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Note: Text has been edited for clarity.

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The 2012 Annual Report to OLAW

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Moderator: Jerry Collins, PhD, Yale University

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http://grants.nih.gov/grants/olaw/2012-12-13%2013.02%20OLAW%20Online%20Seminar%20_The%202012%20Annual%20Report%20to%20OLAW.wmv (Windows Media Player - 58 mins).

Slide 1 (The 2012 Annual Report to OLAW)

>> *Dr. Collins:* Our speaker today is Dr. Patricia Brown. Dr. Brown is 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 Penn State University and her veterinary degree from the University of Pennsylvania. She joined the NIH in 1986 and held positions in the Veterinary Resources Program, the National Cancer Institute, and the Office of Animal Care and Use before joining OLAW in 2006 as Director. Dr. Brown.

>> *Dr. Brown:* Hello everyone. I'd like to talk with you today about the 2012 OLAW annual report and the changes to the report that reflect the NIH's adoption of the 2011 [Guide for the Care and Use of Laboratory Animals](#). My talk will cover both the new and the unchanged parts of the annual report. I will also talk about the updated process of submitting your annual report to OLAW. If you have a printed copy of the sample 2012 annual report in front of you, you will be able to follow along as I go through the report sections.

Slide 2 (PHS Policy Reporting Requirements)

To start I will discuss the basic requirement for reporting. PHS Assured institutions are required to provide a report to OLAW once every 12 months. The report is filed by the IACUC through the Institutional Official or IO. This requirement is described in the PHS Policy, Part IV.F. With a few exceptions, most Assured institutions are on a calendar year reporting schedule.

Slide 3 (Reporting Periods)

As I said, most of the over 1000 Assured institutions are on a calendar year reporting schedule. There are still a few institutions that retain the historical legacy of non calendar year reporting. OLAW began transitioning all Assured institutions to calendar year reporting during the renewal of Assurances in 2012 because it effectively ensures compliance with the reporting requirement and helps to prevent having the report be delayed. For calendar year reporting the annual report is due to OLAW by January 31, 2013. For the few remaining institutions on non calendar year reporting the report is due to OLAW 30 days past the end of the 12 month reporting period.

Slide 4 (PHS Policy Reporting Requirements (Part IV.F.))

This slide shows the formal language of the PHS Policy. It says that at least once every 12 months, the institution will provide OLAW with a written report of any program or facility change which would place the institution in a different category than specified in its [Animal Welfare Assurance](#), namely whether the institution's animal care and use program is accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care, International [AAALAC]. And, any change in the animal care and use program as described in the institution's Animal Welfare Assurance. I am certain that many of you are wondering exactly what changes, in light of the new *Guide*, must be included in this year's report. I will provide an explanation later.

Slide 5 (PHS Policy Reporting Requirements Part IV.F.)

Information to be reported also includes: a change in the IACUC membership. And, the dates that the institution performed the [semiannual program review](#) and the dates of the [semiannual facility inspections](#).

Slide 6 (PHS Policy Reporting Requirements Part IV.F.)

If there are no changes to the institution's animal care and use program, the institution is required to report to OLAW, in writing, that there were no changes and provide the dates that the semiannual program review and facility inspection evaluations were performed.

Slide 7 (Adoption of the *Guide*)

As you all know, NIH adopted the *Guide* 8th Edition in December of 2011 and required institutions to implement the *Guide* in 2012.

Slide 8 (*Guide* Implementation)

To implement the new *Guide*, institutions must have completed at least one semiannual program review and facilities inspection using the 8th Edition of the *Guide* as the basis for the evaluation by December 31, 2012. It is not required that all necessary changes be completed by December 31, 2012, but the evaluation must have been conducted by December 31 and it must include a reasonable plan and schedule for making any required changes based on the standards in the 8th Edition.

Slide 9 (*Guide* Implementation)

As part of implementation, Assured institutions must verify to OLAW, that they have met the required schedule for conducting the semiannual review and facility inspections using the *Guide* 8th Edition. This verification is to be done through the 2012 annual report. In addition, institutions will be asked to document implementation the next time their Animal Welfare Assurance is renewed. How will this differ from their report of changes in this year's annual report?

The 2012 [sample annual report](#) has been modified to enable OLAW to easily assess the status of *Guide* implementation at each Assured institution. We have updated the sample report with a series of statements and check boxes to allow easy verification by Assured institutions. Please use the updated sample document for the 2012 reporting period and do not use the past years format.

Slide 10 (2012 Annual Report)

The updated sample was posted on the OLAW website in November and IACUC Chairs should have already received a reminder about the report due dates with a link to the sample report. OLAW staff sent that reminder e-mail on December 4 and 5. As with past annual reports, OLAW requires the annual report be signed and dated by the Institutional Official and the IACUC Chair.

Slide 11 (Completing the Annual Report)

The easiest way to complete the annual report is to download the annual report sample document, save it locally, and complete the document. Then print the form, obtain the necessary signatures, and scan and save the signed version as a PDF file and submit it by e-mail. I will present more details about submission later in this talk.

Slide 12 (2012 Annual Report)

I will now go through the pages of the sample and highlight the changes that have been made in the 2012 report. If you have a printed copy of the sample document, you can follow along as I go through the report sections.

On the top of the first page the report asks for the name of the institution, the Assurance number, and the reporting period. For 2012, the reporting period is January 1, 2012 to December 31, 2012. The next section of the first page provides a reminder statement about the requirement to verify implementation of the *Guide* 8th Edition.

Slide 13 (2012 Annual Report cont.)

Further down on the first page in a section labeled "Implementation of the 8th Edition of the *Guide*" are two boxes listed A. and B. and then box B. has a Yes or No question associated with it. If your institution has conducted its evaluation and fully implemented all of the changes identified to meet the standards of the 8th Edition, you should check box A. If your institution conducted its evaluation and has a plan and schedule for

changes needed to meet the standards of the *Guide*, but has not fully implemented all of the changes, then you should check box B. and check the answer Yes.

If your institution has been unable to conduct its evaluation using the new *Guide* or to develop a plan and schedule of changes to implement the *Guide* prior to December 31, 2012, then you should check box B. and answer No. In addition, please provide a brief description of the reason or reasons for the delay in the evaluation or in the development of the plan and schedule and when and how the institution intends to meet the requirement.

Slide 14 (2012 Annual Report Part I.)

At the bottom of the first page, and continuing on the top few lines of the second page, is the section labeled Roman numeral I. Program Changes. This section is unchanged from the previous version of the sample annual report. I will briefly review how to complete this section. If there have been no changes in the institution's program of animal care and use as described in the Assurance, you should check box A. and skip the remainder of the section. If there have been any changes in the animal care and use program, as identified in the items listed under part B., then you should check box B. and also all the applicable items.

The first item on the list of changes has to do with AAALAC accreditation. If an institution is listed as Category 1, which is AAALAC accredited, and they had a covered component added to their Assurance, which has not yet been accredited by AAALAC, this would result in the institution changing its status to Category 2 – until such time that the new covered component achieves AAALAC accreditation. By a covered component we mean an organization that has existing facilities and ongoing operations. If this component was not AAALAC accredited and had to be brought in line with your program and oversight, during the interim period when the component was added to your Assurance and until they attained accreditation, your Assurance would have a Category 2 designation.

The reverse also occurs. If a Category 2 institution achieves AAALAC accreditation during the reporting period, then the annual report would include that information and the institution's status would change to a Category 1.

The next item on the list asks if the program of animal care and use has changed and references the PHS Policy section IV.A.1.a. through i. You should check the box for Program Changes on the annual report, and on a separate page, provide a summary of the changes. I will present a list of the types of program changes that should be reported later in this presentation.

The third item on the list is asking if the Institutional Official has changed. If so, check the box and provide the contact information for the new IO in Item V.

Lastly, if the membership of the IACUC has changed check the box in program changes and provide the current roster in Item VI.

Slide 15 (What to Report: Changes in the Animal Care and Use Program)

Here is the list of the type of animal care and use program changes that should be reported. It includes changes in the lines of authority or administrative reporting channels, modifications to IACUC procedures as described in Part III.D. 1. through 10. of your Assurance, or modifications to the occupational health or training programs. As mentioned earlier, if the program has changed, check the box for ~~program~~ Changes on the form, Roman numeral I., and attach a separate piece of paper summarizing the changes. There is no need to submit a revised Assurance document for every program change, but rather submit a summary of the change in the annual report.

We will retain your changes with the annual report. OLAW will determine if a revised Assurance document needs to be submitted based on the changes to your animal program, as described in your annual report updates. This review by OLAW, as to whether or not you need to submit a revised Assurance document, is done on a case-by-case basis.

Slide 16 (What to Report: Changes in the Animal Care and Use Program cont.)

Here is the continued list of types of program and facility changes that should be included in the annual report:

- Change in the veterinarian, to include their qualifications and percent of time contributed to the program as requested in Part III.B. of the Assurance;
- Change in the veterinarian's authority or responsibility; and
- Changes in buildings, species, or approximate number of animals housed.

It is likely that most changes to programs as a result of implementation of the new *Guide* are not likely to meet the requirements for reporting in the annual report.

Slide 17 (2012 Annual Report Part II.)

Section Roman numeral II. part A., Program Evaluations asks for the dates that the two required program evaluations were conducted during the reporting period. For each of the dates, you should check the box that indicates whether the 7th Edition of the *Guide* was used for the evaluation or the 8th Edition. To be in compliance with the implementation requirements, at least one of the semiannual program reviews must use the 8th Edition of the *Guide*.

Just below the boxes to indicate which *Guide* was used, we ask that you indicate what method was used by the IACUC to conduct the program evaluation. Was the [OLAW Checklist](#) used? If so, check that box. Or did the IACUC use the relevant chapter headings of the *Guide*? If so, check that box. Was another method used? If so, check the box labeled Other and briefly describe the method in the space provided. For example, some IACUCs use their AAALAC program description for the program evaluation while others have developed their own checklist.

Slide 18 (2012 Annual Report Part II. cont.)

Section Roman numeral II. part B., Facility Inspections asks for the dates that the two required semiannual facility inspections were conducted. If the IACUC conducted more than two inspections of each site during the reporting period, then you should attach a list of the dates.

Again, for each of the dates provided, you should check the box to indicate whether the 7th or 8th Edition of the *Guide* was used for the inspections. To be in compliance with the implementation requirements, at least one of the semiannual facilities inspections must use the 8th Edition of the *Guide*.

As in section A., just below the boxes to indicate which *Guide* was used, we ask that you indicate what method was used by the IACUC to conduct the inspections. Was the OLAW Checklist used? If so, check that box. Or did the IACUC use the relevant chapter headings of the *Guide*? If so, check that box. Was another method used? If so, check the box labeled Other and briefly describe in the space provided. For example, some IACUCs use their AAALAC program description for the inspections while others have developed their own checklist.

Slide 19 (2012 Annual Report Part III.)

At the bottom of page 2 is Roman numeral part III., Minority Views. If no minority views were submitted by IACUC members during this reporting cycle, then you should check box A. If any minority views were submitted by members of the IACUC regarding the reports listed in [Part IV.F.](#) of the PHS Policy and filed during the reporting cycle, then you should check box B. and attach the minority views to the annual report.

This includes minority views included in the records of semiannual IACUC reports, as well as any minority reports in recommendations to the IO regarding any aspect of the institution's animal program, facilities, personnel training or other aspects of the program. Minority views involving noncompliance reports should also be included. Minority views do not include a no vote by a member during a protocol approval.

Slide 20 (2012 Annual Report Part IV., V.)

The top of page 3 in Roman numeral part IV., Signatures, is where the names, signatures, and date of the annual report are signed by the IACUC Chairperson and the Institutional Official. Roman numeral part V. is the place to provide information about a change in the Institutional Official.

Slide 21 (What to Report: Change in the IO)

Please provide the name, title, degree/credentials, address, e-mail, phone and fax number for the new IO.

Slide 22 (2012 Annual Report Part VI.)

Continuing on page 3, in Roman numeral part VI., Change in IACUC Membership, please provide the name of the institution as it appears in the current Assurance, and then please list the contact information for the IACUC office.

Slide 23 (What to Report: IACUC Office Contact)

This includes the mailing address and e-mail address for the IACUC office along with the phone number and fax number for the IACUC office. OLAW is no longer collecting contact information for the IACUC Chair to protect the Chair's contact information from release under the Freedom of Information Act.

Slide 24 (2012 Annual Report Part VI. cont.)

Just below the IACUC contact information, please provide the new IACUC Chairperson's name, title, and degree/credentials, if there has been a change in the Chairperson.

Slide 25 (Annual Report Part VI. cont.)

At the bottom of page 3, is the IACUC roster. You should fill out this section if there have been any changes in the membership, or you may just attach the roster.

The items on the IACUC membership roster that most often require revisions are the position title column, that's the third column. It should list what the individual's title is at the institution. Only in the case of the nonaffiliated member, it should provide a general description such as lawyer, ethicist, clergy, retired police officer.

PHS Policy membership requirements are identified in the fourth column. That column should identify what position all individuals fulfill on the committee, such as veterinarian, scientist, nonaffiliated member, or nonscientist. All members listed should have a PHS Policy membership designation.

If a member is not one of the required four designations, then the term "member" may be used. For alternate members, the entry should indicate the position for which they are an alternate such as alternate scientist or alternate nonaffiliated. If the committee has nonvoting members, they should be identified as nonvoting in the fourth column.

Occasionally institutions provide information about members that is not required on the roster, such as complete names, addresses, and home or office telephone numbers for members. The PHS Policy allows institutions to represent the names of the members, other than the Chair and the veterinarian, by a number or symbol in the annual report.

Slide 26 (Annual Report Part VI. cont.)

Page 4 provides an expanded explanation of the IACUC roster reporting requirements including the definitions for the required members.

Slide 27 (Submitting the Annual Report)

Once the annual report has been signed and converted to a PDF, it should be e-mailed to OLAW at the following e-mail address for annual reports: olawarp@mail.nih.gov. This e-mail address is used exclusively for annual report submissions. Plans are in development for an on line submission process for future years, but it is not currently available.

Do not fax the report and do not send a hard copy by mail or express delivery. We have found these methods require the most processing so we are only accepting e-mailed PDF reports for the 2012 report.

Upon receipt, the annual reports are logged into our database as received and then the document is reviewed by personnel in the Division of Assurances. If there are program changes, these are reviewed by an Assurance Officer for appropriateness with the PHS Policy and compliance with the provisions of the *Guide*. If OLAW has questions, we will contact the IACUC for clarification or updates. Once reviewed and accepted, the IO and the IACUC will receive a letter of acceptance. A copy of the report is maintained in the Assurance file.

Slide 28 (Please send questions to OLAW via the question box on your screen)

>> *Dr. Collins*: Thank you Pat. Dr. Brown will now answer your questions. We will begin with ones received prior to this seminar but please continue to submit your questions during the live broadcast even as earlier ones are answered. If we are unable to get to all of your questions we will append them, along with answers, to the transcript that will be posted on-line. As a reminder this seminar is being recorded and that recording, along with a transcript of the seminar, will be made available at the OLAW website under the general heading Education. [See [Education Resources](#)]

Slide 29 (Question 1)

>> *Dr. Collins*: Our first question. **Our last report covered the non calendar year ending March 31, 2012, and we were informed that our next report was due by April 30, 2013. More recently, we received an e-mail stating that the due date for all annual reports was January 31, 2013. Could you clarify which of those two dates applies to our institution?**

>> *Dr. Brown*: Your report would be due by April 30, 2013. As I mentioned earlier, a few institutions are still on non calendar year reporting. For non calendar year reporting, the report is due to OLAW 30 days past the end of the 12 month reporting period. OLAW began transitioning all Assured institutions to calendar year reporting during the renewal of Assurances this past year. When your Assurance next comes up for renewal your reporting period will be changed to the calendar year, January to December.

Slide 30 (Question 2)

>> *Dr. Collins*: Our next question. **Does the institution have to submit an annual report if they have recently renewed their Animal Welfare Assurance?**

>> *Dr. Brown:* Yes, an annual report is required to be submitted to OLAW at least once every 12 months, regardless of when the Animal Welfare Assurance was last approved. The Assurance renewal has no bearing on the annual report. The annual report and the Assurance documents are separate requirements to OLAW.

Slide 31 (Question 3)

>> *Dr. Collins:* **If there are programmatic changes after the annual report has been submitted to OLAW, how should the institution report these?**

>> *Dr. Brown:* If the program changes occur in the new calendar year and they are not a change in the IO or a change in the IACUC contact information, they can be submitted to OLAW in the following year with the annual report. If the change is to the IO or the contact information for the IACUC, we would request that this information be provided to OLAW when the change occurs – including the mailing address, the telephone number, the fax number, and the e-mail address and – I'll repeat – we need the e-mail address for the IO and the IACUC office (not the IACUC Chair) – as much of our communication with institutions is electronic.

Slide 32 (Question 4)

>> *Dr. Collins:* **For the semiannual program review and facility inspections, does the institution have to list all of the facilities and the dates they were inspected?**

>> *Dr. Brown:* If the semiannual inspection of the various facilities is performed throughout the six-month period, the institution should provide us with a list of the dates of the reviews and the inspections. They should keep in mind, however, that the same areas should be inspected and reviewed on a six-month schedule so the program oversight is consistent.

Slide 33 (Question 5)

>> *Dr. Collins:* **If the inspections are performed throughout the six-month period, does the report have to identify which facilities were reviewed at which times?**

>> *Dr. Brown:* Yes, although codes may be used to designate the different facilities, the facilities and when they were visited must be listed. This allows OLAW to confirm compliance with the PHS Policy.

Slide 34 (Question 6)

>> *Dr. Collins:* For the folks that are participating here, you notice that we have a series of these questions up on the screen for you, and we would encourage you to take a look at them and see if you can come up with the correct answer that matches what Dr. Brown is providing us. And the next question. **What happens if the semiannual dates are more than six months apart?**

>> *Dr. Brown:* During OLAW's review of the annual report, if it is noted that the semiannual dates are greater than seven months apart, the institution will receive a letter accepting the annual report but noting that the semiannual reviews were not in compliance with the PHS Policy. We will request the institution to align their next semiannual program and facility inspections to be every six months. If the following year the institution again has extended intervals for program review or inspections, the annual report will be submitted to the Division of Compliance Oversight for follow up as noncompliance.

Slide 35 (Question 7)

>> *Dr. Collins:* And another question about submission. **Can we submit the annual report prior to December 31?**

>> *Dr. Brown:* The answer to that one is no. Prior to December 31, the institution has not completed the full 12 months of the reporting period. Unanticipated program changes may occur in your animal care and use program in the last few months. For example, you finish your second semiannual report on October 31 and decide to submit your calendar year report to OLAW on November 1. You are reporting for a twelve-month period but you've only completed ten months of that period. You should wait until the end of the reporting period, December 31. Then compile the annual report and submit it to OLAW prior to January 31.

Slide 36 (Question 8)

>> *Dr. Collins:* **What if the annual report is submitted late?**

>> *Dr. Brown:* The annual report is due to OLAW by January 31. On or about February 28, OLAW will determine which institutions have not complied with the PHS Policy and send reminder notices. Not submitting the report is considered noncompliance with the PHS Policy reporting requirements.

Slide 37 (Question 9)

>> *Dr. Collins:* **What is considered noncompliance regarding information contained in the annual report?**

>> *Dr. Brown:* Missing dates for the semiannual program review and facility inspection are an example, or performing the reviews in a time span that is greater than seven months apart would also constitute noncompliance with the PHS Policy. Another example is a minority view that describes a reportable incident that was not promptly reported by the institution. Another is changes that were made to the IACUC which result in a not properly constituted committee. A last example would be if the program changes that were made involving the protocol review process were not compliant with the PHS Policy for either designated member review or full committee review.

Slide 38 (Question 10)

>> *Dr. Collins:* **Do the minority views need to be explained in the annual report, or just report the dates?**

>> *Dr. Brown:* The minority view, itself, needs to be provided to OLAW. If the minority view is part of the semiannual report, or is in the minutes of an IACUC meeting or in other IACUC records of recommendations to the IO, the section containing the minority view needs to be submitted with your annual report.

Slide 39 (Question 11)

>> *Dr. Collins:* **Is a no vote by a member when the IACUC is voting on acceptance of a protocol a minority view?**

>> *Dr. Brown:* No. However an individual who feels very strongly may choose to write the reasons for his or her no vote in the form of a minority view. If a member makes that choice, the written objection becomes a minority view and must be included in the annual report.

Slide 40 (Question 12)

>> *Dr. Collins:* **What if the IO is not available to sign the annual report?**

>> *Dr. Brown:* The IO may assign another individual as having signature authority. That person is authorized to sign the annual report. However, OLAW must have a copy of a letter or memo on file, stating that signature authority has been assigned to another named individual and the document must be signed by the IO.

Slide 41 (Question 13)

>> *Dr. Collins:* And a related question. **What if the Chair is not available to sign the report?**

>> *Dr. Brown:* A Vice Chair may sign in place of the IACUC Chair.

Slide 42 (Question 14)

>> *Dr. Collins:* And now some questions about adding new components. **If a new program component is added, and it's not AAALAC accredited, does that change the status of the institution from Category 1 to Category 2?**

>> *Dr. Brown:* If all components of the animal program are not yet AAALAC-accredited, the Category would change from a 1 to a 2.

Slide 43 (Question 15)

>> *Dr. Collins:* And continuing on that theme. **If we open a new building that becomes part of our existing AAALAC accredited animal program does this change our Category designation?**

>> *Dr. Brown:* No, we would not consider your program a Category 2 because of a new building. Since all components of your current AAALAC-approved program would be applied to the animal care and use in the new building, the addition of the new building would not change your designation. As described earlier, an example in which the Category designation would change is if your Category 1 institution were to acquire a separate component that has existing facilities and ongoing operations, is not AAALAC-accredited, and has to be brought in line with your program and oversight because it needs renovations or other improvements or changes to meet AAALAC standards. During the interim period from when the component was added to your Assurance and until they attained accreditation, your Assurance would have a Category 2 designation.

Slide 44 (Question 16)

>> *Dr. Collins:* **Should changes in the Assurance be reported in the annual report or as they occur?**

>> *Dr. Brown:* Generally changes that occur in your animal care and use program across the year should be reported to OLAW with the annual report. However, there are some exceptions that I named earlier. If the IO or the IACUC contact information changes, you should inform OLAW as soon as the change occurs as we may need to communicate with your institution and to contact the appropriate people or office.

Slide 45 (Question 17)

>> *Dr. Collins:* For the next question – for the attendees again, if you could take a look at it, I'll read it, you can think in your own mind what the right answer is, you can see how close you are to what Dr. Brown tell us.

In preparing our OLAW annual report we have identified some major changes that have occurred in our program including:

- **an updated PI and IACUC member training policy;**
- **a newly developed occupational health and safety program;**
- **new IACUC members.**

Is it correct that we include these major changes in our upcoming annual report?

So I'll give you two or three seconds to see what your answer is, Pat?

>> *Dr. Brown:* Yes, the three changes that are listed need to be included in the report: the updated PI and IACUC member training policy, a summary description of that change; an updated description of the occupational health program, a summary of that change; and of course new IACUC members, as we know, those are added on an updated IACUC roster.

Slide 46 (Question 18)

>> *Dr. Collins*: Okay and we'll try that exercise on this question as well. **The following changes do not alter our animal program as much as they change the mechanism used to comply with the requirements. Do we need to include these in our upcoming annual report?**

- **Creating a new subcommittee of the IACUC to follow up on animal use concerns;**
- **Adding the harm/benefit analysis of animal use in research during our protocol review;**
- **Correcting a sentence in our Assurance concerning how we conduct designated member review.**

So those of you participating away from Bethesda now know what you think your answers are. Pat, what are they?

>> *Dr. Brown*: As I mentioned earlier, if changes in IACUC activities as described in part III.D. of the institution's Assurance have occurred during the reporting period then they should be summarized in the annual report. Of the three you have described, Jerry, who follows up on animal welfare concerns is a change regarding item III.D.4. of the Assurance and should be included as a summary description in the annual report. The addition of the harm/benefit analysis would not need to be included, but the correction of your description of how the Committee conducts DMR is a change regarding item III.D.6. and should be included.

>> *Dr. Collins*: So it's going to be very important for the folks that are listening to go back and take a look at III.D.4. and III.D.6. to make sure they have a full understanding of this particular issue.

Slide 47 (Question 19)

>> *Dr. Collins*: Our next questions. **If an institution had to make tons of program changes to implement the standards of the new *Guide*, how much information should they report? The instructions under program changes indicate: "This institution's program for animal care and use has changed (PHS Policy IV.A.1.a-i.). [Attach a full description of the changes.]"**

>> *Dr. Brown*: We would like to limit your burden and also your descriptions to a brief summary concerning the list that I previously discussed: changes in the lines of authority including that of the veterinarian, changes in the membership of the Committee as we've said, you attach an updated IACUC roster. How the IACUC carries out its required activities, as I've mentioned, we encourage you to review section III.D. of your Assurance, that's an effective way to determine any changes that you've made regarding how your IACUC carries out its activities. If the occupational health program changes, and major changes in the training program for scientists and animal technicians.

Slide 48 (Question 20)

>> *Dr. Collins:* Okay, next question. **Can you please clarify the species change notification requirement? What kind of changes are we talking about?**

>> *Dr. Brown:* If an institution formerly used only mice and rats and now they've begun research with guinea pigs, then that is a program change to be attached to the annual report.

Slide 49 (Question 21)

>> *Dr. Collins:* **Our IACUC created a policy to use designated member review subsequent to full committee review in our IACUC review process. Should we report this as a program change in our annual report?**

>> *Dr. Brown:* Yes, this is the type of program change that should be included in the annual report in the attachment of program changes.

Slide 50 (Question 22)

>> *Dr. Collins:* **Should Interinstitutional Assurances approved by OLAW be included in the annual report?**

>> *Dr. Brown:* No, Interinstitutional Assurances are not to be included in the annual report. OLAW already has a copy of this type of Assurance because we review and sign them.

Slide 51 (Question 23)

>> *Dr. Collins:* Question 23. **If our Assurance has substantially changed, but is not due for renewal for two years, would OLAW prefer to receive the changes via the annual report or a completely new Assurance?**

>> *Dr. Brown:* We would prefer to receive a summary of the changes attached to your annual report. You would check the box on the annual report form that says changes have occurred and then include the summary. When you submit the annual report to OLAW, it will be reviewed by our Assurance Officers who will make the determination based on the depth of the program changes whether or not a revised Assurance is needed. But it's not necessary to submit a revised Assurance with your annual report, unless OLAW asks you for one.

>> *Dr. Collins:* I'm going to encourage folks to continue sending questions into us. As you can see, we received a large number of questions prior to this particular webinar. We've already received a good few questions now, so we probably won't be able to get to all of them. As I said earlier, all of the questions will be attached to the transcript along with the audio portion of this webinar as well. And just a reminder, when I say submit your question, if you're listening to the transcript afterwards – the audio recorded one, you can't submit then, so only during the live broadcast.

Slide 52 (Question 24)

>> *Dr. Collins:* **Since our programs have been updated to implement the *Guide* 8th Edition and the OLAW sample Animal Welfare Assurance was revised earlier this year, is it expected that we submit an updated Assurance for approval?**

>> *Dr. Brown:* You do not need to submit an Assurance renewal at this time. The Assurance renewal should be submitted four months prior to its expiration date.

Slide 53 (Question 25)

>> *Dr. Collins:* This entity wrote the question: **We have a disaster plan completed but the IACUC has not yet completed reviewing the document and may require more revisions. How should this be reported?**

>> *Dr. Brown:* If the IACUC has a reasonable plan and schedule in place prior to December 31, 2012 to review and approve the disaster plan in 2013, then the institution has met the implementation requirements. If all other aspects of the *Guide* standards have been implemented, then you should check box B. and check the answer Yes in the Implementation section of the report. However, if the plan and schedule are not in place by the end of December, then you should check box B. and check the answer No and provide a brief description of the reason for the delay and how the institution will meet the requirement.

Slide 54 (Question 26)

>> *Dr. Collins:* And this next question is along the same vein. **You have mentioned that our institution should have a reasonable plan and schedule for implementing the changes that are required to meet the *Guide* 8th Edition standards. What does OLAW consider a reasonable plan and schedule?**

>> *Dr. Brown:* OLAW expects institutions to approach their plan and schedules keeping in mind the wellbeing of the animals and making every effort to not delay necessary changes in the animal care and use program. Recognizing that the scope of changes needed varies considerably across institutions, OLAW cannot give a specific date for final completion by all institutions. This is why we have asked the question about the status of implementation in the 2012 annual report.

Slide 55 (Question 27)

>> *Dr. Collins:* **Our agreements with collaborating institutions are being written but since this requires both IACUCs to review the changes, it has taken longer than expected and we do not have them completed. How do we report this?**

>> *Dr. Brown:* This is similar to the previous circumstance. If there is an IACUC plan and schedule completed prior to December 31, 2012 to develop written agreements with collaborating institutions, then the implementation requirements have been met.

Slide 56 (Question 28)

>> *Dr. Collins:* **It is my understanding that** (that is the writer who wrote this or the person that submitted this question is this person's understanding) **if an institution has undergone an AAALAC site visit during the year – that it would suffice for the annual report. Is this correct?**

>> *Dr. Brown:* No. An AAALAC site visit is not an annual report. You may be referring to the use of an AAALAC site visit to serve as one of the semiannual facility inspections and program reviews. That's different from the annual report. What you would submit would be the dates of your AAALAC site visit for the date of one of your two semiannual facility inspections.

Slide 57 (Question 29)

>> *Dr. Collins:* **If our PHS Assurance is being evaluated for renewal, would the renewal Assurance document complete the requirements of the annual report?**

>> *Dr. Brown:* I think we answered this something similar to this earlier. The answer to that is no. The annual report and the Assurance document are separate stand-alone documents required by the PHS Policy. Even though your Animal Welfare Assurance has recently been renewed by OLAW, you're still required to submit an annual report. The only place that OLAW collects the dates of your semiannual program and facility inspections is in the annual report.

Slide 58 (Question 30)

>> *Dr. Collins:* Question 30. **Are the completed annual reports to OLAW posted online or available via FOIA?**

>> *Dr. Brown:* No, although the annual reports are not posted on-line, they would be releasable under the Freedom of Information Act if they were requested.

Slide 59 (Question 31)

>> *Dr. Collins:* **Can you clarify the requirements for the IACUC Chair and members' addresses, phone numbers, et cetera? Do those need to be reported if it is not the address and phone number for the IO or the IACUC Office?**

>> *Dr. Brown:* You do not need to provide contact information for the IACUC members. We need the name of the veterinarian. We need the name of the Chair with his or her title and degree/credentials. We do not need the Chair's contact information if we have the IACUC office contact information. For the IO, we need their address, phone number, fax number, as well as their e-mail address.

Slide 60 (Question 32)

>> *Dr. Collins:* This next question is an interesting one. **What if the IACUC office does not have an e-mail address?**

>> *Dr. Brown:* You may provide an alternative e-mail address used within the institution to most easily contact the IACUC.

Slide 61 (Question 33)

>> *Dr. Collins:* **Is e-mail submission of a PDF document the only accepted method this year?**

>> *Dr. Brown:* That's an overwhelming yes! The completed annual report sent as a PDF document in an e-mail to olawarp@mail.nih.gov is the only method of submission for this year's report. It allows us to better track submission and send you an acknowledgement. We are also able to process the record and associate it with the electronic record of your Assurance file more efficiently than fax or hard copy reports. NIH has gone to almost 100% electronic submission with PDF attachments for grant applications. We plan to have an online submission for the annual report in the near future.

Slide 62 (Question 34)

>> *Dr. Collins:* **Does OLAW recognize the category of nonvoting member of an IACUC and if so what responsibilities could such a member have?**

>> *Dr. Brown:* OLAW acknowledges that some institutions have persons in advisory positions who regularly attend IACUC meetings. These institutions would like to identify these positions on the IACUC roster. In such cases OLAW allows this and asks that the positions be labeled as "nonvoting" to distinguish them from voting members of the IACUC.

Slide 63 (Question 35)

>> *Dr. Collins:* **Do minority views of nonvoting members of the IACUC need to be provided in the annual report?**

>> *Dr. Brown:* Minority views for nonvoting members do not need to be provided in the annual report. However, anyone including a nonvoting member should have the opportunity to bring any animal welfare concerns to the attention of the IACUC for consideration and investigation.

Slide 64 (Question 36)

>> *Dr. Collins:* And a similar question. **Do nonvoting IACUC members need to sign the semiannual report?** And I'm just going to point out this is the semiannual report to the IO, not the annual report to OLAW that we've been talking about a lot in this webinar.

>> *Dr. Brown:* No, only voting members of the IACUC may sign the [semiannual] report.

>> *Dr. Collins*: So again, since we've been talking a lot about annual [report], clearly that question was focused on the semiannual report following the program evaluation and facility inspections that's sent to the IO.

Slide 65 (Question 37)

>> *Dr. Collins*: Question 37. **If the AAALAC site visit doesn't coincide with our semiannual inspection date, will it still be acceptable as one of our inspections?**

>> *Dr. Brown*: Well, to meet PHS policy requirements, the reviews of your semiannual program and facility inspections need to be conducted within approximately six months of each other. If you choose to use an out of cycle AAALAC site visit for your semiannual review and facility inspection, then you'll need to do another review six months from when the AAALAC site visit occurred. For example, if your reviews were on a January – July cycle, and you did a January semiannual program and facility review, but AAALAC came three months later in April. To use the AAALAC site visit and be in compliance with the PHS Policy, you would be changing your cycle so your second semi that reporting year was in April. OLAW would require that you do another site visit at six months in September. You would report all three inspections in the annual report. And your cycle for the following reporting year would change then to April and September. Let us hope that in three years when AAALAC comes again it will be in the same time frame.

Slide 66 (Question 38)

>> *Dr. Collins*: **If we are not required to list IACUC member names, how does OLAW track and review the IACUC members?**

>> *Dr. Brown*: We verify that the appropriate roles are being held by the appropriate person. If you complete columns three and four, you've given us the background and the position title of the individuals named as members and you've also given us their PHS required role, whether that is a veterinarian, scientist, nonscientist, or nonaffiliated. However, we may ask for further information and clarification to confirm the membership reflects a properly constituted Committee.

Slide 67 (Question 39)

>> *Dr. Collins*: **What's the earliest date that annual reports can be submitted?**

>> *Dr. Brown*: [In the case of the 2012 annual report] January 1, 2013. As I stated earlier, if you submit an annual report prior to the end of the reporting period, you really could have program changes occur and you're sending in a report that only covers 11 months of that period.

Slide 68 (Question 40)

>> *Dr. Collins*: **What protects IACUC members from having their contact information used by animal activist organizations?**

>> *Dr. Brown:* As I noted earlier, with the exception of the IO, OLAW is transitioning away from having contact information for the Chair and substituting the IACUC office contact information. The IACUC roster does not require that you submit names of your IACUC members. The only information that we must receive in the roster are the names of the veterinarian and the IACUC Chair.

Slide 69 (Question 41)

>> *Dr. Collins:* And now the last question that we received prior to this seminar: **What does OLAW do with the annual reports?**

>> *Dr. Brown:* OLAW reviews each annual report. If there is missing information, problems with a described change in the animal care and use program, or an incomplete IACUC roster is included, OLAW will ask for revisions to the report. After all items are corrected by the institution, OLAW sends an acceptance letter and the corrected report is included in the Assurance file.

>> *Dr. Collins:* In one of our early question, somebody talked about a ton of changes in the program, we now have a ton of questions we received from you participants, and again, please keep sending them in during this live broadcast, they will be appended along with answers to the transcript, and as I begin each question, you're going to hear me mention a letter, that's only so Dr. Brown knows which of the questions I'm asking so she has at least a moment or two to think about them.

A [Question 42]: **If we are on AAALAC probation, do we still report accredited or do we have to report probational accreditation?**

>> *Dr. Brown:* You should report accredited. The status probational accreditation is not public information.

>> *Dr. Collins:* C [Question 43]: **We already reported the change in our IO in July of 2012. Do we have to report it again in annual report?**

>> *Dr. Brown:* We would say, yes, please include the change in the IO, with the contact information in your [2012] annual report, if the change occurred in 2012.

>> *Dr. Collins:* D [Question 44]: **A new IO will be assigned in January of 2013. Since we already know who it will be, should this be reported in the 2012 report or should we wait 'til the 2013 report to identify the new IO?**

>> *Dr. Brown:* We would ask you to include the information with all of the contact information of the new IO in the 2012 report.

>> *Dr. Collins:* E [Question 45]: **We have a central animal facility for nonhuman primates which is AAALAC accredited, if we add a satellite mouse facility overseen by the veterinarian at the central facility, do we need to check Category 2 because the mouse facility is not AAALAC accredited?**

>> *Dr. Brown:* The inclusion of a new facility, as long as it's covered under the standards established by the institution, would not be considered changing the Category from Category 1 to Category 2.

>> *Dr. Collins:* F [Question 46]: **If inspections are done on a rolling basis, does each date need to be listed or can the institution give a range of dates in which all facilities were reviewed?**

>> *Dr. Brown:* We need the list for the dates on a separate sheet for each facility inspection.

>> *Dr. Collins:* G [Question 47]: **What are the consequences of failure to use the 8th Edition of the *Guide* in 2012?** And by that, I assume they mean for one of their two semiannual reviews and inspections.

>> *Dr. Brown:* Well, this would be considered noncompliance and would be reported to our Division of Compliance Oversight for follow-up. The institution will be required to provide OLAW with information on how it plans to comply.

>> *Dr. Collins:* H [Question 48]: **If you do not have a change in section V. or VI., do you still need to complete those sections?**

>> *Dr. Brown:* The answer is no.

>> *Dr. Collins:* I [Question 49]: **Who must file the annual report? Does it have to be the IACUC Chair or the IO?**

>> *Dr. Brown:* It must be signed by the IACUC Chair and the IO, but any member of the institution who's authorized may submit it on behalf of the institution.

>> *Dr. Collins:* J [Question 50]: **For the IACUC roster, if some membership has changed, should the report include the complete roster or just the positions which have changed?**

>> *Dr. Brown:* Please include the complete roster, if there are any changes to the membership.

>> *Dr. Collins:* K [Question 51]: **Will we receive a confirmation of delivery or receipt for the e-mailed PDF report?**

>> *Dr. Brown:* No, but you will receive a letter accepting the annual report at a later date.

>> *Dr. Collins:* L [Question 52]: **If we have already notified OLAW in 2012 that there is a new IO, should we also check the block in I. program changes as well as in V. change in IO in the 2012 annual report?**

>> *Dr. Brown:* Yes, please make those changes.

>> *Dr. Collins:* And I apologize; that was probably a Roman numeral I., rather than 1.

N [Question 53]: **If the second semiannual evaluation is after 12/31/2012, for example, in January, but all inspections were conducted in 2012, will this be an issue?**

>> *Dr. Brown:* As I mentioned earlier, OLAW is looking for an up to a seven month interval between inspections and evaluations. So if you're within that window of time, then we would consider that acceptable. We would like an explanation if you have not used the 8th Edition of the *Guide* for at least one of your evaluations in 2012, however.

>> *Dr. Collins:* We've got about two minutes left, we should be able to get to at least one or two more questions. R [Question 54]: **If the Animal Welfare Assurance captures the changes in the IACUC membership, do we also need to indicate a change in the annual report or will the Assurance document cover this?**

>> *Dr. Brown:* Well, if the changes in the IACUC membership occurred in 2012, then the updated roster should be included with the annual report. What we're – the reason that this is important is that each annual report is a separate document that's part of your Assurance file, but is considered separate and a separate entity from your actual Assurance agreement.

>> *Dr. Collins:* Going to move on to question U [Question 55]: **In section VI., Changes in IACUC Membership, would we need to list the change such as nonscientist and alternate switched positions? That is our voting nonscientist is now the alternate and the person who was the alternate is now the voting nonscientist on the roster.**

>> *Dr. Brown:* Yes, please provide an updated IACUC roster appropriately completed.

Slide 70 (Upcoming Webinars)

>> *Dr. Collins:* And with that, I want to thank Dr. Brown once again for providing us with information that I know a lot of people were anxious to hear. This was one of the highest attendee lists of all our webinars, so hopefully you've gotten some guidance on what you

should be doing. I also want to thank the participants for your continued efforts to ensure humane animal care while facilitating research. We hope that you will join us in the new year for future seminars. The topics for the first two are listed on this final slide. As always, we encourage you to contact the OLAW office with ideas for future topics. We in the OLAW office wish you a happy and safe holiday season.

Additional Submitted Questions Not Addressed During the Webinar

[56] How does OLAW define the words “policies”, “procedures”, and “guidelines” in the *Guide*? (eg. Policy: written policy statement, Procedures: written standard operating procedures, etc)

We frequently refer to the “PHS Policy” or “Policy”. Both are abbreviations for the Public Health Service Policy on Humane Care and Use of Laboratory Animals.

OLAW uses standard English definitions of policy, procedure and guidelines:

- Policy: a principle or rule to guide decisions and achieve rational outcomes; a plan or course of action, as of a government, political party, or business intended to influence and determine decisions, actions, and other matters.
- Procedure: a manner of proceeding, a way of performing or effecting something, a series of steps taken to accomplish an end.
- Guideline: a statement or other indication of policy or procedure by which to determine a course of action.

[57] For 2012, we used the old *Guide* for the January semi-annual and we used the AAALAC inspection of July 2012 for the July 2012 semi-annual. Is this OK?

Yes. See also slides 17, 18, 28, and 37.

[58] Our chair's term on the IACUC ends Dec 31, 2012. The new chair starts Jan 1, 2013. In section "VI. IACUC Chairperson" would I list the chair that was in office during 2012 or the new chair coming into office?

Please list the new Chair. See also answer to question 44 (D).

[59] Could you review section I.B. and AAALAC accreditation designation once again and how this question should be answered?

Please see slide 14.

[60] If an institute was AAALAC accredited in 2012, but came up for re-accreditation in 2012 – and did receive re-accreditation, is there anything to report to OLAW in its annual report about AAALAC accreditation status?

No.

[61] Could you please clarify IACUC office? Is it the same as IO's office? What if there is no identified IACUC office?

The “IACUC office” is the location OLAW can communicate with the IACUC. Many institutions have an office that is the headquarters for IACUC activities. For example, it may be the workplace of an IACUC administrator or the contact information of someone responsible for IACUC business. In any instance, OLAW must have a mailing address, telephone number, FAX number and an e-mail address that will allow us to communicate

with the IACUC. We are offering IACUCs the opportunity to have an official mailing address and e-mail contact that do not contain the name of the Chair, as these addresses will be released if requested through the Federal Freedom of Information Act (FOIA). Let me be clear that we are not requiring the institution to have an IACUC office.

[62] Is the IACUC roster for current members needed if there has been no change in membership.

No.

[63] If a researcher using animal quarters had to have a protocol suspended does this need to be reported and where in the report would this be included?

Noncompliance must be **promptly** reported to OLAW. See [Reporting Noncompliance](#). The annual report is not the place to report noncompliance or suspensions to OLAW.

[64] Our IACUC inspects the facilities one to two months before discussing at the convened meeting. Can we use the convened meeting date as the date for reporting facility inspections?

No, OLAW expects you to report the actual date that you inspected the facility on the annual report.

[65] How prevalent is it that the institutions are not submitting the annual report on time?

It is very rare for an institution to submit an annual report after the deadline. Most institutions work diligently to comply with the requirements of the PHS Policy, as this is a term and condition NIH Grants Policy Statement.

[66] We have a possible change due to occur on January 1, 2013. Since the reporting period is supposed to end Dec. 31st, should we submit our Annual Report and then within 30 days submit an additional report?

It depends. If the change to the program will actually occur beginning in January 2013, then include it in the annual report. If the change occurs sometime later in 2013, then it would be reported in the 2013 annual report. Please contact the Division of Assurances with specific details. See also questions 44 (D) and 58.

[67] What is an acceptable timeframe to submit semiannual reports to the IO.

OLAW expects semiannual reports to be submitted to the IO in a reasonable timeframe and at least every six months. If there are significant deficiencies in the semiannual report it would be imperative to share that with the IO in a timely manner.

[68] What are examples of a minority view?

The following are examples of a minority view that must be attached in the annual report to OLAW:

- a member provides a written objection to findings of deficiencies in the animal care and use program or facilities inspections;
- a member provides the reasons for his or her no vote in writing in the meeting minutes;
- a member thinks differently about recommendations made by the IACUC to the IO and provides those thoughts in writing;
- a member has a different opinion about a noncompliance or suspension action taken by the IACUC and expresses that opinion in writing.

[69] What do you do as part of the institution if you feel the institution is not really complying and may be falsifying information on the annual report?

Intentionally supplying false information to OLAW is noncompliant and potentially may be legal misconduct. OLAW accepts confidential reports of noncompliance from concerned individuals. OLAW will determine if such reports must also be referred to additional offices, such as the Office of the Inspector General, and will make such referrals, if needed.

[70] If the Chair is not available to sign the report and there is no Vice Chair (not a required position), who can sign the report in place of the Chair?

The Chair may designate another IACUC member to sign IACUC documents in his or her absence. OLAW has found that it is an effective best practice to have a Vice Chair.

[71] We just had a member leave the IACUC. Do we indicate that this person has left in section VI. in some manner?

Please provide an updated current IACUC roster in section VI. of the annual report.

[72] Our institution is small and we do not have a dedicated IACUC office. Whose contact information should be provided in section VI. IACUC Contact Information?

Please provide the contact information of someone responsible for IACUC business. OLAW is offering the option to use a mailing address and an e-mail address that do not contain the Chair or IACUC administrator's name, as this contact information may be released under the Federal Freedom of Information Act, if requested.

[73] If an institution has established a new Memorandum of Understanding with other institution(s), should this be included in the Annual Report?

No, this does not need to be reported, nor does OLAW need copies of institutional MOU's.

[74] Please provide examples of items, other than major capital expense items, that may be implemented after 12/31/13 to comply with the 8th Guide.

Institutions are expected to implement the 8th Edition of the *Guide* during 2012. OLAW expects institutions to approach their plan and schedules keeping in mind the wellbeing of the animals and making every effort to expeditiously implement necessary changes in the animal care and use program.

[75] If an institution has received AAALAC re-accreditation in 2012 (and AAALAC used the 8th Edition of Guide), would this be sufficient proof to OLAW that this institution's AC program is now compliant with the new Guide?

Please follow the 2012 sample annual report form. Your answers will indicate that your institution has implemented the 8th Edition of the *Guide*.

[76] Are electronic signatures acceptable?

Yes, if they are verifiable.

[77] Should an expert who routinely assists with a review of the animal number justification but does not attend meetings be listed as a non voting member.

No, it is not required, but such a person may be listed if the IACUC so desires. Some committees have a biostatistician as a member.

[79] If an animal use room has been added during the reporting period that has not gone through AAALAC accreditation review, would this change our category from 1 to 2?

No, not if the animal room is operated as a part of your AAALAC-accredited program. See also question 45 (E).

[80] If one of our semiannual meetings occurred 5 days after the time it occurred in the year before does this need to be reported?

If you mean a semiannual program review and facility inspection, conducting the semi-annual program evaluation five days later than six months is within a reasonable period of time and would not be a reportable incident to OLAW.

[81] Whom do you contact to find out if you (the IACUC administrator) is listed as an authorized person to submit the report via email.

The institution may have anyone it chooses submit the annual report to OLAW. We require only that the annual report be signed by the IO and the Chair.