**TRANSCRIPT**

**NIH Grants Policy Updates FY2025 Edition**

**Event date: October 17, 2024**

Kimberly Biondi: Welcome. Thank you for joining us today for the NIH Grants Policy Updates: FY2025 Edition. I am Kimberly Biondi, a Communication Specialist with the NIH Office of Extramural Research.

Today's webinar is scheduled for one hour, and with already thousands of you here, and thousands more in attendance from all over the world. We're happy you're here. Thank you for joining us. We did receive many pre-event questions, and many of those questions will be answered throughout the webinar today. They have been incorporated in the presentation, but if you have any questions, please be sure to use the Q and A box to submit, and responses will be provided as time permits. The PowerPoint is also available for this event. You will be able to find the PowerPoint on the Events page, and I will be dropping that into the Chat in a minute. The transcript and recording of this webinar will be posted on the exact same Event page, in approximately seven to ten business days. So that's where you'll be able to find it. Oh, look at everybody jumping and saying "Hi" -- I love that. Then also, at the end of the event, please share your feedback with us. A short survey will pop up, and we'd love to get some feedback from you.

Before I introduce the presenters for today, we'd like to know who's in the audience. So, using the poll that's going to be popping up in just a second, if you could tell us a little bit about you, your primary role, classification at your organization, choose the option that's most relevant to you. We'd love to get to know who is joining us today.

So, with that, I am pleased to now introduce our presenters for today's event. Michelle Bulls is the Director of the NIH Office of Policy for Extramural Research Administration, also known as OPERA, and Kristin Ta, the Deputy Director in OPERA. And with that, I will turn it over to Michelle.

Michelle Bulls: It's been a long time since I've been with you guys doing the NIH Grants Policy Updates, and so I'm excited to have an opportunity to spend some time with you today. Kristin and I have been talking about how long it's been. So, we're going to be going over a few critical areas; the budget, policy updates, as well as the system processes, and the compliance updates. Of course, we always give you policy reminders, because that's what we do. And then we'll always want to provide you with resources to make sure that you are in the know on all of the various areas that need to be had by our extramural community. Kristin?

Kristin Ta: Want to kick us off with some budget updates, Michelle?

Michelle Bulls: I'm going to kick you off with some budget updates. Wasn't sure if you wanted to introduce yourself.

Kristin Ta: Oh.

Michelle Bulls: But that's all good. Everybody knows who you are, so that's great.

So, with the budget updates, guys, we know that the POTUS signed a CR which extends the government's operations through December 2024. When is the last time that we haven't had a CR? So, for that, we are grateful that it came early this year, this fiscal year. I want to make sure that you guys know that while the CR is in place and the budgets remain the same, ICs will still continue to provide and lay out their fiscal policies and their funding strategies under the CR. While we know that there is a CR in place, there are a few things that will not change under the CR; the legislative mandates, the salary cap for grants and cooperative agreements -- and I'm going to put an asterisk there for your information -- and then of course the NRSA pre- and postdoc stipend levels and tuitions and fees, as described in our Guide Notice. We still try to put out our Guide Notices just to make sure that everyone recognizes that those CRs remain in place before our salary cap. We're going to take you to the next step. Next slide.

So, for the salary caps, we have our legislative mandates. We recognize that effective with October 1, 2024, there was a policy change that makes sure that we outline the fact that the executive level amount for 221,900 has not changed, but there is a applicability change that we want to raise to your attention. And that is that the salary cap not only applies to direct salaries, but it also applies to the indirect salaries, meaning the uncapped pools that are negotiated within your IDC rate agreements, such as Operation and Management, as well as the library positions. And this is a change, and it is effective October 1. NIH will release a Guide Notice that will align itself with the HHS policies. And we do recognize that while there might not be an updated nor improved indirect cost rate agreement, or there may be an updated new indirect cost rate agreement, the new requirement for the cap on indirect executive salaries that are outlined in these various cost pools, depending upon, of course, your negotiated rate agreement, will be applicable. So again, NIH will put out a updated salary cap limitation Guide Notice that will definitely give you a snapshot into what that looks like, and we probably will be able to change some of the calculations so that you can see how this will look. Next slide.

Kristin Ta: So, before we move on, Michelle, I do have a quick question, just because this is a bit of a change, right? So just so I'm clear, the salary rate limitation now, so does it apply to just direct salaries, just indirect salaries, or is it both direct and indirect salaries it applies to?

Michelle Bulls: So, I want you to be clear, but I want our audience to be crystal clear. It's direct and indirect, so it's direct salaries for those that are directly linked, and the direct activities charged to the grant, as well as indirect, which are your executive salaries that may be identified in these uncapped cost pools.

Kristin Ta: Great.

Michelle Bulls: Great question, thank you.

Okay, so for our childcare cost updates for NRSA fellows and trainees, you will recall that NIH began to provide childcare costs to recipients to full-time NRSA fellowships in April 2021, and we have been very committed to that and making certain that the biomedical workforce is protected. Not only did we do that for our NRSA fellowships, but we extended that to the NRSA training awards in September 2021 as well. So that meant that it was our fellowships and our NRSAs. NIH will remain committed to protecting and providing the success that is needed to our workforce, by expanding the costs to F9/K00s. So effective in 2025, October this year, this fiscal year, we intend to provide childcare costs to support individuals supported under the full-time recipients of the Predoctoral to Postdoctoral Fellowship Transition Award, which is our F99/K00 programs. And we want to make sure that we get that Guide Notice out early and soon, so that we can get that on the books for you all to recover those costs.

Kristin, did we have any questions related to that, because I know that you --

Kristin Ta: Yeah, I do have one question. So, the F99/K00's kind of a phased program. These childcare costs, though, they only applied to the F99 phase? Or is it both?

Michelle Bulls: F99.

Kristin Ta: Okay. So, it lines up right with the other fellowship.

Michelle Bulls: Absolutely. And I hope everyone takes note of that. That's an important note.

We have received, and we consistently receive questions, honestly, regarding cost escalations. And I remember back in the heyday when you would get a three percent or a four percent cost escalation, and it was a policy of NIH that we would put that out and make sure that our recipient or applicant community recognized it. So, I'm going to just reiterate something that we said for a very, very long time -- applicants and recipients should request whatever is needed to accommodate the science in the budget. We do not have, in general, a policy on escalations anymore. We have long since kind of rescinded that policy, and we say that if there is an escalation needed and that escalation is allowable and allocable and necessary for the project, I fully encourage our applicants and recipients to please, please request those costs, because what we don't want to put you in a situation where you have to request an administrative supplement for costs you knew were needed at the outset of that at that budget and at that award. So, we want you to make those requests, make those clear. Make sure you justify them, and we will encourage you to continue to do that. But we also wanted to make sure that we provided a Develop Your Budget link in the slide that you will have access to, to make sure that you are able to take a look and see what that budget preparation page looks like and making sure that you just kind of keep yourself up -to-date on some of these budget reminders.

I also want to be very clear that costs beyond the period of performance are generally unallowable. Now I do know that we have had a couple of policies that have come up of late that have said that you can charge costs beyond the period of performance, and we'll talk a little bit about that as we move into some of the other pieces of the slide deck. But we want to be clear that that is typically not allowed. And where it is allowed, we will provide that information in a Term and Condition of the award to make sure that we provide the adequate protection that we need to provide to our applicant and recipient community. But we will definitely encourage you to develop your budget by clicking on that link and taking a look at those instructions and getting the up-to-date information. Next slide.

So, I'm going to go through some policy updates, NIH policy updates that I think you'll just be happy to hear about. I might not go into as much detail as you would like for us to do today, and I will tell you right now, the only reason why we probably won't go into those details is because we are still putting together our plan to make sure that we have the clearance of our counsel, legal counsel, as well as we want to make sure that others within the department are clear on NIH's implementation. But the 2 CFR 200, I'm just going to go through kind of a quick overview. So, in April of 2024, I know that you guys have been in other venues where OMB has announced and others have announced that they've issued revisions to the uniform administrative requirements for grants and cooperative agreements, and of course that's located in our administrative regulations at 2 CFR 200.

One of the things that I think is really important is that NIH continues to fight hard to make sure that our recipient community has the ability to take advantage of the OMB administrative flexibilities that went into effect October 1, 2024. And those flexibilities are in place for many of the increased thresholds. And we do have some areas where it will depend on the negotiated and direct cost rate agreement, and whether or not that allows it. We also want to be clear that many of the changes within the areas of the FNA, or indirect cost rate agreement will likely only apply to new and competing renewal awards without changes to the noncompeting continuation -- that' the plan at this time. NIH will continue to work very closely with HHS, and other HHS operating divisions, recognizing that you all have -- they have some of the same recipients that we provide grants to.

And we want to make sure that whatever we do that we are transparent to the other operating divisions, making sure that we don't place an administrative burden on our community by not being transparent, and making certain that folks know what we're planning to do so that we can make sure that we kind of go in this thing together. So, we've had many discussions, I've been on many calls with the other agency grants management officials, and the department, and we are all in agreement that this needs to work for the entire community, especially where those applicant and recipient groups overlap. So that's something that you guys know that NIH is wedded to, and we will remain wedded to it, and we will definitely push to make sure that this happens. I want to make sure also that you all are very accustomed to NIH and NSF issuing research terms and conditions. And those will not be updated at this time.

We will work with all of the federal agencies to update the prior approval matrix and the national policy requirements to make sure that those pieces are clear, so what you will see, and right now what's in the research terms and conditions, are to their different matrixes; there is one that is a prior approval matrix and it kind of goes through and tells what each agency will do for prior approval, but a lot of that is really what's in the uniform regulations, which is kind of consistent. I think NIH, at this point, we're going to take it to the next level and make sure we have NIH-specific prior approval requirements that you guys have at your fingertips, and that you can look to, to make certain that whatever the differences are from NIH and other federal research agencies, you will be able to identify those very quickly. I don't know that we have done that level of analysis and review in the past, but we are currently under review for looking at all of the various prior approval requirements that NIH has specific to our grants and cooperative agreement programs. And the same with the national policy requirements, because sometimes those do differ across federal platforms. Next slide.

So, as you have likely seen, NIH has taken a similar position as a few of our HHS operating divisions where we are clarifying that the single audit requirements for foreign recipients and subrecipients need to be at play. So, we have not called them out in the past and decided that it was very important for us to do so, both for audit reasons, as well as for protections to our extramural research community. So effective October 1, we have outlined the fact that form recipients that expend $750,000 cumulative amount or more in federal awards during their fiscal year, during the foreign entity's fiscal year, will either conduct a single audit or a program-specific audit as required by the terms and conditions of the award. The NIH grants policy statement for FY '25 will be updated, and it will include that provision, and make sure also that we call out the fact that anytime there's a specific audit requirement, or a program-specific audit requirement, that that is a decision that is made by the institute and center that requires prior approval from both the foreign recipient, the foreign sub, the domestic sub, anytime there's a program-specific audit that requires prior approval. And it requires prior approval from the institute center prior to conducting the program-specific audit. So, I want to make sure that it's very clear that if that's not done prior to the program-specific audit, the entity runs the risk of having to cease and desist on the program-specific audit and be required to conduct a single audit. So that's something that we've been talking about within our compliance, grants compliance space, and then of course amongst OPERA leadership between Kristin and myself, just to make sure that we lay out those clear guidance for our community, just to make sure that you all understand a prior approval would not be accepted from our division of financial advisory services. It must come from the institute or center who manages the program and would be able to say that this is the only assistance listing number program that the audit is impacting. We want to make sure that that is very clear for our community. Next slide.

Kristin Ta: And I think we have a poll question before we head into this next set of slides.

Michelle Bulls: Okay.

Kristin Ta: All right, so I hope everyone can see it. When is the effective date of NIH's adoption of the Common Forms for bio-sketch and current pending other support? So due dates on or after which one of these?

Michelle Bulls: Don't cheat, Kristin.

Kristin Ta: Well, you're going to tell us the answer anyway. So, let's see who knows it.

Michelle Bulls: Oh!

Kristin Ta: Close!

Michelle Bulls: Very!

Kristin Ta: Okay. So, Michelle, do you want to give us the answer?

Michelle Bulls: It's on or after May 25th, 2025. But I think that we're going to clear up that confusion, because that's something that we talked about a little bit earlier, right Kristin --

Kristin Ta: Yeah.

Michelle Bulls: -- is that folks are kind of mixing the FORMS-I, implementation. Look, I love these sighs. It sounds like your whole soul is lost. Come on, guys! It's not wrong, and I'll tell you why it's not wrong, because you have so much going on with this FORMS-I and the disclosure requirements that your soul does not need to be lost. But you're definitely going to have the information today.

All right, so let me just start by saying, thank you guys for being transparent. You know, I love when I can just put a little zinger in there, and then you guys' just kind of tickle me, I love it. But that whole lost soul thing -- that emoji is great, Kristin! Oh, my goodness. I look like that every day.

So, let's just say here that for the Common Forms for the bio-sketch and current pending other support -- there has been a lot, a lot of work done within OSTP, as well as the NSTC, that developed the Common Forms. That was a co-chairing effort between NSF and NIH. And I think we landed in a really sweet spot. We were able to truly harmonize the Common Forms and come to a place where our community will have the benefit of actually having a Common Form where folks are truly adopting the common principles. Now there may be some outliers in terms of additional things that need to be collected, but that's because you have 26 or 27 different federal agencies. And we all don't serve the same mission. And we all don't have the same legislative and grant-making authorities. So that's that little piece that we might ask for additional content. But I'll guarantee you that the form itself, most folks are adopting it as is. So, effective on or after May 25th, 2025, we do plan to make this a requirement, the Common Forms. We will implement that form, like I just said, without changes, and then I am going to unpack that nice little zinger that I gave you that NIH and others have different authorities and different regulatory requirements and different legal requirements. So, NIH goes plan to continue to collect the three required agency-specific data elements outside of the Common Form, personal statement, contributions to science and honors, just to make sure that we are able to fully assess the qualifications. That is a mainstay within our forms, and the intent of collecting data so that we can make sure that those qualifications are clear. The data elements, like I just said, will be collected separate from the Common Forms, and we will be having a new NIH Biographical Sketch Supplement Form. Next slide.

Kristin Ta: So, Michelle, with the Common Forms, there's been a lot of chatter about using Science CV to generate the Common Form, so Bio-Sketch and Other Support. Once these Common Forms are effective in May, is Science CV going to be something that's still optional? Or is that going to become a requirement?

Michelle Bulls: Well, so you are right in my head, because that next slide is getting ready to give you all the information that you need. And I'm so glad that you're advocating for this kind of information, Kristin, because that's exactly what the community wants to know. This will not be an optional form. This will be a required use of Science CV, and that will be effective, of course, May. We will require Science CV and ORCID ID implementation. And we did something kind of nifty here, in that we allowed our colleagues at NSF to go out before us to test the waters, and to make sure that those pieces are very, very clear. And then we will come out with it in May. We've shared this information over and over and over again, so this is not -- shouldn't be new to the community. But NIH will require the use of Science CV. And we also will require that all senior key personnel enter their ORCID ID into Science CV and the PID section of the Common Form. We will require, for all of our senior key personnel, to link their ORCID ID to their eRA Commons Personal Profile, and then of course information on linking that ID to eRA Commons is on the ORCID ID topic and the eRA Commons online help. eRA's always going above and beyond to help us and to help the community on figuring out how to make this work. So, we encourage you to tap into that help and make sure that you have what you need to be compliant.

So, another really critical part of disclosure is to make sure that once we have that information, that we provide a transparent way of sharing with the community how we make the determinations for each of our foreign interference cases. And we recognize that we probably will not be able to give you the full scope, but we do try to give you some high-level criteria that we use to make those determinations. A large part of it depends on the information that's provided or not provided, or what we're able to obtain to help fill in the gaps for making those decisions. But how we make those decisions are clearly very consistent in our approach. We use criteria that are outlined in the matrix, and the criteria applied to all of our senior key personnel in our entities, regardless of the type. Our colleagues within NIH OV Research Integrity Unit, along with Dr. Lauer, have taken a lot of time to really go through and identify the factors, identify how we conducted the reviews, and how we have come up with the outcomes. So, it's a really good decision matrix that we encourage you to take a look at. We gave you a snapshot here on the presentation, but we want to make sure you have an opportunity to gone through in-depth, so we did provide that link for you.

Moving on to another critical area, there's three common areas under the research NSPM-33, as well as the Research Securities, and that is Disclosure Requirements and the Research Security Programs, which we'll talk about in a bit. But this is the third one where we have the Malign Foreign Talent Recruitment Program. And not only do we have guidelines from OSTP, but we actually have definitions within those guidelines that cover the covered individuals, and making certain that they are prohibited, our senior key personnel are prohibited from participating in a federally funded research and development project, if they are participating in the Malign Foreign Talent Recruitment Program. We have outlined the fact that individuals, as well as institutions must provide clear certification. So, the institutional certifications will be provided through application instructions, and you'll see those up and coming, as well as the individual certifications. They will be captured in our Common Forms and certified in our Common Forms. And all of these changes will be updated both in our application instructions, as well as the FY '25 NIH Grants Policy Statement. We find it very important to align ourselves with OSTP and with the rest of the federal research platform, government platforms. So, NIH will absolutely adopt and incorporate the Malign Foreign Talent Recruitment Program, definition and certification, within that policy statement.

So now I'm going to get into that third tier of the Research Security Guidelines. That's something that I know many of you are very in tune to. This has been ongoing for a long time, but effective on July 9th, OSTP actually issued guidelines related to the Research Security Programs at covered institutions. And we'll go into the definition of covered institutions. But our covered institutions will be required to certify that they have to complete the Research Security Training, they have completed those trainings, they've completed it at the institutional level, and then individuals have completed those trainings as well. There are four critical components of the training. So, one of the things that folks have been asking us is, do we have to take the NSF training? Do we have to implement that? What we're saying is that we encourage you to implement the NSF trainings. We've gotten a lot of feedback that the NSF training is extremely long, but we are saying that any criteria that are within that NSF training, if the institution is going to develop its own Research Security Training, it does need to map to those criteria that are aligned in the NSF training. So, it might be a big more condensed, but you're covering the key principles of Research Security, because I want us to remember that this is really about protecting the biomedical research and making certain that we don't have any kind of scenarios where our securities are being threatened or continuing to be threatened. So having us aware, having our researchers aware of that, having the institution aware of that is extremely important.

So, for the Research Security, that the institution will require the covered individuals to complete this research training. And like I said, we do encourage the NSF where we recognize that's long, so there are folks that are looking at condensing it, but those principles need to be applied. And I will say that if there is a scenario where there's a institutional type training and there is non-compliance, I'll guarantee you that we'll be looking at trying to make sure that the other principles and other pieces of that NSF training are added to it, because we just want to be safe and secure. And we know you guys and the faculty and researchers feel the exact same way. The Research Security Training can be implemented, it's ready to be implemented in NIH, and others are -- and I'm just going to just speak for NIH -- NIH is ready to submit our plan. And we have it in our back pocket, ready to submit. I'm just making sure that we identify a few other areas. Export Control -- that's a part of the Research Security, and that's ready to be implemented as well. Institutions are definitely required to have covered individuals who perform R and D involving export control technologies to complete that training, and that each of those individuals had that completed training, so it's at the institutional level again, and at the individual level. We had the cybersecurity, which implements the cybersecurity program consistent with the cybersecurity resources for research institutions, that's described in the CHIPS and Science Act. And that's to be completed within one year. The challenge with that, though, is that we are looking to implement that, but we do have a NIST resource that we are waiting to implement. So, NIH is -- I'm standing ready to support that as that comes up. And NIST, of course, is the National Institute of Standards and Technology, and that is under the Department of Commerce. And they'll publish that resource soon.

And then, of course, the Foreign Travel Security institutions will implement periodic training on Foreign Travel Security and ensure that all such covered individuals take that training at least once every six years. Again, that's pending an OSTP federal contract resource. So, we recognize that these various areas are in different implementation stages. But NIH will release a Guide Notice once we submit our plans to OSTP, so that our community is very aware of what we will be doing and how we will be implementing those research guidelines.

So, the way in which we define covered individuals is using the following threshold, which is that the individuals, A, if it's an institution of higher education, an FFRDC, a nonprofit research institution, which are area institutions as I lovingly refer to them, and B, if it receives in excess of $50 million per year in fiscal year 2022 and going forward. And so, one of the things that we want to make sure of is that we followed those guidelines and that we provide that information to our colleagues, or our research institutions as well as the institutions of higher education, just to make sure those definitions are clear. And we are adopting that in [INAUDIBLE]. We also want to make sure that we make it clear that recipients that do not meet this funding threshold will not be required to certify that they have implemented the Research Security Programs. Now I've heard from a great deal of folks that don't meet the guideline that they actually are planning to issue and implement the Research Security Guidelines, because you just never know, and they do feel they need to do that. But at this time, that is not a requirement that NIH nor the federal OSTP is placed -- the federal guidelines and Research Securities are placing on those that don't meet the threshold. And those that intend to comply and put something in place, feel free to reach out and let us know what you're thinking, and how we can help support you.

And then also, I just want to make sure that we recognize that the Disclosure Requirements are a mainstay. They are a separate guideline from the Research Securities. They're a separate guideline for the Maligned Talent Foreign programs, so we want to be sure that you guys recognize that there are two different, three different requirements, and the disclosure requirements remain intact and must be adhered to.

Okay, and so I know that many of you, in terms of the Research Security Guidelines, are aware that NIH, like I said at the outset, cochaired with NSF. And we have promised ourselves, we've promised you all in different areas, venues, I'll say, different forums, as well as we are aligning ourselves with other federal research institutions, or federal research platforms to make sure that when we implement and participate in the OSTP and research agency discussions that we identify the streamlined implementation of the certification requirements for institutions. We recognize that this could be probably really concerning to our institutions that we are going to have an institutional-level certification. And I'm just going to speak for NIH -- the 24 walls of NIH with hundreds of programs within each of those single 24 walls, that could be very concerning for our grants management staff and for our program staff. It could be extremely confusing for our community. You might get a different response from one program within the same IC, or from one program to the next across the ICs, so we know that this is something that we are committed to making sure that we align ourselves and find a central solution with others. So, we are going to be participating in some discussions on how we can find a single certification solution for our institutions and making certain that there is a one-stop shop where you guys can submit those certifications. We were looking at SAM.gov -- that didn't quite pan out, so we are looking at other options, and we're excited about doing that.

So, more information to come. You guys know the more I talk, the more I'm going to share. So, I'm going to stop and go to the next slide, Kristin.

Kristin Ta: All right, new topic.

Michelle Bulls: All right, so this is a topic that I'm really excited about. And Kristin's going to give us all the latest and greatest. She's a bit more refined. She won't tell you as much as I do, but she'll get right close to it. So, one of the things I just want to give a shout-out to, our Federal Demonstration Partnership, FDP, has been an amazing partner to NIH and other federal agencies for many, many years. We have struck gold here with the DMS pilot. And the reason why I am just really excited about the data management and sharing pilot is because we heard from the community that there was some concerns about having multiple policies and templates and different things that were just happening in various ICs, within the same IC, asking for different plans. And we know how hard OER has worked, our OER colleagues, as well as our OSP, Office of Science and Policy colleagues have worked to make sure that we are aligned with the new DMS policy. So, as it relates to FDP, we've been extremely excited to partner with them on a demonstration where the first phase of that pilot, we conducted a lot of -- well, one goal was to look at developing a single template for the DMS plans. And we went back and forth and forth and back, and somewhere in between, and we literally were able to identify the fact that we could pilot test two of the DMS plan templates, Alpha and Bravo. And that is still an option. But then we collected feedback on those templates, as well as feedback on the OER template. And we have taken it to the next level. So, Kristin, I'm going to turn it over to you, but I do want to give a shout-out to, NIHs FDP pilot program officials and data management and sharing leadership across the institutes and centers. When I tell you that that's the part of this demonstration that has made such a huge difference, most often, when we get into our FDP pilots, it's been all about administrative programs and administrative staff. Here -- yes, take the soul out of that one -- because here, what we've done is, we made an opportunity and a true effort in partnering with our NIH program officials, as well as our NIH data management and sharing leads across institutes and centers, across the NIH OD. We've had a lot of good participation, a lot of solid feedback. And it just shows that when we partner with FDP, which is our research institutions and that membership, and with the leadership of FDP, we are in a solid place. And so, I'm going to kick it off to you, Kristin. I'm going to take some water, and we'll go from there.

Kristin Ta: All right. So, yeah, as Michele mentioned, we've gotten some amazing feedback. And we are really excited about the new template that we are currently finalizing. A lot of you all are probably familiar with the current OER format page, which is kind of a lot of free text in the different areas. And we really took the feedback that we got through the testing and Alpha and Bravo, and our conversations with program staff and staff at institutions, and we've put together what we think is a really good, updated template that we're excited to roll out. So, this slide just gives you a quick overview of some of those changes that we've made. The first is to utilize tables. And for those of you who have seen the RPPR questions, you've kind of gotten a sneak peek of how tables work in this area. But we have tables with the line for each type of data to really try to organize it, and make sure that all of the information that's required is being provided for each item in the plan. We've also utilized dropdown menus where we're able to. And where we're putting dropdowns, we're trying to come up with more standardized and established terminology so that it's easier to look across various DMS plans, and then compare things more consistently. So, for example, in the Data Type, we've used some of the NIH Biomedical Informatics Coordinating Center categories to help start coming up with standards that we can use for those types of data elements. We also have clarified some of the sections regarding limitations, so limitations related to consent and privacy considerations are a little bit different than if you're just not going to be able to share the data for some other reason. So we've clarified those areas. And we've also tried to design the question wording in a way that provides guidance on what information you need to provide, right? So instead of an open-ended question about what's your timeline for sharing, we have a question that asks about, how do you plan to share by the time that you first publish or by the end of your period of performance, to kind of prompt people to the policy requirements and help them get a better response.

And so, in terms of what's next with the pilot, we are working on that Charlie template as Michelle mentioned. We're coming up internally with our plans for how that rollout is going to work. Then we're also going to be moving forward into the cost phase of the pilot, or Phase 2 -- Michelle, I don't know if you want to give a little highlight of what Phase 2 is going to look like.

Michelle Bulls: Yeah, so we're excited about Phase 2, because when we first started off, we were looking at the templates, and then we said we're going to pivot right into those costing policies. And the reason why we're going into the costing policies is because folks have been very concerned about what policies are applicable, how could we -- what are the things that we need to do in terms of making certain that it's clear what those policies look like, what would be allowable, what's allocable, what's reasonable, and developing cost categories that are specific to IDMS requirements. So that's going to be a really high-charged effort, and we are looking forward to the outcome and working through some of that with NIH, with OMB, and of course with our research community.

Kristin Ta: Great. So, alongside all the work we've been doing on the template for the plan that's submitted with the application, we've also developed our PPR questions that we're going to be using to monitor compliance with, and make sure that everybody is following what they've laid out in that plan, because it does become a Term and Condition of award once it is approved. So effective October 1st of this year, our PPRs are now required to address the Data Management and Sharing Plan. And you can see the specific questions here on the slide. But essentially, we're asking for what data have you generated so far, and how are you sharing it if you're sharing it yet? And does that align with your plan, right? Are there any changes that need to come in the next year, and those types of questions, so that as our program officials are reviewing the RPPR, they can assess whether or not you're complying with that approved DMS plan. And the instruction guide for the RPPR has been updated with all of those new questions and instructions so that folks can use it right away.

And then so alongside providing updates in your RPPR, there also may be times when you need to request a change to your DMS plan. So, this is not really a policy change, this is more of a process change. The prior approval requirements for a DMS plan are still the same. If you're making a significant change, such as a new scientific direction, a different data repository, or a change to your timeline, you need to update your plan and submit it for prior approval to NIH. And that needs to be done for an authorized organization representative. So, it shouldn't just be the PI sending an email with an updated plan.

And in order to kind of help us better-track those things internally, we've developed some updated processes for submitting the plans, the revised DMS plans, for NIH approval. So, there's a couple of different ways that this can be done, depending on where your award is at. The first is at Just in Time -- so if you're updating your plan during that Just in Time negotiation process, that's submitted through the Just in Time Module. And it's done in a new section we created called Data Management and Sharing Plan. If your award has already been issued and you need to modify your plan, that can be done in two different ways. If the request is right before you're getting ready to submit your RPPR, within 30 days of that, you can submit the request for the perspective change in your RPPR. And we have an RPPR question that asks about that, if you have perspective changes, if you say yes, and you upload a new plan. If you're doing it outside of the RPPR, so it's coming up at some other point during the year, you would do that through the Prior Approval Module. And previously we've asked folks to put that in what we were calling "Other" requests, but now we've actually created a whole new section just for DMS, so we ask that you put that in the Prior Approval DMS Request section.

Michelle Bulls: So, I have a question for you, Kristin.

Kristin Ta: Mm-hmm?

Michelle Bulls: And I guess I'm just wondering, are folks encouraged to stop using Alpha and Bravo? Should they only use the OER format? All of the above? None of the above? What should they do?

Kristin Ta: So yeah, the OER format page, we know a lot of folks kind of default to that, because it's the one that OER put out, but that is an optional format page. So, applicants can continue to use Alpha and Bravo and try those tools out. They can use the OER format -- really, whatever works best for the plan that you need to submit to us.

Michelle Bulls: Sounds good, thank you.

Kristin Ta: All right. FORMS-I -- so we talked about these dates a little bit earlier, right? And there was a little bit of confusion. So, the Common Forms are May 2025. But FORMS-I -- so this is our big annual forms update, and that's going to be happening January 25th, 2025. And you can see here a couple of the updates that are going to be happening as part of that update. And like I said, the Common Forms is May 2025. So that's kind of a second piece of the FORMS-I update.

All right, so one of the main pieces of the updates coming in January -- and there are a lot, but we've tried to put all of the relevant resources on the slides here so that you guys can have all of the important details. So, the first big change is the Simplified Review Framework. This is something that's been underway for a few years. It started with a request for information all the way back in 2022, and then last fall, NIH issued the final framework. And this is an update to the Peer Review criteria for our research project grant activity codes. And essentially what it does is, it's taking the five regulatory criteria that were previously in place, and it's reorganizing them into three factors to better focus the peer reviewers on the questions that they need to assess the scientific and technical merit. So, the three factors are, importance of the research, rigor and feasibility, and expertise and resources. So, Factor 1 and 2 will be scored factors, Factor 3 will be evaluated for sufficiency. And all of those, as a whole, will contribute to that overall impact score that the reviewer's assigned to the application.

Then this slide just gives some more recent updates on Simplified Review Criteria. We've put out additional guidance on the activity codes that it's going to apply to. And while this is part of FORMS-I, there actually aren't any form question changes associated with Simplified Review Framework. But you will need to use the FORMS-I packages for all of your applications that are coming in for due dates on or after January 25th, because those packages are tied to the review criteria that we use down the line in all of our systems.

So, another set of application changes that we have coming is to our Fellowship applications and review process. Again, for fellowships, the review criteria are also being updated. They're being reorganized from five scored review criteria into three. And we're making some associated forms updates to align with those restructured criteria. That will also be effective in January, and you can see all of the relevant fellowship activity codes here on this slide, that this change applies to.

And then the last one for FORMS-I -- and I know this is a lot -- is related to our Institutional Training Grant Applications. So, these changes are actually not peer review-related, these are simply application updates. So, we are making the recruitment plan to enhance diversity. It's going to become its own separate attachments. We're also going to be clearly defining the mentor training expectations in the parent T32 Notice of Funding Opportunity, to make that clear for the community. And then the training data tables are also being updated to reduce burden, and to promote consistency in how we're collecting information across all of our various training programs. So, all of those changes will be effective in January. Our NOFOs are currently being updated, and you'll see that through the next month or two as the packages and things are added, and everything gets ready to go.

Michelle Bulls: Lots of changes.

Kristin Ta: Lots of changes. But lots of resources, too, so definitely check out the slides for all that information.

Michelle Bulls: Yeah.

Kristin Ta: All right. So just a couple of SBIR-STTTR policy updates that we have for you all as well. So, this first one relates to our foreign disclosure requirements for all of our small business innovation research and technology transfer research programs. This is a requirement that came out in our most recent reauthorization from Congress for the SBIR program, and they required NIH to put in place a due diligence program to assess security risks for foreign collaborations and foreign relationships that recipients of these awards may have. So effective for competing SBIR and STTR applications submitted on or after September 5th of last year, you're required to submit a form during Just in Time that includes information on all of the company's foreign affiliations and relationships to foreign countries. And NIH conducts a risk assessment of those forms, and we use that to support the funding decisions that we are making.

And then alongside that, as a better way to track the subawards that we have for these SBIR-STTR awards, we recently issued policy guidance that implemented a change for that specific program, SBIR-STTRs have to request prior to approval for adding a new, domestic subaward to their project. So, if they have a new domestic subaward that wasn't part of the original peer reviewed or approved application, they have to come in for prior approval for that change. And if that new subaward results in a change to the required disclosures of foreign affiliations that was submitted at Just in Time, they'll need to provide an updated form so that NIH can rereview and conduct that risk assessment and make sure that there are no risks that are identified. Any questions on that one, Michelle, before we keep moving?

Michelle Bulls: No, I don't have any more questions.

Kristin Ta: All right. All right, now we're going to go into a couple of systems process updates. These are really more informational; these aren't policy changes. This first one is the retirement of our automated Just in Time email notification. So those of you who've been around for a little while may be familiar with the emails that eRA used to send, essentially an automated email saying, it's time to submit your Just in Time, and here's how to do it." We were finding that recipients were getting both that automated email as well as more specific emails from their funding institutes and centers asking for information, and it was causing some confusion. So, we decided to retire the automated emails that go out from eRA. But you'll still receive an official email requesting Just in Time materials. It'll just be coming directly from the NIH staff that are reviewing that award. And you'll still submit in the same place in Just in Time Module.

Michelle Bulls: So, Kristin, I do have a question here.

Kristin Ta: Mm-hmm?

Michelle Bulls: We're retiring all of these Common Data, Commons Demo and Quick, we're requiring Just in Time email notifications that you're going to go through. Why are we doing all this? Why are we retiring everything? Is everything this old? Is it me? What is it?

Kristin Ta: Nothing's old -- we're not old. We're not old.

Michelle Bulls: Seasoned. Seasoned.

Kristin Ta: But yeah, so a lot of these tools were created kind of in the early days of eRA Commons, right, when things were a little bit simpler.

Michelle Bulls: Right.

Kristin Ta: And as tools and systems have developed over the years, there are new security requirements that are in place that we have to comply with. So, kind of keeping those older tools up to date is a real challenge.

Michelle Bulls: Yeah.

Kristin Ta: So, when looking at it, we realized, I have the slide-up with the Commons Demo and Quick Queries, this information is available in other places, right? So, for the Commons Demo you can use our User Testing Tools, and then for the Quick Queries, all that information is available either in Commons or through Reporter. So rather than continuing to maintain these older systems and try to keep them up to date, we've decided to retire them and point those folks to the new tools that we have that can get them that same important information.

Michelle Bulls: Okay. Well, you made me feel a little bit better, thanks.

Kristin Ta: All right. And then we do also want to point you to our new, redesigned NIH Grants and Funding Site. This is our Grants.NIH.gov page that has all of the amazing resources that OER maintains. And our communications folks have done a lot of work to get user feedback. They've kind of redesigned it with a focus on new users and folks who may not be super-familiar with NIH, so we've tried to make it as easy to use as possible. So, we really recommend that we check it out, update your bookmarks and links, and take a look at all those resources.

Michelle Bulls: Yeah, I just want to give a shout-out to the Division of Communication. I think that this office has done an amazing job in trying to keep the community updated on all of the changes, the latest greatest, and just making improvements to our sites. So, shout-out to the Director, Megan Columbus, and Sheri Cummins, her team, and everybody else that has participated in this. Kristin and I spend less time looking for things, and more time doing some of the other things that we need to do. And we're really happy for that. And I know that our divisions benefit from that as well. Shout-out to OPERA staff as well, because they do a lot of assisting and reviewing these sites and making sure that the updated policies are available. So, yeah, this is great. Thank you.

Kristin Ta: All right. And now we're going to wrap up with a couple of compliance updates. BESH.

Michelle Bulls: BESH? What's going on with BESH? BESH, it's been around for a while. What updates do you have?

Kristin Ta: It's a throw-back. It's for our seasoned folks that have been around for a minute.

Michelle Bulls: Now, that should get a good, like --

Kristin Ta: So yeah, BESH flexibilities are something that we put out, gosh, I think all the way back in 2018 or 2019 when the CT policy was still kind of new and fresh, and we were trying to understand the needs of that BESH community. But so, this most recent extension that came out earlier this year did extend the best flexibilities, but we've set an end date at this point, right? So, in September of 2025, BESH applications and awards that were submitted to a BESH notice, so a Basic Experimental Study with Humans noticed a funding opportunity. For those applications that come in after September 25th, 2025, they are now going to be expected to register in ClinicalTrials.gov and report their summary results information. And they'll have the option to do that either in CT.gov, or in Regulations.gov. So, I mean, we recognize that there is some flexibility needed in terms of how BESH is reported. But we do want those results reported, because it's important for the science. So that's kind of where we've landed after these many years of BESH flexibility.

Michelle Bulls: This is amazing, like this is a very nice landing. And I hope the community sees it and understands that we've really tried to find that way forward. And kudos to us, NIH, that is, for making their finding that way.

Kristin Ta: We finally got there.

Michelle Bulls: Finally got there, my goodness.

Michelle Bulls: Yep.

Kristin Ta: All right, and now I've got a question for you.

Michelle Bulls: Uh-oh.

Kristin Ta: So Unilateral Closeout Reporting -- all of a sudden this is showing up in SAM.gov. What changed?

Michelle Bulls: We were cited with an audit. And that's what changed, right? We really wanted to make sure that we were allotting ourselves with the regulatory requirements. And for a long time, what we've tried to do is be very accommodating to our recipient community to understand that some of these reports, especially the closeout reports, there were delays in submitting it at the 120th day. So, during COVID, that was hard. And we had some flexibilities there. But it really started way before that, where we recognized that there were subaward agreements that just didn't have timelines and the agreements to make sure that the subs were submitting timely to the prime. And so, as a result, it used to be 90 days, we worked our way to 120 days. And that still wasn't doing the job.

On top of that, we were supposed to be unilaterally closing out when all the reports weren't submitted timely. And so, we were told that NIH has got to do a better job in making sure that these reports are completed, and if they're not completed, you need to make sure that you identify this as a unilateral closeout. Then the next step was to report them in the Responsibility -- or SAM.gov, where the responsibility and qualification record resides. So, we have started to do that. We'll do that, and we'll initiate the unilateral closeout for all NIH awards that fail to meet the closeout requirements within one year. We had thousands of grants that were sitting open in the PMS system. We were cited by HHS, we were cited by the auditors. And we made sure that we addressed this by updating and making certain that we placed our financial closeout responsibilities within OPERA that aligns with the administrative closeout responsibilities. So, it's like a hand in a glove, they work hand-in-hand. And it's been a great marriage in that way. We are also required to submit the Responsibility and Qualification Determinations for Unilateral Closeout for any entity that doesn't submit all of the closeout reports within one year of the period of performance, we talked about that a little bit. And then, of course, recipients are also -- they can comment on the reports that are displayed in SAM.gov under the Contractor Performance Assessment Reporting System, known as CPARS, formerly known as FAPIIS, to provide a public statement and response to NIH's report. We've gotten a lot of questions from federal agencies on why we've done it. And we've got just as many questions from our recipient community as to why you're doing this. And we have to say we know there are times -- there are anomalies, and we are very aware of the fact that there are anomalies where investigator might lead the institution prior to the final RPPR, you're not able to obtain that final RPPR information. And then you find yourself in unilateral closeout. And such cases, I do heavily encourage you to contact your institute or center, who will work very closely with the Division of Grants Compliance and Oversight within OPERA to make sure that we are able to identify those anomalies and address those in a very succinct way, even if it's a matter of us placing that information into CPARS. We just want to make sure, though, that we are contacting, and that there's a dialogue. And we have to have proof that the individuals have left. So, there are anomalies, we recognize it, but we want to make sure that we follow what the regulatory requirements are. And we have not been, and we are doing such now. The record will remain in SAM.gov for five years, but again, the recipients can comment on it, and that's just where we are.

Kristin Ta: I know we're over time, so I don't know if we have time for all of the policy reminders, but I will say to check them out, because the policy reminders for things like Closeout and such will help you prevent things like unilateral closeout in SAM .gov.

Kristin Ta: That's exactly right. That's exactly right. The closeout reminders are critical -- I'm just going to give a shout-out to one of the main reminders that we want to pull here today is, the NIH policy for subaward consortium and written agreements -- making certain, honestly, that our form recipients place in their written agreements the need to provide access. It doesn't mean you have to give your primes books and boxes of records, but providing access to copies of any lab notes, documentation that informs the outcome of your RPPR -- that's extremely important for us, for the prime, and for the sub. We want to make sure that whatever the outcomes are in that RPPR can be informed. And we have documentation that we can access to provide the auditors or making certain even for our program officials that they are clear. That is a frequency no less than once a year, so it's really aligned with the RPPR. We tried not to go outside of that standard timeline.

But with that being said, I do know we're out of time. I could talk to you guys forever, but we do have a time slated. And I thank you so much for staying with us. And so, our time is up. And we thank you for yours.

Kristin Ta: Thank you.