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Note: Text has been edited for clarity.

Contents: Transcript

Update to the Reporting Period of the Annual Report to OLAW

Speakers:

- Eileen Morgan, Director Division of Assurances, NIH, Office of Laboratory Animal Welfare
- Jane Na, DVM, CPIA, Senior Assurance Officer, Division of Assurances, NIH, Office of Laboratory Animal Welfare

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View Recording: <https://youtu.be/YjWyhgZI4ww> (YouTube)

Slide 1: Update to the Reporting Period of the Annual Report to OLAW

>> *Neera:* Hello everyone. Welcome to another OLAW Special Webinar, titled: Update to the Reporting Period of the Annual Report to OLAW.

Today is Wednesday, June 17, 2020. My name is Neera Gopee and I am the Director of the Division of Policy and Education at OLAW. Today it is my pleasure to welcome our speakers, Ms. Eileen Morgan and Dr. Jane Na to this special OLAW webinar.

Eileen Morgan currently serves as the Director, Division of Assurances in the Office of Laboratory Animal Welfare (OLAW) at the National Institutes of Health (NIH). Ms. Morgan previously served as a Senior Assurance Officer in the Division of Assurances within OLAW. Eileen holds a Bachelor of Science degree in Technology Management from the University of Maryland and an Associate degree in Animal Health Technology. She has 37 years of experience in animal models-based biomedical research and compliance oversight in the humane care and use of laboratory animals. Her experience includes service as Chief of the Facility Management Branch in the Division of Veterinary Resources, NIH Intramural Program, and positions at Johns Hopkins University School of Medicine, the American Red Cross Holland Laboratory, Cleveland Research Institute, and Affinity Biotech Inc. She has served as an [Institutional Animal Care and Use Committee] IACUC member and an IACUC Chair.

Dr. Jane Na currently serves as a Senior Assurance Officer in the Division of Assurances in OLAW at NIH. Dr. Na completed her laboratory animal medicine residency as well as her Bachelor of Science in Biopsychology and Cognitive Science at the University of Michigan, and attained her Doctor of Veterinary Medicine degree from Michigan State University. Her research experience includes work as a Research Specialist at the Yerkes National Primate Research Center, summer research at the University of Cambridge, and undergraduate, pre-veterinary, and postdoctoral research at the University of Michigan. Prior to joining OLAW in 2017, Dr. Na was the Lead Analyst in the Institutional Animal Care and Use Program Office at the University of California San Francisco.

It is my pleasure to welcome you both to this special webinar, and now, Eileen, I'm sure you're excited to get this discussion started.

Slide 2: Learning Objectives

>> Eileen: Thank you Neera. Good Afternoon. Today I plan to share with you the details for the update on the OLAW reporting period. The learning objectives for today are:

- to provide a rationale for the change in the reporting period for the Annual Report to OLAW
- to describe the changes in the reporting cycle
- to identify the Public Health Service Policy requirements for the Annual Report, and
- to use the instructions to successfully prepare the Annual Report to OLAW

Slide 3: Background – 21st Century Cures Act

First some background. The 21st Century Cures Act, Section 2034(d), directed the NIH, in collaboration with the [United States Department of Agriculture] USDA and [Food and Drug Administration] FDA, to conduct a review of applicable regulations and policies for the care and use of laboratory animals and to make revisions, as appropriate, to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals. A working group comprised of the three Agencies—NIH, USDA, and FDA—conducted a review as directed, and identified areas to reduce administrative burden on investigators.

Slide 4: 21st Century Cures Act Working Group Recommendation

The harmonization of the annual reporting period between the NIH OLAW and the USDA was recommended by the 21st Century Cures Act Working Group so that both agencies will now use the federal fiscal year reporting period, October 1st - September 30th. This recommendation is included in the Working Group report, "Reducing Administrative Burden for Researchers: Animal Care and Use in Research" [PDF document](#), which can be found at the link on this slide.

Slide 5: Annual Report to OLAW Updates

The harmonization moves the annual reporting period for the OLAW Annual Report from the calendar year to the federal fiscal year. Therefore for 2020, the OLAW reporting period will be for a partial year, January 1st – September 30th, with the Annual Report due to OLAW on or before December 1st, but not earlier than September 30th.

Two items to note: the reporting period ends September 30th, so institutions have 60 days to compile and submit the Annual Report to OLAW. And on this new schedule, the due date of December 1st, 2020, is only 60 days earlier than the previous report due date of January 31st.

For future years, beginning in fiscal year 2021, the annual reporting period will be October 1st – September 30th, with the Annual Report due to OLAW on or before December 1st, but no earlier than September 30th.

This slide shows the link to the [OLAW Annual Report Form](#) on the OLAW [website](#). The Annual Report Form is Office of Management and Budget (OMB) compliant with the Paperwork Reduction Act of 1995 and has OMB clearance.

Slide 6: PHS Policy Requirements – Annual Report

According to the [PHS Policy IV.F.1., 2., and 4.](#): at least once every 12 months, the IACUC,

through the Institutional Official (IO), must report to OLAW any changes in the institutional program of animal care and use.

Slide 7: PHS Policy Program Changes to Report

Information to be reported according to the [PHS Policy](#) includes the following:

Any changes in these four items:

- the institution's accreditation status
- the institution's program of animal care and use or facilities
- the Institutional Official, or
- the IACUC membership

Other information to be reported is the dates that the IACUC conducted its semiannual evaluations of the program and facilities, and any minority views filed by members of the IACUC.

Please note, if there's a change in the Institutional Official (IO), provide the information for the current IO (that's the one signing the Annual Report to OLAW). If the IACUC roster has changed, provide an updated roster that reflects the current IACUC membership.

Slide 8: 2020 Annual Report Program Changes: NASA Funding

OLAW negotiated a memorandum of understanding (MOU) with [National Aeronautics and Space Administration] [NASA](#) in 2020. The MOU provides coordination and harmonization of agency efforts to ensure appropriate laboratory animal care and welfare, and ensures consistent and effective oversight of animal welfare in activities funded by NASA.

Based on the MOU, all the components of your Animal Welfare Assurance with OLAW now apply to any NASA-funded animal activities or to those animal activities that utilize the International Space Station. In your Annual Report, please state if your institution has NASA funding for research involving animals or utilizes the International Space Station.

Slide 9: 2020 Annual Report Program Changes: AAALAC Accreditation Changes

Let's go through the program changes, using the Annual Report Instructions.

Item 1, Program Changes: for AAALAC accreditation, only make a selection if your organization has achieved AAALAC accreditation during this reporting period or is no longer AAALAC accredited, and that change occurred during this reporting period.

Slide 10: COVID-19 Pandemic Program Changes Not to Report

For program changes made due to the pandemic, let's first note what not to report.

- Do not include program changes that were implemented by your program temporarily.
- Do not include revisions to your institution's disaster plan unless they update information currently described in your Assurance.

Slide 11: Temporary Program Change: Examples Not to Report

Here are some examples of temporary program changes that do not need to be reported.

Changes adopted during the pandemic, approved by the IACUC and updated in the disaster plan or emergency preparedness plan, such as:

- using an expedited number of days for the designated member review (DMR) process, or
- using DMR more often than it is typically used for protocol review by the IACUC

Slide 12: Temporary Program Change: Examples Not to Report

Here are more examples of temporary program changes if only intended to be used during the pandemic, or during other situations described in your IACUC-approved emergency preparedness documents, such as:

- using virtual methods of conducting semiannual facility inspections (such as Skype or Facetime), or
- using *ad hoc* members for conducting semiannual facility inspections for non-USDA covered species, as is always acceptable to OLAW

According to the PHS Policy footnote #8, at the bottom of page 12, "the IACUC may, at its discretion, determine the best means of conducting an evaluation of the institution's programs and facilities. The IACUC may invite *ad hoc* consultants to assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and the report."

If these are to become permanent changes as part of your animal program, they should be included in the Annual Report and in your next renewal Assurance document.

Slide 13: Summary: Temporary Program Changes

So, in summary, do not report temporary changes in your Annual Report.

Slide 14: COVID-19 Pandemic Program Changes to Report

I discussed temporary changes to your program due to COVID-19, and noted what not to report.

Now let's talk about changes your institution may have made during the COVID-19 pandemic that are going to become permanent. Perhaps they reduce burden or increase efficiency. If your institution adopted program changes (flexibilities) due to COVID-19 (such as use of telecommunications to conduct IACUC business), and these are going to become permanent program changes to your animal care and use program, and they are not currently described in your Assurance, then include them in your 2020 Annual Report to OLAW.

Slide 15: Permanent Program Changes: Examples to Report

Examples of permanent program changes that should be included in the Annual Report to OLAW include changes in IACUC processes described in the Assurance document, Part III.D. 1 – 10, such as creation of an IACUC approved Veterinary Verification and Consultation (VVC) policy, or designed member review process and/or DMR subsequent to FCR policy. Include these if your IACUC created these processes or policies this year, but had not previously used these flexibilities.

Slide 16: Summary: Permanent Program Changes

In summary, include permanent program changes in the Annual Report. However, do not submit an updated Assurance document with the Annual Report. These changes and updates will be captured in the next Assurance at time of renewal.

Slide 17: Changes to the Institutional Official and IACUC Roster

Changes to the Institutional Official and the IACUC Roster. If a change in IO occurred since January 1st, 2020, provide the information for the current IO (the IO signing the Annual Report to OLAW) in Item V. If the IACUC membership has changed since January 1, 2020, provide an updated roster that reflects current membership (members as of the day of Annual Report submission) in Item IV.

Slide 18: 2020 Annual Report Semiannual Program Review

In addition to the typical Annual Report program changes due to the partial year reporting period, your institution may have conducted only one program review. If only one semiannual review was conducted during this partial year reporting period, for Date 1, include only one semiannual review date on the Annual Report as pictured above on the slide. For Date 2, provide a date or dates of the second program review if a second review was completed or leave Date 2 blank, if only one review was completed due to the partial year.

Slide 19: Institutions Granted Waivers for the Semiannual Facility Inspection

If, due to the COVID-19 pandemic, OLAW granted your institution a waiver from conducting the semiannual facility inspection, you may only have one date or no date for facility inspections between January 1st and September 30th. List any dates for inspections that did occur during this time and state if your institution received a waiver from OLAW for facility inspections. OLAW expects institutions that were granted waivers to conduct the inspections that were postponed as soon as the IACUC can safely do so, or consider using flexibilities as described on the [OLAW COVID-19 web page](#).

Slide 20: 2020 Annual Report Semiannual Facility Inspections

To reiterate, if your institution was granted a waiver from OLAW due to the COVID-19 pandemic to conduct your semiannual facility inspection, you may have one date or no date for facility inspections.

For Date 1, provide the date of the facility inspection, if one was completed. Or leave blank, if no facility inspections were completed if you received an approved OLAW waiver. For Date 2, provide a date or dates of the second facility inspection if a facility inspection was completed. Or leave Date 2 blank, if only one facility inspection was completed due to receiving an approved OLAW waiver or due to the partial year.

Slide 21: Minority Views

For Item III, Minority Views, attach the minority view(s) exactly as submitted by the IACUC member(s). If the minority view is part of the meeting minutes, submit only the minority view portion of the minutes. If the minority view is part of the semiannual report, please submit only the minority view portion of the report.

To summarize, attach the minority view submitted to the IACUC by the IACUC member, in the IACUC member's words. Do not submit meeting minutes unless the minority view was only recorded in the minutes, and then please just submit the minority view portion of the minutes. Do not provide semiannual reports. Please submit just the minority view if the minority view is part of the semiannual report.

Slide 22: Completed the Annual Report, Next Steps?

Once the Annual Report is downloaded and completed, and signed by the IO and IACUC Chair, it can be submitted to the OLAW Annual Report email box:

olawarp@mail.nih.gov, listed there on the slide.

Slide 23: Summary

In summary, the reporting period for the Annual Report to OLAW is changing to the federal fiscal year, October 1st – September 30th. The reporting period for 2020 will be for a partial year, January 1st – September 30th, with the report due to OLAW by December 1st. Review the OLAW website and instructions for assistance with the program changes required to be reported and

how to include your semiannual evaluation date or dates. Don't hesitate to contact OLAW if you have questions regarding what or how to report the information.

Slide 24: Call or Email the OLAW Division of Assurances

OLAW personnel are here to answer your questions and are happy to assist you in appropriate completion of your Annual Report.

Slide 25: OLAW Resources for Annual Report

Here are the OLAW resources links to assist with the Annual Report completion.

- [[NOT-OD-20-109](#)
- Annual Report to OLAW [website](#)
- Submit the Annual Report to olawarp@mail.nih.gov]

Slide 26: Learning Objectives

Let's go back over the learning objectives. I provided a rationale for the change in the reporting period for the OLAW Annual Report, described the changes in the reporting cycle, identified the PHS Policy section and required reporting elements, and used the instructions to successfully prepare the Annual Report to OLAW.

Now let me turn the presentation over to Dr. Neera Gopee, to go over some questions we received regarding this topic.

>> *Neera*: Thank you, Eileen, for providing such a wonderful and concise clarification on the update to the reporting period of the Annual Report to OLAW.

Slide 27: Questions?

We do have some questions on this topic for Dr. Na to address, and so we'll proceed with question 1.

Slide 28: Question #1

Question 1: How do I submit the Annual Report?

Slide 29: Answer #1

>> *Jane*: To submit the Annual Report, first download the [Annual Report form](#) off of the OLAW Annual Report website, either from the website itself or from the link in the 2020 Annual Report instructions. Please do not reuse a previously completed Annual Report. Then you would complete the Annual Report form with program changes and obtain the IO and IACUC chair's signatures. Finally, email the signed report to the OLAW Annual Report email inbox at olawarp@mail.nih.gov by December 1st, but no earlier than September 30th.

Slide 30: Question #2

>> *Neera*: So, a second question asks: Are there any updates regarding the shared portal with the USDA that was mentioned with the 21st Century Cures Act recommendations?

Slide 31: Answer #2

>> *Jane*: No, not at this time. Updates will be communicated when they are available.

Slide 32: Question #3

>> *Neera*: Question 3: What if I don't have NASA funding? Should I indicate that I don't have any?

Slide 33: Answer #3

>> *Jane*: Oh, this is a great question. Please only report funding that is NASA funding if your program has funding from NASA involving the use of live vertebrate animals, or if your program uses the International Space Station to conduct animal activities.

Slide 34: Question #4

>> *Neera*: Question 4: Which institutions are eligible for requesting a waiver for the conduct of the semiannual facility inspections?

Slide 35: Answer #4

>> *Jane*: Assured institutions unable to conduct facility inspections within the six-month plus 30-day time frame due to the COVID-19 pandemic may request a waiver. Refer to the link to NIH Guide Notice [[NOT-OD-20-088](#)] for additional information regarding waivers.

Slide 36: Question #5

>> *Neera*: The follow-up question to that question 4 is: How can I request a waiver if my institution is unable to safely conduct the semiannual facility inspections within the six-month plus 30-day time frame?

Slide 37: Answer #5

>> *Jane*: An authorized institutional representative such as the IO, IACUC Chair, IACUC Coordinator or Attending Veterinarian, may request a waiver for the semiannual inspection due to the pandemic by sending an email request with a justification to olawdpe@mail.nih.gov.

Slide 38: Question #6

>> *Neera*: Can institutions get a waiver to submit the 2020 Annual Report late?

Slide 39: Answer #6

>> *Jane*: At this time waivers will not be considered for Annual Report submission.

Slide 40: Question #7

>> *Neera*: Question 7: I have many program changes to report. It would be easier to submit a revised Assurance to capture all of my changes. May I submit an updated Assurance instead of providing all of these updates in my Annual Report?

Slide 41: Answer #7

>> *Jane*: The Annual Report process permits collection of changes to your Animal Care and Use Program that occur throughout the four-year approval of your Assurance. Please provide the updates in your Annual Report and keep a record of the changes to incorporate into the Assurance document for the next renewal.

Slide 42: Question #8

>> *Neera*: Question 8: Does the update to the Annual Report reporting period and due date change when I submit my Assurance renewal?

Slide 43: Answer #8

>> *Jane*: No. The update for the reporting period and due date for the Annual Report does not change when you submit your Assurance document for renewal. Domestic Assurance renewals are submitted once every four years and the Annual Report is submitted every year regardless of whether or not your Assurance underwent renewal that same year.

Slide 44: Question #9

>> *Neera*: Question 9: If I just renewed my Assurance, do I have to submit an Annual Report?

Slide 45: Answer #9

>> *Jane*: Yes. An Annual Report must still be submitted. The Annual Report includes the dates of your semiannual program review and facility inspections, which are only reported to OLAW in the Annual Report.

Slide 46: Question #10

>> *Neera*: And our final question. Last year our semis occurred in April and October. This year we would only have one semiannual date to report, April 2020. Our next program review and inspections are scheduled to occur in October, which would be after the September 30th cutoff date. To accommodate the new reporting period, should we move our program review and inspections to September or should we maintain our current schedule?

Slide 47: Answer #10

>> *Jane*: You can maintain your current schedule. Due to the partial reporting year, it would be expected for your Animal Care and Use Program's 2020 Annual Report to OLAW to include only one program review date and one date for your facility inspections to continue your regular semiannual schedule. You should only report dates of program reviews or inspections that occur during the reporting period, January 1st to September 30th, 2020. And as always, if you have any questions, you are welcome to contact the OLAW Division of Assurances. Our email address and phone number are included on a previous slide and can also be found on the [OLAW] website.

Slide 48: Thank You!

>> *Neera*: Thank you. We've come to the end of this very informative presentation on the update to the reporting period of the Annual Report to OLAW. We hope that the information provided will prove to be useful and relevant to your animal care and use program. Many thanks to Eileen and Dr. Na who have been exceedingly generous with their time. And should you have any questions or concerns related to this topic, please feel free to reach out to OLAW. And we are always happy to help, as both Eileen and Dr. Na alluded to. Have a safe and enjoyable summer. Goodbye!

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