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Note: Text has been edited for clarity.

Frequently Asked Questions to OLAW

Speakers: Patricia A. Brown, V.M.D., M.S., ACLAM, Director, OLAW and Dr. Kay Carter-Corker, Assistant Deputy Administrator, USDA, Animal and Plant Health Inspection Service, Animal Care

Moderator: Dr. Jerry Collins, Ph.D., Division of Policy and Education, OLAW and Yale University.

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[It takes several minutes for the recording to load]

Slide 1 (Frequently Asked Questions to OLAW)

Hello, and welcome to the next in our series of [OLAW outreach webinars for IACUC staff](#). My name is Jerry Collins, and I'll be the moderator for today's seminar. For those of you who have participated in previous webinars, there is a change in today's plan that we would like to mention. As many of you know, we have at times experienced significant degradation in sound quality. A problem that was all too obvious during the last webinar. In fact, thanks to those of you who suffered through that for coming back and having faith in us and our ability to fix it, and give us one more chance. We've been assured that the use of teleconferencing for the audio portion of the webinar will solve the problem. So, although the use of teleconferencing adds a bit more complexity to your initial sign in process, it should enable all participants to receive a complete audio signal. We recognize that you and

your staff are taking valuable time from very busy schedules to participate, and we want to provide you with a high quality presentation.

As always, we encourage you to submit your questions by using the “submit a question” window in the top left portion of your screen. When submitted, your question will only be visible to the staff here in the OLAW office, and we will do our best to answer all of your questions.

Before I introduce our speaker, Dr. Brown, I want to let you know that she will have a somewhat silent partner in today’s presentation, Dr. Kay Carter-Corker, the Assistant Deputy Administrator for the [USDA, Animal and Plant Health Inspection Service, Animal Care](#). Dr. Carter-Corker will join us at the start of the question and answer session to explain to you the impact on research facilities of the USDA’s transition to an “age of enforcement” approach when repeat noncompliant items are cited by USDA inspectors.

Remember that this presentation will be recorded and made available on the [OLAW website](#) in a few days. Please encourage colleagues who can’t join us today to view the webinar as their schedule allows.

With those housekeeping items out of the way, it’s my pleasure to introduce Dr. Patricia Brown. Dr. Brown currently serves as the Director of the [Office of Laboratory Animal Welfare](#) (OLAW) at the [National Institutes of Health](#). She received her Bachelor of Science degree in Animal Science from the Penn State University, and her veterinary degree from the University of Pennsylvania. She served in the U.S. Air Force for eight years, and while on active duty earned a Master of Science degree in laboratory animal medicine from Penn State. She joined the U.S. Public Health Service in 1986 and has served in a variety of positions at the NIH, within the Veterinary Resources

Branch, the National Cancer Institute, and the [Office of Animal Care and Use](#). Dr. Brown is a Diplomate of the [American College of Laboratory Animal Medicine](#) (ACLAM), has served on the Board of Directors of ACLAM, is a past President of the [American Society of Laboratory Animal Practitioners](#) (ASLAP), and has served on the Board of Trustees of [AAALAC](#). Dr. Brown.

Good afternoon, Jerry, and hello to everyone.

In addition to a discussion of new Frequently Asked Questions to OLAW, which is the title of the presentation today, my update is also going to cover a number of other areas. I will briefly mention some new OLAW guidance to grantees, issued as [Notices](#) in the [NIH Guide for Grants and Contracts](#), some recent commentary that OLAW has published, and new educational resources supported by OLAW.

OLAW considers our [Frequently Asked Questions](#) and Notices published in the Guide for Grants and Contracts as our current guidance on a particular topic, and as such they should be viewed as recommendations that institutions are expected to follow. In some instances, specific reference to the [PHS Policy](#) or the [Animal Welfare Act](#) Regulations will be cited, which would make the requirement to follow the guidance mandatory.

Commentary that OLAW publishes in response to scenarios in Lab Animal magazine, or other publications, is provided to clarify the correct interpretation of the PHS Policy, and is referenced with the appropriate section of the Policy.

We welcome your input on any of the guidance on our website. You can send your questions to the general OLAW e-mail address, which is olaw@od.nih.gov.

Slide 2 (Updates)

So, let's start with [Frequently Asked Questions](#).

Slide 3 (Frequently Asked Questions)

Slide 4 (New FAQs Released in 2010)

This year we have added a number of new Frequently Asked Questions to our website. Our FAQs are divided into seven different topic sections.

These general topics include: Applicability of the PHS Policy; IACUC Composition, Functions and Authority; Institutional Reporting to OLAW; Protocol Review; Program Review and Inspection of Facilities; Animal Use and Management; and Institutional Responsibilities.

We've just added a [topic index](#) to the OLAW website this year, as a new resource to OLAW guidance by subject matter. You can now browse or search for all OLAW responses on a particular topic that occurs in a Frequently Asked Question, or as a published commentary, or in articles written by OLAW staff, or even our Notices published in the Guide for Grants and Contracts. Those would all be listed under a particular subject if there was multiple guidance that we'd issued about that particular topic. The topic index can be found on the [OLAW](#) homepage under "Guidance."

So, now let's focus on some of the new FAQs.

Slide 5 ([Is social housing required for nonhuman primates when housed in a research setting?](#))

One of the two most recent FAQs has to do with whether social housing is required for nonhuman primates housed in a research setting. The answer is yes. It's a requirement of USDA regulations, and considered the default for social species as nonhuman primates.

Slide 6 ([Should positive reinforcement training be used for nonhuman primates?](#))

The second most recent Frequently Asked Question asks about the use of positive reinforcement training. This type of training benefits the animals and the research by being less stressful to the animal, and reducing the need for chemical restraint. It should be used whenever it is safe and feasible to employ for husbandry activities and also for research purposes when appropriate.

Slide 7 ([Are laparoscopic procedures considered major surgery?](#))

The next new FAQ addresses whether laparoscopic procedures are considered major surgery or not. OLAW uses the [Guide](#) definition regarding major surgery, which is equivalent to USDA's definition of a major operative procedure in the regulations. The definition states, "Major surgery penetrates and exposes a body cavity, or produces substantial impairment of physical or physiologic function." OLAW recognizes the authority of the IACUC to determine whether a procedure is major or not and the IACUC should consider a detailed description of the procedure and the anticipated or actual consequences of that procedure. The committee may need to readjust its decisions based on clinical outcome. If the IACUC, after thorough review, determines that the surgical procedure only penetrates, but does not expose, a body cavity and that the procedure does not produce substantial

impairment, the IACUC may conclude that it is not a major operative procedure. The IACUC must ensure that the appropriate analgesia, sterile technique and peri-operative monitoring is employed.

Slide 8 ([Does OLAW expect the IACUC to notify NIH when there is a change in an animal activity supported by PHS funds?](#))

The next question has to do with whether the IACUC has to notify NIH when there is a significant change to a protocol. The terms “significant change” and “change in scope” have different meanings and are used in different contexts. A “change in scope” is used in the NIH Grants Policy, and involves a change in the direction, type of research, or training from the aims or objectives or purposes of the original approved, funded project. There are some examples in the Grants Policy that mention a change in animal model, but those are only potential indicators of what might be considered a change in scope. The PI should always consult with their NIH funding office if they’re unsure about a change that they are making in their research, to determine whether NIH would consider it a change in scope. And, not all changes to animal protocols would be considered necessarily a change in scope where the NIH would need to be contacted. It is not the IACUC’s responsibility to report a change in scope. It’s the PI and the authorized organizational official’s responsibility, and it’s the NIH Grants Policy requirement that it should be at least 30 days prior to the proposed change that notification should come to the NIH Grants Management Officer involved with funding that particular project.

Slide 9 ([Does the IACUC need to approve research studies that use privately owned animals, such as pets?](#))

Another recent FAQ topic considers the use of pet animals in research. The question is “Does the IACUC need to approve research studies that use

privately owned animals, such as pets?" The PHS Policy and the Animal Welfare Act Regulations do not distinguish between animals owned by the institution and privately owned animals. If the research is PHS supported, the pets used in that research must be covered under an IACUC approved protocol. The institution must have an OLAW approved Animal Welfare Assurance covering all performance sites. The institution should ensure that the informed consent of the owner is obtained prior to the conduct of the research. The institution may also want to involve their legal counsel in the development of those informed consent documents.

Slide 10 ([How can the IACUC determine if animal activities constitute veterinary clinical care or research activities?](#))

The last FAQ that I'd like to discuss asks how the IACUC can determine if animal activities are veterinary clinical care or are considered research activities. When a privately owned animal is recruited, with the owner's consent, for participation in a research study or veterinary clinical trial, and the activity includes collection or generation of data for research purposes, such activities are considered research and are subject to IACUC oversight. If the study is PHS-funded, the institution must have an OLAW approved Animal Welfare Assurance covering all performance sites and IACUC approval for the research activity. If the study is being conducted in collaboration with a private clinical veterinary practice, the operational components of that practice associated with the research activity should be a covered component of the Assured institution. The institution is responsible for obtaining informed consent for the research activity. If the research activity is being conducted in collaboration with a private veterinary practice, the institution should consider the use of a Memorandum of Understanding agreement, and, again, the institutional legal counsel may be involved in the development of that document.

Slide 11 (Guidance to Grantees)

I'd now like to focus on some recent new guidance from OLAW published as Notices in the NIH Guide for Grants and Contracts. As mentioned earlier, OLAW issues these Notices as policy guidance and is based on our interpretation of the PHS Policy and its applicability to the particular topic. Institutions are expected to follow this guidance as an extension of the PHS Policy. All of the [Guide Notices](#) that OLAW issues related to animal welfare are posted on the OLAW website on the main webpage under the "Guidance" section.

Slide 12 ([Instructions for Completion and Peer Review of the Vertebrate Animal Section in NIH Grant Applications and Cooperative Agreements](#))

Issued earlier this spring is a Notice concerning the Vertebrate Animal Section of grant applications, and the role of Scientific Review Groups and the IACUC.

Slide 13 (Notice on VAS – Purpose)

The purpose of the Notice was to clarify the information that is required in the Vertebrate Animal Section of grant applications, to explain the process for review of the Vertebrate Animal Section during peer review and to distinguish the roles of the IACUC versus the Scientific Review Group. This Notice should help Principal Investigators to provide concise, complete descriptions of the animal activities in their grant applications. The level of detail in a grant application is quite different from what most IACUCs expect in an animal study protocol, but there are some elements that are similar.

Slide 14 (Notice on VAS)

The Notice reminds investigators that if the Vertebrate Animal Section is missing or incomplete it could result in the application being deferred from peer review or it could negatively affect the impact priority score. If the Scientific Review Group has questions or concerns about the Vertebrate Animal Section of the application, the concerns must be resolved prior to award of the grant, if the decision is made to fund the project. The NIH staff and the program at NIH that is funding the grant will work with the PI to reconcile the concerns and OLAW will review those responses and approve the revisions to the Vertebrate Animal Section and then follow that by lifting the bar to award of the grant.

Slide 15 (Notice on VAS)

The Notice goes on to describe the responsibilities of the Scientific Review Group in evaluating the involvement of animals as part of the scientific assessment of the application. The role of the IACUC is to assure that the animal care and use protocol conforms to the PHS Policy and federal animal welfare requirements. And, lastly, the Notice reminds institutions that it's the institution's responsibility to ensure that the IACUC protocol is congruent with the proposed use of animals in the grant application.

Slide 16 ([Clarification on the Roles of NIH Scientific Review Groups \(SRG\) and Institutional Animal Care and Use Committees \(IACUC\) in Review of Vertebrate Animal Research](#))

In response to feedback that we received from a number of scientific associations about the earlier Notice concerning the Vertebrate Animal Section and the role of Scientific Review Groups, we just last week provided additional clarification and details on how the Vertebrate Animal Section is evaluated as part of the peer review process and is considered as part of the

overall scoring. Further clarification is provided on the oversight role of the IACUC and review responsibility of NIH Scientific Review Groups.

Slide 17 (Clarification)

The clarification includes the following: If the Vertebrate Animal Section is missing, the application may be deferred. If one or more of the five required elements of the Vertebrate Animal Section are not addressed, the application's impact priority score may be negatively affected. Reviewers rate the application as "acceptable" or "unacceptable" with respect to the proposed use of animals and they will include specific comments and concerns assessing the information provided in the application. A vertebrate animal concern is defined as an issue involving animal care and there is a requirement that it must be resolved prior to award. Some examples of vertebrate animal concerns that might be seen coming from a Scientific Review Group include, but are not limited to, the inappropriate animal model, or unjustified number of animals, unnecessary pain or distress, lack of veterinary care, inappropriate anesthetic, or inappropriate use of tranquilizing drugs or restraining devices, or the method of euthanasia is inconsistent with the recommendations of the [AVMA Guidelines on Euthanasia](#) without adequate justification. In addition, if the Scientific Review Group has insufficient information from the application, the application is noted as having a vertebrate animal concern.

As I mentioned before, these vertebrate animal concerns must be resolved before an award is made. Appropriately addressing a concern helps to ensure that the required information on animal care and use in the grant application is in place prior to award. NIH considers the protection of research animal welfare a responsibility that is carried out in every phase of the grant process. Investigators may consider consulting with their

veterinarian for assistance in the development of a grant application involving new procedures with animals prior to submitting the application. The Scientific Review Group is not intended to supersede or serve as a replacement for IACUC review or IACUC approval of an animal study protocol.

Slide 18 (Clarification (cont'd))

An institution that reviews animal study protocols associated with a grant application, after the PI has been notified that a grant is pending an award, this process is called a "Just-in-Time" IACUC approval. The Notice that we just issued reminds institutions that they must support the decisions of the IACUC when the Just-in-Time process is used. Under no circumstances may an IACUC be pressured to approve a protocol, or be overruled on its decision to withhold approval. The PHS Policy requires that modifications required by the IACUC during their review and approval of a protocol be submitted to NIH with the verification of IACUC approval for the grant award. It's the responsibility of institutions to communicate any IACUC imposed changes to NIH staff as a result of the IACUC review and approval that occurs during a Just-in-Time procedure.

Slide 19 (Clarification (cont'd))

It's incumbent upon investigators to be totally forthcoming and timely in conveying to the IACUC any modifications related to the project scope and animal usage that may result from the NIH review and award process that may affect the animal study protocol. Should an institution find that one of its investigators disregards their responsibilities, the institution may choose to determine that all animal protocols from that investigator be subject to IACUC approval prior to allowing that investigator to submit a grant application.

Slide 20 ([Update of the Guide for the Care and Use of Laboratory Animals](#))

Another Notice that we've issued recently was issued in June, and this Notice concerns the release of the prepublication copy of the new edition of the [Guide for the Care and Use of Laboratory Animals](#). [On 1/6/11, the *Guide for the Care and Use of Laboratory Animals: Eighth Edition* replaced the prepublication copy previously at this link.]

Slide 21 (Notice on *Guide* Update)

The Notice announced the release of the prepublication copy. OLAW now has a [PDF](#) file [*Guide for the Care and Use of Laboratory Animals: Eighth Edition* has replaced the prepublication copy previously located at this link] that can be downloaded from our website for no cost. If you've not taken a look at this prepublication copy, I encourage you to visit our website. The guidance in the Notice announced that until the eighth edition of the *Guide* is published in its final form, the 1996 edition will remain the official *Guide* for the purposes of the implementation of the PHS Policy. OLAW will issue guidance on implementation of the eighth edition of the *Guide* after it is published.

Slide 22 ([Report on Site Visits to Chimpanzee Facilities and Associated Resources to Aid Grantee Institutions](#))

In August, we announced the release of the [report](#) of our visits to nine chimpanzee facilities as a Guide Notice. This summary report of the visits includes guidance for Assured institutions that house and use nonhuman primates for research.

Slide 23 (Site Visits – Chimpanzee Facilities)

The site visits were initiated to determine whether the institutions' programs and facilities for the care and use of chimpanzees were consistent with their Animal Welfare Assurance with OLAW and to evaluate the current state of social housing, husbandry, enrichment, veterinary care, and training practices for chimpanzees.

Overall, the institutions were found to be in compliance with the PHS Policy, and the quality of care and commitment to the psychological well being of the chimpanzees and other nonhuman primates was high.

Slide 24 (Site Visits – Chimpanzee Facilities)

The following issues were identified as requiring further enhancement. In situations where it is safe and feasible, chimpanzees and other nonhuman primates should be given positive reinforcement training to perform desired cooperative activities. These could be associated with husbandry or, when appropriate, with research activities. This type of training may also aid in reducing stress from capture and restraint and also the need for chemical restraint.

Slide 25 (Site Visits – Chimpanzee Facilities)

Housing of nonhuman primates in social settings, either as pairs or groups, is a requirement of the USDA Regulations, and single housing is considered the exception. Greater effort must be made for institutions to co-house nonhuman primates. Exemptions to the social housing requirement must be based on strong scientific justification, approved by the Institutional Animal Care and Use Committee or for a specific veterinary or behavioral reason. Lack of appropriate caging does not constitute an acceptable justification for exemption.

Slide 26 (Nonhuman Primate Enrichment)

In addition to releasing that guidance, we've provided a number of resources to enable a better understanding of various aspects of social housing and positive reinforcement training for nonhuman primates and these resources are now available on a special webpage on the OLAW website. This website focuses on [nonhuman primate enrichment and social housing](#). It includes a [pre-recorded online seminar](#) with [slides](#) [PDF] and [transcripts](#) [PDF] by NIH OLAW staff and the U.S. Department of Agriculture staff. And, it includes some discussion from the Animal Welfare Information Center on resources available to explain social housing and different methodology for positive reinforcement training. We've also included on that webpage the new FAQs that cover social housing and positive reinforcement training and we've provided links to Animal Welfare Information Center resources, including a [bibliography](#) on enrichment for nonhuman primates.

Slide 27 (OLAW Commentary)

OLAW has also issued guidance as commentary in a number of published materials, and I'm going to briefly update you on those.

Slide 28 (Commentary in *Lab Animal*)

We continue to provide commentary in Lab Animal magazine on IACUC protocol review scenarios. These are available from the OLAW website, under the heading "Guidance," and the topic heading "[Commentary](#)." OLAW provides this commentary when there is a need for clarification beyond what is provided by the scenario reviewers. OLAW coordinates a response with USDA when the topic applies to both PHS Assured institutions and the Animal Welfare Act regulated community. We also will coordinate a response with the FDA if the topic involves Good Laboratory Practice issues. These are

the two latest scenarios and although these questions seem straightforward, it's best if you review the entire scenario to understand what in many cases are complex circumstances facing the IACUC at Great Eastern University.

Slide 29 (*PI Alert* and *Lab Animal eAlert*)

We have recently been invited to respond to a number of scenarios by the e-magazines *PI Alert* and *Lab Animal eAlert* published by the Principal Investigators' Association. With the permission of the publisher, we have added these scenarios to the OLAW webpage, in the "[Articles by OLAW](#)" section.

Slide 30 (Educational Resources)

OLAW continues to develop new educational resources and I will briefly highlight a few of these.

Slide 31 (Educational Resources)

If you are not familiar with our ListServ, you can sign up on the OLAW website to join our e-mail distribution list, and then you will automatically receive notices when we announce changes on our website, or new resources that we have made available, or educational activities that we are supporting. We also offer [OLAW News](#) as RSS feeds delivered directly to your browser or RSS reader on your computer. There are a number of [printed and multi-media resources available from OLAW](#), and these can be requested or downloaded from the OLAW website.

Slide 32 (OLAW, USDA, and IACUC 101 will sponsor symposium)

OLAW, USDA, and [IACUC 101](#) will be co-sponsoring a [25th anniversary conference](#) in October 2010. This event is modeled after the first symposium on Animal Welfare and Scientific Research in 1984 and is an opportunity to

understand past achievements, engage in discussion of the future of laboratory animal welfare, and learn about advances in science and animal welfare.

Slide 33 ([Animal Welfare & Scientific Research: 1985 – 2010](#))

The dates of the symposium are October 25th to 26th and it will be held in Bethesda, MD. It will be preceded the day before by an IACUC 101 workshop and an AWIC workshop involving Meeting the Information Requirements of the Animal Welfare Act. The evening of October 25th there will be a special keynote presentation by Dr. Charles McCarthy, the first Director of OPRR, the office that preceded OLAW in oversight of PHS funded animal research. AAALAC is supporting the dinner and keynote event. Sessions on day one of the symposium will focus on Animal Housing Facilities, Institutional Animal Care and Use Committees, Education and Training, and Veterinary Care. On the second day of the symposium, leading biomedical scientists will make presentations highlighting their contributions to advancing human and animal health. Early registration for the symposium has been extended to September 15th, and because of the changeover of the fiscal year for many institutions, it's possible to register now at the reduced rate, and pay in October. If you haven't visited the [AWSR website](#), I encourage you to take a look at the agenda and the great things that we have planned for the event.

Slide 34 (Workshops & Conferences)

OLAW supports the IACUC 101/201 program workshops, and the [Scientists Center for Animal Welfare](#) Advanced workshops and Winter Conference. And here is a list of dates and locations for 2010. As I mentioned, there will be an IACUC 101 and an [Animal Welfare Information Center workshop on Meeting the Information Requirements of the Animal Welfare Act](#) on the Sunday before the Bethesda symposium.

Slide 35 (Upcoming OLAW Online Seminars)

Here's the upcoming schedule of topics for 2010 and 2011 for the OLAW Online Seminars. We welcome your suggestions for future topics for the Online Seminars.

Slide 36 (Questions? Please Ask!)

I thank you and I'm happy to take any questions at this time.

Thanks, Pat. At this point in time we are going to be joined by Dr. Kay Carter-Corker, the Assistant Deputy Administrator for the USDA, Animal and Plant Health Inspection Service, Animal Care. She's joining us to respond to a couple of specific USDA questions.

1. Kay, the first question is: We notice that APHIS has changed its approach to enforcement of the Animal Welfare Act. Why are these changes being made and how will they be applied to the APHIS's oversight of research facilities. Thank you, Jerry and Pat, for allowing me to join the seminar and to answer some of these questions. USDA's Office of Inspector General recently conducted a review of APHIS's regulation of dog dealers. To address those concerns of the audit, as well as to ensure the agency enforces the Animal Welfare Act to the fullest extent, Animal Care developed an action plan. The links to the audit, as well as to our action plan, can be found on our [Animal Care](#) website. Animal Care is committed to improving our enforcement methods and working to ensure that all licensees and registrants provide humane care and treatment for their animals by meeting the standards of the Animal Welfare Act.

Agricultures' Deputy Secretary, Kathleen Merrigan, spoke to our employees at our national meeting in April to reinforce the Administration's support for the animal welfare mission. She highlighted the need to transition from an age of education to an age of enforcement in which APHIS gets tougher on repeat offenders and moves more quickly and consistently to take enforcement action.

Although the audit and action plan focuses on problematic dealers, the improvements to our inspection and enforcement methods apply to all regulated entities, including research facilities. To improve the consistency in the approach used for inspections, we produced and distributed to all Animal Care personnel, a new inspections requirements handbook. This handbook addresses how to document inspection findings, communicate the findings to the licensee or the registrant, when to take inspection photographs, and many more of our procedural guidelines.

In 2005, the Office of Inspector General (OIG) also reviewed APHIS's inspection and enforcement activities, but specifically for those regarding research facilities. In one of those findings, OIG was critical of the penalties that were assessed to facilities that were not in compliance with the regulations and standards. The auditors recommended that APHIS seek legislative change to increase the fines from \$3,750 to \$10,000 per violation. In 2008, Congress changed the maximum penalty per violation to \$10,000 per violation. We are therefore updating our guidelines for calculating penalties. In June, we began issuing monthly press releases of enforcement actions that we take to address Animal Welfare and Horse Protection Act violations.

Since the 2010 audit focused mainly on problematic dog dealers, we are adding more inspectors primarily in the dog dealer concentrated areas of the

country. We are also adding more supervisors to improve the supervision of the inspectors overall. We believe our activities will improve our enforcement methods and will strengthen our efforts to ensure the humane treatment of animals. So these changes will affect all of the regulated entities that Animal Care is involved with.

2. Kay, the next question is for you as well. It says, when is a facility considered a repeat offender, and what enforcement actions will

APHIS take when repeat noncompliant items are found? That's a good question. In our inspection requirements handbook, we clarify that a noncompliant item is considered a repeat whenever the citation is the same section and subsection that was identified on the previous inspection report. That applies even if different animals or different portions of the facility are involved. A noncompliant item may be designated as a repeat if that same section and subsection, or the same issue, were cited on previous inspection reports, even if it's not the most recent past inspection report. It's not considered a repeat if the same noncompliance is identified in multiple locations of the facility during the same inspection. For example, during an inspection an inspector may find outdated drugs in the lab of a Principal Investigator A. On the subsequent inspection, though, outdated drugs were found in the lab of a Principal Investigator B. Now, this would be considered a repeat noncompliant item. The institution is the registered entity, and is responsible to ensure that all personnel involved in the regulated activity comply with the regulations and the standards. A facility would be considered a repeat offender if repeat noncompliant items are found during the inspection. For all repeat noncompliant items, the inspector must communicate with their supervisor to recommend an enforcement action. Possible actions may include a re-inspection within a specified timeframe, or an official warning notice, or a monetary penalty, or if it gets to that point, a

referral to our Office of General Counsel for adjudication. We see that this is an excellent opportunity for the institution to identify ways to remain in compliance, and by doing that during the exit briefing at the end of the inspection. The inspector will conduct an exit briefing with the responsible officials of the institution. During this time, the inspector will discuss everything that's occurred during the inspection, the noncompliant items that were found, what may be done to correct the problem, if you want to know. The inspector will also make efforts to ensure all understand what's expected of the facility, clarify any misunderstandings of the Animal Welfare Act, the regulations and standards, and obtain signatures, and as well explain how the inspection report will be delivered to the facility. I hope that answered the question appropriately.

Thanks, Kay. We actually are going to transition now to some questions for Pat, but I would encourage folks that are sending in their questions, if you have questions that are specific for the USDA, put that into the question as well and then we'll know which of our guests is going to be most appropriate to answer it.

3. Pat, our next question, and first one for you is as follows: When will OLAW release the new *Guide*? [Silence] Ok, I'm now off mute. OLAW does not have a role in determining when the newest version of the *Guide* will be released. Although NIH supported the update of the *Guide*, the release date will be determined by the publisher, which is the National Academies of Science and ILAR. So, at this point in time we are like you, waiting for that final publication, and it's unclear at this point when that will occur.

4. Next question for Pat. If a singly housed nonhuman primate has been highly trained to perform a behavioral task, and is currently being used in a long-term study, and there is a concern for the disruption of this study, is that adequate scientific justification for continuing to singly house that animal? The final determination about scientific justification for singly housing a nonhuman primate is the responsibility of the institution's IACUC. In this particular situation, if it was determined that single housing should continue based on strong scientific justification, then we would expect that that decision would be revisited when the long-term study was completed.

5. Next, from a regulatory perspective, which is more important, [FAQs](#), [Guide Notices](#), or [Commentaries](#)? Well, we consider the Notices published in the NIH Guide for Grants and Contracts as the most significant guidance of the information that we share with Assured institutions. One of our primary functions in OLAW is to advise institutions concerning implementation of the PHS Policy. The Notices provide guidance that represents our current thinking on a significant topic involving animal welfare or grants administration. This guidance is based on our experience with the subject matter and draws on best practices followed by the biomedical community. Unless specific statutory or regulatory requirements are cited, the Notices should be viewed as recommendations and an institution may use an alternative approach if the approach satisfies the requirements of the Policy and is determined acceptable by OLAW.

6. Next question. If the NIH review of a grant application results in a reduction of the number of procedures or the invasiveness of procedures, does the PI still have to inform the IACUC of those changes? Yes, our recent [Notice](#) released last week clarifies the role of the

IACUC and the Scientific Review Groups, and it states that it's incumbent upon investigators to be totally forthcoming and timely in conveying to the IACUC any modifications related to project scope and animal usage that may result from the NIH review and award processes. So, this would include changes recommended, either that alter the original procedures, even if they reduce or refine the animal activity. Those need to be shared with the IACUC when the IACUC is doing its review of the animal study protocol.

7. The next question is from a facility with nonhuman primates. It says: We currently have quite a few nonhuman primates singly housed and do not have scientific justification for many of them.

How soon must we implement social housing; do we need to inform OLAW of our current status? Well, OLAW would consider single housing of nonhuman primates without strong scientific justification, or if you're lacking specific veterinary or behavioral reasons, we would consider that noncompliance with the Animal Welfare Act Regulations and the *Guide for the Care and Use of Lab Animals*. So, such noncompliance should be promptly reported to OLAW with a plan and schedule for correction. [[FAQ F14](#)] **So, would that plan for correction then provide at least some feedback as to the length of time the facility might expect to be allowed to use in order to correct the problem?** Yes, we would expect a reasonable plan and schedule based on the individual institution's circumstances.

8. Next question. What is the IACUC staff responsibility in regards to minority opinions and informing IACUC members of the options to voice their concerns? It says, "I realize that I do not need to report minority votes, however, do I need to do anything when an IACUC member discusses his agreement or disagreement with IACUC

program policy, etc., during a meeting or at any other time?" Well, interestingly enough, we have an OLAW FAQ that addresses the requirements for recording and reporting minority views. It's [FAQ C6](#) and a minority view is expressed when a member disagrees with recommendations being made by the committee to the Institutional Official or with findings during the semi-annual inspections and program review. These minority views must be included in the [Annual Report to OLAW](#). Any IACUC member may submit a minority view directly to OLAW addressing any aspect of the institution's animal programs, facilities, or personnel training. Whether OLAW receives a minority view as part of the Annual Report, the renewal Assurance document materials, or directly from the dissenting IACUC member, we will carefully review the information provided in accordance with the requirements of the Policy and provisions of the *Guide*. Our sample Annual Report that's available on our OLAW website for download includes a section on minority views. OLAW considers it a best practice for the IACUC members to be reminded periodically of the opportunity to express minority views. The Chair or the IACUC staff or some other member of the IACUC may be an individual willing to take on this task and, as I said, it would be a best practice from our standpoint that the committee is reminded periodically about the opportunity to express minority views. Also, as a reminder, an IACUC member's dissenting vote on an animal study protocol, or when the IACUC votes to suspend an animal study protocol, must be recorded in the minutes, but the dissenting votes do not constitute a minority view for reporting purposes.

9. Next question. What is OLAW's preference regarding procedures to follow during a meeting for a potential noncompliance issue or animal concern raised to the IACUC that involves a PI who was a member of the IACUC? Should the PI's name be mentioned during

the discussion, and when should the PI be asked to leave the room or recuse him or herself? Well, both the Public Health Service Policy [[IV.C.2.](#)] and the Animal Welfare Act Regulations clearly state that no IACUC member may participate in the IACUC review or approval of an activity in which that member has a conflicting interest. [[Lab Animal Volume 39, No. 6, June 2010](#)] That is, they are personally involved in the activity, except to provide information requested by the IACUC. In the circumstances described, it's important to gather the facts from all individuals involved with the concern, including the PI. Having the PI present for the initial discussion of the circumstances would allow for clarification by the PI. Once the committee is ready to move forward on a decision about any corrective actions, then the PI should be recused. A conflict of interest may arise under a number of circumstances, including where a member's personal biases may interfere with their own impartial judgment, where a member is involved in a competing research program that's under discussion or where access to funding or intellectual information may provide an unfair competitive advantage to one individual. Neither the recused nor the excluded members may contribute to the quorum necessary to conduct IACUC business.

10. OK, our next question. When does a rodent need to be counted against the protocol? When it's born, or after it undergoes a procedure? Does the rodent get counted if it was born and found dead? Well, we've provided a response to a Lab Animal scenario [[Lab Animal Volume 35, No. 1, January 2006](#)] to a similar circumstance back in 2006 that addresses these questions, and we also have an FAQ that addresses tracking animal usage in our Animal Use and Management section, and it's [FAQ F2](#). So, the PHS Policy applies to live vertebrate animals used in research, including pre-weanling animals. Although the PHS Policy

does not explicitly require that an institution have a mechanism to track animal usage, it does require that proposals specify and include a rationale for the number of animals to be used and that the number be limited to the minimum necessary to obtain valid results. To meet this requirement, institutions need to appropriately monitor and document number of animals acquired, including through breeding or other means, as long as those animals are part of the approved animal activities. Monitoring should include all animals whether they are inadvertently produced or purposefully produced in excess of the number needed, or even those which do not meet criteria for the research, such as genetic characteristics established for the specific study. As I said, again, OLAW has an FAQ that goes into more detail about tracking animal usage, and I would refer you to that [FAQ](#).

11. Next question. Is IACUC oversight or review required for a privately-owned animal to be used in a theatrical presentation associated with the institution? If that theatrical presentation was PHS funded, then our answer would be absolutely, it would require IACUC approval. However, this is more of a local institutional decision as to what aspects involving animals within the jurisdiction of the institution they want to assign to the IACUC. And, that often does vary across different institutions.

12. This next question looks as though it's for both Pat and Kay. Do animals used for clinical research or clinical trials need to be reported when estimating animal usage for Assurance purposes or in Annual Reports to USDA, particularly in cases where the institution does not care for the animals, or has periodic and short periods of access to the animals, for example minutes or an hour or two to collect samples or evaluate the animal? From an OLAW standpoint, the

animal usage associated with an Assurance does cover all performance sites that are covered by that Assurance, so the average housing numbers may, in some cases, reflect those numbers of animals. It's really going to be determined on a case-by-case basis, depending on the circumstances involving that institution, but as I said, it depends on the performance sites that are covered by that institution's Assurance.

13. Kay, just to sort of reiterate the question, it sounds like they're asking if there's clinical research or a clinical trial where there is contact with the animal for a fairly short period of time, does that need to be reported in the annual report to USDA? It would need to be reported in the annual report if that activity is monitored by the IACUC and has an IACUC approved protocol. So, we're not looking as to whether the amount of time that an investigator is in contact with the animals. It's how the principal investigator has framed the involvement of those animals, and is providing opportunity for the IACUC to oversee that activity. So, it would be looked at on a case-by-case basis then and it depends on how the IACUC is monitoring it.

Sounds like a situation where it would make sense for the individual institution to get in touch with the appropriate regulatory group to get clarification on what needs to be done if there is any uncertainty there.

14. The next question. Do studies that use clinical samples, tumor, blood, etc., require IACUC approval? From a PHS standpoint, it would depend on how those samples are collected. If they are collected as part of a normal standard of care for veterinary purposes, then the answer would be "no." But, if those samples are collected as part of the research protocol,

even though they involve pet animals, and they go above and beyond the typical standard of veterinary care that would be provided in a veterinary situation, then most definitely there would need to be IACUC review and approval.

Kay, any additional comments on that one? No, we would agree with that interpretation.

15. OK. If using a pet, does the IACUC have to inspect the home of the pet as part of their semi-annual inspection? I guess it would depend on what the study involved. I can think of a circumstance where if the research is actually being conducted in the home, then that might be a very rare circumstance where they might have to be involved. What we are concerned about here, in terms of the pet oversight, has to do with the actual procedures being conducted on the animal that involve the research and the IACUC's responsibility would typically involve those conducted within the institution's framework in the facilities at the institution.

Kay, any comments? That's an interesting question. We would – it's definitely dependent upon how the animal is used, as well as the housing and care provided, as described in the protocol. And so, if it is going to be involved in that protocol, then we would expect that the institution is evaluating all aspects of the care and use of that animal. But, we would defer to the IACUC to make that decision on the details of whether a very specific pet required IACUC committee site visits.

16. OK, moving on to another question. A primate must be housed with other primates. That has been made clear to us today. What if your institution only has one primate? Can you still house that

primate? I am going to defer to USDA for this one, because it's primarily the Animal Welfare Act Regulations that require this.

I've got to pull out my little reference here just to make sure that I'm giving everyone the right answer, but there are options if there's a singly housed primate to where human interaction is an option and ensuring that the animal has appropriate enrichment. And, that's about as far as I want to go in an answer that I feel comfortable with and if there is more detail that's needed, I'll be glad to do some more research on that and to provide a more explicit answer.

And, I think that's an important point for all of our listeners to recognize that both of these organizations are available to provide feedback and information, especially for these fairly unique situations where it may not be immediately clear to anyone what the best way to proceed is.

17. Next question. After full committee review, the IACUC Chair designates a DMR since IACUC has agreed that it will be handled that way. The question arises when the individual designated is not available to review the material. Should the Chair inform the whole committee that he has designated either himself or another reviewer? Can he designate a replacement without informing IACUC members? We would consider it important, since there's been a change from what the committee had originally been informed that there was going to be a particular individual as designated member for review that it would be a best practice for the committee to be informed of the change. It is the Chair's responsibility to assign designated member reviewers, but just out of common courtesy it would be reasonable to let the committee know.

18. Next question. A change in duration, frequency, or number of procedures is considered significant. Shouldn't a change in the type of procedure also be considered significant? Shouldn't all procedures be described in the protocol and approved by the IACUC before implementation? I guess I am not quite sure if this is referring to FAQ D9. I'm not really prepared to go into detail about that one. I believe that has to do with the... **Why don't I suggest we'll move on to a couple of the other questions, and maybe one of the other staff members here could pull up [FAQ D9](#) for Pat; she can take a quick look at it.**

19. The next question. Pat, you are being asked to repeat your comments regarding the requirements for PIs to submit their IACUC protocol to NIH during JIT, Just-in-Time. Currently the only requirement found on Commons is for the approval date. I did not say that the PI submits the IACUC protocol to the NIH during just in time. The institution is required to verify IACUC approval as part of the Just-in-Time process. What I did say was if the SRG has comments that involve animal welfare, those comments will go to the PI and they must be reconciled prior to award. And, those comments should hopefully also be shared with the IACUC if it involves the animal study protocol itself. Often times they are very related topics, and they need to not only be reconciled by the PI in their response back to NIH, but they also need to be shared with the IACUC.

20. Pat, it looks like this next question is sort of the other side of that coin. It asks, do the modifications requested by the IACUC cover both those to protocol and proposal? Must both be reported to the NIH? So, I think what they are asking is – if the IACUC required changes to the protocol, and I'm assuming this is with just in time,

do those changes have to be reported to NIH? Yes, the significance of the changes is probably the next question people are going to ask. We're looking for the substance that was originally proposed in the grant application in the Vertebrate Animal Section, the procedures described there. If those are changed by the IACUC as a result of its review of the animal study protocol, that information has to come back to the NIH program officer, so that they're aware that the IACUC has made changes from what was originally described in the grant application.

If we go back to that earlier question about FAQ D9, it's clear that we have more questions than we are going to be able to answer today. So, that'll be one of the questions that will be included in the materials associated with the recordings of this session, and will be answered offline. So, you'll have a chance to see your answer to that question later on.

21. The next question. Are all modifications required by the IACUC following a Just-in-Time notice required to be submitted to NIH, or just major...I think, Pat, you just answered that one, because that's a similar kind of question. Yes.

22. The next one is, if a PI wishes to test the utility of a new piece of equipment, like a new imaging apparatus, and the equipment will only be available for a couple of hours when a vendor rep visits, does the test need to be described in a protocol, considered an amendment to an existing protocol, or considered a veterinary procedure? If there's live animals involved, I would hope it would be covered by an IACUC approved protocol, whether it's PHS funded or not. I

think that the institution would be in their best interests to cover any research involving, or any activity involving, live animals along those lines.

It's especially unlikely that it could be considered a veterinary procedure since clearly the purpose of it is to demonstrate a new piece of equipment.

23. The next question. Does OLAW have input as to any requested changes to the new *Guide* prior to final publication? So, I guess between pre-publication and final publication is OLAW involved in any way in any of those changes? OLAW, like any of the other readers of the pre-publication copy, we were given the opportunity to send in typographical changes, and corrections to references, and comments, and we did carry out that responsibility like, I believe, many others did.

24. Kay, this one is for you. Are pictures taken during a USDA inspection, which may or may not relate to a deficiency contained in the final report, are those pictures FOIAble? Ok, repeat the question, please. **Sure. "Are pictures taken during a USDA inspection, which may or may not relate to a deficiency in the final report, are those pictures FOIAble?"** Well, the instructions to the inspectors are to be taking pictures of noncompliant items. So, only those that are of the noncompliances would be included in the inspection report. I know there are some circumstances in which an inspector might take a picture or two that's not considered at that point in time a noncompliance, but for discussion with their supervisor on the circumstances of that issue. Any document that the USDA or the government produces – anything that the government produces – can be requested through the Freedom of Information Act and the program is responsible to provide that information to the Freedom of

Information Act coordinator in the office. That office is responsible to review the request to ensure that the document that we are providing satisfies that request and if there is sensitive information to address whether it can be excluded from the response to the requestor. So, the bottom line is if we have it, yes, it can be requested and, yes, we would be required to provide that to the coordinator. It would not necessarily be released and included in the response. That's not something that we would have that decision on.

25. And, a final question, also for you Kay. And, again, I'll remind our listeners that we have more questions here than we have time to answer. All of them will be answered and those answers included with the questions in the materials for the recorded version of this. Final question. Research facility inspection guide on the APHIS website is a 2001 version. The questioner is asking, "Where is the revised version available?" The guides are in the process of being revised, and it has to go through several layers of clearance, but what's currently posted on the website is the most current version of the Inspection Guide.

26. And, I'm going to throw in a last sort of personal question. Will those revisions include the new directions as it relates to the new era of enforcement? Yes, it is supposed to include all of the changes that have occurred in the program and our procedures and guidance, since the original inspection guides were created.

Great, thank you both very much for sharing your insights with our participants, and participants thank you for taking time from your schedules and for continuing to participate in these webinars. Our goal is to provide you with timely information that will be of assistance as you face the

daunting task of facilitating the IACUC process at your institution. We encourage your feedback and remind you that you can send in questions or comments to us at the hotlink entitled [OLAW Help](#) that can be found at the bottom of the OLAW webpage to submit your comments. For all of us here at OLAW, thank you for what you do to ensure humane animal care and use in research, teaching, and testing, and we hope to see you all at the October session that Dr. Brown spoke about earlier in her presentation. Thank you again, and good-bye.

Additional Submitted Questions Not Addressed During the Webinar

27. Is there any way USDA could review a scientific justification for single housed primates before an inspection to see if they would agree? A registrant may consult with USDA on ways to comply with the regulations and standards at any time. They may consult with their inspector or the appropriate regional office. During the unannounced compliance inspection, we will evaluate the many factors associated with housing of non-human primates, including any IACUC approved scientific justifications for single housed primates.

28. For research on client owned animals at off-site locations, what guidance should the IACUC be looking at? Should the IACUC expect the facility to meet all of the requirements of the *Guide*? Similar to a procedure area or a satellite facility, the length of time the animal is being handled, the types of procedures being performed, and the area where procedures are performed should be considered using the *Guide* as a basis for the review.

29. Regarding notification of changes in grant applications. How does that influence a protocol that includes an NIH grant and funding from another source such as institutional funding? If there is a change in any of the animal activities from original grant application, the NIH funding component should be informed of the changes made by the IACUC.

30. For OLAW, do you recommend mandatory tetanus vax for all animal care personnel? We will defer this question to our September 2011 webinar on occupational health and safety.

31. We have an Assurance with OLAW but are not AAALAC accredited. We would like to have someone visit our facility to let us know if we have an adequate animal program. Could we request an OLAW site-visit? Yes. Any accredited institution could request a site visit but the prioritization of site visits may not allow for us to honor all such requests. However, keep in mind that all Assured Institutions may contact OLAW staff with questions or guidance about their animal program or IACUC activities. Informal requests for information or guidance can be addressed without establishing a formal report.

32. When the USDA conducts an inspection they may cite us for significant problems that we identified and corrected. If similar problems were identified during an OLAW site visit what would OLAW do? OLAW's expectation is that Assured institutions will promptly report to OLAW events as they occur along with the corrective actions that were taken to address the problem. OLAW would not expect an institution to report past problems but if during a site visit many unreported problems are

identified OLAW would expect the institution to undertake corrective actions to ensure that prompt reporting became part of the animal program.

33. If OLAW and USDA conduct a joint inspection, who has the most authority? It is important to recognize that OLAW and USDA have separate and different authority and responsibilities. Both agencies work together to ensure humane animal care. OLAW is charged with ensuring that the specifics of an Institution's Assurance are being met, using the PHS Policy and the *Guide for the Care and Use of Laboratory Animals*. The USDA is charged with ensuring that the requirements of the Animal Welfare Act and Regulations are being met.

34. If an OLAW site-visit uncovers an ongoing significant deviation from the *Guide*, how far back could NIH demand return of funds? OLAW is not responsible for overseeing the possible return of funds. The role that OLAW would play is to inform the funding component of the NIH or other Public Health Service agency that funded the activity of the possible inappropriate ongoing expenditure of funds. The institution has the primary responsibility to inform the funding component of the problem. On a case-by-case basis, the NIH funding component with guidance from the NIH Office of Policy for Extramural Research Administration (OPERA) would decide if a return of funds was required.

35. If OLAW receives an anonymous report of animal cruelty are they, like USDA, required to conduct an inspection? OLAW investigates all such allegations. Initially OLAW would ask the institution to investigate the charges and would provide guidance to the institution. Serious concerns may result in OLAW conducting a site-visit to the institution.