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Note: Text has been edited for clarity.

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21st Century Cures Act: Next Steps

Speakers:

- Patricia Brown, VMD, NIH, Office of Laboratory Animal Welfare
- Betty Goldentyer, DVM, USDA-APHIS Animal Care
- Brianna Skinner, DVM, MPH, Food and Drug Administration

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Slide 1 (21st Century Cures Act Next Steps)

>>Neera: Hello. Today is Thursday December 5, 2019. I am Neera Gopee, Director of the Division of Policy and Education at OLAW, and today it is my pleasure to welcome our speakers, Drs. Pat Brown, Betty Goldentyer, and Brianna Skinner to the [OLAW Online Seminars](#) to present 21st Century Cures Act: Next Steps.

Dr. Pat Brown currently serves as the Director, Office of Laboratory Animal Welfare. She received her undergraduate degree in Animal Science from The Pennsylvania State University and her veterinary degree from the University of Pennsylvania. She completed her lab animal residency at Penn State Hershey Medical Center and is a diplomate of ACLAM. She served on active duty in the Air Force before joining NIH in 1986, serving in several clinical and management positions in the intramural research program before joining OLAW in 2006 as the Director.

Dr. Betty Goldentyer is a graduate of Tufts University School of Veterinary Medicine. She came to USDA after working in a small animal practice and then with a humane society in Chicago. Dr. Goldentyer was an animal welfare inspector in Wisconsin, and a Regional Animal Care Specialist before becoming the Regional Director for Animal Care in Raleigh. In July of 2017, she moved to DC to serve as the Associate Deputy Administrator for Animal Care and in July of 2019 became the Acting Deputy Administrator. I am happy to report, that as of today, Betty is now officially the Deputy Administrator. Dr. Goldentyer is proud to represent Animal Care but spends many hours traveling back to Raleigh to see her twin granddaughters.

Dr. Brianna Skinner is a Commissioned Corps Officer in the U.S. Public Health Service. She is assigned to the Office of Counterterrorism and Emerging Threats (OCET) within the Office of the Commissioner at the U.S. Food and Drug Administration (FDA) and serves as a Senior Regulatory Veterinarian. She is an animal model expert for the administration of policies to facilitate the availability of safe and effective medical countermeasures against chemical, biological, radiological, nuclear agents, and emerging threats. Prior to transferring to the FDA, she worked at the Centers for Disease Control and Prevention for over 11 years supporting infectious disease research and consulting with principal investigators on animal care and use in compliance with federal laws and regulations. She is a diplomate in the American College of Laboratory Animal Medicine and earned her Doctor of Veterinary Medicine degree from Tuskegee University. She then earned a Masters of Public Health at Benedictine University.

Slide 2 (21st Century Cures Act: NIH Actions)

It is my pleasure to welcome you to OLAW Online Seminar and now to hand the microphone over to Pat.

Slide 3 (Objectives)

>>Pat: Hello. I'm going to start with a discussion of the 21st Century Cures Act and the NIH actions proposed in the final report. The objectives of this part of the presentation are to describe the history and key elements of the 21st Century Cures Act with potential impacts on animal programs and IACUCs, and then to evaluate proposed actions by NIH to change policies and guidance to reduce administrative burden on researchers.

Slide 4 (21st Century Cures Act, What is it?)

Let's start with what is the 21st Century Cures Act? It's comprehensive language [legislation] that was passed in December 2016. The overall intent of the 312-page law is to advance biomedical research from basic research through to advanced clinical trials and to streamline the drug and device approval process to bring treatments to patients faster. The law also addresses the opioid epidemic and mental illness, among other purposes. In particular for our interest today, is that it mandates federal efforts to reduce administrative burden for researchers. Section 2034(d) 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 it Ask?)

What does Section 2034(d) specifically ask? It says that not later than two years after the law was enacted, the Director of the NIH, in collaboration with the Secretary of Agriculture and the FDA Commissioner, will complete a review of applicable regulations and policies for the care and use of laboratory animals.

Slide 6 (What does it Ask, cont.)

It goes on to say that the agencies will make revisions, as appropriate, to reduce administrative burden on investigators, while maintaining the integrity and credibility of research findings and protection of research animals. It says that in carrying out this effort, the NIH Director shall seek the input of experts, as appropriate.

Slide 7 (21st Century Cures Act: Details)

The law goes on to specifically direct the agencies to identify ways to ensure regulations and policies are not inconsistent, overlapping, or unnecessarily duplicative with a focus on inspection and review requirements by the federal agencies and accrediting associations such as AAALAC International.

Slide 8 (21st Century Cures Act: Details, cont.)

It asks further that the agencies take steps to eliminate or reduce identified inconsistencies, overlap, or duplication among the regulations and policies; and...

Slide 9 (21st Century Cures Act: Details, cont.)

...lastly it asks that the agencies take other actions, as appropriate, to improve the coordination of regulations and policies with respect to research with laboratory animals.

Slide 10 (Working Group Timeline)

Following the passage of the law, the NIH convened our first meeting of the Working Group in February 2017. The Working Group was made up of the members of the standing committee that represents NIH, FDA, and USDA under the Memorandum of Understanding (MOU) between the three agencies concerning laboratory animal welfare. The MOU standing committee was first formed in 1995 and has met since then at least annually. In addition to the MOU standing committee members, each agency added legal and policy subject matter experts for a total of 19 members.

At its first meeting the Working Group decided to start their effort by reviewing relevant regulations and policies. This occurred over the course of 2017.

The Working Group held listening sessions and meetings in 2018 to: explain the requirements in the 21st Century Cures Act; provide updates on the Working Group's progress; and encourage the research community, other stakeholders, and the public to provide their individual ideas for how to meet the requirements of the law. In many cases the listening sessions were part of presentations by Working Group members at regional and national conferences and workshops of such organizations as AALAS, the American Association for Laboratory Animal Science, the Scientists Center for Animal Welfare, SCAW, the Federal Demonstration Partnership, FDP, Public Responsibility in Medicine and Research, PRIM&R, and the IACUC Administrator's Association, IAA.

In March 2018, NIH released a Request for Information also known by its acronym, RFI, for public comment on the preliminary suggested actions that the agencies had identified to improve the coordination and harmonization of the regulations and policies. The RFI also asked for feedback from stakeholders on tools and resources that would be helpful for reducing burden on investigators. There was a 90-day public comment period and the RFI received over 19,000 comments.

Based on the responses to the RFI and the Working Group's prior reviews, they released a draft report in December 2018. A 90-day comment period was opened at the time of the

report's release, and then based on the further input from stakeholders that was received in response to the draft report, the agencies released the final report in August 2019.

Slide 11 (Working Group Activities)

In these next slides, I will detail the Working Groups' activities throughout the process and what the Working Group used in developing the draft report and the final report. The Working Group started off by reviewing the regulations and policies that the Group considered inconsistent, overlapping, and unnecessarily duplicative. The Group used as documents to help support our review, the reports and surveys and communications that had resulted from several nonprofit organizations and federal surveys from 2013-2018 that had addressed investigator burden.

Slide 12 (Documents Reviewed)

This slide and the next one list the reports, communications, and surveys evaluated by the Working Group. Note that the list includes reports and surveys obtained by such scientific and research-related organizations as the Federation of American Societies for Experimental Biology, FASEB, the Council on Government Regulations, COGR, the American Association of Medical Colleges, AAMC, the National Science Board of the National Science Foundation, the National Academies of Science, and the Federal Demonstration Partnership, FDP.

Slide 13 (Documents Reviewed, cont.)

This continued list includes documents received from other stakeholders including the National Association for Biomedical Research, NABR, and focused on OLAW's prompt reporting guidance, the Humane Society of the United States and Humane Society Legislative Fund who expressed their concerns about the recommendations from the FASEB, COGR, AAMC report, and a statement from the People for the Ethical Treatment of Animals also expressing concerns about the FASEB, COGR, AAMC recommendations. All of these reports and surveys are available for review on the [21st Century Cures Act webpage](#) on the OLAW website.

Slide 14 (More Working Group Activities)

In response to the RFI, the Working Group received approximately 19,240 comments from stakeholders that included researchers, academic and research institutions, animal issue advocacy groups, scientific and professional societies and associations, other not-for-profit organizations, and the public. The Working Group analyzed the public comments and used those to develop the draft report.

The Working Group received 1,342 comments from stakeholders to the draft report. Overall, the comments about the draft report from the research community were very supportive. This support was balanced by concerns presented by other stakeholders, including animal issue advocacy groups and the public. The Working Group then refined the final report to include input from the comments on the draft report.

Slide 15 (21st Century Cures Act)

If you would like to read the [final report](#), the location where you can find it on the web is listed here in this slide. It's on the OLAW website in a page that is dedicated to the 21st Century Cures Act. Now I would like to focus on what the report says the NIH plans to do, and we're going to start with the guidance that we plan to review and update.

Slide 16 (NIH Steps to Update Guidance)

Here's a list of OLAW's guidance and policies that we will review and update that focus on semiannual inspections, protocol review, and reporting.

In coordination with USDA, we will develop guidance to address existing flexibilities in who and how the semiannual inspections by IACUCs are conducted. The PHS Policy affords flexibility in the designation of IACUC inspectors and the conduct of inspections. For example, OLAW allows the substitution of the AAALAC site visit for the semiannual program evaluation and will provide details on the criteria for this option.

The agency plans to review and enhance our current resources to support IACUC use of the existing options that streamline protocol review and significant changes to approved protocols. This includes updated resources to encourage the use of designated member review, or DMR, for such things as low-risk activities and for three-year complete review, and also the use of the Veterinary Verification and Consultation, or VVC, process for certain significant changes where it is applicable.

In coordination with USDA, we plan to provide updated resources on what is exempt from IACUC review.

And we also will consult with the FDA to review and update OLAW's guidance on non-pharmaceutical-grade [substances] to further clarify the options for IACUC's review of such activities.

We also plan to review OLAW's prompt reporting guidance found in NIH Guide Notice NOT-OD-05-034, and to refine and update the examples of what are reportable situations to OLAW, examples of situations that are not normally reported, the timeframe for reporting, and the information that should be reported.

We will also be reviewing existing guidance and clarify the PHS Policy requirements for IACUC reports of departures from the *Guide for the Care and Use of Laboratory Animals* that are required in the semiannual report to the Institutional Official.

Slide 17 (NIH Steps to Improve Coordination)

We also are taking steps to improve coordination, as required by the law.

The 21st Century Cures Act specifically says that the agencies take steps to improve coordination of regulations and policies, and on this and the next slide are the steps that we plan to undertake:

OLAW, working with USDA, plan to allow annual reporting to both agencies on the same reporting schedule. The agencies will explore the development of a single reporting portal. We do not anticipate that this action will be able to take place for the 2019 annual report to OLAW, but we will be looking at this for the 2020 report to OLAW that would be due in the end of 2020. And we will have more information available on that later this year or early next year.

OLAW also has plans to change our instructions to the domestic Animal Welfare Assurance to support the use of AAALAC Program Description elements. This would enable consistency and limit the rewriting of responses relevant to both documents. We also plan to coordinate with AAALAC about options for harmonizing documents that would then meet both organizations' requirements. An institution's AAALAC Program Description would not be collected or viewed by NIH OLAW as part of this plan.

We also plan to provide a minimum of 60 days for comments regarding significant policy guidance. The type of guidance we're considering that would fall under this 60-day comment period would include such things as interpretations of the PHS Policy, the *Guide for the Care and Use of Laboratory Animals*, and the American Veterinary Medical Association Guidelines for the Euthanasia of Animals. Such guidance primarily will focus on high-risk animal welfare concerns and policy guidance changes as an outcome of the final report.

We also plan to review our disclaimer concerning OLAW's current guidance to emphasize that "unless specific statutory or regulatory requirements are cited, the guidance should be viewed as recommendations in that an institution may use an alternative approach if that approach satisfies the requirements of the PHS Policy."

Slide 18 (NIH Steps to Improve Coordination, cont.)

Here is the continued list of steps that we plan to improve coordination.

OLAW will review existing guidance on grant-protocol congruence in consultation with the NIH grants policy office, and clarify the requirements, and again we'll seek public comment on that updated guidance.

Although it's outside the scope of the 21st Century Cures Act, we also will, in coordination with USDA, engage with the Department of Defense and the Department of Veterans Affairs about options for harmonizing requirements that would reduce burden on investigators for those who receive support for their research with animals from these other federal agencies.

We plan to support the continued development of industry-led training through such educational venues as the ICARE workshops, the IACUC 101 Series, the IACUC Administrators Association Best Practices Meetings, the Scientists Center for Animal Welfare workshops, and the Public Responsibility in Medicine and Research conferences, and provide resources that would assist institutional leadership, IACUC members, and IACUC administrators in reducing administrative burden on investigators.

We will continue to support the efforts of the Federal Demonstration Partnership to create the Compliance Unit Standard Procedures (or CUSP) repository that reflect common practices for standard procedures used for research with animals. After the CUSP repository is piloted by Federal Demonstration Partnership institutions, NIH will coordinate with USDA to offer resources to IACUCs to integrate CUSP into their institutional processes to reduce administrative burden on researchers. Use of the CUSP repository would be optional and would also be open-access to the greater community.

In coordination with USDA, we also will continue to support the efforts of the IACUC Administrators Association to create a repository of IACUC common practices. After the repository is piloted, we will, in coordination with USDA, offer those resources to IACUCs to integrate those common practices into their institutional processes to reduce burden on investigators. Again, use of this repository would be optional and open-access to the greater IACUC community.

We also will simplify the OLAW sample animal study protocol form and pilot the revised protocol form through the Federal Demonstration Partnership. This process has already begun with a cadre of institutions that are part of the FDP that are currently working on developing a sample animal study protocol form.

We also will develop new website resources in coordination with USDA that focus on improving IACUC function, enhancing IACUC communication with investigators, and recognizing pitfalls that increase burden.

Slide 19 (21st Century Cures Act and USDA APHIS Actions)

And now I'm going to turn this over to Betty to talk about USDA's proposed actions.

Slide 20 (Objectives)

>>Betty: Thank you, Pat. I'm going to talk about a few of the proposed actions that are specific to the Animal Welfare Act (AWA) regulations and to USDA Animal Care.

Slide 21 (USDA Steps to Reduce Burden: Inspections)

We'll start with the IACUC inspections. Both the Health Research Extension Act and the AWA require the IACUC to inspect animal care and use facilities, including sites used for animal surgeries, every six months. A change in the frequency of those IACUC inspections would require statutory changes to both laws and it does have a likelihood of negatively impacting animal welfare. So as Pat mentioned, NIH in coordination with USDA, will develop guidance to address existing flexibilities while fulfilling the purposes of the Acts.

Section 2143(b)(3) of the Animal Welfare Act requires the IACUC to inspect, at least semiannually, all animal study areas and animal facilities of such research facility, and review as part of the inspection – (A) practices involving pain to animals, and (B) the condition of animals, to ensure compliance with the provisions of the AWA to minimize pain and distress. Exceptions to the requirement, or a flexibility, of inspection of such study areas may be made by the Secretary if animals are studied in their natural environment and the study area is prohibitive to easy access.

Another flexibility is in how and by whom the semiannual inspections are conducted. For example, the AAALAC site visits that are consistent with Section 2.31(c) of the Animal Welfare Regulations may be counted as one of the IACUC semiannual inspections.

Slide 22 (USDA Steps to Reduce Burden, cont.: Protocol Review)

Now with regard to protocol review, the agencies plan to review and enhance current resources to support IACUC use of existing options that streamline protocol review and significant changes to approved protocols. And this includes updated resources to encourage the use of designated member review for low-risk activities and for three-year complete review.

The agencies plan to provide updated resources on what is exempt from IACUC review.

And last but not least, USDA will propose, through notice and comment rulemaking, a regulatory change to Title 9, Chapter 1, Subchapter A-Animal Welfare, Section 2.31(d)(5), to remove the requirement that IACUCs conduct continuing reviews of activities covered by the Animal Welfare Act at appropriate intervals, but not less than annually; and instead of that, we would insert a requirement that the IACUCs conduct a three-year complete review of activities. IACUCs would continue to review, approve, require modification to, or withhold approval of significant changes regarding the care and use of animals in ongoing activities, as currently required by [9 CFR §§] 2.31(d)(7) and 2.31(e). This regulatory change would align USDA and NIH requirements and reduce the time and effort dedicated to reviewing protocols on an annual basis, while retaining the benefits of a thorough complete review every three years and ongoing review of any significant changes. And of course the IACUC may choose to review a protocol at any interval more frequently than three years as part of a program review.

Slide 23 (USDA Steps to Reduce Burden, cont.: Reporting)

As far as reporting goes, USDA recently developed an online portal for submitting annual reports, and we did include the research community in planning and developing the system. The online annual reporting system is already streamlining data submission, and we thank those of you who are already using the system.

We intend to expand that to allow [USDA and OLAW to do] annual reporting to both agencies on the same reporting schedule, as Pat mentioned, and hopefully through the development of a single reporting portal.

And then, USDA intends to pursue a regulatory change to Section 2.30(a)(1) which would eliminate the need to renew the research facility registration every three years. The annual report will be updated to contain sufficient information, and we can update our USDA records, and then no further information regarding the registration would be required.

Slide 24 (USDA Steps to Improve Coordination: Guidance on Federal Standards)

With regard to guidance on federal standards, USDA will make any revised and future policies involving the use of animals in research, teaching, testing, and experiments,

available for public comment using regulations.gov or some sort of similar service for public comment.

And we will include a statement on any policies, or in the policy manual to explain that such policies are clarifications or interpretations of the Animal Welfare Act and Regulations, which are the only legally binding requirements.

Slide 25 (USDA Steps to Improve Coordination, cont.: Agency Coordination)

And finally with regard to agency coordination, as Pat mentioned, we're going to engage with the Department of Defense and Veterans Administration to develop options for harmonizing requirements, which will help reduce administrative burden on those investigators who receive support for research with animals from multiple federal agencies.

Slide 26 (21st Century Cures Act: FDA Actions)

And with that, I'll turn it over to Brianna.

Slide 27 (Objectives)

>>*Brianna*: Thank you Betty and good day everyone. Today, I will discuss FDA's contribution to the 21st Century Cures Act. I will also discuss proposed actions by FDA to assist USDA and NIH in changes to the policies and guidance to reduce administrative burden on researchers.

Slide 28 (FDA Steps to Reduce Burden)

On August 24, 2016, FDA advertised a notice of the proposed rule to amend the Good Laboratory Practice (known as GLP) for Nonclinical Laboratory Studies regulations in the Federal Register. There was an initial 90-day comment period that was extended another 60 days. Over 3,100 comments were received from the public.

FDA's rulemaking with respect to part 58, the GLP for Nonclinical Laboratory Studies, is still ongoing. Any comments made in response to the 21st Century Cures Act Request for Information regarding the subject of the GLP rulemaking will be taken under advisement as finalization of the proposed rule is considered.

Slide 29 (FDA Steps to Reduce Burden, cont.)

In the next two years, NIH, USDA, and FDA intend to make progress on the steps and actions described in the report and will identify additional areas to protect animal welfare while reducing unnecessary administrative burden on researchers. Opportunity for public comment is planned throughout the roll out of new guidance and policy. NIH's Office of Laboratory Animal Welfare, in consultation with FDA, plans to review and update the guidance on non-pharmaceutical-grade [substances] to further clarify the options for IACUC review.

Slide 30 (Implementation)

Following the implementation of policy and regulatory changes in the next two years, the agencies plan to evaluate the outcome of the efforts to reduce administrative burden while maintaining scientific integrity and animal welfare.

Slide 31 (Evaluation of Steps to Reduce Burden)

We plan to enlist the assistance of our stakeholders in identifying what changes they have been successful in implementing at their institutions and the impact it has had on their investigators.

And now, I will hand it over to Neera.

Slide 32 (What did you like in the Report on Reducing Burden?)

>>Neera: Thank you, Pat, Betty, and Brianna that was quite informative. Now, we'd like to get some input from the audience. We've developed a series polling questions to address some of the proposed changes that were just discussed. There are no wrong or right answers, we simply ask for participants to please choose the option that you feel is most relevant to your institution regarding the reduction of burden.

[Audience Polling Questions—Continue to next page]

[Poll Question 1]

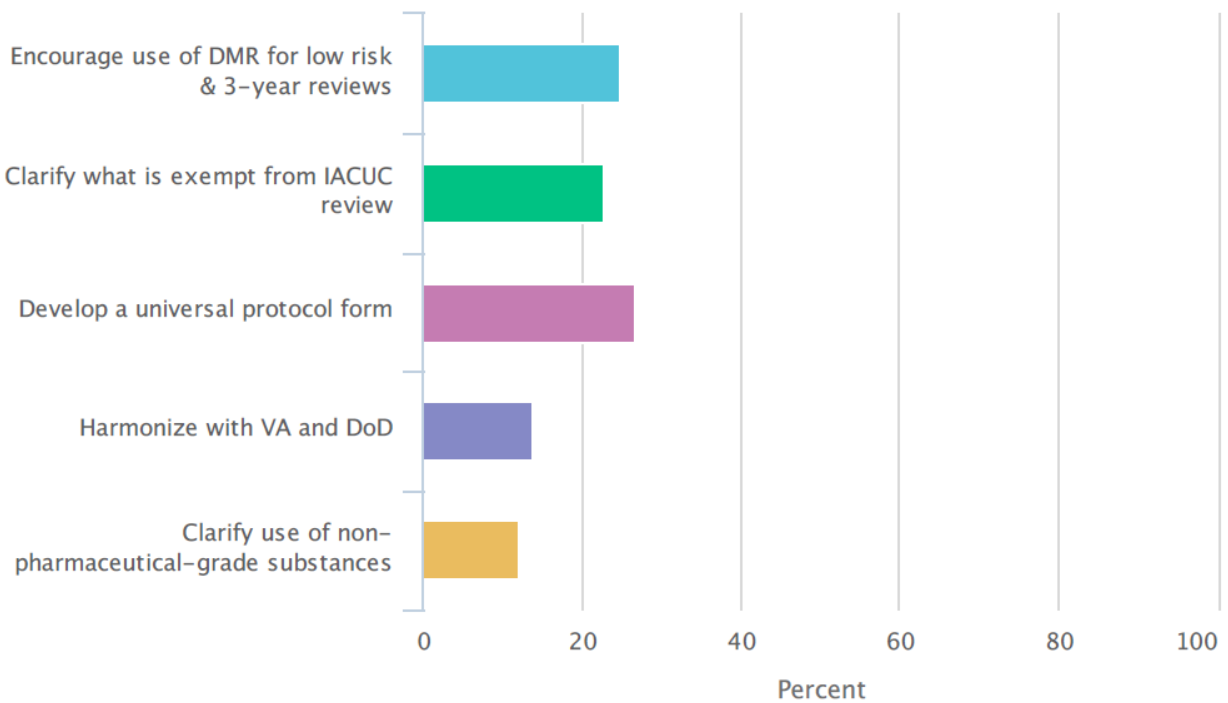
So here's our first question: Which NIH action would most reduce burden on your PIs? Would it be encourage use of DMR for low-risk and 3-year review? Clarification of what is exempt from IACUC review? Develop a universal protocol form? Harmonize with VA and DoD? Or clarify use of non-pharmaceutical-grade substances?

Audience, please vote.

I'll leave it open just for a few more seconds. We have 75% who voted so far. Okay. We have 84% voted... 85%. I'll go ahead and close out this poll, and let's see what the audience thinks what NIH's action would most reduce burden on their PIs.

And we have – it looks like there's an even distribution between encouraging use of DMR for low-risk and three-year reviews at 24%. Clarifying what is exempt from IACUC review at 23%. And developing a universal protocol form at 28%.

Which NIH Action would MOST reduce burden on your PIs?



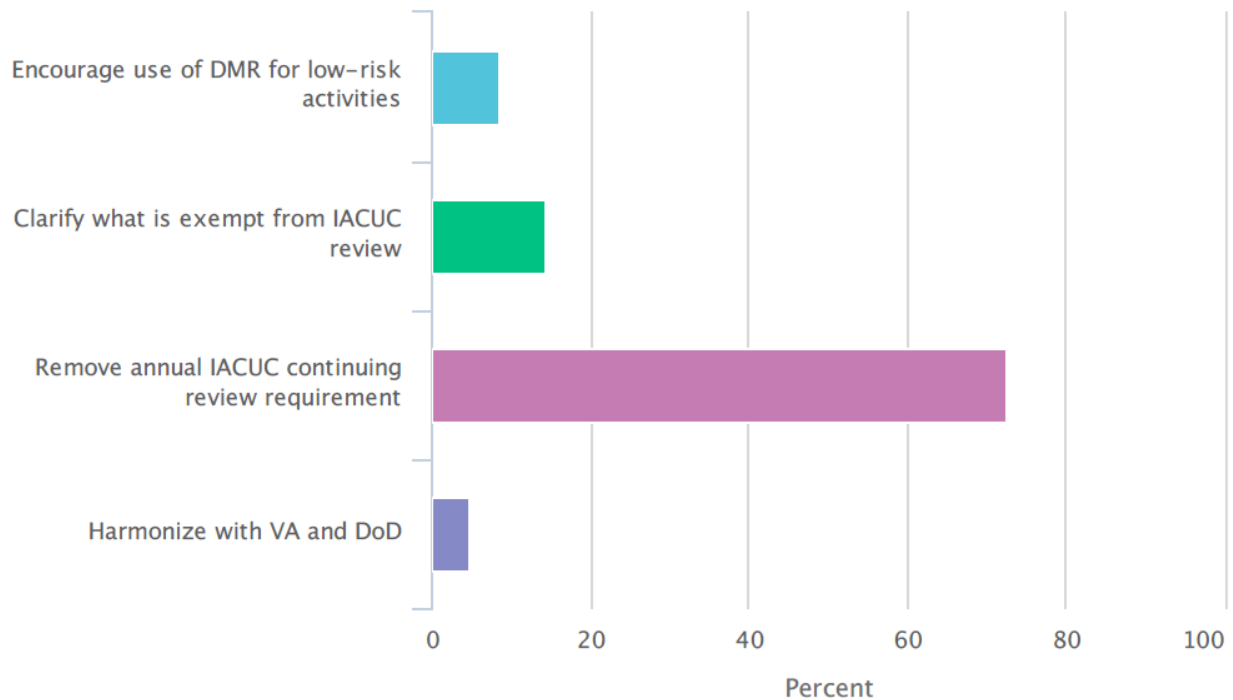
[Poll Question 2]

Let's go on to our second polling question: What USDA activity would most reduce burden on your PIs? Is it encourage use of DMR for low-risk activities? Clarifying what is exempt from IACUC review? Remove annual IACUC continuing review requirement? Or harmonizing with VA and DoD?

Please enter your response.

We'll leave it open for another 30 seconds. We have 86% voted. I'll close this poll. Let's see what the results are. There's an overwhelming majority selected remove annual IACUC continuing review requirement. That isn't surprising. This is followed by 14% that responded clarifying what is exempt from IACUC review. And nine percent encourage the use of DMR for low-risk activity.

What USDA activity would most reduce burden on your PIs?



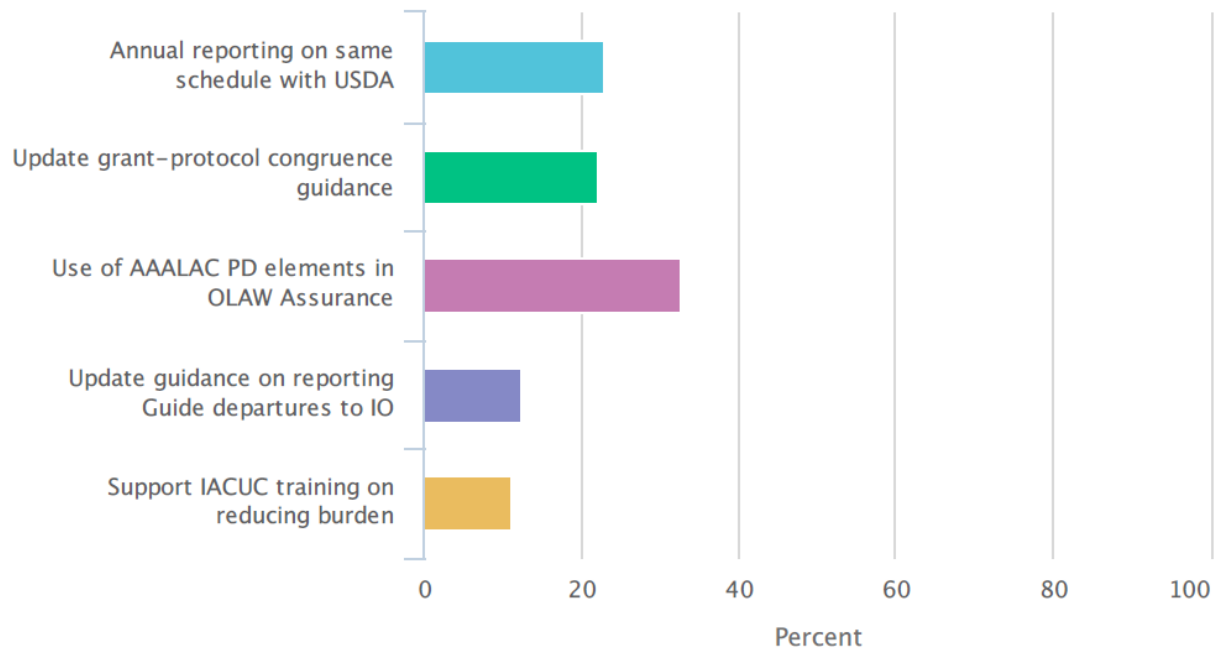
[Poll Question 3]

Our third polling question: Which NIH action would most reduce burden on your IACUC and animal care and use program? Is it annual reporting on the same schedule with USDA? Update the grant to protocol congruence guidance? Use of AAALAC Program Description elements in OLAW Assurance? Update guidance on reporting *Guide* departures to the IO? Or is it supporting IACUC training on reducing burden?

Please submit your answers, your response.

We have about three-quarters of the audience has voted so far. I'll leave it open for another 30 seconds. Okay. I'll go ahead and close the poll. And again, looks like there's split reactions or responses to this question. We had about 33% that stated they'd like the use of AAALAC Program Description elements – would reduce burden on their animal care and use program. This is followed by an even 22% split between annual reporting on the same schedule with USDA and updating grant-protocol congruence guidance. Trailing behind was updating guidance on reporting *Guide* departure at 12% and supporting the IACUC training on reducing burden at 11%.

Which NIH action would MOST reduce burden on your IACUC and animal program?

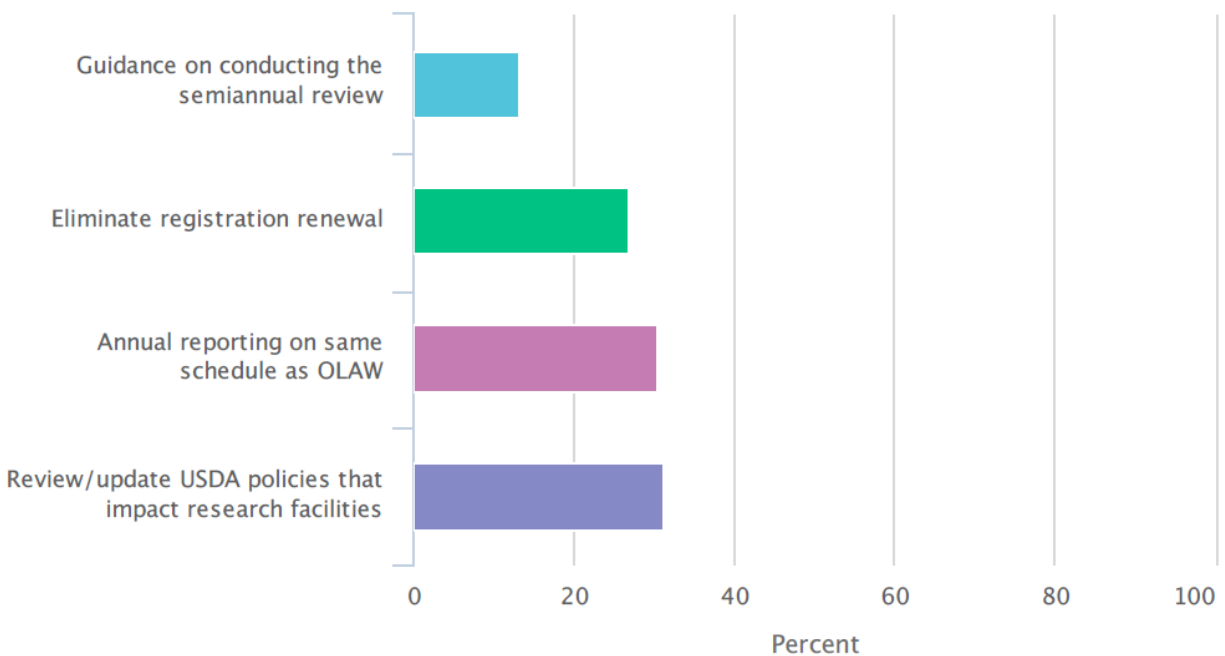


[Poll Question 4]

Let's move on, this is a USDA question: Which USDA action would most reduce burden on your IACUC and animal care and use program? Is it guidance and conducting the semiannual review? Is it eliminating registration renewal? Annual reporting on same schedule as OLAW? Or reviewing or updating the USDA policies that impact research facilities?

I have 80% voted so far. I'll leave it open for another 30 seconds. Okay. So I'll close this poll. It looks like we have another split response and it seems to be evenly distributed between annual reporting on the same schedule as OLAW at 30% and reviewing our updating the USDA policies that impact research facilities coming in at 31%. Trailing just right behind is elimination of the registration renewal process at 26% and guidance on conducting the semiannual review came in last at 13%.

Which USDA action would MOST reduce burden on your IACUC and animal program?

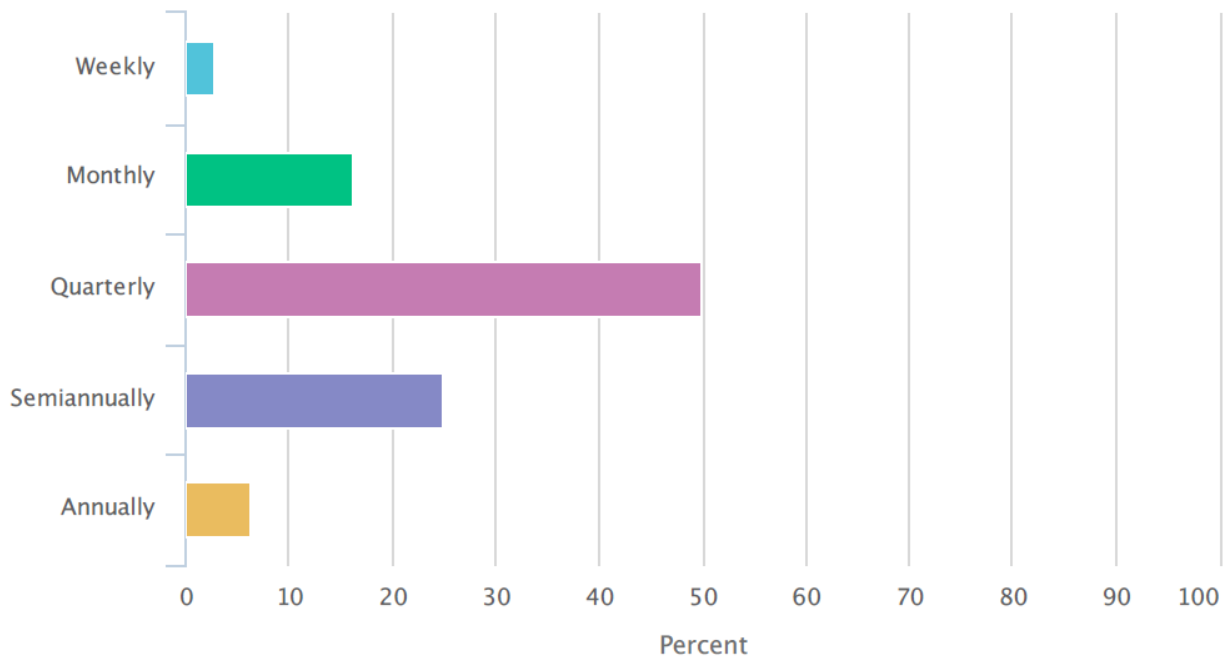


[Poll Question 5]

We have two more poll questions. And this one: How often would you like to be updated on the agencies' progress?

I'll leave it open for another 30 seconds. We have 85% voted so far. Let's close this poll. We had a majority, about half of our participants would like to be notified at least on a quarterly basis followed by 25% semiannually, 16% monthly, and annually there's a 6% interest in being notified on an annual basis and 3% of our respondents would like to be notified on a weekly basis.

How often would you like to be updated on the agencies' progress?

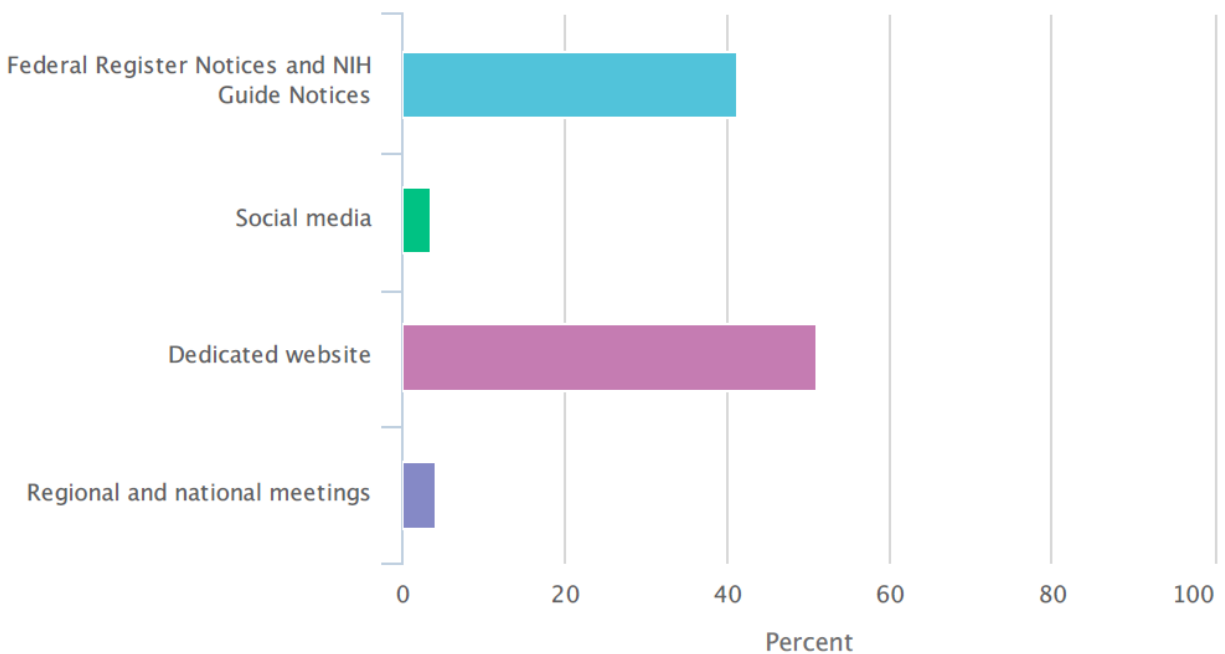


[Poll Question 6]

We have one final question: What is your preferred way to learn about updates on implementation of the 21st Century Cures Act? Is it through the Federal Register Notices and NIH Guide Notices? Through social media? A dedicated website? Or through regional and national meetings? Choose your most relevant response for this one.

I'll go ahead and close this poll and let's share. And we had 51% of our respondents voted in favor of a dedicated website. Trailing just close behind is 42% where they would like to be notified through Federal Register Notices and NIH Guide Notices. Social media and regional and national meetings don't seem to be as popular. They came in at 3 and 4%, respectively.

What is your preferred way to learn about updates to implementation of the 21st Century Cures Act?



Slide 33 (Questions?)

I'd like to thank everyone for participating in these polls. This helps us better understand our stakeholders needs, as well as it gives us a perspective to prioritize 21 CCA actions.

We now have time for some questions, and I am sure the listeners have a lot of questions. Listeners, please type your questions into the chat box on your webinar control panel. OLAW may edit the questions for clarity, duplication, and fidelity to today's topic.

Now we'll move on to some questions that we received prior to the webinar.

Slide 34 (Question 1)

>>Neera: Our first question is "Did the recommendations made in the 21st Century Cures Act report consider programs that used diverse animal species including wildlife, USDA-covered species, and lab rodents? Pat, would you like to answer this one?"

>>Pat: Sure, Neera. The Working Group received input from numerous institutions and researchers that conduct biomedical research of all types and use a diversity of species in their research. All of those were considered, and all comments that we received were given thoughtful consideration in the development of the recommendations that became the agencies' action plans in the report.

>>Neera: Thank you, Pat.

Slide 35 (Question 2)

Our second question is "How will you engage with stakeholders while implementing 21st Century Cures Act action items?" Pat, again, would you like to answer this question, as well?"

>>Pat: Certainly. From the answers to the polling questions, there is interest in the agencies using multiple communication methods. Along with notifications through various means, we are also considering creating webinars and podcasts as resources to explain how the new policy guidance may be implemented by IACUCs. We will be looking for institutions willing to try out the new policies and then share their experiences with the greater community on how the changes impacted their programs. So if you're interested in volunteering, as we roll out this guidance, get in touch with us.

>>Neera: Great, thank you, Pat.

Slide 36 (Question 3)

Our third question, moving right along, is "How do you intend to evaluate the agencies' ongoing efforts to reduce administrative burden?" Pat?

>>Pat: We would like to enlist the organizations that play key roles in sharing information with and representing the researchers and the IACUCs. Examples of those organizations include the Federal Demonstration Partnership, FASEB, COGR and AAMC, plus NABR, the IACUC Administrators Association, and PRIM&R, just to name a few. We envision a

cooperative, collegial engagement to evaluate what is working, what is being implemented, and what still needs further refinement.

>>Neera: Thanks, Pat.

Slide 37 (Question 4)

Our fourth question is a bit long, but it brings up important points about how critical semiannual inspections are to animal welfare. The question is: In the final report, OLAW indicated that animal welfare would be negatively impacted by reducing semiannual inspection to annual, rather than semiannual. It was cited that "approximately 7% of the self-reported noncompliant incidents were identified during semiannual inspections." What percent of the 7% cited actually involved animal welfare? Pat, this one is specifically for you.

>>Pat: That's a great question, Neera. As this pie chart shows you, there were direct impacts on animal welfare in 50% of reported noncompliance to OLAW that were identified during semiannual inspections. As I said, just a few examples are demonstrated up here on this pie chart. The ones I'd like to point out are:

- Improper euthanasia with dry ice
- Finding inadequate postsurgical monitoring with complications and/or failure to report the complications to the veterinarian
- Live and dead mice found in the dirty side of cagewash
- Unapproved activities with mice there were resulting in 40% weight loss
- Mice housed in unapproved locations
- There were many examples of deviations from approved protocols involving failure to provide analgesics or use of unapproved anesthetics
- Failing to properly wean animals resulting in younger litters being injured
- Failing to euthanize animals in timely manner

There was an additional 13% of the reports where it was unclear in the report itself the direct impact on animals. But, the nature of the noncompliance that was reported had a very high risk of impacting animal welfare. An example is use of expired drugs and, in particular, the use of expired analgesics.

89% of the reported noncompliance had the potential to impact animal welfare. An example is failing to give post-op analgesia when no clinical signs of pain were reported, but there was still certainly a potential for observable impact on animal welfare, because failing to give analgesics post operatively has a high probability of increasing pain. A similar example would be failure to apply aseptic technique. Not having dehiscence or infection may be due to luck or to the use of antibiotics, but it is a high potential risk to animal welfare that would qualify.

Slide 38 (Question 5)

>>*Neera*: Excellent response, thank you Pat. Question 5. This next question is specifically for USDA. The question is, "When can we stop conducting the annual continuing review?" Betty, would you like to answer this one?

>>*Betty*: Yes, thanks Neera. The answer is, not yet. I'm really happy to see support for this change, but this will require a regulatory change and that takes time. The process includes a proposed rule for public comment, then the agency will review the comments and make any necessary adjustments, then a final rule can be published with an effective date. We will keep you informed every step of the way, but until there is a new final rule in place, until the final new rule, the current regulation stays in effect. So we have to continue the reviews no less than annually.

Slide 39 (Question 6)

>>*Neera*: Thank you, Betty. The next question is also for you. "When will the USDA Policy Manual be reposted?"

>>*Betty*: That's a good question. We are going to be moving very deliberately and transparently as we review and re-propose these policies. I think you'll see one policy at a time posted for review and comment. Once we have completed the opportunity for comment, and we make sure there is no added burden or regulatory overreach, then we'll post them as we get them approved. Some of the previous policies that we had are no longer needed and probably won't come back but we do recognize that some of the topics were helpful in clarifying the regulations and we're going to work through those one by one.

>>*Neera*: Thank you, Betty. I know we're all interested to see the new manual when it comes out.

Slide 40 (Question 7)

And one of our final pre-advanced questions are directed towards Brianna last, we have two questions specifically for FDA. The first question is: "At what stage of review are the GLP rules?" Brianna?

>>*Brianna*: Thank you, Neera. FDA is still reviewing comments to the proposed rulemaking, and as we explained before, it takes a while for these types of changes to occur.

>>*Neera*: Thanks, Brianna.

Slide 41 (Question 8)

And last but not least, "When will the next version of the GLP rules be available for public review?"

>>*Brianna*: FDA will coordinate with NIH and USDA as per our MOU for the final clearance before the final rule is published.

>>*Neera*: Thank you, Brianna.

Slide 42 (Questions?)

Now we'll move on to some questions that we received from the participants. We have about three minutes left.

[Question 9]

Our first question is something that was not discussed but would be helpful would be harmonization of the actual annual report content that is required for USDA and OLAW. Pat or Betty, can you comment on that, having the content of the annual reports being similar for the USDA and OLAW?

>>*Pat*: This is Pat. Well, the issue here is that the requirements that USDA has for what needs to be reported in their annual report are quite different from what the PHS Policy says are required elements in the annual report to OLAW. We do not intend to have those be merged into a single document. They will be – you'll be submitting that information to each of us as you already do, but you will be doing it through a shared portal and you will be doing it on a similar time schedule to what USDA currently requires, which is by December 1st. OLAW will be transitioning to that schedule in the coming year and we will be giving you updates on how we expect you to do that. As I said, either later this year or early next year.

[Question 10]

>>*Neera*: Okay. I think we have time for just one more question. Betty, this one is directed for you. Would the USDA consider changing semiannual inspections to annually? And would you amend the AWA?

>>*Betty*: The USDA can't make a change in the Act, so opening up the Act to change that would be above us. That would be a congressional action. And I think that the semiannual – as Pat showed and as we know from experience with our inspections, it's a very useful activity. We think that the IACUCs are doing great work out there with the semiannual inspections. And I don't see any change in that in the immediate future.

>>*Neera*: Okay. Thank you, Betty.

Slide 43 (Next Webinar)

So, we've come to the end of the questions. These are all interesting questions, and for such an interesting and hot topic. If you listeners think of additional questions in the next week or two as you reflect on this webinar, please send them in to us and we will impose on Pat, Betty, and Brianna to answer them, and then amend them to the end of the transcript, which we'll be posting on the OLAW website. My thanks to all of you – Pat, Betty, and Brianna, and especially to our participants. You have all been incredibly generous with your time.

We look forward to meeting with you again at our next OLAW Online Seminar on March 12, 2020. Ted Myatt at the University of Rhode Island will discuss his work on Building a Research Occupational Health Program. In this interactive session, Ted Myatt will discuss strategies to gain support of senior leadership, build a team, develop a sustainable program, and implement continual improvement processes to ensure that your program complies with requirement as described in the *Guide for the Care and Use of Laboratory Animals*, 8th Edition, the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids, and U.S. Occupational Safety and Health Administration (OSHA) standards.

I wish everyone safe and Happy Holidays! Thank you, and goodbye!

Additional Submitted Questions Not Addressed During the Webinar

Question A: It is my understanding that the AAALAC visit could always be used in lieu of the IACUC [semiannual inspection], as long as it met the 6-month criteria. Betty, what is different in what you stated?

>>*USDA:* That's correct. For many years it has been possible to use the AAALAC site visit as one of the semiannual IACUC inspections. I brought this up because we think it is an underused flexibility. This is just one of several flexibilities that are available to reduce the burden of the semiannual without impacting scientific integrity or animal welfare.

Question B: PHS Policy footnote states: "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 report." Based on this footnote, OLAW allows the IACUC to delegate the conduct of facility inspections and program reviews to at least one trained and qualified individual on its behalf as long as the IACUC remains responsible for the evaluation and report. Will USDA adopt the same?

>>*USDA:* The AWA is prescriptive as to the conduct of the semiannual facility inspections and program reviews. Ad hoc consultants are currently allowed and encouraged as needed but Section 2143 (b)(3) of the AWA requires that the "Committee shall inspect at least semiannually" and therefore Animal Care does not have the authority to approve delegation of that function.

Question C: Will the current Designated Member Review (DMR) process be reviewed as part of the streamlining process?

>>*USDA:* We aren't going to review the DMR process itself, but we are going to look at a wider application of DMR. Judicious use of the DMR process can result in effective oversight while reducing the burden of using FCR.

>>OLAW: OLAW has no plans to change the DMR process as it is described in the [PHS Policy IV.C](#). OLAW's guidance will focus on the effective use of DMR by IACUCs and how it allows for an efficient IACUC approval.

Question D: Can USDA APHIS make the eAuthentication procedure less demanding and easier?

>>USDA: There have been recent changes that made eAuthentication less onerous. And we have heard that there are further improvements in the works. That said, eAuthentication is a department-wide security requirement and although Animal Care and APHIS provide feedback, USDA's Chief Information Officer is responsible for the security of the information and has the final say on security requirements.

Question E: Guidance pointing to using DMR for "low risk" activities, including 3-year renewals, would be backtracking. In the past, OLAW has always stated that DMR is an EQUAL review method as FCR. Taken literally, institutions may now only consider DMR for "low risk" activities instead of a primary/default review method.

>>OLAW: While no distinction is made in the PHS Policy between Full Committee Review (FCR) and DMR in terms of fulfilling PHS requirements, OLAW acknowledges that some institutions prefer to leverage the expertise of the full IACUC in its deliberations. One way to keep these benefits while reducing self-imposed administrative burden is to utilize DMR for low-risk activities.

Question F: While eliminating semiannual inspections may not be possible given the cited findings, is there a possibility of a risk-based model? For example, labs with no findings on three consecutive inspections move to annual until they have a finding. This provides an incentive for labs to strive for compliance and is consistent with federal agencies efforts on risk-based analysis.

>>USDA: As I mentioned, the AWA is clear on the semiannual inspections and the agency does not have the statutory authority to change to a risk-based model.

>>OLAW: The [PHS Policy IV.B](#) requires IACUC's to inspect the institution's animal facilities (including satellite facilities) semiannually. OLAW has no plans to change the PHS Policy. However, there is much flexibility in the Policy for who conducts the inspections and how IACUC's oversee locations that do not qualify as animal facilities or satellite facilities. OLAW plans to expand guidance on the flexibilities that the PHS Policy allows.

Question G: What types of clarifications are expected to be included within the guidance for grant congruency?

>>OLAW: OLAW will provide clarification on the following:

- a) The institution and not the IACUC is responsible for congruence to ensure that the animal activity described in the grant has been reviewed and approved by the IACUC.

- b) There is no requirement for a one to one relationship between the grant and the approved protocol. There can be more than one protocol associated with each grant, or one protocol associated with more than one grant.
- c) A congruence review only needs to be conducted at the time of award and does not continue into the life of the project.

Question H: [Questions pertaining to timeframe]

- 1) When will the annual renewal requirement be officially removed?

>>USDA: This will require a change to Section 2.30(a)(1) of the AWAR. We are hoping to publish a proposed change sometime next spring. Then there will be a comment period and time for review and adjustments. Best case scenario, we'll have a final rule in 2020 with an effective date sometime in 2021.

- 2) What is the timeline for actually changing the guidance discussed in this webinar?

>>USDA: The guidance can happen relatively quickly and OLAW and USDA staff are already working on it.

>>OLAW: OLAW staff are diligently working on revising guidance on several topics concurrently. OLAW plans to have the first guidance rolled out in 3-6 months for public comment.

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