Current Issues at NIH Grants Policy Updates

>> Michelle Bulls: Hello, everyone. This is Michelle Bulls. I'm introducing myself as the director of the Office of Policy For Extramural Research Administration. I'm excited to be here, joined by my colleagues, Kristin Ta and Kasima Garst. Kristin, would you like to introduce yourself?

>> Kristin Ta: Sure, I'm Kristin Ta. I'm a senior advisor also in the NIH Office of Policy For Extramural Research Administration, or OPERA.

>> Michelle Bulls: Kasima?

>> Kasima Garst: Thanks, Michelle. Hi, everyone. I'm Kasima Garst. I'm a systems policy analyst in OPERA's Systems Policy Branch.

>> Michelle Bulls: I'm so excited to have both of my colleagues here with me today. So what we're going to do today is introduce some current updated policies and application instructions. So Kasima and and Kristin are joined with me on our panel to begin to go through these updates, and to talk to you about the current issues at NIH from a policy and compliance perspective. Kristin, you want to start with the slides?

>> Kristin Ta: All right. So we're going to kick off with the topic that I know everyone's been hearing about for the past several months now, which is COVID-19, and so I wanted to just start by emphasizing that since we're recording this presentation ahead of time, everything is current as of September 14th, 2020. So if there are any late-breaking updates before you all view this presentation in October, we can handle those in the live Q and A session after the recording. So for all of our up-to-date OER information on COVID-19, I'd encourage you to visit our OER website, which is listed on the slides here, grants.nih.gov. And as always, we just want to emphasize that NIH's main concerns are for the health and safety of people involved in NIH research, and about the effects of COVID-19 on the biomedical enterprise, and so we understand that most of our institutions have been impacted, and we're working to provide as much flexibility as we can. As you may know, in March of 2020, OMB issued some memos providing flexibility to our recipients. But at this time, most of those flexibilities have now ended. Do you want to talk us through that a little bit, Michelle?

>> Michelle Bulls: Sure, but before I get started, you guys know that I always want to make sure that you all are safe and that your families are safe. So I want you to stay strong and stay safe because we need you out there to make our biomedical workforce work. So with that in mind, I just want to talk to you a little bit about some of the changes and some of the effective dates that have passed. Kristin, do you have any specific questions you want to ask me so that I can just direct them right to the answers? How do you want to handle that?

>> Kristin Ta: Sure. So I know there have been some questions about the flexibilities for salary charges when work is not being performed on a grant. Can you talk a little bit about that flexibility and when it's ending or ended?

>> Michelle Bulls: Yes. So let's talk about the fact that most of the original flexibilities that OMB issued have already ended. They ended effective June 16th, and for M-20-11, flexibilities ended on July 26th. But the two flexibilities that were extended under M-20-26 is where they allowed the charges for salaries where no work is performed through the end of September 2020, and we're really grateful to OMB for that, and we hope that additional extensions may be sought or realized. But for now, we have until September 30th, 2020. We also have an additional extension of the single audit submission which has been extended with our current recipients with single audit deadlines up to September 30th as well. We do have an extension for up to 3 months, so that flexibility will officially end around December 31st. So we want you to keep in mind, stay closely plugged to the NIH OER website so that you can see all of the latest changes that will occur or that have occurred. We want you to be in the know so that if there's any kind of audit questions that are outlined, because the flexibilities were not clear, we'll have them on our website available for you, and if you need additional assistance, you can always call us.

>> Kristin Ta: Absolutely. And speaking of where to go for COVID-19 information, we also have put all of our COVID-19 funding opportunities in one central place for folks who are interested in applying for research that's specific to COVID-19. As you may know, NIH has gotten funding through some of the supplemental COVID-19 appropriations that Congress has passed, and so you can find all of those opportunities, not only where they normally are in the NIH Guide to Grants and Contracts, but also on our OER COVID-19 page. And Michelle, you were mentioning at the end of the last slides some information about audits and documentation. So in terms of all those flexibilities, even though they've ended, folks may still have questions about how to document how those flexibilities were used, and maybe how that information might be reviewed later. Can you talk a little bit about that?

>> Michelle Bulls: So one of the things that we know and understand is that our grantees, our recipients, must document all of their actions taken under any grant, and they must maintain that documentation in your official file for your grants, specific projects. It's important for you to maintain that at the recipient level. NIH does not need that information to be submitted to us unless we ask for it specifically. But for us, we want to make sure that, again, any audits that come through, any costs that are questioned, you have the correct documentation in place in order to provide it to the auditors and to cover yourselves.

>> Kristin Ta: So moving on from COVID-19 to some other policy updates. This first one focuses on our expectations for recipients, that they're providing a safe working environment for their staff. Earlier this summer, we issued a Guide notice that outlines the expectation that recipients include information in their request for change in PI and change in recipient institution when that change is due to concerns about safety or the work environment. So, Michelle, can you tell us a little bit about why this is something that NIH wants to know about?

So for us, it's very important for the research environment to be a safe and productive environment. And when we ask for this information, one of the things, Kristin, that we've heard from our recipients is, do we have to submit information about PIs that we don't necessarily know about? I'm going to let you answer that question because I think it's important for us to state the expectation for us to make sure that we are understanding and know about any changes in the workforce, or in the work place, where safety is not provided and where research will be hindered. But my question to you is, if they don't know about the reason why a principal investigator is changing institutions, do they need to go back and do research, or find out from others as to why the individual has moved, or do they just tell us what they know?

>> Kristin Ta: So I think the answer to that question is when there is an issue that's significant enough that that's the reason why someone is changing, typically the institution is going communicate that to the folks who need to report to NIH about it, and I think we've clearly stated that expectation through this policy update and through other presentations and announcements, that we expect institutions to notify NIH when they are aware of those changes. If someone ...

>> Michelle Bulls: So the back end to that would be that if they don't know, then we are not holding them accountable, correct?

>> Kristin Ta: Correct.

>> Michelle Bulls: Okay.

>> Kristin Ta: And there's no need to include any information in the requests when it's not due to those types of issues. We're only expecting you to disclose to that when there is an issue NIH needs to know about.

>> Michelle Bulls: And that they know about. Okay.

>> Kristin Ta: So moving on to a bit more of a systems update regarding electronic administrative supplement applications, Kasima, do you want to ... Go ahead.

>> Michelle Bulls: No, I was just going to start pinging Kasima. So, Kasima, most of the grant applications come in electronically, but there's been one area that we have not required, and that took us more time to implement, which was the administrative supplements. So beginning on July 25th, NIH now requires all administrative supplemental applications to come in electronically. Can you talk to us a little bit about that, Kasima, and what that looks like for us?

>> Kasima Garst: Absolutely. Most of the information that NIH captures in our applications is done in a way with structured data, or that's actually captured in our eRA databases. This allows to run reports and track different data elements about our applications and the awards that NIH makes. Paper-based application submissions on our PDF forms, and the streamlining submission through the eRA Commons that had previously been in place for administrative supplements were challenging for NIH staff when trying to track and capture structured data elements as it relates to the administrative supplement request. And as we have seen with COVID-19, and increasing number of administrative supplement opportunities have recently been in need, and so we have recently required electronic submission through Grants.gov to address these issues, and that the Guide notice that is referenced on the slide.

>> Michelle Bulls: You mentioned the streamlined submission process in eRA. That's not going to go away, is it, Kasima?

>> Kasima Garst: Yes. The previous streamlined submission method through the eRA Commons has been discontinued. This is because we weren't able to actually obtain all of the information that our NIH ICs needed in order to evaluate their administrative supplement requests. Instead, we've replaced that method with an option to initiate administrative supplement applications within the eRA Commons in order to take advantage of pre-population and other features, and to actually complete their application submission through NIH ASSIST.

>> Michelle Bulls: All right. So now we're moving on to slide 10, commitment transparency. Kristin, you and I have spent a lot of time working with the staff, both policy compliance and our systems policy experts on pulling together and making certain that we have the JCORE implementation requirements in place. One of the areas that we wanted to remind folks is that much of what we have put out is already in the grants policy statement, and if we can just take a step back a little bit and think about the fact that we had updated the grants policy statement, but there were two key resources, source documents, that we needed to address, along with that Grants Policy Statement. It was the application instructions and the forms. And we wanted to make sure that the application instruction and forms, along with the Grants Policy Statement, aligned with the JCORE requirements. The goal really is to make sure that all of the information from other support, to biographical sketch, to financial conflicts of interest, to foreign components are communicated to NIH in a timely manner, and communicated to NIH. Once you know it, we need you to tell us. So it's really facilitating that transparency, and reporting of all of our research activities, both from a domestic and international standpoint, and not nearly financial. So I'm going to let you guys know that we've worked really hard on a fed-wide level to collaborate with our colleagues at NSF to make sure that whatever changes that have been implemented through the PAPP Guide are changes that we could live with, and that we would identify in our application instructions and our application data-collection points. And I think we did an outstanding job in highlighting the changes that we've made, and we took some time to pore over some of the questions and comments and requests that came in from NSF, and we thought, "Why would we want to recreate the wheel when we can take a look at what our recipients and our applicants stated to the NSF?" We could take a look at that, and we would leverage the information and make the changes accordingly, and that's exactly what we did. So, Kristin, why don't you talk to us a little bit about the changes that we made under Biosketch, other support, forms and application instructions that will help our recipients and our applicants know the direction that we're planning to go in, probably within the next few months?

>> Kristin Ta: Sure. So as you just mentioned, we took the approach, we looked at the JCORE guidance, we looked at what NSF was doing, and then we went and analyzed all of our NIH materials to see what changes we needed in those areas to kind of align with what was going fed-wide, and all the information that we need at the NIH level. So I'll start with the Biosketch. So we made some updates to align with some of the terminology in JCORE, specifically when it's talking about appointments, which is something we haven't really addressed in our NIH instructions and forms in the past. We also are going to be removing the section on research support. We found when we looked at it that it nearly completely duplicates the information that's being provided in your other support section, and so we realized we didn't need to be asking for that in both places, and so those are the main changes.

>> Michelle Bulls: Let me stop and ask you a question about that, Kristin. You know, we've heard several questions from folks saying the research support is support that was available at the time of the application. So will we not need to include that in other support? And I believe the answer to that is yes. You would include it if it's active. Is that correct?

>> Kristin Ta: So you would include in your support and other support will capture your active awards, your pending awards, and it will also start capturing some of your completed work, which was something that was previously included in the research support section.

>> Michelle Bulls: And I think that that's very important for folks to know. Thank you.

>> Kristin Ta: And so looking at other support. So as Michelle mentioned, last year we clarified some of the policy language in our GPS regarding other support. We're making a few additional updates to clarify things where we've gotten a lot of questions, such as the definition of a gift, and also expectations for reporting in-kind resources, rather than just monetary resources. And so along with that, we've basically taken our other support format page, which I'm sure you're familiar with, that's just a word document where you're filling in your other support, and we're really turning it into a much more structured form where there will be specific fields to enter all of the data elements, and you'll recognize it because it looks a lot like the NSF Current and Pending Support form that was rolled out earlier this summer. And we've also developed a detailed instructions document to go with it, which has all of the terms clearly defined, exactly where to put it, and exactly what's expected to make it as clear as possible.

>> Michelle Bulls: And I think that's important because one of the things that we talked about as we were meeting with our NSF colleagues is that it wasn't just about NIH taking NSF's and duplicating it, but making sure that when our recipients, you, our partners, look at our forms, or look at what we put out in the application instructions, versus what NSF has in their PAPP Guides, we wanted to be a continuity of information. Not for you guys to have to look in different places where at NIH, you were looking in one section. At NSF, you were looking at another section. We really tried to make it very complete, very continuous. We didn't want to have you guys put in any thought because it's important for us to identify ways and means by which we can streamline. And really, I think folks play this down, but even having a form looking similar is something that really just takes down the stress level of trying to figure out what you need to do for NIH, what you need to do for DOD, or what you need to do for NSF. So that was really the method behind our madness, and that's important for us to alert you to.

>> Kristin Ta: Yes, absolutely. Okay, and so just one last topic since it wasn't on the slide for the other support and Biosketch, which I'm sure is going to be the first question that everybody asks is when will this be rolling out. Michelle, do you want to take that question?

>> Michelle Bulls: Yes, so what we're hoping is that we will have final clearance throughout the NIH and update that by November. And so there's a couple of thoughts there. One is we want to make sure that we roll it out in a way that makes sense, and one of the main key reasons for that is that we do have the changes for 2 CFR Part 200 that would need to be implemented by November. So we thought instead of issuing the NIH Grants Policy Statement and application at a separate time, and having all of these different pieces go in at separate times, we would hold all of our changes to the other support and our other policy changes to match the two 2 CFR effective date. So that's why we're going to do that in November. It's an opportunity for us to make sure we have everything right and in order, and provide you with the best package that we can in order for us to make sure that we don't cause any consternation within the recipient organizations, causing you to change systems and practices where they're not needed at the time and having you see the full package in a single submission. So there you have it. We're looking at November.

>> Kristin Ta: Great. So now we're going to go into some system process updates. I'm going to turn it over to you, Kasima.

>> Kasima Garst: Great. Thanks, Kristin. So this slide is announcing a new simple systems process update regarding the NIH summary statement we have made available starting effective this past June of Signing Officials through the eRA Commons will have access to the overall impact score, and the NIH summary statements. This is in order to help facilitate the award management and communication with applicant organizations via the Authorized Organization Representatives for applications that are submitted to the NIH.

>> Michelle Bulls: So how would an AOR access this information in the system, Kasima?

>> Michelle Bulls: Great question, Michelle. The AOR will be able to access the summary statement and the impact score through the Status module in the eRA Commons. They will need to have a Signing Official user role in eRA Commons, and the notice that is linked here on the slide provides additional details related to instructions on how to search and access that information.

>> Michelle Bulls: All right. So we're going to next the slide where we're talking about the HHS and fed-wide system updates. And so as we're moving into this, these are areas that are going to come about over the next few months. We're excited to announce them. So Kasima, can you walk us through the updates that are coming through the SF-425 FFR? This is something our partners and colleagues have been waiting for for a long time, so I'm really excited about this one.

>> Kasima Garst: Absolutely. So the SF-425, or the Federal Financial Report, commonly referred to as the FFR, is starting January 1, 2021. NIH grant recipients will be required to be submit their FFRs in the Payment Managements System, or PMS's FFR module. Currently, they have been using the eRA Commons FFR module, but now all HHS awardees and recipients for NIH will be utilizing the PMS FFR module. This will be an additional benefit for recipients because the PMS is the official system of record for HHS recipients, and it will be one less system that recipients will have to utilize to submit their financial reports.

>> Michelle Bulls: Will that impact the NIH due dates for FFRs?

>> Kasima Garst: Absolutely not. There will be no change to FFR due dates.

>> Michelle Bulls: All right. Is this the only change that will be coming for the FFR? I know that there's that second ... This is the first phase, and we have a second phase that makes me even more excited because really many of our recipients and our colleagues rolled up their sleeves with us to help us get this one going, Kasima. Do you want to talk about the phase 2?

>> Kasima Garst: Sure, I can do that. Phase 2 will be the removal of the requirement to submit quarterly cash transaction reports in the Payment Management System, or PMS, for the recipients for which that was a requirement. Instead, recipients will certify at the time of draw down of the funds for reimbursement of costs incurred, and will be used within the three business days. So that means, Kristin and Kasima, that we do not have to continue to talk about reconciling those two reports that meant nothing to each other. Is that correct?

>> Kristin Ta: Yes, that is correct, and I know this is something you've been pushing for for years, so I know you're very excited about it, but we will no ...

>> Michelle Bulls: I am excited. I hope our colleagues are too. It's a really, really good.

>> Kristin Ta: It's a huge step, especially since we're in sub-accounts now. The FCTR was just really outdated and it's good to see us moving forward from that.

>> Michelle Bulls: Yes, it is. What's the timeline for phase 2, Kasima or KT?

>> Kristin Ta: So we're still waiting on the final policy updates and implementation word from HHS, but we're expecting that it's going to be happening some time this fall. So as soon as we get final information, we'll be sharing that with everybody.

>> Michelle Bulls: That's great. That's really good. So we want to move to the notice of award, page one. So, Kristin, I think you have a question for Kasima. Let's see if she's going to answer it.

>> Kristin Ta: Yes, so this another change that's coming from HHS. So Kasima, do you want to tell us a little bit about what exactly is going to be changing?

>> Kasima Garst: Sure, you're correct. This is another HHS Reinvent Grants Management Initiative to standardize the format of the first page, or what we're calling the Notice of Award Page One for all HHS awarding agencies. So this is effective for all NIH Notice of Awards issued on or after October 1, 2020, and this will include some standardized data elements at the first page, right up front for recipients to be able to see nice and conveniently. Terms and conditions, however, will still be continued to be outlined in Sections III and IV of the Notice of Award.

>> Michelle Bulls: That's a good point that you make about the terms and conditions, Kasima, because that's the question that I was going to ask, and I imagine others are asking too. While we have the standard Notice of Award Page One, that does not keep us from having specific information regarding to our terms and conditions outlined in other places within the Notice of Award. Is that correct?

>> Kasima Garst: That is absolutely correct.

>> Michelle Bulls: So it will still be NIH behind the general wall, right? The coverage page is standard, it's general, applies to all HHS OpDivs, but NIH will still have the specific requirements behind that manage and govern the terms and conditions of the award.

>> Kasima Garst: Absolutely.

>> Michelle Bulls: Okay. So we have some standing policy reminders that we'd like to go through with you all. Don't forget, you have to submit timely RPPRs. The annual progress report is in the RPPR format, has been for a very long time. The due dates haven't changed. They're outlined here in the slide presentation. If you have any questions with regard to delays, or you have any questions with regard to multiyear funded and how that works, please get in contact with your grants management specialist so that they can assist you. We want to remind you that timely financial reporting is extremely important. The FFR SF-425 expenditure data is to submit accurate data, timely data. The recipients will need to reconcile until we move into phase 2 that is. Their PMS federal cash with the expenditures. We want to make sure that focus are able to close out their awards timely, so that's important for now. We also want to make sure that you are submitting your FFRs no later than 90 days after the end of the calendar quarter in which the budget period ended. Again, that's a current requirement and that will go away when we move into that phase 2 of the FFR. And then the finals are, of course, 120 days following the end of the project period. Please make sure that you submit your invention reports HHS 568s timely at the conclusion of the NIH award, meaning at the end of the performance period. And then, of course, closeout requirements. We continue to require you to comply with a longstanding requirement for closeout. You need to make sure that you submit your closeout reports, at least 120 calendar days. They will be late after the 120th day. So 121, you're late. We want to make sure that we don't move into any kind of unilateral closeout, so we are encouraging our recipients, if you have questions, if you have delays, if you have concerns specifically as it related to COVID-19 and those kinds of things, please, please feel free to reach out to the grants management official. If it's a general question about closeout and how NIH is handling it at the enterprise level, feel free to reach out to the Division of Grants Policy and we'll give you some e-mail information at the end of this presentation. But make sure that the reports are submitted timely, or reach out directly to find out what you need to do about delayed reports.

>> Kristin Ta: And speaking of those e-mail address, here's the contact information for all our divisions at OPERA so that you can reach out to us, like Michelle said, with any kind of general questions about NIH policy, compliance, systems, anything you have a question about.

>> Michelle Bulls: And with that, thanks for your time.