important functions because, as we just heard, there are some agricultural animals used in research that do not fall under the jurisdiction of USDA or OLAW. However, institutions with these types of animals can still demonstrate their commitment to excellence in animal care by voluntarily pursuing accreditation through AAALAC.

AAALAC provides an invaluable service for these programs by providing an independent third-party assurance that their institution is responsible and accountable for the ethical and humane treatment of all animals used in research at their institution. Today there are more than 1100 companies, universities, hospitals, government agencies and other types of research institutions in more than 50 countries all over the world that have earned AAALAC accreditation. And when you first hear that number, it may sound like most or at least a lot of programs are accredited. However, if you think of all the research programs that exist, both large and small around the world, you realize that this is actually a very small percentage of the total. So that means if you are an accredited program, you are part of a very elite group of world leaders in animal care. Next slide please.

Slide 29: Growth of Accredited Programs

This slide illustrates how the number of accredited programs is growing and expanding every year. The graph starts at 1993, when there were just a little over 550 accredited programs and runs through 2023, when that number has grown to over 1100. It shows that the number of accredited programs has more than doubled in 30 years and is continuing to increase. Next slide.

Slide 30: Accredited Programs by Industry Sector

The pie graph on this slide illustrates the breakdown of accredited programs by industry sector. Commercial programs, which include pharmaceutical companies, animal suppliers, and contract research organizations represent the largest sector, accounting for about 46% of all accredited programs. Next are universities that make up 27% of the total, followed by programs administered by government agencies and organizations, which account for about 13% of the total. Then nonprofit organizations at around 10%, and last, independent hospital research programs coming in at about 4%. In each of these sectors, there are accredited units that conduct research with agricultural animals. In some cases, the use of agricultural animals is selective, and in other cases agricultural animals may account for most of the program. Next slide.

Slide 31: Accreditation Principles

Just to repeat, AAALAC is not a regulatory agency. It doesn't make or enforce any [legal] rules or regulations, and instead it's governed by a set of rules for accreditation which explain AAALAC's organizational structure and the minimum criteria that institutions are required to meet in order to apply for and maintain accreditation. The foundation for these criteria or standards is found in published guidelines or documents that are widely endorsed by the international animal research community. In addition to these principal documents, AAALAC also publishes supplemental guidance to inform accredited programs about emerging topics or concerns that otherwise may not be clearly defined. Some examples of topics that are covered include occupational safety and health as it pertains to animal program staff, facility safety concerns, what's meant by adequate veterinary care, and AAALAC's perspectives on the accreditation of programs that use farm animals for either biomedical or agricultural

research. All of these resources can be found at the AAALAC website, which is www.AAALAC.org under the Accreditation Program tab. Next slide.

Slide 32: AAALAC's Three Primary Standards

There are...here are the three primary standards that are used by AAALAC. The principles outlined in these documents are the primary drivers that guide the accreditation process, and they are continuously referenced throughout the assessment and evaluation process. From the left, they include the eighth edition of the *Guide for the Care and Use of Laboratory Animals*, which is published by the National Research Council and also known as the *Guide* or *NRC Guide*. In the middle, the *Guide for the Care and Use of Agricultural Animals in Research and Teaching*, or *Ag Guide*, which is published by the main animal societies including the American Society of Animal Science, the American Dairy Association, and the Poultry Science Association. This is the primary reference that's used to evaluate programs that conduct agricultural research with farm animals. And on the right is ETS 123 which is published by the Council of Europe and outlines humane practices involving vertebrate animals that are used for experimental and other scientific purposes by member nations.

Because agricultural animals can be used for both agricultural and biomedical research applications, the standards that AAALAC uses to evaluate them will vary according to the type of research that's being conducted. AAALAC has issued a position statement on how appropriate standards for the care and use of agricultural animals should be determined, and relies heavily on the collective professional judgment of the IACUC or oversight committee at that institution, and scientists and veterinarians who have knowledge and experience with these species to make that determination following a performance approach. And that approach should take into consideration the species that are involved and the requirements of the study. Next slide.

Slide 33: Reference Resources

In addition to the three primary standards, AAALAC also refers to other specialty publications for supplemental information about procedures or techniques related to the care and use of laboratory animals. These specialty publications are referred to as reference resources. The documents included on this list have been formally reviewed and adopted by AAALAC's Council on Accreditation as guidance for use by accredited units, as well as the members of a site visit team during their evaluation of a program. These references may also be used during Council deliberations when issues identified during site visits are discussed. When appropriate, a reference may have clarifying notes appended that further explain any exclusions or clarifications needed to interpret or apply that reference during the accreditation process. Next slide.

Slide 34: Additional References

AAALAC has also compiled lots of other useful information about animal programs on its website, which are published as position statements or frequently asked questions, and offers access to a resource library that provides additional information and educational materials on a variety of topics, such as the 3Rs, agriculture, and facility design. These are a few. This serves as a good starting point if your institution is trying to develop any unique performance standards or local policies appropriate for your animal program. Next slide.

Slide 35: Accreditation Process

So what exactly does the accreditation process involve? The first step is that the institution completes a comprehensive self-assessment by preparing a rather extensive document known as the Program

Description, or PD for short. The program description goes through each aspect of the animal care and use program, such as the number and types of animals, all housing and procedural areas, the equipment used for animal care, and experiments. The professional staff, including those who work in the facility, the veterinarians and the administrative support staff, and the Institutional Animal Care and Use Committee (or IACUC) or similar oversight body that provides policies and also assumes oversight for the program. When the AAALAC Executive office receives the program description, a site visit team is assigned to conduct the onsite program evaluation. This team is led by a council member who's accompanied by other subject matter experts who are knowledgeable about the types of animals and research activities that take place at the institution they will be evaluating. Individuals with agricultural backgrounds and experience will be selected if your program's research portfolio includes these types of studies. A date will be established for the site visit, and the specific schedule or agenda that is followed will vary depending on the size and complexity of your program.

A typical visit includes an opportunity to review information provided in the program description, tours of the corresponding animal facilities and procedure areas, interviews with animal program and research staff, and additional document reviews. The entire visit may take place in person, or some aspects may be conducted virtually as a hybrid visit if there is a need. At the conclusion of the site visit, the team will provide its preliminary feedback, which includes commendations for those aspects of the program that were found to be exceptional or outstanding, in addition to any deficiencies that require a response or action in order for the program to maintain its accreditation status, and these are known as mandatory findings. The site visit team will likely also have some suggestions to offer that are intended to further improve or enhance the quality of your program, and the institution is always given the opportunity to respond to this feedback, and that's requested within the first two weeks after the visit.

Site visit team members must then prepare an internal report which undergoes multiple reviews by other council members. Additional questions may be asked to clarify what the site visitors observed, and whether the response provided by the program fully addresses the concerns raised. This is one of the reasons why the site visit team asks so many questions while they are onsite, since they know additional questions will come up as the report goes through the peer review process. And then finally, the full council decides on the program's accreditation status, which is presented to the Board of Directors for their endorsement and the institution is notified of the outcome after that decision has been affirmed by the Board.

Because AAALAC is not a regulatory agency, all aspects of the site visit are confidential. Team members are not permitted to keep any documents or discuss specifics of the visit with anyone who was not directly involved with the site visit. And this process gets repeated every three years, with a new site visit team being assigned for each visit to ensure that the program receives a new set of eyes and fresh perspective. Accredited programs are also required to submit an annual report that includes animal use data and any significant changes that affect the program, and there's also an expectation for institutions to promptly report any significant adverse events involving animals to the AAALAC office, specifically those that could negatively impact the reputation of the program or the accreditation process. The intent is to keep the AAALAC office informed, particularly if this information could become public, so that they're prepared to respond in an appropriate manner. Examples might include major incidents such as a significant loss of animals, criminal activities, fires, and other catastrophic events. Next slide.

Slide 36: Key Terms

The first chapter of the *Guide* is focused on clarifying certain terms and key concepts that are essential to understanding the *Guide's* intent and expectations for its use. Three terms that are used repeatedly throughout the *Guide* and can be confusing are, must, should, and may. Starting with “must:” Whenever

this term is used in conjunction with a procedure or standard, the program is required to comply with whatever is specified, because that procedure or standard is regarded as a critical factor that's necessary to ensure an appropriate level of animal care. During an AAALAC site visit, if it is found that you are not meeting a "must" requirement, the observation is documented as a mandatory finding and your program will be required to develop an appropriate plan of action to implement that requirement, or it could be in jeopardy of losing its accreditation. The next term is "should" which can be thought of as a strong recommendation for achieving a goal. [There] are lots of examples of "should" statements in the *Guide*, and AAALAC regards these as best practices that are highly encouraged, but optional and adopted at the institution's discretion. These sometimes come up during site visits as recommendations for you to consider that will further enhance or improve your program. In other words, your program is satisfactorily meeting minimum expectations, but there is still room for improvement. For that reason, AAALAC refers to these "should" practices as suggestions for improvement (or SFIs) because they are viewed as suggestions that in the opinion of the Council will enhance your program. Your program is encouraged to consider any SFIs that are presented, but in some cases may determine the SFI is not appropriate and has the option to decline. And finally, the third term is "may" which indicates a suggestion that should be considered but is completely optional. AAALAC does not have a corresponding term or category of finding that aligns with the word... with the way "may" is used throughout the *Guide*. Next slide.

Slide 37: Engineering vs Performance

Another important distinction involves the difference between engineering and performance standards, which are two different approaches for ensuring that a specific outcome is achieved. An engineering standard is a standard or guideline that specifies in detail a method, technology, or technique for achieving a desired outcome. Engineering standards tend to be prescriptive and offer limited flexibility. They don't always take into account that on occasion, plans may need to be modified or revised if unusual circumstances arise, or if a new and better alternative method becomes available. Advantages for using engineering standards are that the evaluation of compliance is relatively straightforward, and they can also be used to establish a reasonable baseline when no other options exist. Earlier versions of the *Guide* were full of engineering standards because that level of detail was needed to standardize programs and operations across the country. Parameters like room temperature, humidity, cage sizes, light cycles, door sizes, and corridor width were all assigned specific values or a range of values to make sure that all programs operate in a similar fashion. Managing a facility was like following a recipe in a cookbook.

A performance standard, on the other hand, means a standard or guideline that, while describing a desired outcome, also provides flexibility in achieving this outcome by granting discretion to those who are responsible for managing the animal care and use program or conducting the research. This approach requires professional input, sound judgment, and a team effort to achieve the intended goals. It's critical that the desired outcomes or goals are clearly defined, and that performance measures are regularly monitored and validated to make sure that the process is successful. Performance standards are advantageous because they allow for the consideration of many variables, such as the type of animal, the facilities, staff expertise, and research goals so implementation can be adapted to meet the goal [of meeting] the *Guide's* recommendations. A team approach that includes all stakeholders: the investigator, veterinarian, facility manager, IACUC, and facility staff, always yields the best results. And in a perfect world, the goal should be a balanced mix of engineering and performance standards that allows each institution maximum flexibility to determine the set of best management practices that are most appropriate for their program. And now we'll hear from Dr. Cunningham.

Slide 38: Agricultural Animals in Research (Oklahoma State University)

>>*Nicolette Petervary*: Dr. Cunningham, I'm just going to jump in. In the interest of time, please put your questions in the chat rather than raising your hand, because we don't want to miss your question, and we'll append it to the end of the transcript if we run out of time. And the other thing is OLAW looks at "should" statements differently, and I would refer you to the OLAW website for that guidance. Dr. Cunningham, the floor is yours.

>>*Debbie Cunningham*: Good morning or good afternoon, depending on your location. My name is Debbie Cunningham. I'm at Oklahoma State University. My title is Assistant Vice President for Research and Director of University Compliance. I'd like to thank OLAW for allowing me the opportunity to speak with you and to be part of such a distinguished panel. I'm grateful. I don't know if you can see my fine feathered friend video here that should be playing [*video of a chicken on a nest*], but I absolutely love this video because it reminds me of a couple of things. It reminds me to be calm and to breathe, and also if you watch her, you know, she blinks at around three seconds and then you see her take a breath at around five seconds in that cycle. But I just absolutely love it. Next slide.

Slide 39: OSU Introduction

So I won't go into great detail about our process at Oklahoma State University, but I'll kind of hit the highlights. We all know that a PI (Principal Investigator) submits a protocol to the IACUC office. Here at Oklahoma State, we do an administrative review. I think that's really important because I'm sure none of you out there have ever had a copy and paste error where you have, you know, retired people still in the protocol or wrong dates or people who are no longer at the university. So those are things that we pick up on the administrative review. Also, our IACUC manager, after that's completed, decides if we're going to do a full committee review or a designated committee review, and we have an SOP (standard operating procedure) for that. And then everybody places their comments and it gets batted back and forth [and eventually it gets approved].

At OSU, we have many studies occurring. Most of the time people stay in their lanes. What do I mean by that? I mean that, you know, our ag people usually have ag research for improving animal nutrition, breeding, production efficiency or improving quality of food or fiber, as well as teaching. And then we have the biomedical studies. Typically rodents are utilized, but a few times a year we have ag studies utilized in biomedical research. We have multiple IACUC members with agricultural species and agricultural research experience. We do use the same protocol review process for agricultural research animals and biomedical research animals. So the review process is the same.

So, some of the topics that we're going to look at today. Next slide please.

Slide 40: Today's Topics

We're going to look at some use cases. We're going to look at agricultural research and some biomedical research use. We're going to look at training for vet students, residents, veterinary technicians, ag students, biomedical researchers... Then we'll discuss special challenges with agricultural species, some compliance considerations, challenges with agricultural use, ways to optimize welfare, and then I'll leave you with a few resources. Next slide please.

Slide 41: Overview of Why Farm Animal Use Has Special Challenges

The biggest challenges with agricultural species, in my opinion, are determining the use case and whose rules apply. Sometimes it's unclear, and many more times... [m]ore than one set of guidance can apply. Let me give an example with some blurred boundaries. How about the status of an ag donor animal

supporting a non-PHS-covered biomedical research project indirectly, but that animal is kept under farm conditions. This generated a lot of discussion with AAALAC and evaluation of specific use situations. Ultimately, here at Oklahoma State no changes were recommended, but this illustrates how the lines can be blurred and that specific situations matter.

Let's look at another. Ensuring welfare and compliance when managed in farm settings, especially when the *Guide for the Care and Use of Lab Animals* applies. The *Guide* specifically states on page 32 that it applies to agricultural animals used in biomedical research, including those maintained in typical farm settings. It further emphasizes the use of farm animals in research should be subject to the same ethical considerations as the use of other animals in research. Finally, the U.S. Government Principles provide a good framework for thinking about welfare of these animals, no matter how they're being used. The principles discuss the importance of minimizing discomfort, pain, [and] distress when consistent with sound scientific practices, euthanasia for severe chronic pain or distress, living conditions that contribute to health and comfort, and veterinary care. Next slide please.

Slide 42: Funding

So we've all heard the phrase "follow the money." We all know that the federal government likes to follow the money. We've heard "follow the money" in the movie *The President's Man* or, you know, "show me the money" used in a Jerry Maguire movie. The PHS policy and the *Guide* defines the minimum standards (or the "must") and the performance standards (the "shoulds") that OLAW expects of Assured institutions. In many instances, institutions and IACUCs elect to exceed the standards described in the *Guide*.

Let's look at some activities that are exempt from the AWA regulations. Species used for food (like meat, rabbits) or fiber, working animals (you know, sled dogs, herding dogs, guarding animals) fairs and exhibits that promote agriculture, research for improving animal nutrition, breeding, production efficiency, or improving the quality of food and fiber. And for the most part, federal facilities are exempt. Next slide please.

Slide 43: Location

We've all heard "location, location, location," and we know that matters with real estate, but not just with real estate. AAALAC accreditation: for AAALAC accreditation, location matters too! Here's why I say that. The IACUC is responsible for the oversight of vertebrate animal activities supported by PHS and those supported by NASA, NSF, and VA in accordance with PHS policy. Factors to consider on whose rules apply include the ability of conditions for non-covered animals to affect covered animals. So what I'm saying is, if animals not covered by USDA, OLAW, or AAALAC requirements are located next to animals that are covered and a disease outbreak happens in our non-covered animals, that can affect our AAALAC accredited [and OLAW Assured] areas. You can bet that entities like OLAW would care, and I believe that OLAW even has a frequently asked question about this that Dr. Petervary pointed out. Next slide please.

Slide 44: Special Challenges

So let's look at some special challenges. Housing can be challenging because sometimes you want to house biomedical... ag animals in a biomedical area where the PI wants to keep everything under ag conditions, or they want to have specific pathogen free animals or tethered animals or even the care for calves. And we'll look at some of that specifically in a minute. The IACUC should establish performance indices [for] housing related to animal well-being. An example of that is space. So a cage should provide sufficient space to meet the physical, physiologic, and behavioral needs of the animal. Using tigers as a

nonagricultural example, an enclosure that's only four foot high is not appropriate for that species, since that species tends to stretch upward and that's considered a normal postural adjustment for them. This principle can also be applied to ag species. So let's look at a meat rabbit. That would be classified as an agricultural species. They must be able to sit in that cage or enclosure, and if it's normal for that species of rabbit to hold its ears in an upright position, then the cage has to allow enough space for that to occur without their ears touching the top of the cage or being folded over.

Another challenge is pain recognition for farm species, and it's essential and may require a culture shift. What I mean by that is training people to recognize pain and understand [that] things like limping is painful and require intervention. Some farm personnel believe lameness is normal for dairy cows. We'll talk about that more in a minute. We also need to meet behavioral needs. You know, if they're a social animal, they need social housing. [We] need to give them enrichment. And behavioral concerns are an important consideration because generally they're herd animals. Most of the farm species are flock or herd animals and need social enrichment while preventing common issues and social situations such as resource guarding, [and] cannibalism or feather pecking in poultry. For example, I went to a facility housing multiple pigs with one water source, and there was a boss sow standing there guarding that water source. None of the other animals had access to water. Dealing with behavioral needs involves building an appropriate environment that prevents common... that provides resources for all the animals housed there and encourages species appropriate positive behaviors and minimizes aggression and distress.

Handling considerations. Most farm animals are prey animals as well as being herd animals. This means that they can be very reactive. It's important to design facilities with this in mind and understand handling in terms of the animal's flight zone, which is the distance at which the animal will try to flee. You can utilize knowledge of the flight zone to get the animals to move calmly and in a direction that you want them to move. Temple Grandin has a lot of online information about this concept and I have to say, they work incredibly well. All these examples so far tie into the concept of differing welfare standards, lab animal standards versus ag animal standards.

Often these discussions require a culture shift, both on the part of the ag folks as well as the biomedical research folks. For example, sanitation standards can be very difficult. Sanitation standards for biomedical research may involve cleaning and disinfection every two weeks, as well as ATPase testing in some cases, for example when performance standards are used, but biweekly disinfection and ATPase testing for feed bunks and water troughs for ag animals under farm conditions is not feasible or expected. Production animals are usually viewed from population perspectives, and so a shift in focusing on a welfare state of an individual animal can be challenging. I mentioned feather pecking and cannibalism can be an issue in poultry flocks. Even if one animal is affected, it would be an issue that needs to be addressed. However, farm personnel may look at a single animal as not necessarily needing intervention, but those animals do need intervention. I once visited a poultry facility where one bird had been severely feather pecked and cannibalized. The bird required immediate euthanasia. I had to explain the concept to the farm personnel and link it back to the population perspective. Even if one animal was affected, it could reveal opportunities to improve health and welfare on a population level. The definition of animal welfare is the state of the individual animal, and it's a culture shift for farm managers and farm personnel to think in this way, or to connect individual welfare concerns to the improvement of the overall herd or flock well-being. They may also not associate issues with pain and distress. So, you know, as long as the animal is still walking around and eating they might have the lens that everything is fine.

Teaching activities include those regulated by USDA and those that are not. So teaching ag science students, for instance, would not be. Vet schools that teach ag standards, such as castration without pain control. If this is still being done, this practice should stop. There's now a lot of literature on pain associated with these procedures in farm animals, and best practices are critical, especially when teaching the next generation of professionals. Proper analgesia and anesthesia are necessary to ensure good welfare.

Emergency management is an important consideration and may be challenging in farm situations. Be prepared for risks such as whatever natural disaster occurs in your region. I'll elaborate more on that in a housing scenario. And finally, I'll talk about compliance challenges later in this talk, and how good communication and the use of clear and detailed standard operating procedures can prevent these issues. Next slide please.

Slide 45: Scenarios – What would You Do?

So how would you approach this housing scenario? This is agricultural research in an AAALAC accredited location. The PI requests the use of a non-dedicated space for a group of weaned calves. So we had the IACUC inspect it. And when all of the... inspect the area... and when all the deficiencies were corrected, we realized that we had an issue on how to best allocate space. There's no guidance on space requirements for weaned calves in the fourth edition of the *Ag Guide*. There is one in the third edition of the *Ag Guide*, but the expectations from regulation...regulators and accredited organizations is that we use the most current version. So what does one do? Well, I consulted with AAALAC. The determination was to begin with industry standards, and the recommendations in the third edition were consistent with those standards. However, that was just our starting point.

We went a little bit further and used this as a launching point for creating some performance standards. Even though the PHS policy doesn't apply here, OLAW provided some good information on well-thought-out performance standards. We mainly want to make sure that performance standards support scientific objectives of the study, as well as the health and welfare of the animals. A justified performance index with associated outcomes will tell you if the objectives you want are being met, and also allow you to monitor metrics of success over time. In this case, because there was no engineering standard, we developed performance data. We decided to double the space recommendation as an industry standard, which allowed for the growth of these calves and also for safe handling. Some of our research technicians weren't as experienced with ag animals as our farm personnel are. We put two calves in the space recommended for four, and set it up to facilitate shifting and cleaning by creating an alleyway when the gates open. We tracked success by evaluating sanitation, handling, and whether the calves were stressed, as well as by checking in with the PIs. And we did observation through our post-approval monitoring program. All of these indicators showed the approach to be effective for the study. We decided on performance standards. It's critical to incorporate the health and welfare of the animals, the study requirements, and the health and safety of the personnel as illustrated in this scenario. Next slide.

Slide 46: Diagram

So this slide is just an example of what that layout looks like. So you have eight enclosures here. And you can see two gates (or actually four gates) are open, which allow the shifting of the calves from the top enclosure down to the bottom. If, let's say, the calves are in the top enclosure and you want to shift them to clean, if you put food in that bottom, open the gates; they just walk in. I'll give you some more views of this just to help.

Slide 47: Ground Level View (briefly passed)

This is a lot of rails and kind of difficult to see through, but if you look at the left, all the gates are closed. And if you look at the right, you can see that the gate is open. So you would have an individual standing in the forefront there between and holding that gate. So as the animal shifted, they could close that gate behind them. Another view just to make it a little bit easier. These are the exact same pictures as on the previous slide, but

Slide 48: Elevated View

we're at an elevated view so you can appreciate it. Next slide. Uh yes, the elevated view. So you can appreciate the gates being closed and get a little better perspective of things. Next slide.

Slide 49: Scenarios – What Would You Do?

So here's another housing scenario. Again this is agricultural research, so not regulated by USDA or OLAW. But we are an AAALAC accredited institution. So we had some weaned calves coming into the facility, and we had a huge Arctic front coming in a day later... and in Oklahoma we get cold weather, but we don't go to -20 with a windchill or -30. So we decided that we should develop some contingency plans just because this was highly unusual in our area. I think redundancy is critical for this. We added extra heaters, bedding, straw, and blankets.

So the big concern was that we had four air exchanges per hour, but what happens if during that air exchange our temperatures dropped too low? So we decided to set up a failsafe system that caused additional heaters to turn on at a set temperature. We set that temperature five degrees above the minimum standard, which would allow us time to respond if this happened. Also, we made sure that emergency care staff were on standby as per our disaster plan. You know, we all know that emergency vet care is a must. They have to be available during regular hours, after business hours, on weekends, holidays, even in the middle of a weather event. The failsafe system that we put in place works so well that we've adopted into similar areas that house other agricultural species and farm conditions. Emergency management under farm conditions can come up [and] can create some unique challenges. USDA has some disaster resources for emergency management and disaster planning for livestock included. And so I've included those links at the at the end of this talk. Next slide please.

Slide 50: Optimizing Animal Welfare in Agricultural Species

Perhaps the most important factor in optimizing welfare for agricultural species is setting expectations and training. For agricultural research, many farm personnel are used to doing things without checking with the veterinarian. You know, a lot of times for farm personnel are “get ‘er done” kind of people, so it requires a little bit of a culture shift for them to realize that they have to involve the veterinarian. A lot of times before this training takes place, they may not even realize they need to call the vet if an issue occurs. That's why detailed SOPs are so important. It's important to know who to call and what to report. At Oklahoma State, we designed a flowchart with contact numbers to make sure that everybody understands the reporting requirement and what it looks like, and we also have set in those SOPs some trigger points to ensure that farm staff call the veterinarian in a timely manner.

PI training is also important, especially for surgery and perioperative care. It's important to evaluate their knowledge and skills and ensure that they understand aseptic technique and what appropriate pre- and post-operative management looks like. This also is another function of our PAM (post-approval monitoring) program.

Finally in record time, training on recordkeeping is essential. Records on the ag side are often not as rigorous as what we see on the biomedical studies, but it's essential— especially if an animal ends up in the food chain. Drug selection, administration and withdrawal times must be meticulously recorded. Study animals that are to be used for food purposes must be handled as food animals, and must be clearly documented throughout their life up until slaughter. Our biosafety team trains all PIs on hazardous materials and agents, and it's important to coordinate with biosafety and university health sciences on waste disposal. Large animals exposed to hazardous agents are incinerated. And it's critical that such animals never enter the food chain for human or other animal consumption. Next slide.

Slide 51: Optimizing Animal Welfare in Agricultural Animals

>>*Nicolette Petervary*: I'm just going to jump in to Debbie. We have... we are over time. But if people are going to bear with us, we're going to wrap this up in about an extra 5 or 10 minutes. Thank you all for staying.

>>*Debbie Cunningham*: Local farm managers are typically highly dedicated to animal welfare, but as I mentioned before, they're not used to close communication with the veterinarian. A big culture shift for some farm personnel is the idea of ownership. Instead of treating the animals as though they're their own farm animals, they need to understand that research animals belong to the institution, and they cannot manage them without coordinating with the institutional veterinarian, the IACUC, and others in the overall animal care and use program.

Obtaining AAALAC accreditation allows organizations to do a deep dive into their program's functions. It allows for corrections of items that they may not have that that may have recently happened. You know, I often refer to this as using “inspector lenses.” It's very easy for us to have blinders on when we look at our stuff, and so it's better to have another perspective and to utilize inspector lenses.

Recommendations and best practices can be meaningfully implemented through the AAALAC accreditation process. When you're developing your program description for AAALAC, if you haven't already taken the opportunity to have the Attending Veterinarian and the farm manager sit down and talk about how they want to do things, what vaccines they want to use, how they want to treat common diseases such as pinkeye, foot rot, or lameness, that's the time to sit down and have those conversations and create those SOPs. I would recommend having those conversations up front before there's an issue. And again, all SOPs should have a trigger point on when the Attending Veterinarian or the or the veterinary staff is brought in. Next slide please.

Slide 52: Scenarios – What Would You Do? (1)

The culture shift of application of welfare standards is imperative. Here's an example. Earlier in this talk, I said that some farm personnel believe that lameness is normal for dairy cows. In my past, I would hear things like, “Hey doc, all dairy cattle are lame.” My response would be to educate those and say, “Lameness is not physiologically normal and it's painful for the animal.” Then I'd evaluate the animals at the farm and look at the farm practices and try to determine a root cause. In one instance, I determined that the mattress sizes for the cows were too short, causing hock lesions leading to lameness. The facility was old and had mattresses that were from the 1970s. While perfectly acceptable for the dairy cows of the 1970s, selective breeding has resulted in a much bigger and taller cow, and the mattresses wouldn't work for these animals. When the mattresses were changed, the lamenesses improved. Next slide.

Slide 53: Scenarios – What Would You Do? (2)

Here's another example involving behavioral needs. For many farms, the transition from individual crates to stall or group housing sows is very recent. While the group housing meets social and welfare needs, it

can result in issues, especially when animals from different groups are mixed. I went to one facility and the practice was to mix the animals at every transition. As one could imagine, this resulted in scratches, abrasions, and mild aggression. So what does one do? We discussed and determined ways to improve, including mixing at earlier ages, adding visual blocks, adding enrichment, and also having more feeding bunks and water spouts. Adequate feed bunks and water spouts are especially important as resource guarding can result in some animals lacking access to food and water. I mentioned previously a boss sow guarding a water source, and I discussed the challenges with that. Pigs in groups form social hierarchies. And so this is really important to remember. The *Ag Guide* third edition had a requirement for two water sources. However, the fourth edition didn't carry that over. Next slide please.

Slide 54: Animal Care and Compliance Considerations for Agricultural Animals in Biomedical Research

If agricultural animals are used in biomedical research, they're biomedical animals and they need to meet the standards of the *Guide*. However, some standards are essential no matter how the animals are housed and used. So the *Guide for the Care and Use of Laboratory Animals* states: "Regardless of the category of research, [ag or biomedical] institutions are expected to provide oversight of all research animals and ensure that pain and distress are minimized" (*Guide*, p. 4). You know, pigs are smart social animals. They like the social interaction. As with this caretaker [*pictured on slide*], they like to nibble on things and root. So things like balls and puzzle toys and other enrichments should be provided that allow them some of these rooting and problem-solving opportunities. Next slide please.

Slide 55: Animal Care and Compliance Considerations for Agricultural Animals in Agricultural Research

There are times when the differences between ag standards and biomedical research becomes apparent. I'll provide a couple of examples. One is when lab animal technicians are used, they're used to working with small animals in a biomedical setting. And now they start to work with farm species in a farm setting. Even if trained, they lack the experience. So it's important to monitor them closely because of occupational safety concerns. I mentioned in my first housing scenario that we allocated space for calves in a way that made sanitation and shifting easier by providing that extra space in the alleyways when the gates open. It's also important to teach handling methods that don't necessarily necessitate going in with the animals. For example, how to move the animals with one's own body position in the animals' flight zone. You know, that works really, really well probably 99% of the time. If that doesn't work a rattle paddle usually takes care of that other very small percent. But this improves safety and reduces the stress for the animals. The second example is explaining to farm personnel running biomedical research in a farm setting, that rust and porous surfaces aren't accepted in biomedical research. Enclosure surfaces need to be sanitizable and impervious. So the culture shift can go in both directions. And again, good communication is the key. Next slide.

Slide 56: Animal Care and Compliance Considerations for Agricultural Animals in Agricultural and Biomedical Research (1)

I talked a bit about communication and using different lenses to evaluate animal programs and setting expectations. So the expectations include [that] animals receive adequate vet care. The Attending Veterinarian is informed on all animal health issues. Farm managers and staff will commonly provide care. This can lead to a failure of communication if you don't have those SOPs in place. I'll give you a couple of examples. One example was in a fish farm. The fish had fin erosions... quite a few of the fish had fin erosions. The staff thought it was normal since all the fish had it. They didn't really have knowledge of water currents, stocking density, or water quality, and so they needed to be educated on professional acceptable standards. Another example involved pinkeye in a herd of cattle. It was widespread in the farm. Personnel were just letting the disease run its course. It didn't occur to them

that this disease could be being spread by flies. So pest control could have made a world of difference. We brought in some... we instituted some better fly controls and the incidence decreased. Farm staff may also be less aware of requirements to keep accurate veterinary medical records, as compared to what the veterinarians or the veterinary technicians and biomedical research studies keep. So going over forms with them, making sure they understand and that the forms are easy to fill out. Again, anything that's routine that follows the SOP for clinical management does not have to be reported directly to the Attending Veterinarian as long as records are kept on file. Direct, clear, straightforward lines of communication of responsibility and corresponding authority function well and allowing organizations to respond quickly and effectively when necessary.

Slide 57: Animal Care and Compliance Considerations for Agricultural Animals in Agricultural and Biomedical Research (2)

So just a couple more slides and I'll wrap it up. As mentioned, USDA... (OLAW, NIH— they're not typically involved with ag use) but USDA does regulate agricultural animals used in biomedical research, as well as those used in teaching scenarios to train vet students or vet technicians. The teaching activities can differ depending on who's being taught. For teaching of veterinary technicians and veterinarians or veterinary students, we have an SOP that we follow. We don't have that SOP for teaching of animal science students. The important issues to look out for in teaching activities is how does it impact the animal and potential safety issues. So questions to consider: What's being performed? How many students are performing it? How many times? How many... how frequently is this occurring? How are the students being supervised? What are the relevant occupational health and safety concerns for the students and the staff? And then what are the trigger points to make sure to remove an animal from the protocol or to call the veterinarian? I want to reiterate that. Next slide.

Slide 58: Oversight Perspectives (1)

I want to reiterate that... next slide. I want to reiterate that maintaining the animals in an ag setting according to lab standards are impractical or impossible, and personnel doing biomedical research don't often understand production practices or industry standards.

Slide 59: Oversight Perspectives (2)

We talked about sanitation standards for biomedical research not being feasible in farm settings. Another example of this is the use of barn cats. Barn cats are rodent controls, and they're not a biosecurity issue on farms. Barbed wire is the industry standard for the fences, but sometimes that has to be explained to biomedical researchers unfamiliar with farm practices. Again, communication regarding specific expectations and specific settings is critical.

Some production standards need to be changed, though. Lack of adequate analgesia or anesthesia for production practices like castration and dehorning, in my opinion, are an issue. All of this requires a culture shift, and it's hard for that shift to occur because we're shifting from economics to a welfare focus. The European Union seems to have managed this. More government requirements and humane certifications for marketing may be the reason. While Certified Humane and other welfare marketing certifications are starting to catch on in the US, we're not quite there yet. And we also need to improve consumer education. The designation of organic is not a welfare certification. Why is this important? Because we need ag faculty and ag researchers to be the trailblazers on this. Next slide.

Slide 60: Common Challenges with Agricultural Animal Use (1)

OSU has several teaching herds. We have a Ferguson dairy herd. We have a beef quality herd that's ran through the feedlot, so students get feedlot experience. We have a breeding herd undergoing selection for production improvements. All of these have high...they're high cost to maintain. We're having fewer students in this area and we have declining budgets. We might not be able to maintain them much longer. Next slide.

Slide 61: Common Challenges with Agricultural Animal Use (2)

None of us want to see this [*picture of gate with a sign saying "farm closed"*]. I find this slide disturbing, and I trust that land grants and others continue to find ways to keep teaching herds, university animal science and veterinary schools, with budgets.

Slide 62: Summary

So to summarize things that we discussed. You know, how ag animals are used matters— farm setting versus lab (research labs). Again, I think communication is key and welfare standards should always be improving. I told you I'd give you a slide of some resources. Next slide.

Slide 63: Resources

So this is a beef quality through the farm program link. There's a beef quality assurance calf care. The USDA tech note on pain categories is wonderful. This came out in June of 2023. And, you know, an animal tethered for days or weeks... [is] considered a category E. I think that's important to note. It's one of the things that our IACUC batted back and forth for a while. I gave a resource for Temple Grandin on livestock handling. And then lastly, emergency management resources for livestock from USDA. Sorry that we went over. Thank you very much for your time.

Slide 64: Next Webinar

>>*Nicolette Petervary*: Yeah. Thank you very much for staying on. I'd like to thank our presenters and remind you that all that the questions that we didn't have time to get to will be appended to the end of the transcript and forwarded to our presenters for a response. The webinar materials will be posted to the OLAW website once we've processed them for 508 accessibility and you will receive a survey once you leave the webinar. And please take the time to share your thoughts because it helps us make better content for you in the future. Our next webinar will be held in the summer and thank you very much for staying on. Goodbye.

Questions

These questions were collected from the chat, Q&A, and email after the session and provided to the speaker. Questions have been edited for clarity and similar questions may be combined. The responses represent the speakers' comments and opinions and may not be generalizable to your specific circumstances.

1. What qualifies as “biomedical” research when defining research projects?

Response from OLAW: Page 32 of the *Guide* states that: “animal models of human diseases, organ transplantation, and major surgery are considered biomedical uses; and studies on food and fiber production, such as feeding trials, are usually considered agricultural uses.”

The PHS Policy applies to an activity when both of the following criteria are met:

- The research project is a “PHS-conducted or supported activit[y] involving animals” ([PHS Policy II](#)), which includes those supported by funding from the NIH and other PHS funding components, as well as entities which have an MOU with NIH (NASA, NSF, and VA); and
- The animals involved are “live, vertebrate animal[s] used or intended for use in research, research training, experimentation, or biological testing or for related purposes” ([PHS Policy III.A.](#)).

Response from USDA: Biomedical and other non-agricultural research is covered. Research not done to improve animal nutrition, breeding, management, or production efficiency, or to improve the quality of food or fiber is covered. Biomedical research is the study of biological processes and diseases with the ultimate goal of developing treatments and cures, and includes veterinary medical research.

Response from AAALAC: AAALAC International expects each accredited program to determine which standard(s) are most appropriate for the care and welfare of any agricultural animals that are used for research, teaching, and testing at their institution. Factors that should be considered include the specific research or teaching objectives, funding sources, and applicable regulations and policies. The results should incorporate the collective professional judgment of the responsible oversight body (i.e., IACUC, Ethics Committee), principal investigator, and veterinarian and clearly reflect performance-based standards that best align with the species and requirements of the study. The rationale for making this determination should be documented.

2. Can agricultural research animals return to the food system after a biomedical research project? If not, what options are available to prevent waste of potential food or food products?

Response from OLAW: Activities covered under the PHS Policy are expected to comply with all other applicable federal regulations, including those regarding drug use, withholding times, and food safety standards. Per the NIH Grants Policy Statement, “The signature of the AOR [authorized Institutional Representative] on the application certifies that the organization complies, or intends to comply, with all applicable policies, certifications and assurances referenced (and, in some cases, included) in the application instructions” ([NIH GPS 4.1](#)).

When reviewing animal activities, IACUCs should seek appropriate institutional guidance to ensure that post-study animal dispositions meet all applicable institutional and regulatory requirements, and consider potential impacts to human, animal, and ecosystem health and safety. Regarding animals used for food, institutions are encouraged to reach out to the appropriate food safety regulatory authorities for additional information about what requirements apply to their specific circumstances. In cases where carcasses are not permitted to enter the food chain, IACUCs may consider other alternatives to prevent waste, such as tissue banking or sharing, if consistent with regulatory requirements and institutional policies.

Response from USDA: The Animal Welfare Regulations are silent with regard to this question, except that animals must be euthanized in accordance with the way the term is defined in the Regulations, unless a deviation is justified for scientific reasons, in writing, and approved by the IACUC. Under the Animal Welfare Regulations, *euthanasia* means the humane destruction of an animal accomplished by a method that produces rapid unconsciousness and subsequent death without evidence of pain or distress, or a method that utilizes anesthesia produced by an agent that causes painless loss of consciousness and subsequent death.

Response from AAALAC: Accredited institutions are responsible for developing a plan for the humane disposition of all animals, including agricultural species, that are used in research, teaching, or testing. Euthanasia is often the most appropriate option and must be performed according to methods described in the American Veterinary Medical Association Guidelines for the Euthanasia of Animals: 2020 Edition (AVMA, 2020). However, in some cases, AAALAC International realizes the AVMA Guidelines for the Humane Slaughter of Animals and/or the AVMA Guidelines for the Depopulation of Animals may provide acceptable alternatives these animals and defers to the local oversight body to make that determination in consultation with regulatory agencies that ensure the safety of animal products intended for consumption.

3. If agricultural animals are used for development of an ANIMAL/AG vaccine, or the response to a vaccine, are they still considered biomedical?

Response from OLAW: Vaccine development activities, when meeting the criteria outlined in OLAW's response to Question 1 of this transcript, are subject to the requirements of the PHS Policy.

Response from USDA: Yes, vaccine development is biomedical research.

Response from AAALAC: Governmental agencies that regulate veterinary products (e.g., pharmaceuticals, devices, biologicals, insecticides, etc.) offer guidance on animal studies conducted to demonstrate their safety and effectiveness. AAALAC International expects accredited institutions to consult with these authorities to determine the types of studies and specific data that is needed. The rationale for these decisions should be documented.

4. Is there any sort of oversight for the welfare of animals used for agricultural purposes, i.e., not under the purview of the PHS Policy or the Animal Welfare Act?

OLAW Response: While institutions may choose to delineate animal areas that are programmatically and functionally separate and that do not support PHS animal activities, such as a herd of beef cattle used for food production or a stable of riding horses, care should be taken that activities in these areas do not adversely impact PHS-supported activities. Further,

institutions may choose to apply PHS standards to all animals to avoid perception of a double standard and to promote uniformity and consistency. AAALAC International, while not a regulatory body, is one way to ensure oversight for care and use of institutional animals not subject to regulation. See OLAW FAQ [A.1](#). (Should institutions apply the PHS Policy to all animal activities regardless of the source of funding?) and the section on Applicability of the PHS Policy in [OLAW's Topic Index](#).

Response from USDA: Congress specifically excluded animals used for agricultural purposes from coverage under the Animal Welfare Act.

Response from AAALAC: Accreditation is a viable option for programs that use agricultural species for research, teaching, or testing, regardless of their regulatory status. The accreditation process is a periodic third-party peer review assessment and provides assurance to the research community, stakeholders, and the public that the institution is committed to continuous improvement, humane and ethical animal care, and scientific validity. Institutions must maintain a high level of excellence and adhere to current industry standards for the care and welfare of agricultural animals used in research as a condition of their accreditation.

5. Are activities involving the teaching of veterinary students covered by the PHS Policy and the Animal Welfare Act?

Response from OLAW: The [PHS Policy definition of animal](#) includes any live, vertebrate animal used or intended for use in research training. Covered animals are those that are involved in activities that are PHS conducted or supported, including those supported by funding from the NIH and other PHS funding components, as well as NASA, the NSF and VA (which have an MOU with NIH). Because the PHS Policy may cover some, but not other teaching activities, there are many factors involved in making this determination. Please contact OLAW to discuss your specific situation.

Response from USDA: Yes, teaching veterinary students is considered regulated biomedical teaching.

Response from AAALAC: AAALAC International relies on designated regulatory authorities, USDA APHIS Animal Care and NIH OLAW, to make this determination.

6. If an accident or emergency occurs in a building where animals are housed BUT not within the animal housing area or affected the housing area, is this something that needs to be reported to AAALAC, USDA, and/or OLAW?

Response from OLAW: Per [NOT-OD-05-034](#), institutions are required to report accidents and emergencies in areas not directly supported by PHS funding "if the situation ... is in a functional, programmatic, or physical area that could affect PHS-supported activities." As every situation is unique, institutions are encouraged to call OLAW for specific reporting questions. See also [FAQ A.1](#). (Should institutions apply the PHS Policy to all animal activities regardless of the source of funding?).

Response from USDA: USDA has no reporting requirements for accidents or emergencies, but research facilities are encouraged to communicate with their local VMO.

Response from AAALAC: AAALAC International provides general guidance on managing and reporting adverse events in Section 2.g. of the “Rules of Accreditation.” Every accredited institution should have an established plan for investigating, managing, and reporting significant, unexpected, adverse events that can have negative impacts on animal welfare and/or human health. The reporting threshold established for each program should be tailored to address that institution’s unique vulnerabilities. The AAALAC International office can provide further guidance on reporting expectations and procedures and should be contacted with specific questions.

7. What regulations apply when performing a study using sheep at a foreign facility, and what paperwork is involved?

Response from OLAW: The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) requires that institutions have an OLAW-approved Animal Welfare Assurance before carrying out any activities involving live vertebrate animals. Please see [OLAW’s webpage on Foreign Assurances](#) for more information. Circumstances may vary, so if you have questions, please contact OLAW to discuss your specific situation.

Response from USDA: The USDA has no jurisdiction over activities performed outside the United States, its possessions and territories.

Response from AAALAC: AAALAC International uses institutional ownership of animals to determine which animals are included as part of the accreditation process. The housing and care of all animals owned by the accredited unit or applicant must be considered during the assessment, regardless of their location. The Council on Accreditation relies on three primary standards to assess and accredit animal care and use programs around the world. These include the 8th Edition of the Guide for the Care and Use of Laboratory Animals (Guide), NRC 2011; Guide for the Care and Use of Agricultural Animals in Research and Teaching (Ag Guide), American Dairy Science Association®, the American Society of Animal Science, and the Poultry Science Association 2020; and the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Council of Europe (ETS 123), although ETS generally applies to programs in countries affiliated with the Council of Europe. In addition to these standards, accredited units must also comply with relevant statutes and governmental regulations in their respective jurisdiction(s) that pertain to the care and use of research animals.

Questions Specific to USDA:

Note: Questions regarding the following should be directed to the USDA, as OLAW does not administer the Animal Welfare Act.

- 1. Can you clarify what horses are covered under the Animal Welfare Act? For example:**
 - a. Horses used for the teaching of undergraduates
We do not regulate horsemanship or horse management, so teaching other than horsemanship or horse management is covered.
 - b. Horses used for teaching vet students
Yes, teaching veterinary students is considered biomedical teaching.

- c. Client-owned horses used for teaching any students
No, client-owned animals are not covered.
- d. Horses that are dual-purpose, such as used for teaching veterinary students in one class but undergraduate students in another
Yes, if animals are used for a covered activity, the animals are covered.
- e. Horses on a heaves study
Yes, heaves (or recurrent airway obstruction) is a medical condition; the study of medical conditions with the ultimate goal of developing effective treatments and cures is biomedical research.

2. When are poultry covered under the Animal Welfare Act?

Birds bred for use in research are not covered under the Animal Welfare Act. Under the Animal Welfare Regulations, *bred for use in research* means bred in captivity and used for research (9 CFR 1.1), so poultry that are bred in captivity and used for research are not covered. Any bird not bred in captivity and used for research is covered.

For more information on when poultry may be covered when they are NOT used for research, visit our website – <https://www.aphis.usda.gov/awa/bird-standards>.

3. Can you clarify what types of studies fall under the purview of the Animal Welfare Act? For example:

- a. Agricultural animals used for the development of an animal vaccine
Vaccine development is biomedical research and covered.
- b. Agricultural animals used in a research study that will benefit the animal's health
If the purpose of the study is to improve animal nutrition, breeding, management, or production efficiency, it is not covered. If it is to investigate a disease process with the goal of developing a treatment or cure, it is biomedical research and covered.
- c. Mini swine used in biomedical research
Yes, swine used for biomedical research are covered.
- d. Chickens used in biomedical research, including those bred for research and those not bred specifically for research but used in biomedical research
Birds bred in captivity and used for research meet the definition of *bred for use in research* under the Animal Welfare Regulations; thus, chickens bred in captivity and used for research are not covered, even if they were not intended to be used in research at the time of breeding.