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Note: Text has been edited for clarity.

Grants Policy and Congruence

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http://grants.nih.gov/grants/olaw/2012-06-07%2013.00%20OLAW%20Online%20Seminar%20_Grants%20Policy%20and%20Congruence.wmv (Windows Media Player – 1 hr).

Slide 1 (Title Slide)

>> Dr. Collins: Hello and welcome to the OLAW Online Webinar series. My name is Jerry Collins and I will be the moderator for today's webinar entitled: Grants Policy and Congruence. This webinar will be recorded and the recording will be posted on the OLAW website in the [Education Resources](#) section. [Text related to information for attendees and submitting questions during original broadcast of the seminar has been removed.]

Our speaker today is Dr. Patricia Brown. Dr. Brown currently serves as the Director of the Office of Laboratory Animal Welfare ([OLAW](#)) at the National Institutes of Health. She received her Bachelor of Science degree in Animal Science from Penn State University and her veterinary degree from the University of Pennsylvania. She served in the Air Force for eight years and, while on active duty, earned a Master's of Science degree in Laboratory Animal Medicine from Penn State. She joined the U.S. Public Health Service [PHS] in 1986 and has served in a variety of positions at the NIH, within the Veterinary Resources Program, the National Cancer Institute, and the Office of Animal Care and Use. Dr. Brown is a Diplomate of ACLAM and has served on the board of directors of ACLAM. She is a past president of the American Society of Laboratory Animal Practitioners and has served on the Board of Trustees of AAALAC. Dr. Brown.

>> Dr. Brown: The purpose of today's webinar is to explain to PHS Assured institutions the requirements and responsibility for assuring congruence between animal activities described in the grant application and what the IACUC has approved in the animal study protocol. We will present some of the ways an institution can implement a program to manage these requirements.

Slide 2 (Special Thanks To Tina Neill-Hudson)

I would like to acknowledge the contributions of Tina Neill-Hudson of the University of Iowa in sharing practical suggestions for conducting congruence review based on her many years of experience at her institution. Her contribution is especially important because it provides OLAW an opportunity to share ideas and procedures of an institution as it continually implements the requirements for congruence between grants and IACUC protocols. These examples are best practices. And although the end result – congruence – is required of all PHS Assured institutions, we at OLAW recognize that there are numerous ways to achieve and verify congruence. Institutions may develop and implement their own policies and procedures, as long as those policies and procedures satisfy the requirements of the PHS Policy [[Public Health Service Policy on Humane Care and Use of Laboratory Animals](#)] and the terms and conditions of [NIH Grants Policy Statement](#) [NIH GPS].

Slide 3 (NIH)

Today's topic is very important to institutions that receive NIH funds. So even though the information is very NIH centric and also very much down in the weeds, I hope you will find it useful. We will answer questions that we have received from institutional personnel tasked with confirming congruence, along with the questions that come in from you today.

Slide 4 (What is NIH GPS?)

Before getting into the specifics, I will provide background information to help you understand the sources of the requirement for congruence between grants and IACUC protocols. The NIH Grants Policy Statement is a document that provides all of the policy requirements that make up the terms and conditions that must be met to receive NIH grant awards. It is important to recognize that compliance with the PHS Policy is a term and condition of the Grants Policy Statement. More than just a set of rules, the Grants Policy Statement defines contractual or legal obligations between the grantee institution and NIH. If an institution accepts PHS funds and fails to meet the terms and conditions, there can be fiscal, civil, and/or criminal penalties.

Slide 5 (Contractual Obligations)

Who at PHS Assured institutions has responsibility for meeting the obligations associated with congruence? The AOR (Authorized Organization Representative) represents the entire institution. His or her signature verifies, to the NIH, the institution's commitment to the Grants Policy Statement terms and conditions, including IACUC approval of all PHS-funded animal activities.

By signing the grant application, the PI promises NIH and the institution that he or she will conduct animal activities according to the PHS Policy. A component of that commitment is the conduct of PHS-funded animal activities according to an approved IACUC protocol.

Slide 6 (Why is Congruence an Issue?)

So why is congruence an issue? And a requirement? Well, the NIH Grants Policy Statement requires that grantee organizations establish appropriate policies and procedures to ensure the humane care and use of animals, and that these organizations bear ultimate responsibility for compliance with the PHS Policy in all PHS-supported animal activities.

Slide 7 (Why Is This An Issue?)

The PHS Policy in [section IV.D](#) requires that applications or proposals from Assured institutions include the date of IACUC approval of those components related to the care and use of animals.

Slide 8 (Why Is This An Issue?)

The NIH Grants Policy Statement also states that it is an institutional responsibility to ensure that the research described in the application is congruent with any corresponding protocols approved by the IACUC. These two documents work together to ensure that public funds are used to promote the highest level of scientific integrity, public accountability, and social responsibility as reflected in humane animal care and use in the conduct of science.

Slide 9 (NIH Grant Application)

There are two locations in the NIH grant application forms where these requirements are found. In the Standard Form 424 [[SF 424](#)], the IACUC approval date is entered. In the Public Health Service Form 398 [[PHS 398](#)], the PI attaches the Vertebrate Animal Section, which is a detailed description of the proposed use of animals in the research.

Slide 10 (SF424)

This shows the portion of the SF 424, the Research and Related Other Project Information page, where the IACUC approval date is entered.

Slide 11 (Additional NIH Grants Policy)

It is okay if the IACUC review and approval is pending or has not yet begun at the time of the application. The IACUC approval date is not required at the time of grant submission. NIH grants management staff will request the approval date as a [Just-In-Time](#) requirement in the pre-award stage.

Slide 12 (Additional NIH Grants Policy)

An institution that elects to proceed according to Just-in-Time procedures for IACUC approval bears the responsibility for supporting the decisions of the IACUC. Under no circumstances may an IACUC be pressured to approve a protocol or be overruled on its decision to withhold approval. The PHS Policy requires that modifications required by the

IACUC be submitted to the NIH with verification of IACUC approval. It is the responsibility of institutions to communicate any IACUC-required changes to NIH staff at this time.

Slide 13 (PHS 398 Research Plan)

This shows a page of the PHS 398 form, the Research Plan. The Vertebrate Animals Section is attached as Section 10 and is one of the Other Research Plan Sections.

Slide 14 (Section 10 Vertebrate Animals)

If live vertebrate animals are to be used, NIH requires five points that are addressed in the Vertebrate Animals Section [VAS]. The five points are listed here. [See [VAS Worksheet](#) – PDF] The Vertebrate Animal Section should be a concise and complete description of the animals and proposed procedures. Investigators should be reminded that if they fail to address the five points, the application may be deferred from the peer review round or the impact/priority score may be negatively affected.

Slide 15 (Does the IACUC Protocol Match the Grant?)

Now that I have given you the reasons why NIH expects the grant and the protocol to match, how does your institution know and who is involved in the process? This is most likely the reason you all are tuned in to this webinar today.

Slide 16 (Is the IACUC Required to Review the Grant Application?)

To start off, is the IACUC required to review the grant application? Well, OLAW has answered this question as one of our Frequently Asked Questions. It dates back to an article that the OLAW staff authored in 2003 in *Lab Animal* magazine that became the substance of OLAW [FAQ D10](#).

Slide 17 (FAQ D10 Answer)

The answer to the question is that there is no explicit requirement for the IACUC to do a side-by-side comparison of an application and the IACUC protocol. However, institutions are responsible for ensuring that the information the IACUC reviews and approves is congruent with what is in the application. Institutions are free to devise a workable mechanism to accomplish this end.

Slide 18 (FAQ D10 Answer)

One method to prevent inconsistencies between the information submitted to NIH and that on the IACUC protocol is to implement a procedure for direct comparison. Some institutions have delegated this responsibility to a particular office or position, such as the sponsored programs or compliance office. Others ask departmental chairs to verify consistency, but this is a minimal approach and a high risk to the institution.

Slide 19 (Institutional Responsibility)

So for the final answer is that the institution must document the IACUC's approval of the

animal activities proposed in the grant. The institution, when asked by NIH, must be able to associate each grant or grants with a relevant protocol or protocols. If the institution uses a protocol numbering system, it must be able to link protocol numbers to grant numbers. But a 1:1 ratio is not required.

Slide 20 (What is Congruence?)

So this brings us to the question, what is congruence? Here is a helpful definition from Wikipedia: Congruence is the state achieved by coming together, the state of agreement. Congruence, as opposed to equivalence or approximation, is a relation which implies a kind of equivalence, though not complete equivalence. So each institution needs to determine the extent of the agreement between grants and protocols and what they deem congruent.

Slide 21 (Who May Review for Congruence?)

Who may review for congruence? It is important that whoever is charged with conducting the comparison is qualified to identify inconsistencies. Someone who understands the IACUC protocol review process is a good fit for this review, such as a member of the IACUC office, the sponsored programs office, or compliance oversight personnel.

Slide 22 (When May Congruence be Determined?)

When may congruence be determined? To meet the Grants Policy Statement and the PHS Policy requirements, congruence must be determined prior to grant award. Keep in mind, irrespective of when congruence is determined, the signature of the Authorized Organization Representative on the application indicates the organization's intent to comply with the laws, regulations, and policies to which the grant is subject, including applicable public policy requirements. The AOR is also attesting to the fact that the information contained in the application is true and complete and conforms with federal requirements and the organization's own policies and requirements. The signature block makes it very clear that there are potential civil and criminal penalties for submitting false statements.

Slide 23 (Where to Look in Grant)

Where in the application should one look? There are two primary areas in the grant to concentrate on when conducting grant congruency [review]: the Vertebrate Animals Section and the Approach part of the Research Strategy Section.

Slide 24 (What Content Should be Compared?)

What content should be compared? The review should confirm that the species and all procedures are in agreement and the animal numbers proposed are approximately similar. It's not necessary to use a microscope to make this comparison.

Slide 25 (What if Not Congruent?)

What if the grant and the IACUC protocol are not congruent? If a procedure is in the grant, but not in the protocol, ask the PI for clarification. He or she may choose to modify the protocol to be consistent with the grant. If the PI does not plan to perform the procedure described in the grant, a note should be filed with the institution's record of the grant review. NIH should be informed of the change as part of the Just-in-Time pre-award notification.

Slide 26 (What if Not Congruent?)

What if a procedure is in the IACUC protocol and is not in the grant? Again, ask the PI for clarification. If the PI intends to conduct the procedure, then he or she should determine if the differences meet the definition of a "change in scope". [See OLAW FAQ [B13](#) for information about change in scope.] Please note that this would apply when there is a one-to-one grant to protocol ratio. If multiple grants are associated with a single IACUC protocol, the institution must ensure that PHS funds are expended as described in the PHS grant or grants.

Slide 27 (NIH Change in Scope)

NIH Grants Policy allows the PI to make changes in the methodology, approach, or other aspects of the project objectives; however, he or she must obtain prior approval from the NIH awarding component for a change in scope. A change in scope is a change in the direction, aims, objectives, purposes, or type of research or training identified in the research – in the approved project. The grantee must make the initial determination of the significance of a change and should consult with the Grants Management Officer at NIH as necessary.

Slide 28 (Potential Indicators)

Potential indicators of a change in scope may be found in the Grants Policy Statement. A few examples are listed here. [[Part II: Subpart A: 8.1.2.5](#)] These examples are not intended to imply that any change in animal model, or in approved use of animals, always represents a change in scope. And as I said before, it's always better to consult with the Grants Management Officer to determine whether the NIH Institute or Center funding the grant considers it a change in scope.

Slide 29 (Change in Scope)

So if the Principal Investigator determines that there is a change in scope, the Principal Investigator, through the Authorized Organization Representative, is responsible for requesting approval of that change in scope. The request for a change in scope must be made in writing to the Grants Management Officer, email is okay, to the NIH Institute or Center that funds the grant. The request must be made no less than 30 days before the proposed change and must be signed by both the PI and the AOR. If the PI determines there is not a change in scope, he or she provides an explanation that the institution may

file with the congruency review documentation.

Slide 30 (Review Strategy Summary)

In summary, when conducting the congruence review, start with the Vertebrate Animals Section. In looking at the Research Strategy Section, the Approach part of this section may contain information on animal use. It is recommended to look for the same key words that describe the procedures in both the IACUC protocol and the grant. If inconsistencies are found, have the PI clarify and provide an explanation. Make the changes necessary to the protocol or grant and notify NIH if the grant is impacted by IACUC review or a change in scope.

Slide 31 (Who's Responsibility Is It?)

So whose responsibility is it? I have covered a number of areas of responsibility that I would like to review again for emphasis and I would also want to add one more that we have not yet discussed. The **institution** verifies that there is congruence between the grant and the IACUC protocol when it provides the IACUC approval date, usually as part of the Just-in-Time pre-award submission. The **PI** is responsible to provide an accurate description of the animal activities for review and approval by the IACUC. The **PI and the institution** are required to notify NIH of a change in scope or IACUC-required modifications before conducting the research. If, as a result of NIH peer review, the **PI** is asked to modify the project scope or animal use, he or she **must promptly inform the IACUC**. These requirements are manifested in the NIH grant application forms in two locations, on the SF 424 and on the PHS 398.

Slide 32 (What is Congruence? Questions?)

>> Dr. Collins: Thanks, Pat. We now have an opportunity to address questions sent in by our participants. [Text related to information for attendees and submitting questions during original broadcast of the seminar has been removed.] We will start with some questions that we received prior to the start of the webinar.

[1.] If the date of IACUC approval is not provided at the time of grant application submission, how should an institution provide that date to NIH?

>> Dr. Brown: Well, after the priority scores are released, NIH sends an email requesting the Just-in-Time information for the grants that have been scored within the competitive range for possible funding. This notification is sent to the PI. Just-in-Time information requested includes, among other things, the certification of IACUC approval. Just-in-Time information must be submitted for review and evaluation prior to NIH making an award. This information is submitted via the Just-In-Time function within the eRA Commons. If there are questions about the Just-in-Time process, it's best to contact the Grants Management Specialist for the funding component that has notified the PI about the potential for possible funding.

>> Dr. Collins: I forgot to mention before we started with the questions, that we certainly do appreciate those of you that submitted questions before the webinar. Although we may not include each question verbatim, please be assured that Dr. Brown has addressed the overall issues in her talk.

Our second question: **[2.] Is there an advantage for the institution to wait until Just-in-Time to do the congruence check?**

>> Dr. Brown: Well, the advantage of having review and approval by the IACUC and also the congruence review during the Just-in-Time pre-award period is that it reduces the burden on applicants, the IACUC, and the congruence reviewers, allowing them to focus on the review of applications likely to be funded.

>> Dr. Collins: Our next question: **[3.] If the IACUC reviews proposed animal work after a grant application is submitted and as a result of that review modifications are required in the proposed work, who is responsible for informing NIH? How do they do it? To whom at NIH should that information be sent?**

>> Dr. Brown: Well, the PHS Policy requires that modifications required by the IACUC be submitted to the NIH with the verification of IACUC approval, and it is the responsibility of institutions to communicate any IACUC-required changes to NIH staff as part of the Just-in-Time information. The Just-in-Time feature of the eRA Commons allows the Signing Official (that's also known as the Authorized Organization Representative) to electronically submit additional grant application information, such as the IACUC-required modifications. PI's can upload the Just-in-Time information into the Commons for the Signing Official to submit.

>> Dr. Collins: Our next question relates to the same general area: **[4.] If an institution informs NIH of changes in work proposed in a grant application as a result of IACUC review, will that endanger the possibility of the grant being awarded?**

>> Dr. Brown: No. This is a requirement of the PHS Policy and in no way affects the grant award.

>> Dr. Collins: Our next questioner states that: **[5.] When I served on study section several years ago, the information in the VAS was not adequate for a determination of congruence. Have things really changed that much?**

>> Dr. Brown: In 2010, OLAW in cooperation with NIH extramural review and policy leadership, developed the NIH [Worksheet for Review of the Vertebrate Animals Section](#) [PDF]. We intended it to assist applicants in preparing the VAS for submission to the NIH and also as guidance to reviewers in evaluating the Vertebrate Animals Section. It is now linked in every funding announcement and we think it further encourages consistency in how grantees describe their use of animals. And from our own review of the Vertebrate Animals Sections, which we look at throughout the year, we have noticed that there really

has been an improvement in the amount of information in the Vertebrate Animals Section of the applications.

>> Dr. Collins: Next question relates to the issue of congruence: **[6.] Is a difference in strains of mice enough to make a grant to be not congruent with an IACUC protocol?**

>> Dr. Brown: No.

>> Dr. Collins: Plain and simple answer, thank you. Next question: **[7.] May members of the IACUC participate in determining congruence?**

>> Dr. Brown: Yes. We would say that IACUC members may participate in the congruence review. However, there is no requirement for the IACUC members to conduct the congruence review. Depending on the volume of protocols, this may or may not be a reasonable burden for the members.

>> Dr. Collins: Another question about who should do the review: **[8.] Is it okay for us to simply ask each PI to confirm that all animal work described in a PHS grant application has been approved by our IACUC?**

>> Dr. Brown: Well, as mentioned previously, direct comparison is the most effective method and puts the institution in the best position to meet the terms and conditions of the award. This circumstance described where the PI is confirming the congruence is a little bit like the proverbial story of the fox guarding the hen house. It has been OLAW's experience that having the PI certify congruence places the institution at significant risk of noncompliance with the PHS Policy's terms and conditions and also those of the Grants Policy. We note that some institutions who have used this practice have been required to return funds to NIH for noncompliance.

>> Dr. Collins: Next question, Pat: **[9.] If at Just-in-Time notice, an IACUC determines that a protocol is very complex and that review will extend beyond the planned start date of the award, what should the institution do?**

>> Dr. Brown: Well, again, as I mentioned previously, under no circumstances may an IACUC be pressured to approve a protocol or be overruled on its decision to withhold approval. The institution, through the Authorized Organization Representative, should communicate the delay to NIH staff. If this delay occurs in the last quarter of the fiscal year, the NIH Grants Management Officer may issue a restricted award with a special condition which allows funds to be released, but restricts the use of funds to research not involving animals.

>> Dr. Collins: Next question, Pat: **[10.] Should an institution use different approaches for checking congruence for initial awards versus competitive renewals?**

>> Dr. Brown: The same approach should apply for initial awards and competitive

renewals. With competitive renewals, the focus will be on the progress report and any changes that are proposed for the next performance period of the grant and the congruence with the current IACUC protocol.

>> Dr. Collins: **[11.] What happens if an institution is of the opinion that there is a change of scope but the PI does not agree?**

>> Dr. Brown: Well, any question about the need for prior approval for an activity, which a change in scope is considered a prior approval requirement, this should be directed to the Grants Management Officer of the funding component for their interpretation.

>> Dr. Collins: **[12.] At the time that a progress report is submitted, the PI is asked if there is a planned change of scope. Is it okay to wait until then to inform NIH even if the change happened months earlier?**

>> Dr. Brown: No. As I said, a change in scope requires prior written approval from NIH. The request must be made in writing to the Grants Management Officer no later than 30 days before the proposed change and must be signed by the Authorized Organization Representative. If the request is emailed, it must provide evidence of the AOR's approval. In other words, a courtesy copy to the Authorized Organization Representative is not acceptable. If you – if an institution fails to obtain required prior approval from the appropriate awarding component, this may result in either disallowance of costs, termination of the award, or other enforcement action within NIH's authority.

>> Dr. Collins: This next question is a bit long: **[13.] Each Aim of the Research Strategy Section of an NIH grant proposal includes an Alternatives section, where the investigator describes the alternative methods – procedures that will be used - if the procedures described in the main body of the Aim are not successful or need to be followed up with by other kinds of experiments. Is congruency with an IACUC-approved protocol necessary for these alternative procedures? If so, do the alternative procedures need to be described on the protocol in the same detail as for the procedures in the main part of the Aim?**

>> Dr. Brown: Yes. The alternative procedures – if they involve animals – should be described in the IACUC protocol. The detail provided may be less for the alternative procedures if the PI clearly states in the IACUC protocol that the PI will amend that protocol if the original plan is changed and the alternative procedures will be followed instead.

>> Dr. Collins: Another question about who can do the congruence review: **[14.] Our IACUC staff conducts a comprehensive pre-review of all protocols. Is it okay to do a congruence review check at that time?**

>> Dr. Brown: Yes.

>> Dr. Collins: Next question – actually, Pat, if I could go there for just a second to that last question: **What would happen if the IACUC required some changes in the**

protocol between the time of pre-review and the time that the protocol was actually approved?

>> Dr. Brown: Again, depending on how those changes are different from what was in the application, NIH may need to be notified of those changes in scope of the – what was in the application.

>> Dr. Collins: Okay. So that would be the one issue for folks to remember. That is, if this pre-review happens prior to the actual approval of the protocol, there is a possibility that changes could be required and that there would be a need to inform folks [NIH] of those changes.

Our next question: [15.] Our institution requires IACUC review and approval prior to submission of the grant application; i.e., we do not use Just-in-Time. Is it okay for us to do congruence checking at that time as well?

>> Dr. Brown: Yes, that's also an acceptable practice.

>> Dr. Collins: Okay. This next one sounds interesting: [16.] We have a large number of PHS awards and IACUC protocols. At times we are unable to complete a congruence check prior to award, so we use the most recent date of IACUC approval of the most relevant protocol. If we later discover that congruence is not total, what should we do?

>> Dr. Brown: Well, this scenario is noncompliant with both the PHS Policy and the NIH Grants Policy Statement. We would strongly discourage this approach. If after award, it is found that animal activities described in the grant have been conducted without IACUC approval, the OLAW [Division of Compliance Oversight](#) and the NIH funding component must be notified promptly.

>> Dr. Collins: Here's a question that certainly comes up from time to time: [17.] Why can't the study section review of the VAS fulfill the requirement for IACUC review? We could then eliminate the IACUC and save time and money.

>> Dr. Brown: Well, protection of research animal welfare is a responsibility that is carried out in every phase of the grant process. As part of the initial peer review of application, the Scientific Review Group [SRG] is verifying that any proposed research involving animals is scientifically appropriate, including the suitability of the animal usage and the protections for research animals. But the SRG review, the scientific review group, peer review, is not intended to supersede or serve as a replacement for IACUC review or IACUC approval of an animal study protocol. The fundamental role of the IACUC is to review the proposed research and provide local oversight of individual animal care and use protocols at the organization. IACUC approval indicates that the proposed protocol has been determined by the investigator's IACUC to conform to PHS Policy. While the IACUC considers the appropriateness of the proposed protocol to the investigator's scientific goals, the primary goal of the IACUC's detailed evaluation and oversight of the protocol is to assure that the procedures involving animals conform to all federal animal

welfare requirements and PHS Policy.

>> Dr. Collins: **[18.] Is it better to have one protocol for each grant or to have several grants associated with one protocol?**

>> Dr. Brown: Well, many institutions choose to have one IACUC protocol for each grant, but it is acceptable to have several grants associated with one protocol. Each method has its own benefits and limitations.

>> Dr. Collins: Okay. We're going to continue answering questions, looks like we have about 15 or so left. [Text related to information for attendees and submitting questions during original broadcast of the seminar has been removed.] [Additional] questions and their answers will be included along with the transcript with the recording of this particular webinar.

Next question: **[19.] If a procedure is in the grant and a PI indicates that they no longer wish to carry out that procedure, must it still be placed in the experimental protocol?** And I'm assuming when they say experimental protocol, they're talking about the IACUC protocol as opposed to anything in the grant itself.

>> Dr. Brown: Well, I think this is – we discussed a similar circumstance earlier in my presentation. [See slide 25 discussion.] That if the PI decides that they are not going to perform something that was described in the grant, a note should be filed with the record of grant review that just confirms that that's the PI's choice. And under those circumstances it would not be required to be described in the IACUC protocol.

>> Dr. Collins: **[20.] During a comparison, – I'm assuming they mean in comparison of congruency – it was discovered that the PI only completed the Vertebrate Animals Section with the response “nude mice will be used”; that was the extent of the section which was approved for funding. What is the institution's responsibility in that scenario?**

>> Dr. Brown: Well, this is – this is somewhat distressing to me to hear that the Vertebrate Animals Section had – was, in essence, lacking any substantive information. It would be helpful for the PI to provide the Vertebrate Animals Section in its entirety; and as I said, the Worksheet provides the level of detail of what should be provided in that particular section of the grant application. And that would be really helpful if that was provided as part of the Just-in-Time to clarify that it was not the intent of the institution to submit such paucity of information concerning the Vertebrate Animals Section. I'm quite surprised that the study section would let something like that get through under our current expectations.

>> Dr. Collins: Pat, I guess in addition folks would be encouraged to look at other parts of the grant to see if there was additional information there. And also, I think it would be very important for the institution to recognize that that description would not be

acceptable for the protocol form that was being reviewed.

>> Dr. Brown: That's right, Jerry.

>> Dr. Collins: Next question: **[21.] When the PI uses grant funds to outsource part of the animal studies covered under the grant, such that an OLAW interinstitutional agreement is signed between the PI and the outsourced facility, who is responsible for ensuring congruence with the grant and the IACUC approved protocol animal work conducted at the outsourcing institution?**

>> Dr. Brown: We would say that – that the institution that's accepting the funds is agreeing in providing the IACUC protocol approval date that there is congruence between what's in the grant application and what's been approved at the institution where the activity is going to be conducted.

>> Dr. Collins: Our next question: **[22.] Does a change in scope require a new protocol review by the IACUC?**

>> Dr. Brown: I think a change in scope that the PI intends to – that involves animal activities, it would be important that the IACUC would be informed that if there's any change in what was originally approved in the IACUC protocol. Oftentimes, a change in scope means a whole new direction that the PI is taking, maybe changing a species from one species to another, adding a major new organ system to the study, so that typically ends up being a significant change to the animal protocol that would require an amendment.

>> Dr. Collins: I think that word amendment is important. It's important to recognize that it may not require a new protocol, i.e. an entire review of the entire protocol, but rather the amendment process could be used under these circumstances.

[23.] What if an IACUC approval date subsequently expires during Just-in-Time process? Does a PI need to submit another IACUC protocol?

>> Dr. Brown: A protocol – if a protocol date is provided, the expectation by NIH is that that is an ongoing activity – an ongoing approval of the activity. So NIH will not accept a protocol that is more than three years – an approval date that is more than three years old. So under the circumstances – I'm understanding what's being said here, is that the protocol should not be expiring if it's – unless it's – more than three years old.

>> Dr. Collins: It seems as if this question raises a couple of other issues. Number 1, if in fact there is an approved protocol, we assume there may be ongoing work. So if in fact a protocol has expired, clearly that ongoing work must stop until a new protocol is approved and associated with that particular piece of work. So I think there will be a couple of issues here going beyond just the question of what information had been provided about the congruence itself.

Next question: **[24.] If a grant funds multiple IACUC protocols, which IACUC approval date should be provided? And then the question is, The most recent?**

>> Dr. Brown: This is up to the discretion of the institution, but it's my understanding that most institutions choose to put in the most recent IACUC protocol [approval] date.

>> Dr. Collins: **[25.] If a research protocol is reviewed and the IACUC requires modifications prior to issuing an approval, should the PI inform the Grants Management Officer prior to receiving approval?** I'm assuming they mean prior to receiving approval by the IACUC, not approval of the award.

>> Dr. Brown: I think it's always a good practice to keep your grants management staff informed, if you are anticipating a delay in getting a protocol review and approval. They won't fault you for letting them know that things might be slowed down for whatever reason.

>> Dr. Collins: Okay. Our next question, it actually says not so much a question as a comment: **[26.] On the few occasions in which our IACUC office has notified a PI that they need to obtain approval from their GMO for a change of scope, the response from the GMOs (at the different institutes) has implied that this exercise was not really important. It would be good if the messages coming from IACUCs and GMOs were 'congruent'.**

>> Dr. Brown: Well, we would respond to that by saying that each Institute and Center has its own definition of what rises to the level of a change in scope. So – and there is currently no specific guidance for the GMOs as to what does rise to the level of a change in scope. And we would like to work on that in the future.

>> Dr. Collins: Next question: **[27.] What level of detail of review for genetically modified animal strains is required for grant congruency?**

>> Dr. Brown: Again, we're not looking for microscopic review. I think that we would defer to the reviewers who can confirm that there's a semblance of equality in what's in the grant application and what's approved by the IACUC.

>> Dr. Collins: There are two questions here that are similar. The first is one long; the second one is short. So let me read both of them, Pat, and then perhaps you can respond. The first one: **[28.] What constitutes a change that needs to be conveyed to the NIH? A hypothetical situation, for example: During a congruency review, it is determined that anesthetics being used for procedures specified in the grant are different than those specified in the protocol. The PI indicates that he will use the anesthetics described in the protocol, not what the agents are that are specified in the grant. Is this change significant enough to be conveyed to the NIH?** And then the second question which seems to be related: **[29.] Would a difference in sedating drugs i.e., Avertin in protocol versus IACUC, which has changed to ketamine/xylazine need to be sent to the NIH?**

>> Dr. Brown: I would say this is getting down in the weeds at the level that – NIH I think is looking more for significant modifications made by the IACUC that would really

alter how the PI is going to be conducting the research with the animals. Refinements, such as modification to an anesthetic or an analgesic, I think is well within the IACUC's role and not something that NIH would need to be informed of.

>> Dr. Collins: And just a general comment, we all need to remember that what's written in the IACUC protocol is what must be done. So if there is a discrepancy, it's important to make sure that the IACUC protocol is defining which drugs are going to be used.

Our next question: **[30.] How should we handle the new R21/R33 funding mechanism in which funding is assured for the first two years and only 50% of the awardees will be funded? Should the congruence review focus on the first two years or all five years?**

>> Dr. Brown: Well, the basis for the IACUC review is that it's confirming that the activities described in the grant have been approved by the IACUC. So even if the information is sketchy, it should be in the protocol, but maybe in less detail from what is known is going to occur, as you say, in the first two years. That way the IACUC is aware of what is potentially going to happen with the expectation that the IACUC would see an amended protocol when it looks like the funding may occur further down the road.

>> Dr. Collins: Pat, we now have three questions that look like they are somewhat similar to that one. But rather than trying to combine them, I will read each one. And then if there are subtle differences between them, we can address them. The first one: **[31.] What if a PI submits a protocol that corresponds to a grant and after three years the PI submits a different protocol for the same grant, do we need to notify NIH?**

>> Dr. Brown: I guess I'm not understanding the difference here. NIH expects ongoing IACUC review and approval of the animal activities. Once the award is made, that review and approval must continue, recognizing that the PHS Policy requires a protocol must be re-reviewed every three years. So if the PI submits a new animal study protocol at the three year point, that's kind of the expectation. And it's – it doesn't need to be something that NIH needs to be notified of.

>> Dr. Collins: The next two questions are really very close to each other. It relates to the three years, four years, versus five years. Let me just read one of them: **[32.] Since grants are typically approved for five years and protocols for three years, are PIs required to include procedures that would be performed in years four and five in their IACUC protocol?**

>> Dr. Brown: We've answered this as an FAQ [[FAQ D20](#)]. And what I would just like to say is there has to be congruency between what's in the grant and what's in the IACUC protocol, recognizing that the details for the fourth and fifth years of what's in the grant may not be the same level of detail that the IACUC is approving for the first three years. So the – that information can be there with the explanation that this is the out years and that that, of course, will be refined, amended, at a later time when, you know, typically at the end of the three-year cycle.

>> Dr. Collins: Pat, the next question is talking about a Notice and differences in strains, but it's not totally clear to me what they are actually asking. So I think what we will do is we'll have this be one of the questions that we address off line and it will give us a chance to take a look at it and better understand what we think the person is asking.

The next question: **[33.] Does the institution need to do a congruency check for collaborations described in the NIH grant application?**

>> Dr. Brown: I'm sorry, Jerry, I don't have that question in front of me.

>> Dr. Collins: Okay. Let me go to the –

>> Dr. Brown: Hang on, I found it, sorry.

>> Dr. Collins: Okay. I apologize. I skipped. My fault, these pages of questions are coming in and I wasn't following protocol. So again the question was: Does the institution need to do a congruency check for collaborations that are described in an NIH grant application?

>> Dr. Brown: Not having enough detail about what is meant by a collaboration, all that I would say is the prime grantee, when they accept the award, is agreeing that the IACUC approved activities are congruent with what's in the grant application. So if they can work that out, and have that understanding of whatever the collaboration is and whoever is doing what, they have that responsibility to ensure the congruency exists.

>> Dr. Collins: Pat, if we could get back to the previous page, the question that I unfortunately skipped: **[34.] The IACUC can do the congruency comparison at the beginning when the protocol will be approved. However, the IACUC doesn't necessarily know whether the PI will perform all of the experiments proposed initially in the IACUC protocol. What should the institution do about this situation?**

>> Dr. Brown: Well, we understand that science is a fluid entity. And the expectation is that if the PI changes direction, he needs to amend the protocol. Just like if the PI changes direction in his research and it's a change in scope, he gets NIH prior approval. There's latitude in what is – what the PI does, as long as the IACUC has approved it.

>> Dr. Collins: Okay. Our next question: **[35.] Is congruence review only required at the time of award? What if amendments are later submitted that request changes that could change the congruence between the grant and the protocol?**

>> Dr. Brown: As I said before, the – this comes down to a change in the animal study protocol [that] may not rise to the level of what NIH would consider a change in scope. Changes in scope are usually big types of changes. As I said, changing from one species to another, adding a whole new organ system to the area of research. Things that – as I said, NIH would say, yeah, you're really deviating from what you originally said that you were going to do. Minor amendments that the PI is doing that are still within the framework of the research aim would not rise to the level of having to notify NIH. But as I

said, anything that the PI decides to change that's not in the IACUC protocol, he needs to get approved [by the IACUC] before he can conduct those animal activities.

>> Dr. Collins: Next one looks like it's a question about what section of the grant application they should really look at: **[36.] Is comparing only the Vertebrate Animals Section of the grant to the IACUC protocol acceptable for assuring congruence, and not the Methods/Materials or Approach/Research strategy section of the grant?**

>> Dr. Brown: Well, I think that I covered this. [See discussion of slides 23 and 30.] It's good to start with the Vertebrate Animal Section, but recognize that PIs often also have information about animal activities in other parts of the grant. Now that the page limitations have been put on other parts of the application, we – it's our understanding that most of the animal activity is going to be described in the VAS because the VAS has no page limits.

>> Dr. Collins: I would also just comment that there can certainly be value in also taking a look at any description of preliminary data or of progress that has been made since investigators will sometimes share information there that is of relevant for congruence comparison as well.

Our next question: **[37.] If an investigator is transferring a grant from their prior institution when joining a new institution, and the grant includes animal research, but all of the animal work has already been completed at their previous institution or they are no longer planning to do animal work, what, if anything, should the new institution's IACUC review?**

>> Dr. Brown: I think at this point there's no requirement for the IACUC to do any review at all because there's not going to be any active animal studies ongoing as part of the transfer of the grant. And NIH would consider that grant as no longer requiring IACUC protocol review.

>> Dr. Collins: I think this next question, Pat, probably has been answered. But it doesn't hurt to repeat: **[38.] Is congruence review only required at the time of award? What if amendments – and I'm assuming those are amendments to the IACUC protocols – are later submitted that request changes that could change the congruence between the grant and the protocol?**

>> Dr. Brown: As I said before, this really comes down to the PI's responsibility to keep NIH informed of things that are big, that are changing in their ongoing pursuit of the research aims. If what they are doing is a change in scope, they need to get prior approval from NIH. If what they are proposing to do is changing what is – from what's originally described in the IACUC protocol, that is something that just requires an amendment modification and review and approval by the IACUC. The congruence really does start at the time of the initial award or also the competing renewal.

>> Dr. Collins: This is a question I got about responsibility: **[39.] What is the definition of “the institution” that is responsible to ensure congruence; is this the institution that receives the NIH funds? Or the institution that has an IACUC and provides the animal care?**

>> Dr. Brown: Again, the prime grantee is responsible. In the case of an interinstitutional agreement where the prime grantee has no animal facility, they are going to be dependent on the IACUC where the animal activities will be occurring. I think this is something that they should work out as part of their memorandum of understanding about this requirement for congruence because the expertise, most likely for doing a congruence review in that circumstance, probably would be coming from the institution that has the IACUC. But as I said, it's my understanding that the prime grantee is always held responsible.

>> Dr. Collins: This next question sounds like it probably relates to programs where there's not a one-to-one correspondence between the grant application and an IACUC protocol. The question is: **[40.] Our concern is that all work with animals be appropriately reviewed and approved at our institution. Provided that an investigator does not spend grant funds in any inappropriate fashion, I am not sure why we are concerned about congruence. For example, an investigator might do experiments with local funds which were approved by the IACUC, but which may support the activities of an NIH grant, but not be supported by it. In such a case, there will be no congruence.**

>> Dr. Brown: I would agree with you, Jerry, that this is one where it sounds like there may be an IACUC protocol that is covering multiple-funded activities. NIH still expects that whatever's in the [NIH] grant application has a corresponding IACUC approval of that activity. Each institution has to decide for themselves how best to manage this circumstance. As I said, many institutions do a one-for-one grant to protocol ratio. Others will do a combination of either multiple grants on a single protocol or multiple protocols sometimes covering a single grant.

>> Dr. Collins: And as you said in your presentation, Pat, the important issue there is not only that everything is appropriately approved by the IACUC, but also that the institution has in place a mechanism to assure that funds are spent appropriately as they are related to a particular funding source.

Next question: **[41.] Please identify what funding sources are covered by this requirement. Certainly all NIH, but also, – and this is the question: NCI or DOD?**

>> Dr. Brown: All of the NIH Institutes and Centers, including the National Cancer Institute, are subject to this grants policy requirement. I'm unfamiliar with the Department of Defense's requirements. But my guess is they would probably be similar, but I cannot confirm that at the present time. We'll look into that and provide additional information. [See [DoD Directive 3216.1](#) – PDF]

>> Dr. Collins: Okay. I think, unfortunately, although we do have at least a half a dozen more questions, we are about to run out of time.

Slide 33 (OLAW Online Seminar Series Upcoming Schedule)

So, again, Pat, I want to thank you for taking your time to provide our participants with information on this important topic. And to all of you who have participated, we as always thank you for your participation. [Text related to information for attendees and submitting questions during original broadcast of the seminar has been removed.] As a reminder, this session has been recorded and will be available on the OLAW website in the [Educational Resources](#) section.

From all of us here at OLAW, thank you for what you do to ensure humane care of animals used in research, teaching, and testing. And we hope that you have an enjoyable summer.

Additional Submitted Questions Not Addressed During the Webinar

[42] Is it more important that what the PI describes in the grant is IACUC approved or what the PI actually does is IACUC approved?

Both are important and they are related. NIH Grants Policy Statement (GPS) requires the institution to ensure that research described in the grant application is congruent with corresponding protocols approved by the IACUC. The PHS Policy ([IV.C.1](#)) requires that PHS funded animal activities be conducted under an IACUC-approved protocol. (PHS funded animal activities conducted without IACUC approval are noncompliant with the PHS Policy and must be promptly reported to OLAW.) NIH GPS defines legal obligations between the grantee institution and NIH. These requirements make up the terms and conditions that must be met to legally receive NIH grant awards. It is important to recognize that compliance with the PHS Policy is a term and condition of the GPS. If an institution accepts PHS funds and fails to meet the terms and conditions, there can be fiscal, civil, and/or criminal penalties.

[43] I am concerned that Dr. Brown stated that it is acceptable to have loosely described procedures in an IACUC protocol that are not clearly defined. I fear these sorts of vague descriptions may be cited by USDA.

Are you referring to Dr. Brown's answer to Question 30? "How should we handle the new R21/R33 funding mechanism in which funding is assured for the first two years and only 50% of the awardees will be funded? Should the congruence review focus on the first two years or all five years?" The basis for the IACUC review of proposed animal activities [in out years] is to confirm that the activities described in the grant have been approved by the IACUC. So even if the information and the plans for the activities are limited at the time of the application, it should be in the protocol, but maybe in less detail from what is

known is going to occur, as you say, in the first two years. That way the IACUC is aware of what is potentially going to happen with the **expectation that the IACUC would see an amended protocol** when it looks like the funding may occur further down the road.”

In her answer, Dr. Brown provided a best practice method for meeting the NIH Grants Policy requirement that the research described in a grant be approved by the IACUC before funds can be released to the institution. Dr. Brown suggested that the investigator include information about the research proposed to be conducted in later years (out years) of the grant in the initial IACUC review, acknowledging that research plans for the out years of the grant would not have sufficient detail for a complete IACUC review. However, that proposed research would be re-reviewed and approved by the IACUC prior to conduct of the research. We note that:

- Often, grants are funded for **5 years**.
- The PHS Policy (IV.3.5.) requires that the IACUC conduct a complete *de novo* review and approval of proposed animal activities “at least once **every three years**.”
- “The Animal Welfare Regulations [CFR Title 9 Chapter 1 Subchapter A Part 2.31(5)] require “the IACUC shall conduct continuing reviews of activities...**not less than annually**: ”

USDA requires yearly re-review of proposed animal activities. Inclusion of less detailed research plans anticipated to occur in the future would not be a violation of USDA requirements as long as the IACUC conducted annual review as required by the Animal Welfare Regulations.

[44] In a program project grant that awards funds to multiple institutions, which institution is responsible for the IACUC protocol grant congruence?

This is similar to the situation described in Question 21 and the same answer would apply. The institution that accepts the funds from NIH verifies, by providing the IACUC protocol approval date, that there is congruence between what is in the grant application and what has been approved at the institution where the activity is going to be conducted.

From [FAQ D8](#), “NIH Grants Policy Statement on Written Agreements ([15.2.1.](#)) requires that awardees have a formal written agreement with consortium participants that addresses the negotiated scientific, administrative, financial, and reporting requirements of the grant. This written agreement must include incorporation of applicable public policy requirements, including agreement for meeting the PHS Policy requirement for review and approval of proposed animal activities, significant changes to animal activities, and semiannual facilities review by an IACUC ([IV.B.2.](#)).”

[45a] Can you give some examples of the pros vs. cons of 1:1 vs. 1:many protocol-to-grant association?

[45b] It was stated earlier that congruence is a 2-way street. Often we see

protocols that cover work for multiple grants, and thus during our congruency review, we encounter many procedures/drugs that are irrelevant to the grant currently being reviewed. Should protocols be specific to a singular grant?

The PHS Policy and the NIH GPS allow flexibility so that an institution can maintain compliance while meeting individual program needs. OLAW recommends thinking through the implications in the context of your own institutional needs and IACUC policies and procedures. It may be helpful to talk to colleagues at other PHS Assured institutions to determine the pearls and pitfalls of various methods of congruence review.

[46] Should we also be conducting congruency review at the time of protocol modification?

If the modification includes a change in the scope of the research, it would be prudent to clarify the change with the PI or conduct a review for congruency with the progress report. A change in species of animal used **is** a change in scope. Significant modifications that require IACUC review and approval are not necessarily a change in scope of the research program. See OLAW [FAQ B13](#).

[47] I understand that minor changes that require amendments to the protocol may not lead to a change in scope. However, what if they do? Should the IACUC request the PI confirm approval from the grants office for the change in scope – and should a new congruence review then be done?

Yes. If the PI determines that there **is** a change in scope, he or she, through the Authorized Organization Representative, is responsible for requesting approval of that change in scope. The request for a change in scope must be made in writing to the Grants Management Officer (email is okay) to the NIH Institute or Center that funds the grant. The request must be made no less than 30 days before the proposed change and must be signed by both the PI and the AOR. If the PI determines there is not a change in scope, he or she provides an explanation that the institution may file with the congruency review documentation.

[48] I understand that a change in scope requires NIH approval, but provided the IACUC ensures that NO work is ever permitted without approval (even a change which would be a scope change) then it would seem that the change in scope is an important concern for the PI and OSP (Office of Sponsored Projects), but not for the IACUC. Provided that all activities with animals are IACUC approved, why should the IACUC care about a Scope change; someone should care, but why the IACUC?

There is no explicit requirement for the IACUC to do a side-by-side comparison of an application and the IACUC protocol. However, institutions are responsible for ensuring that the information the IACUC reviews and approves is congruent with what is in the application. Institutions are free to devise a workable mechanism to accomplish this end. One method to prevent inconsistencies between the information submitted to NIH and

that on the IACUC protocol is to implement a procedure for direct comparison. Some institutions have delegated this responsibility to a particular office or position, such as the sponsored programs or compliance office. Others ask departmental chairs to verify consistency, but this is a minimal approach and a high risk to the institution.

[49] Why does Notice [NOT-OD-10-027](#) state it needs strains if the congruence is required by the VAS? This notice says it needs strains and you just said strains were not required to be congruent? Why is this required if the genetically modified strains are not part of congruence review?

The VAS provides information that is required for the NIH Scientific Review Group (Study Section) to conduct its review and make its assessment of the proposed research. This information including the strain of animal is required as part of the grant application and is required by the PHS Policy and the NIH Grants Policy Statement. The grant and IACUC approved animal study protocol are required to be congruent by the NIH Grants Policy Statement. As was presented in the webinar in slide 24, the review for congruence should confirm that the species and all procedures are in agreement and the animal numbers proposed are approximately similar. In most cases a change in the mouse strain does not constitute a change in scope of the research program. If there is a question about a specific situation, please consult the Grants Management Officer of the funding component.

[50] If the investigator determines that a change in species may be more appropriate for their research (or for preliminary research) in the same line of work, and if the institution determines that it is within the 'scope' of what is in the grant, can they make that determination? We have seen different species of macaques, different types of NHP's (changing between macaques and baboons) or using rabbits instead of other species, etc. In most instances, we have been requiring the investigator to request approval from NIH.

A change in species **does** constitute a change in scope. See OLAW [FAQ B13](#). If the PI determines that there **is** a change in scope, he or she, through the Authorized Organization Representative (AOR), is responsible for requesting approval of that change in scope. The request for a change in scope must be made in writing to the Grants Management Officer (email is okay) to the NIH Institute or Center that funds the grant. The request must be made no less than 30 days before the proposed change and must be signed by both the PI and the AOR. If the PI determines there is not a change in scope, he or she provides an explanation that the institution may file with the congruency review documentation. When in doubt, please consult the Grants Management Officer at the funding component.

[51] I would also suggest looking at the performance sites listed as well as resources and environment sections of the grant.

Perhaps this suggestion relates to the discussion of slide 23, *Where to Look in Grant*. "Where in the application should one look? There are two primary areas in the grant to concentrate on when conducting grant congruency [review]: the Vertebrate Animals Section and the Approach part of the Research Strategy Section." Those are good suggestions. In the current grant application form the section names mentioned are called "Performance Sites" and "Facilities". Thank you for your contribution to the discussion.

[52] If PHS funding is given to Institution A, but all of the animal work is subcontracted to Institution B, who is responsible for the congruency review? Is it the Institution that receives the money – because it is part of the oversight responsibilities? Or is it the Institution where the work is performed and the original protocol is reviewed and approved?

This is similar to the situation described in Question 21 and the same answer would apply. The institution that accepts the funds verifies, by providing the IACUC protocol approval date, that there is congruence between what is in the grant application and what has been approved at the institution where the activity is going to be conducted. As mentioned in response to Question 21, NIH Grants Policy Statement requires that awardees have a formal written agreement with consortium participants that addresses the negotiated scientific, administrative, financial, and reporting requirements of the grant.

[53] What are procedures to follow when an investigator introduces changes to IACUC [protocol] needing changes to NIH grant proposal after the grant has been awarded and the PI has started the work? For example a PI submits a change request to add a species which he/she has not indicated in his grant proposal. Where does the process begin?

Dr. Brown discussed lack of congruence with the help of slides 25 and 26: "What if Not Congruent?" If the PI wants to modify the IACUC protocol by adding a procedure that is not in the grant, then he or she should determine if the differences meet the definition of a "change in scope". [See OLAW [FAQ B13](#).] If the PI determines that there **is** a change in scope, he or she, through the Authorized Organization Representative, is responsible for requesting approval of that change in scope. The request for a change in scope must be made in writing to the Grants Management Officer (email is okay) to the NIH Institute or Center that funds the grant. The request must be made no less than 30 days before the proposed change and must be signed by both the PI and the AOR. If the PI determines there is not a change in scope, he or she provides an explanation that the institution may file with the congruency review documentation.

[54] When an amendment is submitted to modify IACUC-approved procedures (in order to meet study needs through the alternative approaches), what is the obligation of the institution to match these procedures with those specified in the grant proposal?

Congruence is required.

[55a] Is it OK for the investigator who only has funding from current grants, to carry out "future" pilot studies, using current grants to fund these pilot studies, although the current grant proposals may totally lack any descriptions of these pilot procedures?

[55b] Is there a mechanism that institutions should use to categorize and approve such use of NIH funds, given that there may not be any description of the new procedures anywhere in the currently funded grant proposal?

In general the program director/principle investigator (PD/PI) may make changes in the methodology, approach, or other aspects of the project objectives. However, the grantee must obtain prior approval for a change in scope. Therefore, pilot studies may be conducted if they are consistent with the scope of work for the current project. If the pilot studies represent a change in scope from the approved project (i.e., change in the direction, aims, objectives or purposes) then prior approval is required from the awarding Grants Management Officer. Any change in animal care or use from what was approved by the IACUC requires the investigator to seek IACUC approval prior to initiating the change. See section [8.1.2.5](#) of NIH Grants Policy Statement for more information on Change in Scope.

[56] Are the institutions required to go back and audit their existing funded grants for congruence? They may identify grant(s) that might not be congruent. If one finds an existing 5 year grant not congruent with the IACUC protocol, does this need to be reported to NIH? In the past (before the protocol-grant congruence age), the investigators' animal protocols only included studies for 3 years.

The NIH Grants Policy Statement states that it is an institutional responsibility to ensure that the research described in the grant application is congruent with any corresponding protocols approved by the IACUC. This is not a new policy; congruence has been required since the PHS Policy was promulgated and is a term and condition of funding the grant. Please refer to the discussion of slides 25 and 26 "What if Not Congruent" for information about determining congruence. If you determine that animal procedure(s) has (have) been conducted without IACUC approval, the noncompliance(s) must be reported to OLAW. See [Reporting Noncompliance](#). If you determine that there has been a change in scope of the grant, the change must be reported to the funding component.

[57] If one finds inconsistencies during the congruence review of a new grant with an IACUC protocol approved 2 years ago and PI decides to modify the protocol to make it congruent with the new grant, what date should the IACUC use as the approval date – the initial approval date or the modified date? If the institution uses the modification date as the approval date, this may give the false impression that the protocol is now approved for 3 years since that date. It

would be ideal if you advise the institution on this perhaps to indicate the initial approval date and modification date.

The institution is responsible for assuring congruence between the grant submission and the IACUC approved animal study protocol. The IACUC has the responsibility and the authority to develop policies that work well for the institution as long as the policies enable the institution to remain in compliance with the PHS Policy. OLAW would support your proposed policy of amending both the initial approval date and the modification date to the protocol in this situation. However, other solutions would also be acceptable; e.g., the IACUC might request that the PI submit a new protocol that is congruent with the new grant.