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Note: Text has been edited for clarity.

Writing a Good Assurance

Speakers: Eileen Morgan, Director, Division of Assurances, OLAW, Kim Taylor, DVM, DAACLAM, Division of Assurances, OLAW and Venita Thornton, DVM, Division of Assurances, OLAW.

Moderator: Jerry Collins, PhD, Division of Policy and Education, OLAW and Yale University.

Broadcast Date: June 9, 2011. A recording of the seminar can be viewed at http://grants.nih.gov/grants/olaw/110609_Seminar%20Writing_a_Good_Assurance.wmv (Windows Media Player - 1 hr).

Slide 1 (Title Slide)

[Text related to submitting questions during original broadcast of the seminar has been removed. See text at the top of this page if you would like to submit questions to the [Office of Laboratory Animal Welfare](#) (OLAW). -- Hello. Welcome to the next in our series of OLAW webinars for [IACUC staff](#). My name is Jerry Collins and I will be the moderator of today's seminar entitled "Writing a Good Assurance."]

Slide 2 (Writing a Good Assurance)

Our webinar today will be presented by Ms. Eileen Morgan, Dr. Venita Thornton and Dr. Kim Taylor.

Eileen Morgan currently serves as the Director, Division of Assurances, in the Office of Laboratory Animal Welfare at the National Institutes of Health. Ms. Morgan previously served as a Senior Assurance Officer in the Division of Assurances within the Office of Laboratory Animal Welfare. Eileen holds a B.S. in Technology Management from the University of Maryland with a minor in Animal Health Technology. She is also a licensed veterinary technician. She has 24 years of experience in animal models-based biomedical research. Her experience includes service as the Chief of the Facility Management Branch in the Division of Veterinary Resources, NIH Intramural Program. She has also held positions at the Johns Hopkins University School of Medicine, the American Red Cross Holland Laboratory, Affinity Biotech, and the Cleveland Research Institute.

Dr. Venita Thornton is a Senior Assurance Officer in the Office of Laboratory Animal Welfare. She earned a B.S degree in Laboratory Animal Science from North Carolina Agricultural and Technical State University, and a DVM degree from N.C. State University College of Veterinary Medicine. She earned a Master of Public Health degree in Preventive Medicine and Biometrics and simultaneously completed a residency program in Laboratory Animal Medicine at the Uniformed Services University of Health Science in Bethesda, Maryland. While at NIH, she has served in a variety of positions within the Veterinary Resources Program and at the National Institute of Neurological Disorders and Stroke.

Dr. Kim Taylor is a Senior Assurance Officer in the Division of Assurances, Office of Laboratory Animal Welfare. Dr. Taylor joined OLAW in November 2007. She has been in the field of laboratory animal medicine and biomedical research since 1994. She obtained her Doctor of Veterinary Medicine degree from the University of Wisconsin, Madison in 1989 and is a

Diplomate of the American College of Laboratory Animal Medicine. Most recently Dr. Taylor served as the Deputy Animal Program Director for the National Institute of Allergy and Infectious Diseases (NIAID), Comparative Medicine Branch. Prior to joining NIAID, Dr. Taylor spent 12 years in the U.S. Army, where she completed a residency program in Laboratory Animal Medicine at the U.S. Army Research Institute of Infectious Diseases located in Frederick, Maryland. It's now my pleasure to hand the microphone over to Ms. Morgan.

Good afternoon. It's my pleasure to talk with you today about writing a good domestic Animal Welfare Assurance. This presentation will cover the information required in a domestic Assurance and provide some general guidance to ensure an effective and efficient review and approval process by OLAW.

Slide 3 (PHS Policy)

First, I will briefly present the [Public Health Service Policy](#) requirements. The requirement for an Animal Welfare Assurance ([Assurance](#)) comes from the PHS Policy as a result of the [Health Research Extension Act of 1985](#). The PHS Policy requires institutions receiving PHS funding for research involving the use of live vertebrate animals to obtain an Animal Welfare Assurance. The Assurance requires the establishment of an animal care and use program and an Institutional Animal Care and Use Committee commonly called an IACUC.

The PHS Policy is built on the premise of institutional self-monitoring, self-reporting, and oversight by the IACUC. If an organization has an impending grant or contract award, but no Assurance, the Office of Laboratory Animal Welfare will work with them to negotiate the Assurance, so that they can

receive their award. The Division of Assurances facilitates the institution receiving their award by assisting them in completing their Assurance.

Slide 4 (Animal Welfare Assurances)

An Assurance is a contract between the institution and OLAW, acting as a representative of the federal government. It describes the institution's program of animal care and use; demonstrates institutional commitment to the humane care and use of animals; and is the basis for compliance oversight by the institution. The criteria for obtaining an Assurance is imminent PHS funding, either direct or indirect.

Slide 5 (Types of Assurances)

OLAW negotiates three different types of Assurances: [domestic](#), [foreign](#), and interinstitutional. Before we go into detail about the domestic Assurance, I will briefly touch on the other two Assurance types.

Slide 6 (Foreign Animal Welfare Assurance)

In compliance with the PHS Policy, a foreign institution receiving direct or indirect PHS funding for the use of live vertebrate animals agrees to comply with the [CIOMS International Guiding Principles](#) and the laws, regulations, and policies regarding use of laboratory animals for the jurisdiction in which the research will be conducted. A [foreign Assurance](#) is negotiated when the prime grantee is a foreign institution or a domestic grantee conducts animal work at foreign performance site. For collaborations between a domestic institution and foreign sub, NIH holds the prime grantee responsible for the IACUC review and approval and for appropriate conduct of the research at the foreign performance site. Foreign Assurances are approved for five years.

Slide 7 (Interinstitutional Assurance)

An interinstitutional Assurance is negotiated when the grantee organization does not have its own animal facility and program for animal care and use and will rely upon those of an Assured institution where the animal research will be conducted. An interinstitutional Assurance is approved for the life of the grant – up to five years.

Slide 8 (Domestic Assurance)

A [domestic Assurance](#) is negotiated when the grantee organization has its own animal facility, is conducting animal research, and has an animal care and use program. Key members of the program include the Institutional Official or IO, the IACUC, and a veterinarian with direct or delegated program authority. The IO should have the authority to allocate organizational resources needed to maintain a smoothly functioning animal care and use program. Domestic Assurances remain in effect for four years and are renewable.

Now Dr. Thornton will begin to describe how to write a good domestic Assurance.

Slide 9 (Sample Domestic Assurance)

A [sample Assurance document](#) is provided on the OLAW website to assist institutions in developing an Assurance that describes their animal care and use practices in compliance with the PHS Policy. It should not be used by:

- Foreign institutions;
- Institutions that currently do not have their own animal care and use programs;
- And, institutions that are proposing to have animal activity conducted solely at a collaborating institution.

Additional guidance, [Frequently Asked Questions](#), and [suggested references](#) are available at the [OLAW website](#). [The [OLAW topic index](#) may help you find information of interest.]

Slide 10 (Sample Assurance Instructions)

The current sample document, posted on the OLAW website in 2008, supersedes all previous versions. It outlines all required elements of an Assurance. Italicized text and notes in brackets [*like this*] provide instructions and should be deleted from the Assurance before submitting to OLAW. Reviewing the text provided in brackets will facilitate writing the Assurance. Providing clear, concise responses and adhering to the sample format will result in efficient and effective review and approval by OLAW.

Slide 11 (Sample Assurance Instructions (cont.))

One or two page attachments are preferred and may be used to provide the following:

- Organizational structure of the animal care and use program;
- IACUC membership;
- Facility and species inventory;
- And lastly, the most recent [semiannual report to the IO](#). This is needed only for programs that are not accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International, otherwise known as [AAALAC](#).

All other program elements should be described succinctly in the Assurance document. Please do not send additional attachments or include CVs, appendices, binders, manuals, protocols, or standard operating procedures.

If someone other than the IO or the IACUC chair is the primary point of contact regarding the Assurance, then indicate who and provide that

individual's contact information. You can submit this information either by using the section at the end of the IACUC roster found in the sample document or by providing the information in a cover sheet.

And, lastly, it has been our observation that when individuals who write the Assurance are knowledgeable about IACUC functions, animal care and use programs, the PHS Policy, and the *Guide (Guide for the Care and Use of Laboratory Animals)*, the resulting document addresses most of the required elements and needs very little revision.

Slide 12 (Assurance Components)

The Assurance provides an in-depth description of the key components of the institution's program of animal care and use. This slide lists those key components. We will now go into more detail about each of these parts of the Assurance.

Slide 13 (I. Applicability)

In [Part I. Applicability](#), the institution should list only the branches and major components that fall under the administrative oversight of the institution and any other PHS funding organization, that is [NIH](#), [CDC](#), or [FDA](#), that the institution chooses to include in its Assurance. All institutional branches and components listed under the Applicability section must receive direct or indirect PHS funding and follow the guidance of the IO and the IACUC of the Assured institution. All components of the Animal Welfare Assurance, including the occupational health and safety and personnel training programs, apply to all components listed under Applicability in the Assurance document.

Slide 14 (II. Institutional Commitment)

[Part II. Institutional Commitment](#). A signed Assurance obligates the institution to ensure the humane care and use of laboratory animals in compliance with the [PHS Policy](#), the [U.S. Government Principles](#), the provisions of the *Guide*, and the Animal Welfare Act and Regulations, if applicable.

Slide 15 (III. Institutional Program for Animal Care and Use)

[Part III. Institutional Program for Animal Care and Use](#), requires the institution to describe the seven major elements of its animal care and use program. This slide lists those key components. We will now describe each of these sections as they relate to the OLAW Assurance document.

Slide 16 (III. A. Lines of Authority)

[Part III. A.](#), entitled lines of authority, requires a description or diagram showing open and direct lines of communication between the key parties involved in administering the animal care and use program. The information provided must describe or depict the interactions between the Chief Executive Officer, the IO, the IACUC, the veterinarian with program authority and the facility management.

A direct line of communication must be demonstrated between the IO and the IACUC, as well as between the IO and the veterinarian. The lines of communication are not necessarily the same as the supervisory chain of command. Unclear or inappropriate lines of authority and responsibility have been the underlying cause for serious cases of programmatic failure. Further guidance is provided in OLAW's [Frequently Asked Question G4.](#), entitled

"What kind of administrative organization works best for ensuring compliance?"

Slide 17 (III. B. Veterinarian(s) Associated with Program)

[Part III. B.](#), requires the names of all veterinarians associated with the program and a description of their qualifications, authority and responsibility, and percent time contributed. All institutions, regardless of size, must have at least one veterinarian with direct or delegated program authority and responsibility for the institution's animal care and use program. If only one veterinarian is associated with the program, then the document must describe the provisions in place for a back-up veterinarian to include the name of the veterinarian and/or the name of the practice or organization. All veterinarians associated with a domestic Assured institution are required to comply with the Animal Welfare Act definition of a veterinarian. This means they have attained one of the following:

- Graduated from an AVMA-accredited veterinary school;
- Or have a certificate issued by the AVMA's Educational Commission for Foreign Veterinary Graduates;
- Or have received equivalent formal education as determined by the USDA Administrator.

Slide 18 (III. C. IACUC Membership)

[Part III. C.](#), the IACUC must consist of not less than five members, including:

- A veterinarian with program authority and responsibility for the animal activities at the institution;
- A practicing scientist;
- A nonscientific member;
- A nonaffiliated member;

- And at least one other member.

The definition of a nonaffiliated member is an individual not affiliated with the institution in any way other than as a member of the IACUC, and not a member of the immediate family of a person who is affiliated. This member is expected to represent the interests of the general community in the proper care and use of animals and should not be a laboratory animal user. A consulting attending veterinarian may not serve as a nonaffiliated member.

The names of the members may be coded on the IACUC roster, except for the chair and the veterinarian with program authority. The roster must also contain the chair's complete contact information. An example roster is located at the end of the sample Assurance. All columns must be completed to allow OLAW to determine whether all appointees are appropriately qualified. The third column heading, "Position Title", refers to an individual's current job position. The term "retired" does not provide OLAW with enough information to evaluate the member's qualifications to serve as a nonaffiliated or nonscientific member. However, "retired banker" would be an acceptable entry in the Position Title column. Alternate members should be listed on the roster, using similar coding if desired and must meet the criteria described in our recent notice in the NIH Guide for Grants and Contracts on alternate members. This would be Guide Notice [NOT-OD-11-053](#), entitled "Guidance to Reduce Regulatory Burden for IACUC Administration Regarding Alternate Members and Approval Dates."

Slide 19 (III. D. IACUC Responsibilities and Procedures)

[Part III. D.](#) consists of 10 items. This section of the Assurance must describe how the IACUC conducts business and fulfills its responsibility to oversee animal activities. Next slide, please.

Slide 20 (III. D. 1. Semiannual Program Review)

[Part III. D. 1.](#), semiannual program review. The Assurance should describe who performs the review, when and where it is conducted, and what program components are included. Some Assurances are submitted with inadequate descriptions of the semiannual program review, where either no description is provided or the description of program review is included as part of the facility inspection. The program review consists of an evaluation of institutional elements, such as the program of veterinary care, IACUC functions, the occupational health and safety program, and personnel training.

A [sample Semiannual Program Review and Facility Inspection Checklist](#) is available on the OLAW website. If the IACUC does not use the OLAW checklist or the topic headings of the *Guide*, then a list of the major program elements reviewed must be provided in the description.

Slide 21 (III. D. 2. Semiannual Facility Inspection)

In [Part III. D. 2.](#), semiannual facility inspection. In this part, it should describe who performs the inspection, when and where it is conducted, and what components are inspected. If the IACUC does not use the OLAW checklist or the topic headings of the *Guide*, then a list of the major facility items inspected must be provided in the description. The facility inspection consists of an evaluation of animal housing areas, procedure rooms, and surgical areas. Investigator laboratories should also be routinely visited if animals are housed there for greater than 24 hours, or if surgeries, either non-survival or survival, are performed.

The PHS Policy states that the IACUC may, at its discretion, determine the best means of conducting an evaluation of the institution's programs and facilities and may invite *ad hoc* consultants to assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and the resulting [semiannual report to the IO](#). If the institution uses USDA-covered species, then the inspections of those areas must be conducted by at least two voting IACUC members. No member wishing to participate may be excluded. A statement of this policy should be included in the Assurance.

Slide 22 (III. D. 3. Semiannual Report to the Institutional Official (IO))
[Part III. D. 3.](#), the [semiannual report to the IO](#). This part should describe the following:

- How the reports are compiled;
- Next, the process used to correct deficiencies identified during either the program review or facility inspection;
- And, the components included in the IACUC's semiannual report to the IO.

The PHS Policy requires semiannual reports to the IO to include the following:

- A description of the nature and extent of the institution's adherence to the *Guide* and the PHS Policy;
- A list of any IACUC-approved departures from the *Guide* and the PHS Policy to include the reasons for each;
- Classification of all deficiencies as minor or significant with a reasonable and specific plan and schedule for correction for each deficiency;
- And lastly, inclusion of minority views, if they exist.

The report must be signed by a majority of IACUC members.

Dr. Kim Taylor will continue with concerns regarding the care and use of animals.

Slide 23 (III. D. 4. Reporting and Reviewing Concerns)

One of the roles of the IACUC is to review reported animal welfare concerns and investigate them, if warranted. [Part III. D. 4.](#), reporting and reviewing concerns, should describe how the information about how to report concerns is disseminated to employees, the methods that the IACUC uses to evaluate reported concerns, and the guidelines for effecting appropriate corrective measures, when necessary.

Slide 24 (III. D. 5. Written Recommendations to the IO)

In [Part III. D. 5.](#), written recommendations to the IO, the institution should describe the IACUC's procedures for making written recommendations to the IO on any aspect of the animal care and use program.

Slide 25 (III. D. 6. Protocol Review)

[Part III. D. 6.](#), protocol review, should describe the IACUC protocol review processes from receipt through final decision. In our experience, this section requires the most clarification when OLAW is negotiating an Animal Welfare Assurance with an institution.

This section should describe concisely the following:

- How the IACUC conducts full committee review;
- And if applicable, designated member review to include listing the possible outcomes for each review process;

- How modifications required to secure approval resulting from full committee review are reviewed and approved when the protocol is resubmitted;
- What happens if protocol approval is withheld following full committee review;
- What specific procedures must be followed when there is more than one designated reviewer;
- And, lastly, how the IACUC addresses conflict of interest or undue influence.

The PHS Policy requires the IACUC chair to appoint qualified members to serve as the designated reviewers. For more in-depth information on protocol review methods that are compliant with the PHS Policy, please refer to the [OLAW FAQ D3.](#), entitled "What are the possible methods of IACUC approval?" and related links [[NOT-OD-06-052](#), [D1](#), [A2](#), [A5](#), [A10](#), [A11](#)].

Slide 26 (III. D. 7. Proposed Significant Changes)

Review and approval of proposed significant changes must comply with the same requirements as review and approval of new protocols as required by the PHS Policy in [Section IV.C.](#) Investigators should be aware that they may not implement significant changes prior to receiving IACUC approval. In [Part III. D. 7.](#), the IACUC's procedures for reviewing and approving proposed significant changes in a previously approved protocol should be described. [See also OLAW [FAQ D9.](#)]

Slide 27 (III. D. 8. Notification of Investigators and Institution)

[Part III. D. 8.](#), notification of investigators and the institution, should describe how the IACUC notifies investigators and the institution or the IO of decisions rendered with regard to protocol or amendment review. The

notification may be accomplished either electronically or by hard copy. Additionally, if the IACUC votes to withhold approval, the written notification must contain the reasons for its decision, as well as allow the investigator the opportunity to respond either in person or in writing to the IACUC's concerns.

Slide 28 (III. D. 9. Continuing Review Activities)

[Part III. D. 9.](#), continuing review activities. This section requires the institution to describe how the IACUC conducts continuing reviews of ongoing previously approved animal activities. The IACUC may determine the best means for conducting these reviews. Additionally, the process that the IACUC uses to perform the PHS Policy-mandated three year protocol reviews should be described in this section. The Policy requires that all ongoing approved protocols, prior to the three year expiration date, undergo a complete *de novo* review by full committee review or by designated member review. Animal work may not continue past the expiration date, even if IACUC review is pending.

Any protocol that uses USDA-covered species must be reviewed annually, by full committee review or by designated member review, per the Animal Welfare Act Regulations.

Slide 29 (III. D. 10. Suspension of an Approved Activity)

[Part III. D. 10.](#), suspension of an approved activity. The IACUC's process for suspending an ongoing previously approved animal activity should be described. [Part IV.C.6.](#) of the PHS Policy states that the IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act Regulations, the *Guide*, the institution's Assurance, or [Section](#)

[IV.C.1.a.-g.](#) of the Policy. The Policy also states that the IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.

The IO plays an important role in the suspension process. If the IACUC suspends an activity, then the IO, in consultation with the IACUC, is responsible for reviewing the reasons for suspension, taking the appropriate corrective action, and reporting that action with a full explanation to OLAW and to any funding agency.

Slide 30 (III. E. Occupational Health and Safety Program)

[Part III. E.](#), occupational health and safety program. The Public Health Service Policy places responsibility with the institution for ensuring a safe working environment for personnel involved in the animal care and use program. An effective animal health and safety program relies on strong administrative support and interactions among several institutional functions or activities, including the research program, the environmental health and safety program, occupational health services, and administration. Small institutions often contract with trained health professionals who specialize in occupational health and safety. OLAW recognizes that occupational health and safety programs may vary widely in scope depending on the size of the animal care and use program at the institution.

OLAW's review of the Assurance ensures that the basic elements as outlined in the *Guide* are addressed. For guidance on the appropriate components of an occupational health and safety program, institutions should refer to the Occupational Health and Safety of Personnel section in the *Guide*. Another excellent reference is the 1997 National Research Council's publication

entitled, "[Occupational Health and Safety in the Care and Use of Research Animals](#)". On September 8, this year [2011], OLAW will offer a webinar on Occupational Health and Safety Programs presented by Dr. James Schmitt, who is the Medical Director of the Division of Occupational Health and Safety at the NIH.

Slide 31 (III. F. Facility and Species Inventory)

[Part III. F.](#), facility and species inventory. Each Assured institution must list all buildings that house animals and the species used. Species should be identified by their common names. For example, nonhuman primate is not a common species name, but rhesus or cynomolgus macaque is. Each species housed within a unit should be listed on a separate line and the approximate average daily inventory for each species must be provided. Institutions may choose to code animal locations. A [sample format for the inventory](#) is available at the end of the [sample Assurance](#).

Slide 32 (III. G. Training)

[Part III. G.](#), training. All individuals working with or caring for laboratory animals must be qualified to do so to ensure the humane treatment. [Section IV.C.1.f.](#) of the PHS Policy places responsibility specifically with the IACUC to ensure that personnel conducting procedures on research animals are appropriately qualified and trained. Appropriate training depends on the size, scope, and needs of the research facility, but must always incorporate the federal training mandated by the [U.S. Government Principles](#). The Assurance should describe the training provided to scientists, animal technicians, and other personnel involved in animal care, treatment, or use to include the following topics:

- Humane animal care and use;

- Methods that minimize the number of animals required to obtain valid results;
- And, lastly, the methods to limit animal pain and distress.

Additionally, a description for how IACUC members are provided the training necessary to understand their responsibilities and duties is required in this section. Pertinent items to be described may include how IACUC members are provided orientation, training materials, and resources. IACUC members must have the proper training to enable them to understand and evaluate the issues that are brought before them.

Slide 33 (IV. Institutional Program Evaluation and Accreditation)

[Part IV.](#), Institutional Program Evaluation and Accreditation, requires the institution to indicate whether it is Category 1 or 2 and serves as a reminder that a Category 2 institution must submit the IACUC's last semiannual report to the IO, along with its Assurance. An Assured institution is considered to be Category 1 only if all components listed in Part I. Applicability are AAALAC accredited.

Slide 34 (V. Record Keeping Requirements)

[Part V.](#), Recordkeeping Requirements. In this part, the institution inserts the name or title of the IO where indicated. This part also provides a brief account of how long records must be retained by the institution.

Slide 35 (VI. Reporting Requirements)

The first half of [Part VI.](#), Reporting Requirements, reminds the institution of when their annual report to OLAW is due. It also describes reporting requirements for AAALAC accreditation status and program review and facility inspections.

The second half of Part VI. lists the reporting requirements for the IACUC and the IO concerning the actions taken for the following circumstances:

- Any serious or continuing noncompliance with the PHS Policy;
- Any serious deviations from the provisions of the *Guide*;
- And, lastly, any suspension of an activity by the IACUC.

If the individual serving as the IACUC chair or IO changes during the year, then the institution should report the change immediately to OLAW. This can be accomplished by sending an e-mail to olawdoa@mail.nih.gov. Include the following information in the e-mail:

- The institution's name and Assurance number;
- The name and credentials of the individual and their position title;
- And, lastly, their complete contact information to include their e-mail address, mailing address and phone number.

For more information on reporting requirements, you may view two archived webinars at the OLAW website entitled "[The Annual Report to OLAW](#)" (Flash - 53 min) presented December 10, 2009 and "[Reporting Noncompliant Events to OLAW](#)" (Flash - 45 min) presented March 5, 2009.

Slide 36 (Please Send Questions NOW via the Question Box on your Screen)
[Note: see the directions at the beginning of this text, if you want to submit a question to OLAW. This is a recording, not a live broadcast, and OLAW is not able to answer your question in real time.]

Thank you, Eileen, Venita and Kim. We now have an opportunity to address your questions. So please submit them using the question box at the bottom of the attendee interface screen. We will start with some questions that we received prior to the start of the webinar. And there are a good few questions coming in now as well. So if we can't get to all of them, we have

about, oh maybe 25 minutes left, all of the questions that have come in will be posted, along with their answers, when we post the recording of this session.

Eileen, the first question – oh, and Eileen Morgan is going to be answering all of the questions here. Eileen, the first question.

1. What is the difference between direct and indirect PHS funding?

Direct funding means that the funds will be used by the grantee at their institution for the work described in the grant application. Indirect funding is when the grantee subcontracts the work to another institution as a performance site for the animal activity. The second institution is receiving PHS funds indirectly through the grantee.

Next question. **2. I would like to include a separate company under the applicability in my assurance. Under what circumstances may I do that?** A separate company, such as *Research Associates*, may be included as a covered component under your Animal Welfare Assurance, if they have PHS funding. If you add a separate company with a different administration, your institution takes responsibility and authority for *Research Associates'* animal care and use program for all PHS funded activities and all components of the Animal Welfare Assurance described also apply to *Research Associates*, including the training and occupational health and safety programs. *Research Associates* must agree to follow the guidance of the IO and the IACUC of the Assured institution. All branches, locations, and companies listed under the Applicability section of the Assurance are entitled to use the Assurance number for grant and contract submissions to PHS agencies.

Eileen, the next question. **3. How can I amend my Assurance to include another branch of our animal program, previously not included in the Assurance?** If the program or animal facility is a branch of the institution and under the same administrative authority, then you can submit the change, when it is made, by submitting a letter on institutional letterhead signed by the IO requesting the addition to the Applicability section of the Assurance. The Assurance is only applicable to the branches, facilities, institutions and companies named under the Applicability section.

4. What if a company is leasing space or animal rooms at an Assured institution, do they qualify for an Assurance? It depends. A company leasing space in an Assured institution must be receiving PHS funding – NIH, CDC or FDA – to be part of the Assured institution and to qualify to use the Assurance number to apply for grants or for contract submissions.

Next question. **5. May two different institutions each obtain their own Assurance numbers and share the same building?** That sounds like an interesting situation. Well, actually, it is an interesting situation and – the reason we're answering it is – this has come to us on a couple of occasions. If the institution or company share common space, hallways, same air handlers, share cage wash, then one of the institution or companies may obtain an Assurance and list the other as a covered component under the Applicability section provided that each has PHS funding. The institution who obtained the Assurance takes responsibility and authority for the animal care and use program and all PHS-funded animal activities for both institutions. Each institution or company is entitled to use the Assurance number for grant and contract submissions to PHS agencies. OLAW does not issue two Assurances to institutions sharing common space because of conflicting jurisdictions and responsibilities.

And these situations have occurred because a company is in a state [situation] where they need to move from their current site and they move into another Assured Institution's animal facility and keep their same number and we usually find out in the aftermath rather than when it occurs. So it's best if you are planning on moving your facility that you contact us and we can work it out beforehand. **So you are suggesting plan ahead?** Plan ahead.

Interesting. The next three questions are sort of together on the same topic, relating to veterinarians. **6. Must all veterinarians comply with the USDA definition of a veterinarian?** Yes, all veterinarians associated with a domestic Assured institution are required to comply with the Animal Welfare Act definition of a veterinarian. This means they have attained one of the following:

- Graduated from an AVMA-accredited veterinary school;
- Have a certificate issued by the AVMA's Educational Commission for Foreign Veterinary Graduates;
- Or have received equivalent formal education as determined by the USDA Administrator.

The next veterinary question. **7. You said that the veterinarian on the IACUC must have direct or delegated program authority and responsibility for activities involving animals at the institution. What do you mean by direct and what do you mean by delegated?** Direct authority generally means that the veterinarian is an employee of the institution and therefore has direct authority by virtue of position. The contract veterinarian is granted delegated authority and responsibility for animal activities by the institution.

And the next question relating to vets. **8. What if there is more than one veterinarian? May they share this authority?** OLAW requires that one veterinarian be assigned to have the direct or delegated program authority so that one individual takes responsibility for the institutional program of animal care and use.

These next two look like they kind of go together, so I will read both of them at once. **9. Our IACUC recently updated our protocol review procedures, how can I amend my Animal Welfare Assurance to include these changes? And should I submit a program change during the year or wait until I prepare my annual report and submit the changes with the report?** Okay. I'll try to answer them together. Most program changes can be made within the institution, be reviewed and approved by your IACUC during the year, and then be reported to OLAW in the annual report. If the Institutional Official or the IACUC chair positions change during the year, we ask that you let us know when that change occurs. And provide us with all of the contact information for the new IO or the new IACUC chair, including the e-mail address. These two individuals are the primary contacts for the Assurance with OLAW and if there are any policy changes or information that needs to be shared with the institution during the year, they are the key points of contacts for the institution.

Okay. **10. The next question is why is the domestic Assurance approval period shorter in length than foreign or interinstitutional Assurances?** PHS Policy states that Assurances may be approved for up to five years. In order to receive an Assurance and review and negotiate the document with the institution prior to the expiration date, OLAW made the approval period for domestic Assurances as four years so that the

institution's Assurance does not expire and make them ineligible to receive PHS funds. Up until about 2004, when this change was made, [some] institutions would submit their renewal Assurance document on the date of expiration. And technically, they would have an expired Assurance the day after the five years. So it was moved back in 2004 to accommodate this and allow the institutions to receive funds.

11. With foreign performance sites, if there are local rules or regulations that are less stringent than those we follow, the current *Guide*, can we still do business with them? Foreign institutions receive an Assurance if they have direct or indirect funding, meaning they are named on a grant as a performance site. They agree to follow the international guiding principles, the [CIOMS Principles](#), and all of the rules, regulations, and policies regarding the humane use and care of animals in their country of origin. If your institution decides to accept their standards, if they meet your standards, then that would be your institutional decision to collaborate with them. In a collaboration between a domestic and a foreign institution, NIH holds the prime grantee responsible for providing the IACUC approval. So it is up to your institution to make that determination. And just as a side note, some foreign institutions are AAALAC accredited, and you can go to the [AAALAC website](#) and look at that.

12. For non USDA species, can a qualified individual serving as an *ad hoc* IACUC member be the sole member of a facility or lab inspection team? Yes. The PHS Policy states that the IACUC may, at its discretion, determine the best means of conducting an evaluation of the institution's programs and facilities and may invite *ad hoc* consultants to assist in conducting the evaluation. By the way, this is on the bottom of page 12 in the PHS Policy. This is a footnote. And it states that the IACUC remains

responsible for the evaluation and the resulting semiannual report to the IO. So the institution can determine, for PHS Policy-covered animals, they can determine how best to perform their semi.

Next question. **13. Is there a minimal frequency for inspecting research labs where animal procedures occur that are not surgery or housing greater than 24 hours?** The IACUC is responsible for providing oversight of these areas. There's no number or minimum frequency. So your IACUC could determine what is a reasonable frequency.

Our next question. **14. Along with my institution's Assurance document, may I submit my training and occupational health and safety program manuals? May I submit my SOPs, which describe our program in detail?** These documents – training manuals, building schematics, and SOPs of your animal care and use program – are not required. You can succinctly describe the training and occupational health programs within the Assurance itself. This allows OLAW to better understand your program description and the complete document is easily accessible in electronic format, as well as the hard copy, if everything is in one document.

15. Does OLAW need hard copy of original documents? Generally OLAW can accept faxed documents or signed documents which have been converted to PDF format. If, however, the documents are not legible when they're received or if we have to scan them into our database and they are not legible, we may ask that you submit a follow-up hard copy Assurance document. On another note, if you provide us with a schematic or a diagram of your organizational chart, it's better if you provide it with a white background because we're finding that the ones that come to us by PDF that have a gray color, or any color, are grayed out when they are in PDF or

electronic format and we can't read the information that's been provided there. So we're going to go back and ask you to submit a hard copy.

16. Our institutional status is Category 2. Not all programs and facilities are AAALAC accredited. How does that affect my

Assurance? If some programs or facilities listed under Applicability in the Assurance document are not AAALAC accredited, then the institution must submit the most recent semiannual report to the IO of the program review and facility inspection for all program areas, along with the Assurance document when it is submitted for obtaining an Assurance or for an Assurance renewal document.

Next for Eileen – and we still have a good few lined up here, so we have got about 10 minutes to go, we will do our best to get to as many of them as we can. **17. What should I do if my Assurance document states that four IACUC members are required to constitute a quorum and must be present for official business, but then later in the year the IACUC membership increases so that a quorum of members is now five.** This is a good one and it comes up now and again. To be compliant with the signed Assurance document, the institution must indicate a programmatic change in the annual report to OLAW and attach a short description for the revised information. Generally, OLAW recommends that the Assurance document not describe the program to that level of specificity. Rather than stating that “four members are required at a convened meeting to conduct a vote”, the document should state that “at least a quorum of voting IACUC members are required at a convened meeting and a majority vote of the members present is required to approve, require modifications to secure approval or withhold approval of a protocol or a proposed significant change.” The latter description meets the requirements of the PHS Policy

but does not affect the Assurance if the number of IACUC members changes. So in effect [in the situation described in this question], you would have an incorrect document if the number of your IACUC members changes.

Okay. The next one. **18. My institution's Assurance states that all IACUC members at a convened meeting must vote unanimously to approve a protocol. Since this imparts a more stringent requirement on the IACUC than the PHS Policy, does OLAW have any comments on this procedure?** Institutions may impose stricter requirements than what the PHS Policy requires. However, this example does not allow the IACUC any flexibility during protocol review and approval. OLAW accepts these descriptions of procedures, but recommends that Assurances be written to meet the requirements of the PHS Policy.

Here's one. I'm going to read this and you're going to understand it but I won't because it's in all sorts of legalese or government speak, it looks like. **19. In Part III. D. 10, would suspension normally result because of a concern raised, Part III. D. 4?** Okay, I think they're talking about Part III. D. 4, animal welfare concerns – reviewing animal welfare concerns in the Assurance, at least that's how I'm going to answer it. My answer would be – it depends and not necessarily. A concern may not be validated after the IACUC performs a fact finding mission and performs an IACUC review of that.

Okay – I apologize, I didn't keep my computer up running properly, so we have changed our screen. We'll get that back in a second. Here's the next question. Is there a minimum frequency for inspecting research labs where – oh, we have already done that, I apologize for that.

Okay. **20. Could you give an example of how the codes would be used for describing the IACUC membership?** What we mean by that is rather than providing a name, you could use initials on the IACUC roster for all members, except the IACUC chair and the veterinarian associated with the program. For the chair, it would require all of the information and their contact information on the IACUC roster. And for the veterinarian, we require their name be included. So you could code them [the other members] like A, B, C, D or any other designation that you determine. You could use initials – their initials. But you just need to keep a copy of the code in case you are asked for it in some audit and if someone should come to your facility like USDA or OLAW.

Next question. **21. May the Institutional Official and the IACUC chair be the same person?** These positions have different roles and are intended to be two different individuals, so, really, the answer is no. The IO is a senior administrator who must have authority to commit institutional resources to ensure compliance with the PHS Policy and the *Guide for the Care and Use of Laboratory Animals*. It's important that the IACUC's authority to approve protocols is independent of the IO. The IO may not overrule an IACUC decision to withhold approval of a protocol. The IACUC serves in an advisory role to the IO and reports to the IO. Therefore, having one individual fill both roles is an apparent conflict of interest.

22. Who may appoint IACUC members? The [Health Research Extension Act of 1985](#) is specific in stating that the IACUC is appointed by the CEO of the entity for which the committee is established. OLAW considers the CEO to be the highest operating official of the organization, such as the president of a university. The CEO may delegate the responsibility to another individual. That delegation must be specific and in writing. Often the

responsibility of appointing the IACUC members is delegated to the Institutional Official or IO.

Next question. **23. Do the two IACUC members who perform the semiannual facility inspections have to be voting members of the IACUC?** It depends. The PHS Policy allows IACUCs to determine the best means of conducting the semiannual program review and facility inspection. The IACUC may use *ad hoc* consultants – I think we answered this one already in a previous question, but I'll just reiterate it. The Policy statement is at the bottom of page 12 and it notes that you may use *ad hoc* consultants if you are using just PHS-funded animals. If you have USDA-covered species, you must have two IACUC members perform the reviews for those areas where the USDA-covered species are housed. But in the case of the PHS Policy, the committee is still responsible for the report.

Okay. We have about five or six more questions and we have five or six more minutes, so it looks like we'll be doing okay. **24. Should alternates be listed on the IACUC roster and if so how should they be listed?** Alternate members should be listed on the IACUC roster using similar coding to regular members. Alternates must meet the criteria of the member for whom they are an alternate. It is allowable to appoint more than one alternate to represent a particular member. If the member fulfills a specific membership requirement, then the alternate must also fulfill that requirement. We do have some recent guidance, Guide Notice [[NOT-OD-11-053](#)] that just came out on reduction of regulatory burden.

Okay. Our next one. **25. What is the *de novo* protocol review?** A *de novo* review means a complete review as if it were a new protocol. That's simply the answer.

All right. That was a quick one. This next one looks like it might take a little longer. **26. As part of a continuing review, must an institution have a formal post-approval monitoring program?** A formal post-approval monitoring (or PAM) program is certainly one way for an institution to provide continuing review. It is not a requirement, however. Continuing review in the form of monitoring previously approved protocols is required by the PHS Policy. IACUCs may use such oversight mechanisms as a semiannual program evaluation, protocol review processes, reporting noncompliance, and ensuring individuals who work with animals are appropriately trained and qualified. The animal care program team includes a multidisciplinary team of individuals who provide daily observation of animals by trained staff, communication with veterinarian staff, postoperative care by trained personnel, hands-on training in animal procedures, and appropriate reporting of incidents involving occupational health and safety. All of these functions and responsibilities imply a level of monitoring at the institution. Ultimately the institution has flexibility in how it achieves compliance. It is important that if a PAM program does exist, that it doesn't challenge the IACUC's authority and responsibility.

It looks like we have about, oh, 15 questions left. We're going to try to get two of them if we can do that in the next two or three minutes. **27. Report to the IO and IACUC approved departures from the *Guide*. We often approve deviations like a longer time between cage cleanings for breeders with a tendency to cannibalize the pups. Is this something that should be included in the report to the IO semiannually?** Yes, it is actually. And I can talk a little bit about departures. An IACUC-approved departure from the *Guide* would be a scientifically justified and approved by the IACUC, example like you gave here, and it would be included every six

months on the semiannual report to the IO with a brief description of what the departure is.

Then our last question, Eileen, it kind of is in keeping with that just previous one. **28. That is what is the difference between the departure and deficiency when talking about the semiannual report to the IO?** An IACUC approved departure from the *Guide*, the PHS Policy, or the Animal Welfare Act Regulations, must be scientifically justified and approved by the IACUC prior to implementing, as well as be reviewed at least annually or more often if reviewed by the Animal Welfare Act Regulations.

- An example of a departure would be not social housing nonhuman primates for scientific reasons or providing rodent chow on the cage floor for newly weaned mice.
- A deficiency, on the other hand, is something found during either the program review or the facility inspection, which is not in compliance with the PHS Policy, the provisions of the *Guide*, the Animal Welfare Act Regulations, or your institutional animal care and use program policies.

Thank you, Eileen. And again, we have a good few questions that we have not been able to get to, but they will be posted along with their answers when this recording is available online. As always, I want to thank you for your participation in the seminar series. We would be grateful to receive feedback from you. You will receive a follow-up message from us tomorrow. And please use that opportunity to share with us your ideas for future topics and also to provide feedback on any technical problems that arose during the webinar – beyond my failure to keep an eye on the screen and us losing the screen there for a moment or two.

As we've done with previous webinars, this session for IACUC staff has been recorded and will be available on the OLAW website in the near future. We certainly hope you can join us for the remaining webinars in 2011 that are listed on the screen now. And then finally from all of us here at OLAW, thank you for what you do to ensure the humane care of animals used in research, teaching, and testing and we hope that you have an enjoyable and productive summer.

Additional Submitted Questions Not Addressed During the Webinar

29. If the chair will be on sabbatical for one semester and another member will act as the chair during that period do we need to submit that information to OLAW? And how and when do I notify OLAW of an appointment of a new IO?

Yes, If the Institutional Official or IACUC chair positions change during the year, we ask that you let us know when the change occurs and provide us with all the contact information for the new IO or chair including a phone number and e-mail address. These two individuals are the primary contacts for the Assurance with OLAW and are contacted if there are any policy changes or information that needs to be shared with the institution. You can submit these changes to the OLAW Division of Assurances e-mail box at olawdoa@mail.nih.gov.

30. How should we handle an affiliated, but separate, institution where some researchers may house vertebrates and conduct animal research? This institution is not covered by a PHS Assurance.

If the animals from your Assured institution being housed at another facility are not PHS-funded, then these animals do not fall under PHS Policy jurisdiction. If the animals from your Assured institution are being used in PHS-funded research and are housed at another institution which does not have an

Animal Welfare Assurance, this situation is not in compliance with the PHS Policy and the terms and conditions of NIH Grants Policy. This would be a reportable event to OLAW and to the funding component and may require return or reconciliation of grant funds as determined by the funding component. You may only house vertebrate animals and conduct animal research for PHS-funded animals at an institution that holds a PHS Assurance.

The site which is housing the animals may be added to your Animal Welfare Assurance or the site may obtain their own Assurance if your institution contacts grants management at the funding component and names them as a performance site in a PHS-funded grant. You are not entitled to draw down funds for a grant in the absence of an Animal Welfare Assurance or in the absence of IACUC approval. Please refer to the allowable costs Guide Notice [NOT-OD-07-044](#) for further information.

31. If we have animals housed in our facility that are from a neighboring academic institution, what type of Assurance would we need? To be clear, their IACUC approves the protocol, our IACUC reviews these approvals and the grant money goes to the [neighboring] academic institution. We only provide housing and lab space for the work. If the work is PHS-funded, the institutions housing the PHS animals would be required to have Animal Welfare Assurances; in this case both institutions would need to have domestic Assurances. If both institutions hold Animal Welfare Assurances, then one institution or the other may review and approve the protocol and the other maintains the approval information. (See response to 30, above.)

32. Is a PHS Assurance needed to receive funding from NSF involving animal use? The criterion for obtaining an Animal Welfare Assurance is receiving PHS (NIH, CDC, or FDA) funding, either direct or indirect, for research involving the use of live vertebrate animals. OLAW has no jurisdiction or authority over institutions receiving funding from agencies such as the DOD or NSF. OLAW's responsibility is limited to oversight of institutions receiving PHS funding, where the funds may be withdrawn if the terms and conditions of award are not met.

33. What is a *de novo* review and when is this required? A *de novo* review means a complete review as if it were a new protocol. *De novo* review is required by PHS Policy [Section IV.C.5](#), which states: "the IACUC shall conduct continuing review of each previously approved, ongoing activity covered by this Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with [IV.C.1.-4.](#), at least once every three years."

34. If our institution is a primary on a PHS award, and a sub award is given for animal work at another institution, but the animal work has already been completed. Would a MOU [Memorandum of Understanding] to assure animal work was conducted according to the PHS Policy, Animal Welfare Act, etc., still be required even though the work has already been completed? The institution receiving the sub-award would be required to have a domestic Assurance as they are a performance site on the grant and meet the criteria to have a domestic Animal Welfare Assurance. Your institution must already have an Assurance if you are receiving PHS funding. Two collaborating institutions, each having domestic Assurances, require no further paperwork through OLAW. If both institutions have full PHS Assurances, they may exercise discretion in

determining which IACUC reviews research protocols and under which institutional program the research will be performed. It is recommended that if an IACUC defers protocol review to another IACUC, then documentation of the review should be maintained by both committees. Similarly, an IACUC would want to know about any significant questions or issues raised during a semiannual program inspection by another IACUC of a facility housing a research activity for which that IACUC bears some responsibility or exposure.

35. Can I write my Assurance to exclude the reporting to OLAW of non PHS-funded activities? The standard language of the Assurance states that it is applicable to activities supported by PHS. This implies that non PHS-funded activities are not covered by the document. Institutions may modify this and state that the Assurance applies to all activities regardless of funding. Even when the standard language is used, OLAW expects to receive reports of noncompliance when there is a potential or actual affect on PHS-supported activities by being in a functional, programmatic, or physical area that could affect PHS-supported activities (e.g., inadequate program of veterinary care, training of staff, occupational health, malfunctioning cage washer, HVAC failure). The boiler plate Assurance allows institutions to not report incidents of noncompliance when the incident occurs in an area that is functionally, programmatically, or physically separate and does not affect PHS-supported activities.

36. If our program has remained the same, but our facility has moved across the street, how do we best report the change – in a letter now, or in the annual report? If your facility moved, it is best to contact OLAW at the time it occurs to determine if changes need to occur in your Assurance and with NIH grants management. If it is a change in

performance site, then the NIH funding component needs to be notified to determine if grants management and program official approval is needed according to the terms and conditions of grant award.

37. If the CEO changes and is not the IO, does the CEO become the new IO? Not sure if I was clear about this. CEO is currently the Chancellor, but the IO is the Vice-Chancellor, delegated by the CEO.

If the current CEO leaves what happens? It depends. If the current IO appoints the IACUC as delegated by the CEO, the new CEO could decide to appoint the IACUC and change the current delegation, or it could remain the same. OLAW provides guidance on the OLAW website on the difference between the Institutional Official and the Chief Executive Officer at the following URL: <http://grants.nih.gov/grants/olaw/faqs.htm#g5>.

38. Does the qualification/training required of the principal investigator apply to the student(s)? Assisting? All personnel involved in animal care, treatment or use are required to be trained and qualified to do so [conduct the work that they do with the animals]. The PHS Policy requires that all personnel as described above receive training or instruction in the humane practice of animal care and use, and be offered training or instruction on research or testing methods that minimize the number of animals required to obtain valid results and limit animal pain and distress.

39. When you need to amend your Assurance, do I revise the entire document or just send you our additions? The annual report is the mechanism used to update or amend the Assurance document. If program updates have occurred at the institution, these changes can be provided with the annual report as an attachment in a summary page format. The program

updates provided to OLAW in the annual report should be retained so that they can be submitted as part of the renewal Assurance document.

If however, the Institutional Official (IO) or the IACUC chair change, OLAW would need to know that when the change occurs along with their contact information including e-mail address. The IO and the IACUC chair are the key points of contact for the institution and these contacts are used to disseminate information should there be PHS Policy or guidance updates.

The End