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Congruence Review

Speakers:

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- Jennifer Klahn, MA, CPIA, Director, Research Safety & Animal Welfare, Institutional Contact for Dual Use Research, University of California, Los Angeles

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Slide 1: Congruence Review

>>*Nicolette Petervary:* Good afternoon. I'm Dr. Nicolette Petervary, part of the NIH Office of Laboratory Animal Welfare. Today is Thursday, January 18th, 2024, and I'm pleased to welcome you and our speakers to our webinar today on Congruence Review.

There are just a few housekeeping details before we get started. If you have questions throughout the webinar, please enter them in the Q&A box. The Q&A box does allow questions to be submitted anonymously. The chat will also be enabled for this webinar. We will be taking questions at the end of the webinar, but if we run out of time or if the question is a little more nuanced or context-specific before the questions to our presenters after the webinar, and then we'll append the questions and answers to the end of the transcript. We'll monitor the chat as best we can, and we encourage you to use it to interact with us and with other participants.

The slides, transcript, and webinar recording will be available after the webinar on our website. They do need to be processed for 508 compliance compatibility before posting, and this can take a few weeks, so please bear with us.

I'll start with an introduction for our speakers, then provide a brief overview of OLAW guidance on congruence review before our speakers share their perspectives. Dr. Julie Sharp is the Executive Director of the Institutional Animal Care and Use Program at the University of California, San Francisco. In this role, she collaborates with faculty and research staff to facilitate their research endeavors while focusing on program and process improvements to reduce regulatory and administrative burden.

She's been involved in animal care and use programs at both public and private academic medical centers since 2003, including Duke University Medical Center, the University of Pennsylvania, and the Research Foundation for the SUNY Downstate Health Sciences University. Dr. Sharp received her Doctor of Veterinary Medicine degree from North Carolina State University, is a Certified Professional IACUC Administrator, and a diplomate of the American College of Laboratory Animal Medicine. She actively

participates with the Federal Demonstration Partnership's Compliance Unit Standard Procedures project as part of the 21st Century Cures Act and serves as an AAALAC International ad hoc specialist.

Jennifer Klahn is the Director of Research, Safety, and Animal Welfare and Institutional Contact for dual-use research at the University of California Los Angeles, aka, UCLA. Jennifer began her career in IACUC administration in 2000, and under her direction, the UCLA IACUC office has expanded to include administrative support for the Institutional Biosafety Committee, Radiation Safety Committees, dual-use review entity, and other safety committees. In addition to her role at UCLA, Ms. Klahn serves as faculty for the Inter-Agency Collaborative Animal Research Education, or ICARE Project, and is a member of the Board of directors for the California Biomedical Research Association. She has five cats.

And now let's get started with an overview of congruence review.

Slide 2: Let's Grow Knowledge About Congruence Review by Starting with the Basics

It's always good to begin with the basics, so let's lead with explaining what congruence review is. Congruence review is the process that ensures that the information in IACUC-approved protocols reflects the information in the application to be awarded. It's not specified as an IACUC responsibility, rather it's an institutional responsibility. The signature of the authorized organization representative on the application certifies that the organization will comply with all applicable federal laws and regulations, including required certifications such as verification of IACUC approval prior to award.

Slide 3: What Congruence Review is Not

It's also important to note what congruence review is not. It's not a requirement for a side-by-side comparison of an entire application with a protocol, and it's not a requirement for everything to be perfectly identical. Also, it's not a requirement for a one-to-one relationship between one single grant and one single protocol. More than one protocol may be associated with one award and vice versa.

Slide 4: Other Terms and Concepts (1)

So let's go over some terms and concepts, just in time or JIT allows certain elements of an application for funding, such as verification of IACUC approval, to be submitted later in the application process. And it permits increased efficiency since instead of writing and approving protocols for every application, you can focus on the ones most likely to be funded once you know that an application is competitive. Applicants are notified primarily by email when just-in-time information is needed, but please be aware that this is not a notice of award. So that's very important to keep in mind. It's also important to keep in mind that just-in-time procedures vary with the NIH funding Institute or Center, so you will need to consult with the applicable Institute or Center on specifics. And you can read more about just-in-time procedures in the NIH Grants Policy Statement section 2.5.1.

Slide 5: Other Terms and Concepts (2)

Restricted awards are usually processed at the end of the government fiscal year when upon request by the NIH funding component. NIH may issue restricted awards because of the limited time available to fulfill requirements for assurances and/or verification of IACUC approval. And this allows NIH funding components in conjunction with OLAW to issue awards with the restriction that live vertebrate animal activity cannot commence or be charged to the award until all necessary documentation is in place. On occasion, restricted awards have been provided for non-NIH funding entities, but this is upon request.

Slide 6: What Grant Applications Require Congruence Review?

Okay, so what grants applications require congruence review? Well, it's required prior to initial award, prior to competing continuation renewals, and in competing revisions in which use of live vertebrate animals is added where there was no live animal vertebrate animal use before.

Slide 7: How Often Does Congruence Review Need to be Repeated?

Congruence review is not required beyond the initial review at the time of award for the application types on the previous slide.

Slide 8: Overview: General Process

And I thought I would present a flow chart of the approximate process, obviously, this varies but this is a very general overview for most situations, and assuming the institution elects to use just-in-time procedures, the process begins once the PI is notified. The PI drafts and submits the protocols to the IACUC for review and approval and the next step is congruence review. And I purposefully made this a black box because there are many flexibilities for congruence review and our presenters will talk about some institutional perspectives on how to conduct reviews later in this talk.

The office or division responsible for the review determines if the protocol and award applications are congruent. If they are, institutions can submit verification of IACUC approval, but if they're not, there may be a lot of players involved to resolve any issues. And these may include the PI, the IACUC, the grants management officer of the NIH funding component or appropriate funding entity contact, and the institution's authorized organization representative as applicable.

Slide 9: Why Congruence Review is Required

A lot of people have pointed to the changes in the common rule for IRB applications and erroneously assume that activities involving human subjects no longer have congruence verification requirements. They argue that because of this, the congruence verification requirements for animal research should also be removed, but this is really based on a misconception. Under the revised common rule, NIH no longer requires IRB review of the entire grant application, however, recipients must certify to the NIH that the IRB has reviewed and approved the human subject research, in other words, the IRB protocols and provide the date of approval. So in fact, the revised common rule actually mirrors the requirements for congruence review for proposed animal use.

Slide 10: How is Congruence Review Performed?

Congruence review actually is very flexible. Many offices can do it, and the only requirement is that the staff are appropriately trained and qualified and as mentioned before, a compliant review does not require exact equivalence. The review should confirm that the species and all procedures agree and that animal numbers proposed are approximately similar. Most of the time, the two main parts of the application to focus on are the vertebrate animal section and the approach portion of the research strategy section of the applications.

Slide 11: Messier Situations

But there are some messier situations, and we'll talk about those next.

Slide 12: Messier Situations: Animal Work for Year 4 or 5 of the Grant

For instance, what about animal work for year four or five of the grant? And OLAW has an FAQ that addresses this, and you can find the URL at the bottom of this slide.

The FAQ allows for a brief description of the animal activities planned for the fourth and fifth year of the award period in the protocol recognizing that the experimental details and procedures will be refined or amended at a later time, or at the time of the three-year renewal.

Slide 13: Messier Situations: Different PI on the Protocol and Application

OLAW has an FAQ for another common question, and that is whether the PI listed on the application and the protocol need to be the same. And the answer to that is no, they need not be the same. And you can read more by going to the URL at the bottom of this slide.

Slide 14: Messier Situations: IACUC Requires Change to the Protocol (1)

If the IACUC requires changes to the protocol, it can be a little trickier to find out what to do. The IACUC absolutely has the authority to request changes, but some changes do require prior approval from the NIH funding component or funding organization, and these include things like a change in scope.

There are several indicators of a potential change in scope such as a change in specific aims, a shift in the research emphasis, or use of a different animal model. Absence of key personnel is another issue that may require prior approval, and you can read about these requirements in more detail in section 8.1.2. of the NIH Grants Policy Statement as well as OLAW FAQ D.21. The URLs are at the bottom of this slide. And for such changes funded by other entities that are subject to the PHS policy, and for example, these would include, the PHS, the NSF, NASA, and the VA, please contact those funding entities directly. These entities require congruence review as well, and we'll discuss that in a little more detail later in the talk.

Slide 15: Messier Situations: IACUC Requires Change to the Protocol (2)

It's important to note that if the IACUC requires changes to the protocol that are not reflected in the grant application, then at the time of certification of IACUC approval, the institution must notify the funding entity of the changes per the PHS policy IV.D.2. And for NIH applications, it's the responsibility of the institution to communicate any IACUC-required changes to the NIH funding component as part of just-in-time information.

Slide 16: Messier Situations: IACUC Requires Change to the Protocol (3)

For NIH applications, the just-in-time feature in eRA Commons allows the authorized organization representative or signing official to electronically submit additional grant application information, such as the IACUC required modifications. PIs can upload the just-in-time information into eRA Commons for the authorized organization representative to submit. So that makes it a little bit easier hopefully.

Slide 17: Applications to Other Funding Entities (1)

And up until now, we've focused mainly on NIH funding components, but now we're going to talk a little bit about other entities such as other PHS entities, the VA, the NSF, and NASA. And congruence review is actually required for all entities complying with the PHS policy.

PHS policy IV.D requires the institution to verify before award that the IACUC has reviewed and approved those components of grant applications and contract proposals related to the care and use of animals.

Slide 18: Applications to Other Funding Entities (2)

So the congruence review requirement applies to NIH and PHS applications, but in addition, it applies to the VA, NSF, and NASA because these entities have directives or guidance that require compliance with [the] PHS Policy. So congruency is a requirement pretty much for all of these entities, however, specific processes may differ, and other funding entities may have additional requirements. So please contact the funding entities directly for specific instructions.

Slide 19: Contracts

Contracts are also subject to the requirement for congruence review. The basis is a little bit different. It stems from the Health and Human Services Acquisition Regulation, but as with grants, verification of congruence review is required prior to award and is an institutional responsibility. It's not a required IACUC function, and it may be performed by other qualified institutional personnel with responsibility designated to a specific office or position, for example, sponsored programs or compliance office. And you can read NOT-OD-22-006 for more information. The URL is on the bottom of this slide.

Slide 20: References: Grants and Contracts

And finally, the last four slides have resources regarding congruence review and will be posted on the OLAW website for this webinar. Resources are divided into categories like the ones on this slide which are applicable to both grants and contracts.

Slide 21/22: References: Grants; References: Contracts

Those for grants only, those for contracts only

Slide 23: OLAW Recorded Webinars

and prior OLAW-recorded webinars. And now I'll let Julie and Jennifer take it from here.

Slide 24: Grant Congruency Common Challenges

>>*Julie Sharp*: Thank you for that information, Nicolette. It's been a really helpful review for us and for the next portion of the webinar, Jennifer and I have put together some of our challenges that we encounter with the grant congruency process and wanted to share our institutional perspectives with the group.

Slide 25: Index: Common Questions

These are some common questions and struggles that we encounter with the various components of grant congruency, and we'll cover them individually in more detail in the following slides. And as a part of that, we'll share our perspectives as we go through them, including additional information from OLAW on each of these topics.

Slide 26: Who Confirms Congruency?

So for the first one, who confirms grant congruency? We would like to launch a poll question to get an idea from all of you, who performs grant congruency at your institution. And please note that you can select multiple responses if this is a shared responsibility at your institution. So we'll wait just a minute here while people provide their response. [silence]

>>*Nicolette Petervary*: Remember, you can select all that apply. It looks like it's slowing down, so we'll give it another few seconds. We have a few more coming in. Okay. So you can see that it's all over the map here.

>>*Julie Sharp*: Okay, well, not surprisingly then this demonstrates the flexibilities that we all have in performing the congruency review at your institution. And certainly, any of these can work for a given program regarding which individuals perform congruency review of the elements that were just detailed by Nicolette. And so whichever approach you select, it'll be relevant to where this expertise is within your institution and your program's level of risk.

So in my experience at previous institutions, this was done by IACUC members maybe when assigned a corresponding protocol for review as well as IACUC leadership, whether that's the chair or vice chairs. And at UCSF predominantly this relies upon the IACUC office staff, [which] looks like [the case for] a majority of our poll respondents. So-- and as you all know, depending on the volume of the awards and the bandwidth of your staff with other activities, performing the grants congruency can definitely require quite a bit of time and effort, especially if they're not congruent. Jennifer, what's your experience with this?

>>*Jennifer Klahn*: Yes, thanks, Julie. So for context, at UCLA congruence reviews are handled by the IACUC and the IACUC office. We have a funding page in our online protocol, and we expect that all extramural grants and contracts that are associated with the IACUC protocol will be listed on that page and then a proposal uploaded to the system so that it can be reviewed. The approval notice that we

generate upon completion of the IACUC review process includes all funding listed in the protocol. And this communicates to whoever sees the approval notice that the animal activities included in the listed awards are covered by the protocol. So when I started my IACUC career many, many years ago, we asked our researchers for their assurance that the animal activities in the grant or contract were covered by the approved protocol. And we do still ask that question, and I'll talk about this a little bit more on the next slide.

But we also perform a review of the proposal against the protocol, and this can be done a couple of ways. So if this is submitted as a funding-only amendment to a previously approved protocol, or if it's a submission that's going through our designated member review process, the congruence check will be done by our chair or one of the vice chairs or the assigned designated member reviewer. If the protocol is going through a full committee review process, we assign a scientist, a veterinarian, and a community member for those reviews. And the scientist member would be asked to and expected to perform the congruence review. And in some urgent cases, myself or other staff will perform congruence checks.

>>*Julie Sharp*: Thank you, Jennifer and Nicolette, what additional information does OLAW have about this?

>>*Nicolette Petervary*: So there's a lot of flexibility with who conducts congruency review and who confirms the grant congruency. It can be performed by individuals provided that they're appropriately qualified and trained. However, it's the signature of the authorized organization representative on the application that certifies that this was done and that the organization will comply with all applicable federal laws and regulations, including the required certification, such as verification of IACUC approval prior to award. So once again, that signature is the signal that this has been performed. It is important to keep in mind that who you decide to conduct a congruence review can vary with an institution, but also vary with risk tolerance.

I know that there are some institutions that have the PIs confirmed congruency. If that's being performed, just be very careful because they may not be aware of all of the requirements of conducting a congruence review. They have to be very well trained, and it's probably a good idea to verify that before relying on a certification from the PI. They may not have the background to understand what's required for that process.

>>*Julie Sharp*: Thank you.

Slide 27: How Many Grants Can I Associate with a Protocol?

>>*Julie Sharp*: Okay. For our next question, how many grants can we associate with a protocol? And as you can see here on the slide, there are multiple options for associating grants to protocols. And the approach that your program takes may vary depending on a number of factors, including capabilities of any electronic systems that you may use, your staff bandwidth, and any program-specific preferences or requirements. Once you go beyond that one-to-one option at the top, consider how you're tracking this for future reference so that you can always go back to see how you conducted the congruency review and the documents that you used for reference. When using these more complex associations, we work hard to keep in mind that this is a one-way review of the grant information to the protocols because in these scenarios, it's common that the protocol will include more than what's described in the grant, especially when there's multiple funding sources.

And that's okay. You know, we're looking to confirm that the animal work within the grant is approved by the IACUC, whether it's within a single protocol or by portions of multiple protocols depending on the

nature of the work. You know, for instance, you might have multiple PIs at your institution that are collaborating and each of them is performing part of the grant work under their respective protocols. You may have species-specific requirements such as USDA-covered species being maintained on separate protocols from non-USDA-covered species, and your grant might include both. And the PI might have multiple protocols of their own and so they're using them to perform maybe separate specific aims from the grant. And the grant may include offsite collaborations that you'll need to consider as well. And we'll talk about that in more detail a little bit later on.

In my experience, I've worked at programs that have used all of these options here on this slide. And the few that were one-to-one eventually transitioned to the other options. You know, the goal there is to reduce regulatory burden on the PIs and the administrative offices with the number of protocols that you are creating, and reviewing, and maintaining. And if your program uses electronic systems for IACUC protocol content and workflow, maybe your grant's tracking and how those are associated and even per diem charges, this may be as detailed as "which cage is being charged to which grant" and the funding source, the level of integration and complexity of the various systems can really introduce additional challenges in how you want to approach this and are going to be unique to each institution. Jennifer, what are your thoughts on this?

>>*Jennifer Klahn*: Yes, thanks. So I'll say that the first option, that one-to-one grant to protocol, certainly seems like the easiest approach [LAUGHTER] for the IACUC office, the IACUC and whoever's doing that congruence check. But it certainly has the potential for increasing burden across the board. The third option, that multiple grants [to] one protocol, is one I often see. Option two, one grant [to] multiple protocols, that introduces some complexity and challenges for congruence checks and potential follow-up. I mentioned that we ask for PI assurance that the animal activities in the grant are covered by an approved IACUC protocol. Our protocol form collects the usual information about an award. So the PI's name, the title, the sponsor, the award number, and it also includes this, yes/no question regarding whether all of the animal work in the grant is covered by the protocol.

And so if the answer to this question is no, indicating that there are some discrepancies, the researcher is prompted to provide details about the animal work in the grant that is not covered by the current protocol. The types of responses we see include that activities are not in the current protocol because maybe this is a new investigator to our institution and they completed some of the work at another institution, or some of the animal activities in the grant are covered by another protocol either at UCLA or elsewhere. So in that latter case, we'd still want to perform a congruence check because we're the responsible party as the award recipient. So we'll obtain the UCLA protocol information or request a copy of the protocol and the approval notice for the offsite work.

>>*Julie Sharp*: Thank you, Jennifer. Nicolette?

>>*Nicolette Petervary*: So as you've heard from our presenters, you can have one-to-one, one-to-many, or many-to-one relationships and institutions are free to choose whichever process works best for their organization while maintaining compliance with the congruence requirements. So as both of our presenters have mentioned, careful tracking is critical for self-reporting in addition to being critical for congruency, especially in instances where charges are to be removed possibly because of a suspension or a non-compliance. So, you have flexibility, just make sure that whatever you're doing really works for you and meets the requirements.

>>Julie Sharp: Yes. Thank you.

Slide 28: How Can We Facilitate Communication & Documentation?

>>Julie Sharp: For our next question, we want to know how can we facilitate communication and documentation of this process. I don't think that I'm alone in the struggles that we might commonly have with that efficient and effective communication as being one of the challenges with this process. And so we've broken this down into external and internal types of communications for the purpose of this discussion. And so looking at the external communications, the fact that the NIH award institute or center only communicates the grant score to the PI and not other members at the institution, certainly in my experience, can create some downstream stress when it comes to just-in-time deadlines. We also sometimes struggle with the inconsistency between the various institutes and centers when it comes to their deadlines for submitting IACUC approval dates and any flexibilities that they have or don't have or wish to entertain when issuing restricted awards, so we-- I don't think we're alone in some of those challenges.

One approach that we do take is if we encounter a time-sensitive item and the PI is worried that they'll lose their grant, and absolutely nobody wants that to happen, we will routinely have the PI forward the communication from their program officer or manager to see what's needed, [and] explore options if there isn't yet an approved protocol in place. You know, for example, I've written letters that the IACUC protocol is under review, that it is congruent with the grant, and that we anticipate approval by a specific date. Those have been accepted when we've submitted those, and that might be an option that can provide you the necessary breathing room for review and approval of that protocol before submitting the approval date.

Jennifer alluded to the transfer of awards if a PI's completed part of the work prior to another institution. This can also be a little bit challenging because we expect that portions of the award have been completed if they've been doing this for a while, but we're asked to confirm congruency again for the transfer, and it's not uncommon that they don't yet have a protocol in place since they're juggling a variety of things involved with that move and they're starting from scratch versus maybe a simpler modification to an existing protocol. And so this, in particular, is an example where, in my experience, that the NIH Institute and Center, they'll work with you during this process because you're on a little bit different maybe time crunch for [IACUC approval of protocol(s) and congruence review], as opposed to a new award at just-in-time.

And so shifting to the internal communication portion of this, this can be accomplished any number of ways depending on who's involved in this within your program. We spend a lot of time communicating directly with our grants office and this is really critical for us, and it can streamline the process for everyone. We also work to keep the PI in the loop because that can be really helpful too, as they're getting some information and we're sort of trying to piecemeal this together. We routinely will have everyone on the same email thread so that we can sort of get past that "the house is on fire" stressor that people might be experiencing and then partner with them so that we can meet all of their requirements for just-in-time.

I'm sure I'm not alone in what Jennifer mentioned is encouraging that frequent and early communication. Certainly, the earlier the PI communicates with the IACUC office the better, we can assess what's needed whether that's a new protocol or a modification to an existing protocol, and then set expectations for approval. And if needed, we can discuss some of those possible interim solutions, whether that's a restricted award possibility or is the letter that I mentioned previously sufficient to give enough of reassurance to that funding component that things are underway and should be happening rather soon. Jennifer talked about how UCLA puts together their-- pulls together their documentation,

and so we also collect portions of the grant by email, or we have the lab upload them to the protocol to our-- within our protocol system to do that congruency review.

We commonly collect the research strategy and vertebrate animal section, other items that you might also wish to collect as a part of your review, you might want to look at the face page, the abstract, or other portions of the grant. We don't necessarily need the budget or the bio sketches or some of that other information, and some researchers have concerns about sharing some of the-- that sensitivity of those documents. So you might consider reducing what you require from the PI if you encounter some of that concern coming back from them. In terms of the documentation, there are so many options for documenting congruency and the bottom line is use whatever system works best for your program. You know, I've encountered at various institutions, some of the examples might be - Jennifer talked about a protocol section that lists all the funding sources associated with that protocol for reference, or their approval letter that lists the grants and any other relevant funding information, and a separate congruency form that's appended to the protocol or kept on file somewhere for reference. And some institutions may rely upon the assurance from the PI that's been discussed, that work in the grant is covered by an IACUC-approved protocol.

And this can work well for a program. It is just important to consider your level of risk tolerance if you're using this approach. The implication that has been mentioned before is that sometimes people don't realize that they haven't updated their protocol to include everything that's in their new grant and so you're operating with a high level of trust and confidence that they're familiar with those congruency requirements.

In our current system, the grant staff have access to our electronic protocol system to see all of the funding sources that are approved on the protocol in a very specific section of the application, and then we append a separate congruency check document to the protocol for reference, and they have access to be able to see that. We don't list all of the funding components on our approval letter, as Jennifer mentioned, but that's just a different way of doing it, and both are correct. And since we operate with the-- that sort of multiple-to-multiple association option, the document that we create helps us track which protocols were used to determine congruency for that given award. And so we keep that for reference as well. Jennifer?

>>*Jennifer Klahn*: Yes. So I will add to what you said. I'll start off by saying I cannot emphasize enough how important it is to communicate with everyone, all the relevant parties, about new awards. I was saying earlier that we had a lab meeting this morning and after going over some general like, welcome to the IACUC, this is what the committee does, the very first question we got from the PI mentioned this stress that he deals with when they have new awards and they're trying to get that IACUC approval. We've—we've been communicating that, and then we've observed it in these emails and phone calls that we receive. Our PIs become incredibly stressed about getting their IACUC approval confirmation, and they worry that they'll lose their grant if they don't receive IACUC approval immediately, yesterday if possible.

And I try to communicate to our team, no one's going to lose their grant. There might be a delayed onset and maybe there's some end of the year timing that needs to be met but if a decision to award is made, we are not going to be the reason that they lose their grant. But that said, communication just remains so critical to understanding what's really needed and the timeline to meet those requirements. So we like to tell PIs to get in touch with us as soon as they can once they receive a good score, but we also recommend that they try to get ahead of the game whenever possible by submitting their protocol

early. You know, maybe even prior to study section review. This can be a lot of work on the research team, but if the protocol goes in early and it's already approved when the just-in-time is requested, then they'll be in a really good position to respond quickly. And so that stress level will just hopefully disappear.

When it comes to documentation, our contracts and grants office has some visibility into what funding is approved on our IACUC protocol, so they can verify that directly through their system. But as I mentioned, and as Julie, as you mentioned, we also list funding on our IACUC approval notices. We only list contracts and grants on the approvals if a congruence check has been done because that approval letter is saying that by virtue of this being listed, we have verified congruence. So we have been asked to issue an administrative approval because somebody needs their just-in-time document now, or maybe the work will be done in several years, they don't have immediate plans and they expect to do a triennial review sometime in the interim before that work starts. And so we will talk about more-- that more in a couple of slides.

>>*Julie Sharp*: Okay. Great. Thank you, Jennifer. And Nicolette, do you have additional information from OLAW?

>>*Nicolette Petervary*: So this was all really good information and, once again, there's a lot of flexibility in how you choose to communicate but if you recall that flow chart that I showed on my slides, it all begins with the PI. And as stated previously, the NIH grants policy statement and PHS policy specified that the review must []-occur prior to award. So some things to consider about timeframes, and I understand that PIs can be very, very stressed about the process, but if they initiate early, it will-- the IACUC will have more time, and the IACUC should not be pressured to rush through this process. I have a few quotes from notices from NOT-OD-10-128, it is incumbent upon investigators to be totally forthcoming and timely in conveying to the IACUC any modifications related to project scope and animal usage that may result from the NIH review and award processes.

It goes on to say, should an institution find that one of its investigators disregards his or her responsibilities, the institution may, for example, determine that all animal protocols from that investigator be subject to IACUC approval prior to allowing that investigator to submit an application. And from NOT-OD-22-005, because obtaining IACUC approval may take several weeks, institutions may want to begin the IACUC review and approval process as soon as the applicant is notified that the impact score or percentile appear to be in a fundable range. Now, that being said, I also liked what Julie was saying and what Jennifer was saying about reaching out to your funding entity if you have any issues because they want to work with you in most cases. And once again, this is all part of open communication. If you're struggling, let them know and there might be a solution to that. So.

Slide 29: What Do I Do If the Award Includes Collaborations?

>>*Jennifer Klahn*: So I think we're going to move to the next slide. Yes, thank you. So next question, what do I do if the award includes collaborations? And this could be a whole webinar on its own [LAUGHTER]. In the interest of time, we'll discuss a few types of collaborations and some of their complexities. And I'll just throw in a quick pitch that it is always helpful to talk to OLAW if you have questions about institutional requirements that are associated with grants. Of course, the PI needs to talk to their program officer and the local contracts and grants office about these more complicated situations, and it'll be tremendously helpful if they involve the IACUC office in some of those conversations. So we see collaborations that involve a grant funded to our institution where some of the work is performed at our site and some of the work occurs at another location.

Some of you may have experience with your institution serving as primary awardee for a grant where none of the animal work is done at your site. There's no local animal work, everything is performed offsite at another institution. In both cases, you may be dealing with international collaborators, in which case a foreign assurance must be in place with OLAW. And there's information on the OLAW website about how to obtain that if it's not in place already. And then regardless of the specifics, it's really important to remember that "should" statement on page 15 of the *Guide for the Care and Use of Laboratory Animals (Guide)*, about collaborations, and I'm just going to read it here. It says inter-institutional collaboration has the potential to create ambiguities about responsibility for animal care and use. In cases of such collaboration involving animal use (beyond animal transport), the participating institutions should have a formal written understanding, (for example, a contract, memorandum of understanding, or agreement) that addresses the responsibility for offsite animal care and use, animal ownership, and IACUC review and oversight. In addition, IACUCs from the participating institutions may choose to review protocols for the work being conducted, end of quote.

So that's the expectation that's put out there in the *Guide* and since it's a "should" statement, means we need to do it unless there's some other way that we're doing this. And that may be through a subcontract through the contracts and grants office, but I won't go into that right now. So I'll very briefly mention that program project grants and cooperative agreements are likely to include multiple PIs, projects, and locations. And your institution should have a process for ensuring that any animal work proposed in these very massive submissions has been reviewed and approved by the IACUC. If your institution is the primary awardee on a grant, you are assuming responsibility for the work performed under that award. So you should have a consistent, thoughtful process for handling any collaborations.

We've posed a few questions here for everyone to think about, and I'll share that neither my program nor Julie's requires dual IACUC review of animal activities. So if there's offsite work, our IACUCs do not also review that after the other IACUC does. If your institution, if your program requires a local review for offsite work that's been reviewed by another IACUC, you'll want to consider the value that's being added by this requirement, kind of weigh that against any delays it may cause, maybe the scale tips that you're getting more out of it than you're not, but just kind of think about that. Think about whether your institution has a process for identifying offsite work and alerting the IACUC office in cases when there's no animal work performed locally.

Does everyone at the institution in the important offices know when and why MOUs and written agreements may be required? Do they know who to contact to initiate one of these agreements? Who can sign, what the timeline is versus your IACUC review process? And do you have a way to manage congruency for, again, those really massive P and U awards that have lots of moving parts and for which animal work may be added after initial approval? So a lot of things to think about there. And I'm going to pitch it to Julie now.

>>Julie Sharp: Okay, great. Thanks, Jennifer. As Jennifer mentioned we don't require dual review either, and when the work is completely performed offsite, we don't require the shell protocol that she described. We would look at the offsite protocol for congruence and submit their IACUC approval date for just-in-time. We still keep that record of how we conducted that congruence review and keep that for file as well, for reference. Usually the grant will delineate which work is being performed at which site but not always. So we're in communication with the PI's lab to gather those details. Getting the collaborating PI information is one of the struggles that we can sometimes have and even their IACUC contact so that we can then reach out with a draft MOU as a part of this process.

Regarding the MOUs the subcontract for the collaboration after the award is issued, it'll sometimes cover some of those MOU details, and so we're talking with our grants office about strategies to remove

some of those duplicated efforts for some of that overlapping information, and also we want to prevent potential for conflicting information of what's in their subcontract versus what's in our MOU as well. In terms of the P and U awards that Jennifer mentioned, we work to perform that initial congruency at the time of award with the animal work that's proposed at that time. We do struggle sometimes with the expectation from the funding agency for the subsequent animal projects since that is such a dynamic type of award, and those develop after the initial award. And so sometimes those don't always necessarily require or have a formal vertebrate animal section. And so we're looking at whatever sort of documentation they did put together, whether that's a summary of what they've proposed for consideration and then been awarded. And so it, again, it's just keeping track of--5 from a documentation standpoint, how did you conduct the review for reference.

>>*Jennifer Klahn*: Great. Thanks, Julie. Nicolette, would you and OLAW like to comment?

>>*Nicolette Petervary*: So you guys have really covered, I think the main points, but I'll just reiterate the requirements that for activities subject to PHS policy requirements, all sub-awardees, collaborator institutions, and performance sites directly involved in live vertebrate animal activities must be under an approved animal welfare assurance. And then, Jen, you mentioned the *Guide*, page 15, which talks about collaboration and it talks about IACUCs from participating institutions may choose to review the protocols for the work being conducted and this can be considered part of the congruence review, but if you leave it to the collaborators, the awardee remains responsible for the animal activity conducted at a collaborating performance site and must provide that verification of IACUC approval. So once again, how you approach it really depends on what works for you, your risk tolerance and whether the reduction in burden is more helpful or whether it's more helpful for you to do a dual review. It's completely up to the institution.

Slide 29: What Do I Do If the Award Includes Collaborations?

>>*Jennifer Klahn*: Great. Thanks, Nicolette. Okay, so for our next question, question five, what if the grant and protocol are not congruent? Never happens. It's always covered, right? [LAUGHTER] Well, unless you require one protocol per grant, you are likely to encounter inconsistencies. And by virtue of the approval cycle for protocols, so up to three years, versus grants which could be up to five years, it is not uncommon to see work that isn't covered by the protocol when the grant is first awarded. OLAW has offered us guidance on how to handle those activities that are planned for later in the award cycle, asking that a brief description of that later year work, the year four to five work, be included in the protocol. This gives the IACUC an opportunity to indicate if maybe such work is just simply not approvable at that location. So that would be a big problem, but it is something that they could conceivably do.

So I mentioned that our protocol has a field for inconsistencies, and this is where we would see some detail about that work that's not expected to start for several years. If the congruence review identifies that there are inconsistencies, my IACUC would ask for a protocol update right then and there. So upon approval of that submission, the new date on the approval notice is what we would be-- what we would consider to be the date used for just-in-time purposes. As we talked about earlier, there can be a lot of stress associated with the congruence review process if the sponsor has started requesting documents and the PI isn't prepared to provide them. In some urgent situations, maybe our PI has another open amendment totally unrelated to their grant. They're adding personnel, and personnel haven't completed training, it's taking a little longer than usual, and then all of a sudden they get this just-in-time request and they've actually got to do it right away.

So because they have this open amendment that's already in process, we may perform the congruence review outside of our system, and then we would notify our contracts and grants office in writing that

the review is complete, the activities in the grant are already covered by the approved protocol, and they can use the date of that email communication as the just-in-time date. Now, if the protocol is being amended to cover animal work not previously approved, -- but this is work that's included in the grant-- so they're submitting an amendment to include the grant and they're bringing the protocol up to speed with the animal activities in the grant - we would wait for the IACUC approval of the full amendment to use that as the just-in-time date. Though we would still, if there's an urgency to the situation, communicate with the contracts and grants office. We've done the review, the amendment that's under review and not yet approved does include the discrepant activities and so the congruence review is complete, and once the approval is issued, you'll have your just-in-time date. And we can also speculate about the timeline to get that approval. It'll be another week. It'll be minutes, days, and whatnot. Julie, would you like to share your experience?

>>*Julie Sharp*: Yes, thank you. Because we allow that multiple to multiple association between grants and protocols, we will routinely have an approved protocol or protocols already in place. And sort of the difference in what Jennifer has described, we use the original IACUC approval date for the just-in-time submission. We'll confirm that the new grant is substantively congruent, and we might identify the need for local non-substantive modifications that are then processed according to our review procedures. Another sort of point in terms of years - for years four and five - and how we do things a little bit differently relative to, say a three-year renewal of a protocol, we'll routinely capture this level of detail through confirmation with an email, the PI clarifying that the work isn't planned until then and would then be submitted and incorporated into the subsequent tri-annual review and approval prior-- and that they would get approval of that prior to initiating that work. And so those communications are then uploaded to the approved protocol for future reference as well.

>>*Jennifer Klahn*: Great. Thanks, Julie. Nicolette, OLAW?

>>*Nicolette Petervary*: Right. So as you both mentioned, that this type of situation can take a little bit of detective work to discover where the grant and the IACUC-approved protocols diverged, and this may require coordination between a lot of people. If a grant has never had its animal activities IACUC approved in the form of an IACUC-approved protocol, a decision date of the protocol review outcome of modification required in order to secure approval is not a correct IACUC approval date. IACUC approvals may not be conditional, and you can see OLAW FAQ D.4. for that information. But if grant activities have been approved by the IACUC and substantive congruence has been determined, in most cases, later amendments to protocols are okay without reporting an updated IACUC approval date to the funding IC. And as Julie mentioned, this often happens with just-in-time for many to many relationships between grants and protocols.

And for example, this can occur in instances where a new funding source is added to an existing activity. The grant activities are determined by the institution to be substantively congruent. Remember, congruence is not equivalence, and it's-- that may be with one or more existing protocols. However, later small modifications may be required for the animal use protocols because they serve a different purpose, that is for really the boots on the ground work on the animal activities. These generally do not necessitate reporting a change in IACUC approval date to the funding IC or to OLAW or conducting another congruence review. They can be handled locally as protocol amendments. It is extremely important, however, to keep records of protocol changes as well as financial records and make them available to NIH on requests because such records may be requested for audits.

And it's also important not to engage in the amended activities until the IACUC approves the amendments, and to remember that for more substantive protocol modifications, as I discussed in the

earlier slide on prior approval requirements, you will need to notify the funding IC for anything that falls under that requirement. And as always, if a specific situation is unclear because there are many shades of gray with congruence review, it can be discussed with the funding IC or with OLAW.

Slide 31: How Can I Reduce Regulatory Burden?

>>*Jennifer Klahn*: Great. Thank you. All right, question six, how can I reduce regulatory burden? This again, could be and has been a webinar all on its own. We've already alluded to some topics to consider if you're looking at burden. So that dual review, do you require dual review by the home IACUC for offsite collaborations? If so, why is it valuable? Do you require specific grant protocol association, for example, one grant per protocol? If so, why is that serving your program? When we have what may be considered an unnecessary burden, we're likely to see increased pressure from our researchers and how we manage those pressures has everything to do with clear processes and excellent communication. Something as simple as asking for a copy of the communication the PI receives from their program officer can really help clarify expectations.

Most program officers will work with you when they have confidence that the IACUC process is in motion and that there's an expected date of approval. They can consider restricted awards to obtain disbursement of funds for use towards the non-animal work while the IACUC review and approval process is underway. A final point I'll make about communication is kind of a personal anecdote. Several years ago, my program prepared and distributed a Q&A that described our processes and expectations for funding amendments, just-in-time, et cetera. It's quite in need of updating at this point. It's a little cheeky, you know, kind of, why do I have to do this? Because, in that conversational tone, I think it was a little more accessible. And we felt that this would be really valuable information to share with our researchers. It turns out I did get a couple of thank yous, so, yay [LAUGHTER]. You know, I'll take it. And so I really encourage you to describe for your researchers what your processes and expectations are. Julie?

>>*Julie Sharp*: Okay, great. Thank you, Jennifer. In addition to the great points that Jennifer made, we also take advantage of those same flexibilities. I'll also offer up that we process our protocols and modification by designated member review. And so that can provide potential to achieve approval sooner than waiting for say a full committee meeting. We also have many members of our IACUC staff available to perform the congruency reviews for flexibility. And the one thing that we do keep in mind with this many teammates performing these reviews, we don't hesitate to escalate a complicated or time-sensitive item to allow the IACUC manager or director to talk through the PI's concerns, maybe alleviate their anxiety by giving them some confidence in terms of what we understand, sometimes explain what they've misunderstood. And that allows our team members to continue their focus on the congruency review while we're-- where we're managing those expectations with the researcher. And then again, if they identify any modifications that are needed, it just, again, from a timing perspective helps to make that a little bit more efficient. So thanks.

>>*Jennifer Klahn*: Thanks Julie. Great point about escalating that and kind of dividing and conquering. Nicolette, anything to add?

>>*Nicolette Petervary*: I really liked Julie's discussion of having multiple ways to route a congruence review that's-- that kind of has some time constraints to it, so that's a great way to reduce burden. The other way that I can think of is a lot of times institutions opt to review multiple sections of the grant application or the entire grant application, but really, focusing on the research strategy section and the VAS is probably going to be the most helpful and review of a well-written VAS which appropriately addresses all the required criteria could reduce administrative burden by minimizing the need to review all those other sections of the grant application. And as always, OLAW is available to help and I suggest

that anyone with questions that are for a specific situation, just reach out to the funding entity because they will likely be able to help you as well.

Slide 32: What Happens if the Grants Office Submits an IACUC Approval Date Prior to Performing the Grant Congruency?

>>*Jennifer Klahn*: Thank you. So our last question, number seven, what happens if the grant's office submits an IACUC approval date prior to performing the grant congruency check? We expect that this will happen, particularly when there are gaps in our processes or staff training, staff turnover. I don't have a good answer, so I'm going to ask Julie and OLAW if they'd like to comment on that. [LAUGHTER]

>>*Julie Sharp*: I also do not have a good answer, so we'll defer to Nicolette for this one.

>>*Nicolette Petervary*: So this is a tough one, but just remember that when an institution verifies IACUC approval, the approval must be for the information submitted in the application or include notification of significant changes required by the IACUC. I'll refer you back to the PHS policy IV.D.2. requirement that modifications required by the IACUC be submitted to the NIH with a verification of IACUC approval. And it's the responsibility of institutions to communicate any IACUC-imposed changes to the staff. Institutions do need to apply due diligence to ensure the congruence review is conducted prior to submission of the IACUC approval date to ensure the information is accurate and timely. And once again, you can look at the PHS policy and NIH Policy Grant Statement [correction: Grants Policy Statement], section 4.1.1.2 that requires congruence review prior to the initial award. Again, it remains incumbent on the investigators to be totally forthcoming and timely. And I know that doesn't help when there's already been an oops, but if there's been an oops, reach out to the funding entity, reach out to OLAW; things happen and we can address those on a case-by-case basis.

Slide 33: Other Questions?

>>*Jennifer Klahn*: Thank you. Well, that brings us to the end of our prepared content, and it is now officially one o'clock Pacific time, I guess four o'clock Eastern. But I think Nicolette, you said there might be time to do questions.

>>*Nicolette Petervary*: I think we're out of time for now, but I will just let everyone know that we will append the answers to questions that have been captured in the chat and in the Q&A at a later time. So those will be appended to the transcript. You will get answers to those questions. As always, for specific or complicated or nuanced situations, just reach out to OLAW directly or reach out to the funding entity directly because we're probably not going to go into very, very unique situations. But we hope this has helped you and we hope that the amended transcript with the questions and answers will help you even more. And thank you. And don't forget that there will be a survey at the end of this webinar. We really appreciate your feedback, in fact, this topic was picked because of feedback we received. So we love to hear from you, and we take it seriously.

Slide 34: Next Webinar

And we will be having another OLAW online seminar in the spring with a topic to be determined. Thanks very much, everyone. Take care.

Questions

These questions were collected from the chat, Q&A, and email after the session and provided to the speaker. The responses represent the speakers' comments and opinions.

Expiration

- **Is a 2nd congruence review required when the initial IACUC protocol expires and is replaced with a new one (a new protocol number)?**

No, while congruence review is required for initial funded applications involving use of live vertebrate animals, additional congruence reviews after the initial review are not required. It is important to note that congruence review is also required for funded NIH Type 2 Renewal applications, Type 7 Change of Institution applications, and Type 3 Competing Revision applications in which live vertebrate animal activities are added where there were none before. For more detailed descriptions of NIH application types, please visit <https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/type-of-applications.htm>.

Qualifications

- **What traits and training make someone appropriately trained and qualified to do congruence reviews (what's the tipping point to ensure someone is appropriately trained and qualified)?**

Personnel conducting congruence review should be familiar with requirements for congruence review and have enough training to be able to determine if the descriptions of the animal work in the application or proposal corresponds to those in the IACUC-approved protocol(s). This requires some understanding of science and scientific terminology.

Collaborations

- **For P20 grants that often involve multiple PI and protocol numbers, are congruence reviews required for new pilot projects funded in later years of the P20? Some funding Centers seem to require this for new projects while others do not.**

Generally, an additional congruence review is not required in later years of the grant, though you should check with your awarding Institute or Center (IC) for any special requirements. As outlined in [OLAW FAQ D.20.](#), a general description in the protocol of activities planned for later years should be compared to the grant application at the initial congruence review. It is understood that experimental details and procedures will be refined or amended at a later time or at the time of the 3-year protocol renewal. However, if proposed modifications fall under prior approval requirements, prior approval must be obtained from the NIH awarding IC. ([NIH Grants Policy Statement 8.1.2](#))

- **Is there a concern if there is one grant on multiple protocols with different PIs?**

[OLAW FAQ D.18.](#) states that it is acceptable to have different individuals named as PI on the grant application and the IACUC protocol. However, if there are issues related to congruence, coordination of activities across multiple protocols, collaborations between institutions, or other concerns, it's best to contact the funding entity or OLAW to discuss your specific situation.

- **When the review involves review of a collaborator’s protocol, do you advise having that attached to the local protocol?**

Regarding “local protocols,” review of a research project or evaluation of a program or facility by more than one recognized IACUC is not a federal requirement, as outlined in [OLAW FAQ.D.8.](#) Therefore, depending on how the responsibilities are delineated between the collaborating institutions, there may not be more than one protocol. In all cases, however, collaborating institutions should have a formal written understanding (e.g., memorandum of understanding) that addresses responsibilities for animal care and use, ownership, and IACUC review and oversight (*Guide* page 15). This may include specifics on how congruence reviews are conducted and documented. Whether dual review is undertaken and how that is handled is an institutional decision. Institutions have flexibility in how congruence review is conducted, documented, and how documentation is maintained, provided all compliance requirements are met.

- **In follow up to the question above: If the congruence review is done by the IACUC staff, is it acceptable to have attachments to the protocol that are not approved by IACUC members?**

Specifics matter for this type of question so it would be best to call OLAW to discuss in more detail.

- **When obtaining animal use protocols from institutions outside your own, what would be the best way to approach resistance to providing this information, for example, due to the presence of proprietary information?**

For collaborations, memoranda of understanding can be helpful in clarifying processes and responsibilities for all parties. A process that indicates descriptions of animal work sufficient for the IACUC(s) to evaluate and for the purposes of congruence review can be listed in the agreement, with provisions for protection of proprietary information. OLAW has a resource page on [memoranda of understanding \(MOUs\) for collaborating institutions](#), which may be helpful, and includes links to a sample document and resources from the Federal Demonstration Partnership.

Grant to Protocol Ratios

- **When multiple grants are attached to a single protocol, can that include "Internal" or "State" funds? Or just federal grants?**

A protocol may include multiple funding sources, including non-federal grants. Not all funding sources are subject to congruence review as described in the PHS Policy.

- **Can you provide more context to not requiring exact matches?**

The review should confirm that with respect to the portions of the protocol(s) relating to the application or proposal undergoing congruence review, the species and all procedures agree, and that animal numbers are approximately similar (needn’t be exact). For specific questions, it would be best to call the funding entity and/or OLAW to discuss in more detail.

- **In a “many grants to a single protocol” model in which the grant being evaluated includes animal numbers; do we need to make sure that animal numbers have increased by that amount to avoid the risk of "double dipping" into the approved animals as part of previously approved grants?**

Numbers need not match exactly. The Public Health Service Policy on Humane Care and Use describes "...approximate number of animals to be used." (IV.D.1.a.)

However, large differences should be flagged for follow up. There are many factors to consider when evaluating discrepancies, including whether multiple procedures are performed on the same animals, and if there is a policy for administrative increases in animal numbers at your institution.

In all cases, when reviewing protocols IACUCs should determine that animals used reflect minimum number required to obtain valid results, consistent with U.S. Government Principle for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training III.

- **If the congruence request includes multiple protocols, which protocol approval date should be reported to the NIH as part of the JIT documentation, or are they all reported?**

It is best to reach out to the funding entity regarding this question to see if they have specific guidance.

Amendments

- **When grant funding is added via an amendment should the date of the amendment approval or the date of the original protocol approval be provided on the JIT?**

The IACUC approval date is the latest date when these animal activities as reflected in 1 or more protocols are approved by the IACUC. [The General Application Guide for NIH and other PHS Agencies for SF424 \(R&R\) - Forms Version H](#) provide instructions to enter the latest IACUC approval date if available, and to leave blank if IACUC approval is pending.

For an ongoing animal activity that is receiving a new funding award, an IACUC-approved amendment would only be required for the purposes of congruence review if the funding application contains new animal activities not described in existing protocols (in other words not substantively congruent with the existing protocol or protocols). There should be written approval of the amendment in such a case, and the date of the amendment approval would be the date of IACUC approval to submit.

If an amendment asks for a change or other item that requires prior approval per NIH Grants Policy Statement 8.1.2, this needs prior NIH approval before the proposed change can be implemented. All other subsequent amendments are made at the IACUC level, and this information needs to be kept at the institution and readily available if NIH asks for it, but does not need to be reported to the funding IC. For other funding entities, please reach out to those entities directly.

To review, congruence review is only required for initial applications involving use of live vertebrate animal, as well as for NIH Type 2 Renewals, Type 7 Change of Institution Awards and for Type 3 Competing Revisions in which in which live vertebrate animal activities are added where there were none before. For more detailed descriptions of NIH application types, please visit <https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/type-of-applications.htm>.

- **If grant funding is added via amendment should there be a separate amendment approval letter documenting the funding addition or can you revise the original approval letter adding the additional funding source and therefore provide the updated approval date?**

Institutions should follow their established processes for addition of funding to a protocol and issuance of IACUC approval letters. See the response to the question above for amendments submitted to the IACUC involving changes to animal activities. For other funding entities, or if documentation of additional funding without new animal activities is required by the funding IC, please reach out to them directly for specifics.

Transfers

- **Why would an institution need to do a grant-protocol comparison when an award is being transferred? It seems that NIH wouldn't need it after the initial comparison, so is this more for the new institutional home to ensure the protocol they have reviewed is aligned with award noting what might already be done?**

The IACUC of the new institution needs to do their own review and approve the work, since they are responsible for oversight of animal activities at that institution. Per OLAW [FAQ F.3](#). "The transfer of PHS-supported research to a different institution requires the prior approval of the funding component. The proposed new grantee institution must have or obtain an Animal Welfare Assurance and possess all the resources necessary to fulfill the conditions of the grant, and its IACUC must review and approve the animal activities. The original IACUC approval is void when the original grantee formally relinquishes the award. The receiving institution must provide verification of IACUC approval prior to receiving funding. Note that the conditions of approval by the IACUC at the receiving institution may differ from those required by the original grantee's IACUC."

Nonaligned grant congruence

- **If an investigator thinks they may not get to some of the items in the grant, does the IACUC still have to review and approve these activities as part of the congruence?**

This question is addressed in [OLAW FAQ D.20](#). It is understood that the need for changes to animal protocols is anticipated and can occur at any time during the life of the protocol, but in almost all cases, if the work is described in the application at the time of initial award, a general description of potential later work is required to be described in an IACUC approved protocol. If at any time the PI is considering a consequential change, such as a change in scope or another change requiring prior approval, it should be evaluated to determine if it requires prior approval and be discussed with the funding entity. ([NIH Grants Policy Statement 8.1.2](#)) All other subsequent amendments that do not require prior approval by NIH are made at the IACUC level and this information needs to be kept at the institution and readily available if NIH asks for it. Please reach out to the funding entity for guidance in specific situations such as this one.

- **Is it problematic for a protocol associated with one grant (and no listed internal funding) to describe methods that are NOT described in the VAS of the grant? I.e., would the NIH take issue with grant funds being used to support methods they have not been made aware of?**

This depends on the nature of the content since congruence review does not mean exact equivalence. For complex situations such as this one, it is best to call the funding entity and/or OLAW to discuss in more detail.

Timeline

- **Generally, how long should a congruence review take?**

The timeframe for congruence review largely depends on the specific processes used at the institution. As stated in the webinar, congruence review is an institutional rather than an IACUC responsibility, and there are many flexibilities available for how the process may be conducted.

- **Question for OLAW: What is the approximate timeline for an institution to obtain foreign assurance?**

Assurance negotiations vary in terms of the timeframe because OLAW may request additional clarification upon review of submissions. Maintaining open communications with the OLAW Division of Assurances and prompt responses to clarification requests speed up the process. Also, OLAW strives to work collaboratively with institutions and will endeavor to assist if there are specific timelines requested by the institution, provided that the Assurance is being negotiated in good faith.

Terms and Clarifications

- **What are *restricted* awards and how are they related to congruence review?**

As outlined in slide 5 of this webinar, restricted awards are those awards with specific restrictions or limitations placed on the proposed work. For example, upon request by the NIH funding component, NIH may issue restricted awards because of the limited time available to fulfill requirements for Assurance(s) and/or verification of IACUC approval (usually this is at the end of the government fiscal year). This allows NIH funding components in conjunction with OLAW to issue awards with the restriction that live, vertebrate animal activity cannot commence or be charged to the award until all necessary documentation is in place. This gives more time for IACUC approval of protocols (and therefore congruence review), or more time to negotiate an Assurance, if needed. Restricted awards may also be provided for non-NIH funding entities, upon request.

- **Would NIH ever (or under what circumstances) rescind an award because IACUC approval wasn't issued within the JIT deadline communicated by the funding center (IC)?**

If animal work is conducted without IACUC approval, noncompliance has occurred and funds need to be returned to NIH. Whenever possible, it is best to contact the funding IC if there is a possibility that additional time would be needed for IACUC approval and/or Assurance negotiation.

Requests

- **If the JIT turnaround time is short, but the congruence review has not been completed, can we submit the other JIT materials with a note indicating that the IACUC approval date will be provided at a later time?**

This sounds like a special situation to discuss with the funding entity. You may ask the funding entity about potential options. For example, if the funding entity is an NIH Institute or Center,

you may inquire about restricted awards, which can be initiated upon request of the NIH funding component.

Other

- **What if an institution requests congruence only for some awards but accepts a copy of a protocol approval letter for others?**

More information would be needed to address this question. We would need to understand the institutional system and the nature of the collaboration. It is best to call the funding entity and/or OLAW to discuss the situation in more detail.