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21st Century Cures Act and Your Questions Answered

Speakers:

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- Elizabeth Theodorson, DVM, MPH, Assistant Deputy Administrator, USDA APHIS Animal Care

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Want to comment? Your input is important. OLAW welcomes questions and comments from viewers of this recording. OLAW will post the comments, questions, and answers on the OLAW website. Please go to the OLAW Webinars and Podcasts page and click on the seminar title for further information.

Slide 1: 21st Century Cures Act and Your Questions Answered

>> Dr. Nicolette Petervary: Good afternoon. I'm Dr. Nicolette Petervary, part of the NIH Office of Laboratory Animal Welfare. Today is Thursday, March 10th, 2022, and I am pleased to welcome you and our speakers to our webinar today, titled "21st Century Cures Act and Your Questions Answered."

I'd like to remind you about some housekeeping details before we begin recording the webinar. If time permits, we will be accepting live questions on webinar topics. If you have a question, please submit your question through the Question and Answer or Chat feature at any time during the webinar. Both icons are located at the bottom of your screen. For the Q & A feature, there's a checkbox that provides the option to submit questions anonymously. Unanswered questions will be forwarded to speakers, and responses will be appended to the end of the transcript. The recording, transcript, and slides will be posted to the OLAW website.

And now, let's proceed with the webinar. Dr. Pat Brown received her undergraduate degree in Animal Science from the Pennsylvania State University, and her veterinary degree from the University of Pennsylvania. She joined the NIH in 1986, serving in several clinical and management positions in the intramural research program before joining OLAW in 2006 as the Director.

Elizabeth Theodorson, DVM, MPH manages Animal Care Center for Animal Welfare, Compliance, and Assurance staff and the National Policy staff at USDA APHIS Animal Care. She received her BS from the University of Arizona and her DVM and MPH from the University of Wisconsin. Prior to joining the USDA, Elizabeth worked in vaccine development at the Wisconsin Primate Regional Research Center, and with the CDC Rabies Intelligence Service in Africa with Lagos bat virus. Before joining Animal Care, she was an epidemiologist for USDA APHIS Veterinary Services, specializing in tuberculosis eradication in Mexico.

Welcome. And now let's begin with Dr. Brown.

Slide 2: 21st Century Cures Act: Updates from OLAW and Your Questions Answered
>> Dr. Patricia Brown: Hello, everyone. I'm happy to be here and have this opportunity to discuss the progress that OLAW has made on the actions that we proposed in response to the 21st Century Cures Act.

Slide 3: Objectives
So here's what I'd like to share with you today; to discuss the history of 21st Century Cures Act and where you can find guidance on NIH's actions in response to the law, to examine our updated guidance stemming from the 21st Century Cures Act, and to also help you understand your new opportunities for commenting on proposed guidance.

Slide 4: 21st Century Cures Act Cliff Notes
So we'll start with, what is the 21st Century Cures Act as kind of a refresher. So, it is bipartisan legislation that was passed back in 2016, with the intent to advance biomedical research from both basic research through to advanced clinical trials, and also to streamline the drug and device approval process that would bring treatments faster to patients. It is a multi-section law, quite large. And for our interest today, we're focusing on Section 2034, that mandated that there be federal efforts to reduce administrative burden for researchers. And Part D of Section 2034 assigns NIH as the lead agency in cooperation with USDA and FDA to focus on animal care and use in research.

Slide 5: What does the 21st CCA say?
So what does that Section 2034(d) specifically say? Well, it says that not later than two years after the law was enacted, the NIH Director, in collaboration with the Secretary of Agriculture and the FDA Commissioner, were to complete a review of applicable regulations and policies for the care and use of laboratory animals, and make revisions as appropriate to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals.

Slide 6: Agency Action Timeline
So what has been happening since then? Following the passage of the law, NIH convened a working group in early 2017, and began their effort by reviewing relevant regulations and policies. In 2018, the agencies held listening sessions and asked the public to provide their ideas for how to meet the requirements of the law. After that, they released a request for information, also known as an RFI, for public comment on the proposed actions that would improve the coordination and harmonization of the regulations and policies. Based on the input from the public, that working group issued a draft report in December 2018, and then a final report that was based on the public's comments, that was released in August of 2019.

So, then we started on our next mission, which in 2020, we issued three requests for information on proposed guidance changes, one Guide Notice that also resulted, and we began our efforts to improve coordination with the DOD [Department of Defense] and the VA [Department of Veterans Affairs], and to also strengthen our outreach efforts with research and the IACUC community through projects with the Federal Demonstration Partnership, and the IACUC Administrator's Association. This past year, 2021, OLAW issued two additional RFIs, and also issued final guidance on four topics. So now let's look at some of that new guidance and where you can find it, and also the resources associated with it.

Slide 7: OLAW Home Page
So how do you find what you need to know about 21st Century Cures Act? If you go to our website, the OLAW website, we have a dedicated landing page. And the turquoise blue banner at the top of the

OLAW home page links you to that new landing page. So, when you click on that turquoise banner, this is what you end up seeing. You reach that landing page. So, each major policy topic that we've updated due to 21st Century Cures Act has its own dedicated webpage that's available from the landing page. So, as we update the guidance, we will update these pages, either with the Request for Information associated with the topic, guidance documents and other resources that are related, as we issue new guidance on that particular topic. And as you can see, we have a number of subpages. Now we're going to look at them individually.

Slide 9: Annual Reports

The first new guidance that came out, how to reduce burden, was released in May of 2020, and it was in guide notice NOT-OD-20-109. What it did was, change the reporting period for the Annual Report to OLAW in order to harmonize with the reporting period of the USDA. And that reporting period is now aligned to the Federal fiscal year instead of the calendar year. And I want to point out on the slide that there are two URLs that you can see; the first one, it has a documents icon, and that takes you to the Guide Notice where you can read the new guidance. The second one, the one that looks like a little laptop, will take you to a dedicated topic webpage where you can find many of the resources related to the Annual Report.

Slide 10: AAALAC Program Description

So the second new guidance that we issued was released in June of 2021, and that was in Guide Notice NOT-OD-21-130, and it encourages Assured institutions that are AAALAC-accredited to use the AAALAC Program Description when they're completing certain sections of the OLAW Assurance document. So now I'd like to ask everyone who's attending a poll question: Nicolette, will you please share the poll? And there it is. Has your institution used the AAALAC Program Description when renewing your assurance with OLAW? Your choices are no, but you plan to, no, not applicable, yes, or not sure. And it looks like the vast majority of you are not sure. Some of you say no, but you plan to. And some, it's not applicable, which is understandable. And some say you already have used it. So, it's really good to know that you all seem to be aware of it for the most part. If you're not aware of it, now you can go ahead and find out about it by going to our website.

Okay, so again, I'm just going to remind you, if you look at that slide on the AAALAC Program Description, that the URL on the slide takes you to the dedicated webpage, and also you can get to the Guide Notice itself. So now, let's look specifically more at the AAALAC Program Description, and what sections of it can you use.

Slide 11: Applicable AAALAC Sections

The whole idea of here is to reuse information that you've already developed that's part of your program that is part of your AAALAC Program Description. So, when you're going to be updating your domestic Animal Welfare Assurance when it comes around for renewal, these are the sections of the AAALAC Program Description that you can incorporate into your Assurance. So, there is a Section, 2.1.B.2., which is on Post-Approval Monitoring in the AAALAC program description that you can use. Also Section 2.1.A.2.B., on Occupational Health and Safety of Personnel. There's a section on Training, Education, and Continuing Educational Opportunities, and also the one on the Role of the IACUC -- all of those have relevance in the AAALAC Program Description to your OLAW Assurance. One reminder, though, is that not all of the sections of the AAALAC Program Description match up perfectly with the OLAW Assurance, so it's important that as you're doing that, you make sure that you don't leave out things that are still required in the Assurance document that aren't actually required in the AAALAC

Program Description; it's not a perfect match, but there are a lot of, as I said, overlaps that make it easy for you to take advantage and not rewrite that information.

Slide 12: Semiannual Facility Inspections

We're going to move on now. The third of the new Notices that we released was back in August of last year, 2021, and that one was on flexibilities for conducting semiannual inspections of animal facilities. And it was developed in conjunction with the USDA, so I'm going to be using Dr. Theodorson's expertise here, and we are going to be jointly discussing this particular flexibility Notice. But before we do, I want to again have another poll question. Can we have that poll question up? Yes. Has your IACUC used any of the flexibilities described in the new guidance from OLAW and USDA on your semiannual inspections? Your options are no, but plan to, yes, not familiar with them, or not sure. And -- many of you, 56 percent actually, say yes, that you have used some of those flexibilities in your semiannual inspection process. That's great. Some of you are not familiar, which is okay, hopefully this will familiarize yourselves with it. Some, you're not sure, which is also understood, and also saying that no, but you plan to. We like that, too. So let's go ahead and we will move on, and we will look at some of those semiannual facility inspection flexibilities.

Slide 13: Semiannual Facility Inspections: Flexibilities [Who, When, Where]

And as I said, Dr. Theodorson is going to be joining me to talk about some of these.

For these next few slides, we have some tables that show where the requirements of the USDA and NIH are the same, and where they differ concerning some semiannual inspection flexibilities. Who should conduct the inspections? Both agencies require that no IACUC member should be involuntarily excluded from the semiannual inspection. And no matter how the inspection is conducted, IACUC remains responsible for the evaluation and the report to the IO. That's the bottom line for that part of the requirement.

Let's move on to what is more unique to NIH. For areas housing non-USDA-regulated species, only one qualified individual or an ad-hoc consultant is needed to conduct the facility inspections. However, the expectation of OLAW is that individuals should have training and a working knowledge of the PHS Policy and the Guide to be able to appropriately evaluate the facilities and identify deficiencies and animal welfare issues. And again, they need not be an IACUC member, or even an institutional employee to be used in that capacity. And now EB, what about USDA?

>> Dr. Elizabeth Theodorson: Everybody, I'm going to be turning off my video just because of the choppiness, but the good news is, is there was no change in the AWA regulations. It continues to be for areas housing the USDA-regulated species, it's a subcommittee, at least two IACUC members are required, and the use of an ad-hoc consultant is allowed~~. The IACUC members involved in these inspections -- they're not required to inspect together, and they may inspect different parts of the facilities~~. Regarding when the inspections occur -- so I hope that everybody is good at math, unlike myself -- both agencies [are] in agreement that the timing of facility inspections can include flexibility of within 30 calendar days of the 6-month interval from the last inspection. Again, the caveat here is, provided there is no forward drift of the date from year to year. To avoid forward drift, the IACUC should consider scheduling facility inspections during the same calendar month from year to year. By having this 30-day flexibility, it really allows that extra time for IACUCs without changing the current or future dates of their subsequent inspections. Pat?

>> Dr. Patricia Brown: Okay, so now let's talk about where. Where should the inspections be conducted? So, for animal facilities that are according to the PHS Policy definition, they must be inspected semiannually, and this includes satellite facilities and surgical areas. But the IACUC does have discretion to determine how frequently to inspect other areas, such as locations for routine weighing, dosing, immunization, or imaging areas. But these areas should be monitored regularly in some way by the IACUC.

>> Dr. Elizabeth Theodorson: For the USDA, the animal facilities as defined by the AWR, Animal Welfare Regulations, include the animal study areas. They must be inspected semiannually but remember -- huge caveat here -- exclude free-living wild animals in their natural habitat.

Slide 14: Semiannual Facility Inspections: Flexibilities [How]

>> Dr. Patricia Brown: Okay, so we'll move on to the next set of topics related to semiannual facility inspection flexibilities. So how should the inspections be conducted? ~~Both agencies agree that remote options are available.~~ Here are the distinguishing characteristics of those remote options, though. For areas housing non-USDA-regulated species, IACUCs may use videos, photographs, written descriptions, or other appropriate remote methods to inspect. This often applies to high containment, remote satellite facilities, or when a pre-recorded or virtual tour is needed for safety purposes. There is no requirement to retain those inspection materials such as the videos or photographs or written descriptions that resulted from the review, once that semiannual report is submitted to the Institutional Official.

>> Dr. Elizabeth Theodorson: ~~For areas housing AWA-regulated species, only live feed is allowed for inspections while using video~~.

>> Dr. Patricia Brown: Okay, so we're going to move on. And both agencies agree on the following ways that IACUCs may conduct the inspections. IACUCs may assign specific facility inspections to subcommittees, but to avoid bias, a committee member or qualified individual should not be the only person assigned to inspect areas for which that person is responsible. And the reason for this is that it provides the checks and balances in the system of self-regulation and avoids that bias potential that could happen when someone is personally involved in the inspection. And because the PHS Policy and the Animal Welfare Act regulations do not describe how to determine a conflict of interest, the IACUC has the discretion to determine which situations require additional inspectors, recusal of the individual, or other methods to minimize bias, based on the extent of the inspector's involvement and the nature of the activity itself. Additionally, inspections may occur on a staggered schedule where all facilities are inspected over time, provided that each animal area is inspected at least every 6 months.

Next, inspections may be announced or unannounced. An advantage to using some announced visits is they may help the inspection process by having key personnel available to answer any questions, and that still doesn't compromise the rigor of the inspection process itself. Now let's ask another poll question. Are your facility inspections announced or unannounced? Your choices are announced, unannounced, mix of both, or not sure. And most of you, not surprisingly, do use announced inspections, or a mix of both brings us up to almost all of you responding, with only a small percentage of you doing unannounced -- which is fine. As I said, the options are there for you to do whatever works best for your institution.

I also want to mention that both agencies also support OLAW's checklist as a resource to assist in conducting inspections. Institutions are not required to use the checklist, and your IACUC may amend it

to match with your institution's program and needs. One suggestion when using the checklist is to include positive findings that you found during the inspections and include them in the semiannual report. In that way, you're encouraging continued improvements in the program by giving your program individuals an atta boy, basically, for the positive things that were seen during the inspection.

>> Dr. Elizabeth Theodorson: Absolutely, Pat. This is one of the most important things as we come into concurrence with OLAW that we do agree -- use that voluntary checklist. And the next question I have as well -- I'm sure many of you are already ahead of us -- what about AAALAC inspections?

Slide 15: Semiannual Facility Inspections: Flexibilities [AAALAC International site visits]
>> Dr. Patricia Brown: Okay, so AAALAC inspections, AAALAC site visits, and how do they apply to semiannual facility inspections? So both agencies allow IACUCs to use an AAALAC International site visit in lieu of an IACUC semiannual inspection, provided that the contents of the semiannual report to the IO meet the requirements of the PHS Policy and the Animal Welfare Regulations, and that the subsequent inspection is conducted no later than six months from when the site visit occurred. That way you're keeping it on the requirement for a truly semiannual process. And this subsequent inspection does have the same 30-day flexibility and timing that we just talked about for your more routine, semiannual inspections.

In addition, the specific provisions for each agency are that for OLAW, the report must comply with PHS Policy IV.B.3, which requires that the report contain information regarding the institution's adherence to the Guide, including a plan and schedule for correcting each deficiency identified in the report.

>> Dr. Elizabeth Theodorson: Okay, so from the purview of the USDA, for those institutions covered by the Animal Welfare Regulations, the report must comply with 2.31(c). ~~These requirements are that the site visit corresponds with the time the IACUC's semiannual inspection was to be conducted, the program and facility inspection address all of the required areas, at least two members of the IACUC assist in conducting the inspection -- remember, they don't have to be at the same place at the same time~~. All members are informed of the evaluation to be conducted by the appointed subcommittee, in sufficient time to request participation. No IACUC member wishing to participate in any evaluation may be excluded. Any identified departures from the ~~AWA Regulations and Standards include a description of, and reason for the departure, and lastly, the report is signed by a majority of the IACUC members. Individual digital signatures are acceptable.~~

Slide 16: Grant to Protocol Congruence (G2PC)
>> Dr. Patricia Brown: Okay. So that's everything you need to know about semiannual facility inspections and flexibilities therein. Now we're going to look at some other guidance that OLAW issued. The fourth and fifth of the new Notices that we released was back in November of 2021, and in those, we provided clarification on Grant to Protocol Congruence Review and Contract to Protocol Congruence Review. And both of these Guide Notices clarify the requirements for congruence review, the responsibility for who conducts congruence review, timing and verification of congruence review by IACUC approval, and methods for conducting congruence review. So now I'm going to ask a poll question. Who conducts the congruence review at your institution? The IACUC, the IACUC administration, sponsored project, compliance, or similar office, or not sure? And our results -- so for 60 percent of you, the IACUC administration is conducting it, and then another 10 percent it's the sponsored project, compliance, or similar office. Then 17 percent of you, the IACUC itself -- someone on the IACUC is doing that review. And as you see, some of you are not sure, which is okay. You can go find out.

Slide 17: Grant to Protocol Congruence Review (G2PCR)

>> Okay, we will move on from there and look specifically at Grant to Protocol Congruence. Key guidance on Grant to Protocol Congruence is that it is not a required IACUC function and may be performed by other qualified institutional personnel. And as we just saw, for many of you, it's someone in the IACUC administrative office that's doing it. It must occur prior to the initial grant award, so that that first award that's being made related to a particular grant application. And also, it must also occur for Type 2 renewal applications, because those are considered competitive applications that do reflect new information and new requests for funding. So those are the two times when congruence review must occur. Principal investigators can provide a brief description in the IACUC protocol, if there's annual activities planned for the fourth and fifth year of the award. And in this case, the experimental details and procedures, the expectation is that they would be refined or amended later, or during the three-year renewal. So, this is allowing the IACUC and the congruence review to confirm that there are activities that will be happening, but they're not part of the majority of the information that is in the IACUC protocol that is being reviewed, with just a short statement about the fourth- and fifth-year plans, with the understanding that those would be updated and reviewed by the IACUC when it reaches that point in time. Hopefully I explained that carefully enough that you understand what I'm telling you.

Slide 18: More on G2PCR

>> Okay, we're going to move on to some other information that might be helpful in the congruence review process. So, if the IACUC review is delayed because the annual activities won't occur until a year or later in the award period, the NIH grants manager will typically issue a Notice of Award that indicates that no funds are going to be drawn from the grant for animal activities until the IACUC approval date is provided. So, this gives that flexibility that allows the IACUC review and the associated congruence review to be delayed until closer to when that activity is actually going to start in the full funding period of the grant.

And next issue is that oftentimes as the PI proceeds with their research once the grant is awarded, they may decide that they want to make certain changes in the scope of the research. And the NIH Grant Policy has specific guidance on what they call a "change in scope". And when these do occur, some of them may involve the animal activities; not all of those changes are going to rise to the level of a significant change, but if they do, they of course require IACUC review and approval of any of those changes from what was originally in the IACUC protocol. But there's not requirement for further congruence review at that point. And hopefully if you have questions about that, please put them in the chat.

Slide 19: How to Conduct G2PCR

Okay, some other guidance on how to conduct congruence review -- and these are just clarifications, I think, on what we've already said in the past, that there's no requirement to do a side-by-side comparison of the entire application and the IACUC protocol, and that the streamlined way to conduct the review is to just limit your comparison to the research strategy and the Vertebrate Animals Section of the application, because that's where the bulk of the information is going to be that's going to be relevant to compare to the IACUC protocol. And there is no requirement for a one-to-one relationship between the grant and the approved protocol, although I know that some institutions do choose to do that. That is not a requirement. You can have more than one protocol associated with a grant, or more than one grant associated with a single protocol.

Slide 20: Contract to Protocol Congruence Review (C2PCR)

We will move on from there, and talk about contract to protocol congruence. So, contract to protocol congruence does have some differences, in that the requirements originate from the Health and Human Services acquisition regulations and the review process that's involved with contract awards. So, we do have a specific guidance in NOT-OD-22-006 that covers contract to protocol congruence review and has more specifics about the requirements, the responsibility, timing, and conduct -- most of it's the same, the similarities are very similar, but in some cases, there are some slight differences.

Slide 21: Contract to Protocol Congruence Review (C2PCR) [continued…]

As is true for grant to protocol congruence, contract to protocol congruence is not a required IACUC function, and it may be performed by other qualified institutional personnel. The review must occur prior to contract award, just like with grants, but once awarded, there's no further congruence review needed for any subsequent modifications to the contract, so it's just a one and done kind of situation. However, if there is a contract that was approved that did not include animal work at all, and then later animal activities are added, then IACUC approval and congruence review would be required prior to the start of those animal activities. So that's the point in time where if you do have a contract that doesn't involve any animal work, and then all of a sudden there's a major modification that adds animal work, that is when you would need to have IACUC approval of course, and confirmation that what the IACUC has approved lines up with the contract.

Slide 22: Requests for Information (RFIs) Pending Updated Guidance

Okay, so in 2021, we also released some new RFIs, some Requests for Information. One was on clarifying reporting requirements for departures from the Guide, and the other was on how to continue to apply -- whether we should continue to apply the PHS Policy to zebrafish immediately after hatching. We had 90-day comment periods for those RFIs, and we want to thank those of you and the organizations out there, too, for your comments that were submitted in response to those RFIs. We're continuing to analyze the responses and are working on our final versions of the proposed guidance. We have no specific timeline for when they'll be released; most likely sometime later this year, so stay tuned. You'll hear about it when we announce it through a Guide Notice.

Slide 23: NIH Steps: Future Steps

So we're also working on some additional topics that were identified in the 21st Century Cures Act report. They're still in development, and there's no draft guidance yet, but these are the topics that you can expect to hear about from us; flexibilities for conducting semiannual program review, streamlining protocol review, what is exempt from IACUC review, updates on reporting noncompliance, and options for IACUC review of non-pharmaceutical grade substances. And we'll be coordinating with USDA for the proposed guidance in these RFIs when it involves topics that are covered by both the PHS Policy and the Animal Welfare Act regulations. And now I'm going to turn this over to Dr. Theodorson.

Slide 24: USDA APHIS Animal Care Updates

>> Dr. Elizabeth Theodorson: Great. Thank you, Dr. Brown. To get started, I just really wanted to acknowledge what a privilege it is to work with OLAW; Dr. Pat Brown, Dr. Nicolette Petervary and [Dr.] Cate Pritchard. So, let's talk about -- next slide, please -- all right, here we go. Again, everyone calls me EB. I'm with Animal Care, I'm Assistant Deputy. And I'm going to be talking today about the changes we made, so let's get started. Next slide, please.

Slide 25: AWA Research Facility Registration Updates, Review, and Reports Regulation
So to have this kind of change in the Federal government, you must have a proposed regulation change. And that's exactly what we did, through a work plan and a proposed regulation means it has to go out to comment, so the regulations that took effect, I'm sure as you all know, in December, was the AWA Research Facility Registration Updates, Reviews, and Report Regulation. Next slide, please.

Slide 26: 21st Century Cures Act: Remove Duplicative and Unnecessary Information Requirements
So as Dr. Brown indicated, we work with the FDA and OLAW to do a complete review of regulations and policies for the care and use of animals used in laboratory research. And what really came out of it is the goal, which where they have a regulation or a policy, it's truly to reduce administrative burden on the research community while maintaining integrity. And just so everyone knows, approximately - to change day to day - there's 1,100 registered facilities that use animals to conduct research-teaching-testing. So, to be registered, remember, you have to have covered species and covered activity. Next slide.

Slide 27: Easing Registration Burden
So there's three really big changes we made, or three changes to be in compliance with the 21st Century [Cures Act]. And what we really wanted to do -- again, registration burden. And as you can see, we modified 2.30. And what is that? That was that requirement to register your facility every three years. We are busy, we have things to do; there's research protocol, funding, keeping up with OLAW -- and I mean that in a positive light. So, eliminating this requirement to register every three years, we thought would be very helpful. And it's one and done. But what I really wanted to point out is, okay, it's easy enough, you put your registration in, and what about canceling? Well, we wanted to be really clear, so conditions for canceling -- you still have to cancel, or you have to cancel. This intermittent inactive is going away. So, we want, and are requiring, submission of a written request to the Deputy Administrator to cancel. That's currently Dr. Elizabeth Goldentyer, and eliminating inactive status. So, we have quite a few facilities that, for years at a time, would not be doing covered activity with covered species. We wanted to eliminate this where a facility will either now be registered or unregistered. And not only is it beneficial, this regulation change, to update, not only is it beneficial to the facilities, because it's paperwork, it's time and effort. However, think about the taxpayer money, when we have to send or deploy or fly out someone with a GOV on time and travel to go to one more inactive facility, which we were doing quite often, that's easing taxpayer burden as well. So, I really do like this regulation for multiple purposes. Next slide.

Slide 28: What do you think?
Let's take a poll. What do you think? A facility with a canceled registration is still required to apply for a registration 10 days before beginning regulated activity. Do you think this is true or false? Okay, true -- all right, excellent, good, we're getting there. That's why we have these. It's actually true. So, lots of options -- there's the email, there's the external portal -- you must be registered to conduct activities within 10 days. So, whether it's a call or an email talking to your veterinary medical officer -- we will help get it done. Okay, next slide.

Slide 29: Review of Animal Activities
Animal Activities -- so those of you who love that Blue Book, it's actually 2.31(d)(5) that was updated. And what the old requirement said is, it's that continuing review of animal activities not less than annually. We had so much positive feedback on changing that to the new requirement, which is in congruence of OLAW, is that a complete review of animal activities every three years. This, again, complies and harmonizes with OLAW and the PHS. So, let's go to the next slide and let's do another poll.

Slide 30: What do you think?
The "Research Rule," which we call this, the regulation went into effect just this December. The most recent complete or continuous review of a protocol, using rabbits, was done on December 30th of 2020. By what date does the AWA require the next complete review of that protocol? Everyone select an answer, see what you think. Okay, excellent, everybody. Majority -- it's actually C, so that's three years, December 30th, 2023. And you know time is flying. Okay. Next slide.

Slide 31: Annual Report Signatures
Last, but not least, it's the annual report signatures. We really very much appreciate everybody using the portal, try to make that as easy as possible for everyone. But this is the 2.36(a) -- it no longer requires the CEO or IO of that registered facility to sign the annual report. Why? This expedites processing, and facilities are left at their own discretion to who can be designated as the signatory. And it could change from year to year. I think that's what we want people to understand, is that it's what works best for the facility at that time. Next poll.

Slide 32: What do you think?
So, what do you think? True or false -- a signatory is not the CEO or IO, who is not the CEO or IO, does not assume the responsibility of those positions when they're signing the annual report. Is it true or false? So, if I am the administrative person and I sign, do I carry the responsibilities, as if I'm the CEO or IO? Okay, good, majority, 75 percent -- it's true. You sign it, you suddenly, thank goodness, do not become the CEO or IO. You are just signing the report as completed and submit it. Okay, next slide.

Slide 33: Picture of the Blue book.
So I'd like to do a tour of the website that we put together of these changes.

[Online Demonstration]
So I'm going to share my screen -- please be patient with me -- from Dr. Brown to track all of these changes. And many of you know, I am sure, even though birds covered under research will not be regulated unless wild-captured -- that's a huge regulation coming up. This is our APHIS webpage. And for those of you who might be new, and I constantly refresh myself, APHIS is our agency. The Department of Ag is our department. Our program is Animal Welfare. And if you ever want the latest and greatest -- it's right here. We're Animal Welfare. So, if you click on this, what happens is, anything -- and I'm going to tell you, there is a significant budget and amount of care and expectation to keep everything up to date; there are so many changes, as we all know, to regulations, no matter what your department. This website will really give you what's happening. And many of you, if not all of you, sign up for Gov delivery, and that's where we send out all our stakeholder letters, et cetera. What you get in your letter will land on this page.

But what I wanted to direct you to today -- so we have a lot of hot topics going on; we have the Welfare Birds, as you can see. We have a serological study coming up with the American Rescue Plan -- $300 million budget. We have so much going on. What we're interested [in] today is, let's hop down to Publications, Form and Guidance Documents, on that left toolbar.

[Publications, Forms, and Guidance Documents]
Many of you already know that if you don't have the Blue Book at your desk, it's found here. But what I wanted to show you today, down here, the Inspection Guide -- let's look at the FAQ's.

[FAQs]

We set up for this regulation, what we call the Research Regulation, we set up our very own Research Reg page. And right here, the content, you can jump to any section. But as I indicated in this slide, we really set it up in the Regulations and its change. So, we can have the 2.30, we can see registration change, annual report signatory or review of protocols, but for each one -- I'm trying to go slow here, because goodness knows I don't want to give anyone whiplash -- we've set up an FAQ page.

So, let's look at it. Come down, you click any topic in the green, and we'll answer your questions. We talked about this -- everyone did very good on this poll question. If you were inactive, we remove your registration; you either write in, or you're removed. If you need to conduct activity, you have 10 days. These are the kinds of questions we wanted to have out there. Can a facility request cancellation of its registration? Absolutely. We talked about that to the Deputy Administrator.

So, the other section is the annual review, which we talked about. There's the regulation in plain sight, and then each green designation has a hot topic. I wanted to click on one that I thought would be very interesting, that we've kind of heard through feedback and other meetings. Will past citations be removed from inspection reports, here, especially those on the public search tool [PST]? If so, how far back? Past citations, under that previous 2.31(d)(5) will not be removed -- that happened in that real-time, that does not change. And citations will continue to be searchable. Just remember that after three years, the records retention rules, that those should fall off the PST.

And last, but not least, we covered the annual report signatures and the FAQs. So, this one's interesting -- will there be a citation if the annual report is not signed? No, the annual report simply will not be processed until there is a signature. So, as you know, when you pass the deadline in December, you might get a naughty 7060, which is a warning letter, but it's not a citation. And we do everything in our power to reach out to you and remind you, we need those reports signed. We are very excited with this next annual report review, for people to say, hey, the CEO isn't here, or the IO isn't here -- no worries, let's find another designee.

So that is our FAQ webpage. And of course, we have Miscellaneous -- everyone wants to know when the Blue Book will be published again. The Federal Registry is up to date, but what's happening is, because we have so many regulations coming out, we have the bird regulations, we have the horse protection -- anyone who's interested in horses -- horse protections coming up, and we have a couple of hot topic items that I'd be fired from my job if I discussed today. But stay tuned for further webinars.

[End of online demonstration]

So, I'm going to stop sharing my screen, and finish up with my remaining slides. There's one poll question that I really want to broach today; I thought it was really important. Thank you, next slide.

Slide 34: What do you think?

So what do you think? The subcommittee, FY22, House Agriculture Appropriation Committee, eliminated the use of teachable moments, or any similar program that obscures findings during inspections. Is this true or false? Okay, well, 50/50 here, and that's why this webinar is so important -- is that it's actually true. So, what happened is, the Congress directed Animal Care to eliminate -- "direction" means not up for discussion -- to eliminate the use of teachable moments. This will actually take effect this coming October. And this is our first kind of notification that this change is coming. And at this juncture, Animal Care does not know how we'll be dealing specifically with what used to be a

teachable moment. We want everyone to know, is absolutely at this point determined is that teachable moments will no longer be used, following this coming October 1st. Next and last slide.

Slide 35: Teachable Moments
Just the specifics here -- this was to ensure consistent, thorough and unannounced inspections, and to ensure compliance when facilities are not within compliance with AWA. This is just not registrants, this is facilities, whether you're A, B or C licensed, or a registration. And this required inspection reports to identify non-compliances and violations, and again, documenting failure to allow access for inspections, and each failure to comply with Animal Welfare Standards -- this is the specific language the House provided to Animal Care. And really, that second to last bullet point, everyone, "ensure that there is no use of teachable moments" -- we had in Congress some very firm stand opinions on teachable moments. As you can see, they will be eliminated.

That's it for me.

Slide 36: Implement
>> Dr. Patricia Brown: Okay, so we're going to wrap up here. We do have some questions that came in in advance, which we'll get to, and then we'll take as many as we can right up until 2:00. Any questions that we don't get to that you've submitted either in the Chat or the Q and A will be addressed in the transcript; we'll do our best to answer all the questions.

So, in summary, what are we doing? Our implementation efforts are ongoing. We're continuing to look for ways to reduce burden. We plan to continue to engage with you as our primary stakeholders throughout the process, and we also plan to evaluate the outcomes of our efforts. So, we will be enlisting an evaluation team to gather input from the research community, from IACUC members and animal care and use program representatives. We've engaged the Federal Demonstration Partnership, and also other key representatives from some of the scientific and professional organizations. And we're going to use their leverage with their constituents to try and develop and distribute surveys, so be on the lookout that over the next period of time, that we will be developing these. And we hope that you all will participate and giving input on whether you think our changes have been effective or not, or that there are things you find useful to your programs in reducing burden.

So again, the intent of the surveys is to gather information on the effectiveness of what we've done, and also, how can we best communicate and encourage institutions to not impose unnecessary burden themselves?

And move on to the first question that came in. And this is for EB, I think.

Slide 37: Question 1
>> Dr. Elizabeth Theodorson: Yes, all right. So, if annual reviews are no longer required for IACUC protocols covering USDA species, and we move to every three years, does this mean that the updated alternative searches on an annual basis are also not required? Would this mean a new alternative search is required every three years, along with a new protocol? So -- and there's two questions here -- the second is, however, if the protocol were to be amended during those three years, a D or E procedure would need an updated alternative search at the time the amendment is submitted. Is this correct? What I can tell you -- write this down, folks, put it on a piece of paper somewhere, you can always call me -- there is no requirement in our regs for annual alternative search updates. The frequency of

updating alternative searches is up to the IACUC. If a new protocol is submitted, or protocols amended that changes or adds a procedure and requires IACUC approval, a search for alternatives is required.

>> Dr. Nicolette Petervary: Thank you, EB. We have several questions in the Q and A and in the Chat, and I think we're going to try to get through the ones in the Q and A first. But as we mentioned before, we will be addressing all of the questions to the best of our ability and append the answers on this topic to the transcript that will be posted after the fact.

Question 2: Please clarify if institutions are required to use the AAALC PD sections in the Assurance renewal.

So here's an interesting question for both the USDA and for OLAW. Please clarify if institutions are required to use the AAALAC PD sections in the Assurance renewal.

>> Dr. Patricia Brown: I can take that one -- no, there is no requirement. It's just a flexibility that we're offering you to hopefully streamline the process for you and your institution.

>> Dr. Nicolette Petervary: Thank you, Pat.

Question 3: Can we only implement the flexibilities for semiannuals if they are described in our Assurance?

We have another question. Can we only implement the flexibilities for semiannuals if they are described in our Assurance? And this is an OLAW question.

>> Dr. Patricia Brown: If you plan to introduce those flexibilities, that's good for you, and then you can inform us. If it does change what's in your Assurance, you can inform us of that at your next Annual Report -- that would be one way to do it. And we would definitely catch it on the next time that you're doing your renewal, too. But we would prefer to know about it at the next Annual Report.

>> Dr. Nicolette Petervary: Thank you.

Question 4: Does the USDA require two members to participate?

So there is some confusion about who can do the semiannual facility inspections. And this question would like clarification of, the USDA requires two IACUC members to participate, unlike the NIH, which only requires one member, who does not need to be an IACUC member. So, as we mentioned before, the NIH requires the use of a qualified ad hoc consultant. You can use as few as one ad hoc consultant to conduct the semiannual inspection, as long as they are qualified. And EB, would you like to recap on the USDA requirements?

>> Dr. Elizabeth Theodorson: I sure would. Just give me a second. Thank you. The good news is that the semiannual inspection regulations have not changed based on the USDA guidance. For USDA-regulated species or covered species who carry registration, the subcommittee of at least two IACUC members are required, and the use of that ad hoc consultant is allowed [in addition to the subcommittee of two IACUC members].

>> Dr. Nicolette Petervary: Perfect, thank you. And I'd like to remind the listeners that they will be getting slides, and there is that handy chart that you can refer to if you ever require clarification, because it is a lot to keep track of.

We have a question about how many participants are on the call -- I will just tell you that that varies, but we had roughly 240 attendees today, if that helps you at all. But remember, we're not capturing

information about which facilities they come from, so I don't know that it will help you decide what to do, based on poll responses.

Question 5: Why can't the USDA inspectors include positive findings in their facility inspection?
We have another question, and EB, this may be putting you on the spot, so if we need to get back to this, we will. But why cannot USDA inspectors include positive findings in their facility inspections?

>> Dr. Elizabeth Theodorson: You know, that's a great question, and I really appreciate that. And we've talked about that a lot. In the history of the inspection report, it's to document citations, and that goes on the public search tool. For something like that to occur, we'd really have to get through a process of, just like I talked about, House and Subcommittee, Congressional, after going to administration to see if that process was possible. I'm not ruling it out in the future, and we do discuss that. It's just not happening at this time.

Question 6: For USDA-regulated species, can IACUCs inspect virtually for distant facilities?
>> Dr. Nicolette Petervary: Thank you, EB, that's helpful. We have another question for USDA. And I'm going to read it, and then I'm going to shorten it down to what I think it's asking: Can a remote facility that's used to temporarily house wild-caught rodents for three to four days, which are USDA covered, be inspected using an ad hoc consultant? It is about a thousand miles away from the institution and is used for three to four days every two to three years. Do we need to send two IACUC members to inspect it? I think what they're asking is, are there any USDA provisions for remote locations, for semiannual inspections?

>> Dr. Elizabeth Theodorson: ~~Well, I don't know why the live feed wouldn't apply here, but I will get back to you, because this is a great question. I'm sure it happens more than we know.~~ [Update March 2024: The use of live feed is not allowed].

Question 7: For USDA certificates that were issued with expiration dates, what will the plan be to issue certificates without expiration dates for those institutions?
>> Dr. Nicolette Petervary: Thank you. This is an interesting question. I'm not quite sure what they're referring to, but for USDA certificates that were issued with expiration dates, what will be the plan to issue certificates without expiration dates for those institutions?

>> Dr. Elizabeth Theodorson: So really, we weren't planning on rolling over these certificates, because you have your certificate, it's valid. Unless it's cancelled, you would get a new certificate. But I will make sure to talk to Program Support. As long as you have your current registration, do not worry, and we'll see if we can get you -- if there is an updated paper change, but you can imagine that regulation is to benefit you, not to harm you because of an old paper certificate.

Question 8: If the teachable moments had to be phased out by October of 2022, why did some VMOs stop using them as soon as it was announced?
>> Dr. Nicolette Petervary: Thank you. And we have a question about teachable moments. If the teachable moments had to be phased out by October of 2022, why did some VMOs stop using them as soon as it was announced?

>> Dr. Elizabeth Theodorson: So -- thank you for the question -- we just announced this to the field two weeks ago, so I think it's something more than an official announcement by Dr. Goldentyer. Part of the issue, being very, very transparent here, is such activity and objectivity is something that we work very hard on our inspectors and our supervisors for. Part of the reason teachable moments lacked support

across external and internal stakeholders in Congress is that we could not, and we were having a very difficult time applying these appropriately when necessary, et cetera. So, while you say, whomever this person is, I very much appreciate why they stopped using -- well, we just officially announced it two weeks ago. So, I hope that helps you.

>> Dr. Nicolette Petervary: Thank you. I imagine that each inspection is situationally different as well, and there are probably a lot of variables that go into whether something qualifies for a teachable moment or not.

>> Dr. Elizabeth Theodorson: Absolutely.

Question 9: Is the DoD following the USDA in eliminating the annual review requirement for activities involving USDA-covered species?

>> Dr. Nicolette Petervary: Okay. So, I am now transitioning over to the Chat. Okay, this is a complicated one: Regarding eliminating the annual review requirement for activities involving USDA-covered species, do you know -- this is a very specific question -- if there's been any update on whether the Department of Defense is following suit? I'm just going to stop right there and say that that would best be addressed by asking the DoD directly. That is --

>> Dr. Patricia Brown: Yeah, OLAW will investigate that and get an answer. We'll answer that one. We'll confirm with DOD what their current practice is.

>> Dr. Nicolette Petervary: Thank you, Pat.

>> Dr. Patricia Brown: Sure.

Discussion of G2PCR and C2PCR

>> Dr. Nicolette Petervary: Okay. So, we have some comments as well, which are not so much questions, because I think we've answered the majority of the questions. But there are some comments that some PIs are taking, the statement that there's no requirement for one-to-one congruence review to mean that there doesn't have to be any review at all -- I think that's what the chat is saying -- and some suggestions to clarify that. So, thank you very much. There is certainly a difference between a one-to-one and one to many congruence reviews, and the actual requirement to do one is always applicable.

>> Dr. Patricia Brown: There was another comment here about program officers not being willing to issue restricted awards, or also requiring a quick turnaround -- we are aware of this issue. We've heard about it recently, too, involving Type 7 awards, where there's a change in the institution, and we are going to be addressing this internally within NIH, in terms of making sure that the program and grant staff are aware that they have to understand that IACUC, IRB, and IBC-type reviews can't often happen in a blink of an eye. So that is something that we are going to be trying to address internally within NIH, and hopefully that will help all of you out there that are dealing with what appears to be high pressure to get quick review and approval.

>> Dr. Nicolette Petervary: Thank you, Pat. That's very good news to hear, I'm sure, for a lot of our attendees.

Question 10: Will a program of veterinary care [PVC] still be required for USDA Registrants?

One other question that I'm seeing in the chat, and this is for USDA -- will a program of veterinary care [PVC] still be required for USDA registrants? And then they clarify that by saying a document, or a paper describing a program of veterinary care.

>> *Dr. Elizabeth Theodorson*: Great question. A PVC is still required. And you do not have -- there's no -- you don't have to use the form that we provide. We recommend it, and most research facilities do, but it's not that required form.

>> *Dr. Nicolette Petervary*: Thank you, EB, that's helpful. And I think --

Discussion of Surveys

>> *Dr. Patricia Brown*: Yeah, I wanted to comment about the comment about the surveys -- can they also include other aspects of reducing burden, including information on how research integrity and animal welfare are protected -- I think that's also a very important element of how they surveys get put together, so I really appreciate you making that suggestion to us.

>> *Dr. Nicolette Petervary*: Thank you, Pat. We are almost 10 minutes over, and I appreciate those of you who have stuck through to the end. But everyone will have access to answers to these questions when we post the transcript.

I thank you very much for participating. And our next OLAW online seminar will be in June, with the topic to be determined. Once again, thank you very much.

Question A:

Regarding eliminating the annual review requirement for activities involving USDA covered species, do you know if there has been any update on whether the Department of Defense is following suit? The last I understood, they are still requiring annual review for DOD funded research involving USDA covered species, but were considering updating their guidance to match the USDA's harmonization with OLAW. Have there been any updates on that?

>> *DoD Response:* Yes, the DoD is currently reviewing updates to its regulation to include the recent changes with the USDA Animal Welfare Act/Regulations with respect to annual reviews.

Question B:

For USDA certificates that were issued with expiration dates, what will be the plan to issue certificates without expiration dates for those institutions?

>>*USDA Response*: There is no federal requirement for a facility to have an updated certificate. For those certificates that have expired, they are no longer considered expired as the new rule states they are no longer required to update their registration. All research facilities have been updated in our database to reflect this change. USDA APHIS Animal Care (AC) is only issuing updated certificates if the research facilities request one directly from AC. We have no plans to send updated certificates. However, we are more than happy to provide one upon request.