**TRANSCRIPT**

**Webinar:** 2024 NIH Grants Policy Updates

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Kasima Garst: ... Thank you so much, Cynthia, and thank you all. We're very excited to have you all here, and we're very excited to be providing you these updates as we move forward. The outcome ... The goal of our presentation today is to provide you some of the latest and greatest news related to policy updates as well as some system-process updates and compliance reminders for everybody as we move forward. As Cynthia said, we have incorporated many of your questions within our presentation, but we are also going to try and save some time to be able to answer some of your questions live from the Q and A portion of the module. My name is Kasima Garst. I am the Acting Division Director of the Division of Grant Systems Integration within NIH OPERA, and I'm going to allow my colleague Brian to introduce himself as well.

Brian Sass-Hurst: Hey, everyone. My name is Brian Sass-Hurst. I'm an Assistant Grants Compliance Officer in the Division of Grants, Compliance and Oversight within OPERA. Thanks.

Kasima Garst: Thanks, Brian.

Brian Sass-Hurst: And thank you.

Kasima Garst: Oh, I'm going to go ahead and turn it over and transition to some policy updates, but I wanted to give this opportunity for Brian to go into some budget updates for us.

Brian Sass-Hurst: Great. Thanks, Kasima. So first, we can talk about the NIH budget updates. The NIH has issued the notice extending the continue ... excuse me ... the Continuing Appropriations Act. The guide notice is expected this week to reflect that the government funding has continued through February, and the salary limitations have also been released, and those are reflective of ... excuse me ... effective January 1st of 2024. Additional guide notice is coming soon to reflect the next continuing resolution, which was recently passed and will be publicly shared as soon as it's ready. Then so, Kasima, I think you have some policy updates for us.

Kasima Garst: Yes, Brian. Actually, I'm going to first turn it over to you for a quick question about our updates related to our subaward and consortium written agreements guidance.

Brian Sass-Hurst: Yeah, thanks, so in September of ... On September 15th, 2023, NIH issued a notice updating the final policy guidance for subaward/consortium written agreements, and that provided several updates to Section 15.2 of the NIH Grants Policy Statement. So, effective January 1st of this year, NIH is not able to support any agreement that does not meet the minimum requirements outlined in the section of the GPS. This requires foreign subrecipients to provide access to copies of all lab notes, data and documentation supporting the research outcomes as described in progress reports to the primary recipient no less than once per year in alignment with the timing requirements for your RPPRs, the Research Performance Progress Reports. This access may be entirely electronic. These actions that NIH took is in response to an OIG recommendation, and subrecipients who are unwilling to agree to the terms and conditions of the agreement should not ... may not enter into an agreement, and we'd recommend that you read the guide notice to read all of the factors that need to be addressed in the agreement between a prime and a foreign subrecipient. We do expect recipients to ask potential subrecipients in the application stage to submit language in their subaward written agreements that acknowledges this requirement. We expect subrecipients to share with prime recipients if the institution is foreign or domestic, and we expect recipients to update existing foreign subaward agreements within 60 days of the effective date, which was January 1, 2024, to address requirements outlined in the notice. Failure to comply with those requirements may mean that the subaward arrangement will not go forward, and once that subaward agreement is signed, NIH does expect subrecipients to comply with the conditions, and NIH will conduct compliance reviews to monitor that. NIH further reserves the right to take one or more enforcement actions, such as disallowing costs, withholding new awards or wholly or partly suspending grants pending corrective action, and more information on how NIH takes enforcement action is also discussed in the Grants Policy Statement, specifically in Section 8.5. Kasima, you wanted to get into some small-business information.

Kasima Garst: Absolutely. So previously last year we issued the notices that are linked on the slide, but in particular with the reauthorization of the Small Business Innovation Research, SBIR, and the Small Business Technology Transfer Research, STTR, programs, there is a requirement that there must be a disclosure of all funded and unfunded relationships with foreign countries of concern as outlined within the link document and form on the slide and is required for all the owners and covered individuals. This involves also the establishment of an NIH due-diligence program that is looking at these relationships and assessing them for any national-security risk. This is effective with all SBIR and STTR applications that were submitted for due dates on or after September 5th of 2023. Now the important thing that we did want to note for the community was that this is not a change to the eligibility for Small Business SBIR and STTR programs. It is specifically looking at whether or not a relationship with these countries of concerns exists and that that relationship poses a risk to national security. So, it is not disqualifying a small-business concern for being able to apply to these programs. It is specifically looking at that national-security risk. Also outlined within that guide notice as well as a clarifying guide notice that was published in November, NIH will not mitigate the security risks that are identified as part of the due-diligence program, and you can refer to those notices for additional information about the process and the program itself. The other thing to note is that there are links on the form that is on the slide that also point to the definitions of those foreign countries of concern as well as who the covered individuals are. These are all the senior key personnel that are identified in the application as part of that initial risk assessment. The other thing to note about this program is that recipients would then also be responsible for making sure and monitoring for those relationships and informing NIH if any of those updated to those foreign disclosures are occurring, so definitely take a look at that guide notice for more information, but we did just want to highlight that for everybody here. The slides also have links to the Small Business Resource Web pages that our Small Business Office within OER does help maintain, and that's going to include some FAQs and some case studies around this area as well as a resource for the applicant community. I also wanted to transition to speak about our Simplified Peer Review Framework that we are instituting for NIH peer-review process. Both this and the small-business items we are going to be talking about a little bit more in the systems-process-update section as well, but for the Simplified Review Framework, this is specifically effective for applications with due dates on or after January 25th, 2025. We have already announced through the guide notice that is on the slide that we are implementing a new framework to help simplify the peer-review process for NIH Research Project Grant Applications. This is specifically related to, for phase one, the the activity codes that are listed on the slide for our Research Project Grant, or RPG, activity codes. This new framework is really designed to help streamline the process, particularly for peer review, to ensure that we're minimizing some of the burden of the things that need to be reviewed at that peer-review process. The input for this streamlining came from a myriad of resources over the years that echoed NIH's concerns that we have heard from the community regarding the lengthy and unclear review criteria and the possible effects of potential reputational bias on the peer-review process. We do expect to better focus peer reviewers on the key questions that are needed to assess the scientific and technical merit of the proposed research projects, and we also want to direct folks to the simplifying review of RPG Applications resource that is on the slide. That is where we'll be posting additional information as this come forth. You can see the actual updated to the Simplified Review Framework, and this is also where further future communications will also be provided as more communications come out. Definitely expect to see more coming this spring and this summer.

So with that, I am going to go ahead and transition into some of those system-process updates for us, so namely and to start things off, a topic that we know everybody is very interested in hearing about, the Common Forms for the Biographical Sketch and the Current and Pending Other Support. NIH has been working very closely with the National Science Foundation, NSF, and other federal agencies on adopting Common Forms ... developing and adopting Common Forms for the Biosketch and Current and Pending Other Support. This is really specifically coming out of the Office of Science Technology Policy, OSTP, Research Security Subcommittee recommendations and guidance and really in response to the NSPM 33 Presidential Memorandum as well. The Common Forms have officially been cleared by OSTP and OMB. We provided a link on the slide to where they are currently posted on the NSF website. The adoption for NIH is going to follow a timeline that aligns with our implementation of Forms I. If you're asking what Forms I is, I am going to get to that at a later point, and know that formal communications on Forms I are going to be forthcoming as well, but that is going to be effective for due dates on or after January 25, 2025. Specifically for the implementation of the Common Forms, we are going to ... In the spirit of moving and expediting the adoption of these Common Forms, we are going to be implementing those and requiring them as of that January 25, 2025, receipt date. Now we also know that, in addition to the importance of adopting these forms, in order to implement and align with NSPM 33 and the OSTP guidance, we also wanted to expedite the ability to minimize and streamline the process and minimize some of the burden for our applicants and recipients. So, we will be ultimately requiring the use of SciENcv, and those templates will be available as early as we possibly can, but we're looking to implement the requirement for their use in May of 2025. The reason that we are delaying the requirement for the use of SciENcv is because we want to ensure that we have some system procedures and updates in place so that we can better accommodate APIs and other Web-service-type functionality to help institutions that do have internal systems that may be better able to communicate and minimize some of the manual input that is currently causing some burden for our applicants and recipients. So, that is when we are going to implement the requirement, when those APIs are in place, but expecting the requirement to go live for May of 2025. Again, formal communications are going to come out that are going to go more into detail. I know Michelle Bulls and others have been very dedicated to this effort, but I do also want to say that, until NIH fully adopts those Common Forms, we do still require applicants and recipients to use the current OMB-cleared NIH Biosketch and Other Support formats for applications at Just-In-Time and as part of any updates through the RPPRs and others, so that still maintains the current requirements for electronic signatures and supporting documentation that is required, and failure to follow the current approved formats may cause NIH to withdraw applications from or delay consideration for funding. We do have the very extensive FAQs linked on the slide and the link noting the NIH Other Support and Biosketch inbox for any questions that you may also still have, but we are also going to be continuing to update those FAQs as we move towards the Common Form adoption, so definitely stay tuned.

Brian Sass-Hurst: Kasima, I've seen a couple questions come in while you were talking about the Other Support, and a few people have asked if they can adopt ... excuse me ... adopt the new Other Support definition now in advance of release of the new Forms I.

Kasima Garst: That's a great question. So, no, right now they still have to use the NIH Current Other Support and Biosketch formats as part of their submissions. We cannot accept the Common Forms at this time. However, we are going to be posting resources and information about all the NIH-specific instructions or anything that is specific to the adoption of those Common Forms well before that January implementation date. So right now, still use the current approved formats for NIH and anticipate that transition over to the new format ... the new forms for January. We wanted to make sure that this information was getting out as early as possible so that institutions can update any of their internal systems to also align with these new formats, but again, stay tuned, more to come.

Okay. Thank you for that. So, going back a little bit to that small-business update that I mentioned earlier, in order to accommodate the submission of the new SBIR/STTR Foreign Disclosure Form, we have already implemented updates to the Just-in-Time section of the eRA Commons within eRA Commons, so that was implemented in this past November, so SBIR/STTR applicants will see the new section, and don't worry. I know the screenshot is small, but we just wanted to give you a flavor of that. We also have a link on the slide to the eRA Commons Online Help, which has zoomed-in screenshots as well. But effectively this will be a new, dedicated section only for those SBIR/STTR applications to upload those disclosure forms upon the request from the awarding IC. So, if your application was submitted to a due date on or after September 5th of 2023 and it has been requested by the NIH IC, then you'll update and post the disclosure form here. If the award is awarded, any post award updates to the Foreign Disclosure Forms must be submitted using the new eRA Foreign SBIR/STTR Foreign Disclosure Request for Additional Materials, or RAM, functionality. Additional details will be provided in future NIH updates. That functionality was deployed in December of this past year. However, we know right now those awards are not quite in the post award process yet, so we're saving some of those details for future NIH updates, but it is available if needed.

And the last systems-process update that I have here is the reminder around the eRA Commons ID requirement. As you all should know, in 2022, we officially updated our requirement for all personnel that are named on the R&R Senior/Key Person Profile Form to require that a valid NIH Common ... eRA Commons ID is entered into that credential field. Previously to help ease the transition into this new requirement, we did implement a system validation at a warning level if that field was blank or does not contain a valid eRA Commons ID. That validation has now officially been updated to an error now that this requirement has been in place for more than a year, and it is in place for all competing applications and submissions moving forward. Applicants are, as always, encouraged to check that their Commons ID account is active well before the due dates to give yourself plenty of time, and we've also linked to the Registration in Commons FAQs that are available on our Web pages, which also provide valuable information for folks that are looking to how to obtain a Commons ID if they may not necessarily be associated with a registered organization with eRA Commons. So, we just want to provide that as a reminder and to let folks know that they will start to encounter that system error if that field is blank or does not contain a valid Commons ID, and all errors must be corrected prior to successful application submission. So, Brian, I think folks have probably heard enough from me for a minute. I'm going to turn it over to you. Can you give us some compliance updates that you might have in store for us?

Brian Sass-Hurst: Sure. Thanks, Kasima. Hi again, everyone. I'll go ahead and provide a few updates on some compliance items. So, first off is single audits. NIH is enhancing its pre-award-risk-assessment procedures to review all institutions' single audit results, and we may take actions based on findings that were reported. As we do this retrospective review, some awards may be released before the review is complete, and those recipients will have a term added to their awards identifying that, based on the outcome of the retrospective review, NIH may take ... may unilaterally take administrative action to safeguard NIH funds in accordance with Grants Policy Statement 8.5.1, which provides the guidelines by which NIH may modify terms of award. Once NIH does complete the review of single audits, additional terms may be added based on the specific risks that were identified by NIH. As a reminder, the single-audit requirements, these apply to organizations that expend more than $750,000 of federal grant funding within their fiscal year, and those are the entities that are covered by the single-audit requirements. There's a detailed table in the Grants Policy Statement in Section 8.4.3, and that identifies the source of the audit requirement as well as where reports should be submitted. For example, states, nonprofits, universities, nonprofit universities, they would submit their single audits through the Federal Audit Clearinghouse whereas for-profit organizations as well as foreign organizations that meet the threshold would submit their audits elsewhere, and all of that is discussed in the Grants Policy Statement. Some recipients are eligible for what's called a program-specific audit. Generally, they're eligible if their only federal funder is NIH, and they meet single-audit threshold. In order to engage in a program-specific audit, written prior approval from your funding institute or center must be obtained in advance. So, I'd encourage anyone that may fall into that group to be considering that now and plan to request that prior approval well in advance.

Next is regarding unilateral closeout. Just about a week ago, NIH issued a new notice regarding Enforcement of Unilateral Closeout Reporting in the System for Award Management, specifically in the Responsibility/Qualification section. Through this, we are strengthening enforcement of longstanding closeout requirements that are outlined in Section 8.6 of the GPS. All NIH recipients before they close their award are required to submit three items, the Final Federal Financial Report, also known as the FFR, a Final Research Performance Progress Report ... We just call it an F-RPPR ... as well as the Final Invention Statement and Certification, and within 120 days of the end of the project period, those three documents are required to be submitted in order to close an award. Without prior approval from the awarding institute or center for a delay in closeout, NIH will initiate unilateral closeout for any awards that fail to meet this requirement within 120 days. And then additionally NIH will report all unilateral closeout actions as a Responsibility/ Qualification record in the entity's information in the System for Award Management retroactively. What that means is, all entities have a record in sam.gov, which is the System for Award Management. Previously there was a system called FAPIIS, which was used to record integrity information, and that's been integrated into sam.gov, and so any unilateral closeout actions that NIH has taken since January 1st of 2023, those will be recorded into the recipient's sam.gov information, specifically in the Responsibility/Qualification section.

Next, I wanted to talk about the 90-day closeout reminder. NIH recipients are required, as I noted, to submit a Final Federal Financial Report, the F-RPPR and the Final Invention Statement within 120 days of the end of the performance period. Up until recently, well, this month, NIH has sent reminder emails to recipients at 10, 120 and 150 days after the project period end date, and starting this month, NIH has begun sending an additional closeout reminder email, and so we've added an additional notification at 90 days after the project period end date, and this started on January 11th, and these reminders are only going to be sent to recipients where there is at least one required closeout report that has not been submitted as of the date that the notification was sent. And this is an effort to ensure that everyone's fully aware of what's required and that something is still outstanding, so we'd encourage everyone to pay close attention to those notification emails if they come to you.

Moving on, as I had mentioned earlier, discussed the Federal Audit Clearinghouse, the Federal Audit Clearinghouse, also known as the FAC, has recently been transitioned from being housed at the United States Census Bureau to be under the service of the General Services Administration, the GSA. In fact, October 1 of 2023, the GSA launched a new website at fac.gov, and the FAC, the Federal Audit Clearinghouse, is where all nonprofits, universities, states, local governments, they would submit their federal required single audits to that website. And as this transition moves forward, there is a little bit of a staggered transition. And so all new single-audit reports that have been completed since October 1st of 2023, those are all being submitted to the new FAC Web page at fac.gov, and that website has a full search feature which allows members of the public to search for publicly available audits. All prior single-audit reports from previous periods are uploaded to the old Census website, and the old Census website is still available to search historical data. The GSA has indicated that they expect the transition to be completed by the end of the year when all audit reports and single-audit data will be available through fac.gov. And then, as a reminder as I noted in a previous slide, for-profit and foreign organizations do not submit their audit reports to the Federal Audit Clearinghouse. Those audits are submitted through the HHS Audit Solution Division. And all of that information is discussed in the NIH Grants Policy Statement. And so, Kasima, I think we wanted to get us started with exciting policy reminders.

Kasima Garst: Yes, thank you, Brian. So, starting off with some reminders for everybody, certainly for some of our more newer folks and working with NIH as well as some of our experienced colleagues. All annual Research Performance Progress Reports, RPPRs, have standard receipt dates based on whether or not they are non-SNAP, subject to our Streamlined Noncompeting Award Process, SNAP, or multiyear funded, so for non-SNAP awards, that's approximately 60 days before the start of the next budget period. For SNAP awards, that is approximately 45 days before the start of the next budget period. And then for our multiyear funded awards, it is on or before the award anniversary date. We do have some searchable lists to determine which progress reports are due, and that resource is linked on the slide. The main ... Oh, excuse me. I'm sorry. I hit that button a little too early. So, the other thing just to keep in mind, the timely progress reports are particularly important because, without providing that, we are unable to issue the subsequent noncompeting award, so it's particularly critical to make sure that you get those timely progress reports in.

One other reminder regarding financial reporting, so of course we have the requirements related to our Federal Financial Report, and we also have some updated guidance regarding the returning of grant funds. NIH recipients who need to return grant funds in the Payment Management System for NIH grant awards that have ended but the funds have not yet expired, this is ... has been updated so that now if they need to return those funds on an NIH grant or subaccount. If the refund is $20,000 or greater, the NIH recipient must first submit a revised FFR and then post the refund to the PMS subaccount document if the funds have not expired and are reconciled and closed in PMS. Any and all refunds that are under $20,000 on the closed PMS documents should be sent directly to PMS with the instruction to post those funds to miscellaneous receipts. It's particularly critical to ensure that those FFRs are reconciled prior to submission, but this is how, if there is a need to return those grant funds, that you would do it based off those new thresholds. We also included on the slide instructions about how to refund grant funds in PMS. And we also have a great compliance resource on our Grants and Funding Web page under compliance resources outlining the updated refund process for various scenarios that you may encounter. So, Brian, I'm going to turn it over to you. Can you tell us a little bit about invention reporting?

Brian Sass-Hurst: Yeah, absolutely. So, as many people know, the iEdison system was transitioned from being within NIH through the eRA to NIST, the National Institute of Science and Technology, which is within the US Department of Commerce. The new iEdison was launched in August of 2022, and as a reminder, reporting of inventions through iEdison is mandatory. So, annually in your progress reports just specifically in Section C.4, recipients are required to identify any inventions, patent applications and/or licenses that are resulting from the award. And as we've mentioned a few times now, the Final Invention Statement is required to be submitted within 120 days of the project period end date. This statement must include all inventions that were conceived or first actually reduced to practice during the course of work under the grant or award from the original effective date of support through the date of completion or termination. And then failure to report all inventions could result in your organization's loss of rights in the invention or other actions as appropriate. Additionally, per the Bayh-Dole Act, the Government Support Clause is a statement acknowledging federal support of a subject invention that is required to be included in the specification of a US patent application or a US-issued patent. The full details of this are discussions in the Grants Policy Statement, specifically in Section 8.2.4. The Government Support Clause is required to identify the National Institutes of Health as the funding agency, and there's some sample text here where the National Institutes of Health is required to be the entity that is listed as the funder, not, for instance, National Institute of Mental Health. And it must also identify the two-letter institute code and six-digit serial number in the Government Support Clause, so that is a requirement when dealing with patented intellectual property. Kasima, I think you were going to share some information on grant-closeout requirements.

Kasima Garst: That's right. So, thanks, Brian. So, basically, the closeout of an award is really done in sort of two manners. Right? There's the administrative grants closeout as well as the financial closeout of the PMS sub-account or document. As we all know that NIH continues to require and enforce longstanding closeout requirements that all the required closeout documentation indicated on the slide are due within 120 days of the project period end date, the end of the period of performance. NIH will initiate unilateral closeout, including potential enforcement actions if recipients fail to submit the final reports on time. And some of the emphasis on this is particularly because of the high commitment by NIH and the Department of Health & Human Services really emphasizing the importance of timely administrative and financial closeout. Some of the ways that we are helping with this are, as Brian mentioned earlier, instituting that new 90-day closeout-reminder letter. I did see some questions in the chat about who those reminders are sent to. They are sent to the authorized organizational representative, and the other standard individuals that receive the ERA closeout notification letters currently, so just wanted to let folks know about that. And then moving onto the secondary part of this, that financial closeout reminder. Another way that we are helping to remind recipients of their responsibilities in this requirement beginning of November last year, our Closeout Support Staff have started sending reminder e-mail notifications to recipients who have final FFRs that are in rejected status, namely, to make sure that when a revised final FFR ... or excuse me. When a final FFR has been rejected, a revised FFR must be submitted in a timely manner in accordance with those closeout requirements outlined within the Grants Policy Statement to ensure that all of the administrative and financial closeout requirements are conducted within the required time frames. This is also specified within the legislative citation that we provide on the side as well. If there are any questions about the final FFR submission or financial closeout and guidance on the resubmission of those rejected final FFRs, please feel free to reach out to OPERA's FFR Reconciliation and Financial Closeout Support Center team, and that resource is linked on the slide. Excuse me. There we go. And lastly, that really brings us to the end of our main reminders. We did provide within the slide deck for you some commonly helpful resources. Of course, the entire NIH Grants and Funding webpage is a wealth and breadth of knowledge, of policy citations, helpful tips and tricks and application-guide instructions, but we wanted to highlight a few areas for you that we know could be particularly helpful related to this presentation. And we also wanted to highlight some of the amazing LISTSERVs that are available to our applicant and recipient community. That is especially the NIH Guide for Grants and Contracts where we are also sending out official notifications in our Table of Contents newsletter that goes out on Fridays related to the publications of grant-policy notices as well as our funding opportunities. And then also, eRA news. Being able to get connected and learn about the different system developments and updates. All of these are really important, and lastly, the last LISTSERV listed on the slide is a plug for our amazing communications and outreach team and our Virtual NIH Grants Conference and events. Please sign up and subscribe to updates so that you can learn about events like these and our future Virtual NIH Grants Conferences where we will continue to provide these types of updates and other ways to connect with NIH staff. And lastly, I'll just leave ... On this slide, we have our points of contacts within OPERA with the different teams depending on the types of questions that you may have, even after this update presentation. But I'm going to go ahead and start transitioning into some of the other questions that we received prior to the event starting through your registration questions. So with that, Brian, I'm actually going to turn to you. Can you tell us a little bit about when the new NIH Grants Policy Statement is going to be published? Doesn't that usually come a little bit earlier in the fiscal year?

Brian Sass-Hurst: Yes. Usually, it does come a little earlier. However, many of you are likely aware that 2 CFR 200, the Uniform Guidance for Grants and Contracts, well, for grants throughout the federal government, that is actually being updated. And so, we will be republishing the updated Grants Policy Statement right after 2 CFR 200 is updated. And I think we're expecting that to be in the March-April time frame. And there will be a guide notice issued around that time to make those edits to align the updates and publish the Grants Policy Statement. And then I also have a question for you, Kasima. Where can I learn the basics of application preparation and submission?

Kasima Garst: This is, in particular for the folks that are a little bit newer to our NIH grant application process, this is a great point. So the NIH Grants and Funding webpage, as I mentioned, has a wealth of resources, including links to presentations specifically about application preparation and submission. And I even created a slide here that specifically speaks to that, so definitely check out this webpage. It not only covers the basics of applying to NIH grant-funding opportunities, but also has the "How To Apply - Application Guide" which talks about all of our different submission policies, how the process works, learning about what kinds of validations your applications will undergo as well as the individual form instructions themselves. And as I mentioned before, we have some presentations that are available that myself and my colleagues in eRA have provided related to how to actually apply and how your application will go through the processing through grants.gov all the way to NIH and eRA Commons and things like that. And also check us out at the NIH Grants Conference where we also provide those same presentations.

Brian Sass-Hurst: Great, thank you. And then I also wanted to ask you, Kasima, about everyone's favorite topic, the Data Management and Sharing Plan. So, how would a recipient request changes to an approved Data Management and Sharing Plan?

Kasima Garst: That is a great question. So, as we all know, and that is effective with the implementation of the 2023 NIH Data Management and Sharing Policy, the approved Data Management and Sharing Plan, excuse me, for funded awards become a term and condition of the award. This means that recipients are required to submit a timely formal prior approval request to the funding NIH ICO if there is a need to update those plans. So, for example, if there's a change in the data repository or a change in the timeline, et cetera. So, effective October of last year, we did issue the guide notice that is linked on the slide that outlines that recipients are required to use the eRA Commons Prior Approval Module to submit those prior approval requests for changes to an approved data-management and sharing plan. Within the functionality in that module, the recipients must select prior approval of the request type, and then the specific instructions are outlined within the guide notice in terms of providing the revised plan, the justification for the change, the effective date and so forth. And again, as I mentioned, if revisions are necessary and this includes things like the new scientific direction or that new data repository, those should be updated by the recipients, and then they must be reviewed and approved by the NIH ICO in which the new plan will become part of the terms and conditions of the award. All the prior approval requests must be submitted by the Authorized Organizational Representative, so this will be a user with the Signing Official role in eRA Commons, at least 30 days in advance to the requested change. But bear in mind that the currently approved DMS Plan will still remain in effect for the award until the request has officially been approved by NIH. Brian, I think I wanted to turn it over to you, and there were some questions about, "Who should recipients contact if they're having issues submitting their FFR in the Payment Management System?"

Brian Sass-Hurst: Yeah, and I think I saw a few questions regarding this in the chat which is moving quite quickly. And really the answer is, these questions should be sent to the PMS Service Desk, which is through the FSD, the Federal Service Desk, and they would be escalated with your PMS account liaison. There's a website at PMS' website where you can locate your account liaison. And any issues with data on the FFR, that should be directed to the eRA Service Desk because the data for the creation of the financial report comes from the eRA systems. And then any other issues should be directed to OPERA, specifically the FFR Center which provides service to financial reports. But really, just to clarify, there are three primary tasks, and they would all go to different places. So, if there's account-access problems, you would reach out to PMS, the Service Desk. If there are issues about the data on the FFR, that would go to eRA and their Service Desk, and if it's something else, then you would reach out to OPERA through the FFRC, and I believe contact info for that is on our contact-info slide which will be displayed at the end of this presentation. And then, Kasima, who should someone contact if the dates on their final FFR in PMS do not reflect an approved No Cost Extension?

Kasima Garst: Thanks, Brian. Yeah, and we've definitely gotten this question a lot. Sort of as you mentioned, the things like the dates are originating from eRA Grant Systems, and we have seen some instances where the final updated dates are being reflected within the accounting side of the Payment Management System when a No Cost Extension has been approved, but not necessarily reflecting on the FFR side. In this case, recipients should contact the eRA Service Desk and request that the new end dates are pushed to the Payment Management System for the FFR, and if you do run into any further issues, you can contact the OPERA FFR Center. That team is absolutely amazing under the leadership of Alan Whatley, and they're incredibly responsive if you do run into any further technical challenges. But eRA will be the group that has to push that new date over to Payment Management System's FFR side. So with that, those are all the questions that we tried to address from before from the questions from the registration. We do have for you, we're going to leave up the points of contacts in our inboxes for any other questions you may have, but let's turn it over to the chat. Brian, I think I saw a question, and I'll hopefully be able to find it again, but folks wanted to know about whether or not there was going to be a change to that single-audit threshold.

Brian Sass-Hurst: A change to the single-audit threshold, not that I'm aware of. I believe it should be, will be, remaining at $750,000. I know a number of years ago it was at 500. If there is a change, I haven't seen it.

Kasima Garst: Great. All right. I'm seeing a question about resubmissions of a P30 application and the first time that they're undergoing this. Definitely check out the same links for the application-submission process on that resource slide, the main reason being that the instructions are the same from the standpoint of how to complete the forms and things like that, and we even have callouts within the application instructions about anything that's specific for the resubmission application type. Also, in the top portion of the "How to Apply - Application Guide" page, we have a link to our submission policies and information about resubmissions, so definitely check that out as well.

Brian Sass-Hurst: And, Kasima, I have an interesting question regarding the subrecipient, foreign-subrecipient data sharing. One person asks if we could address when data is stored on a third-party platform. Does the policy require the PI to retain access, or will they need the actual underlying data?

Kasima Garst: So again, the updated clarification on that final guidance was that they do need the access, not only the PI but also the Authorized Organizational Representatives, as they are the official recipients, the prime recipient, of the NIH grant award. I hope that helps answer your question. And just another further note on the subrecipient piece of things, I know Brian mentioned this, but definitely just to reiterate the value of going and checking out that Open Mike Blog and the recording of the session that Dr. Lauer, Michelle Bulls and Dr. Tabak did, really talking about the driver behind and the importance of this update. And as Brian mentioned, that was in response to the OIG recommendation. So, definitely encourage everybody to check that out.

Brian Sass-Hurst: Now, Kasima, I saw a couple questions about people who wanted to know about SNAP, the streamlined funding program. What is the difference between SNAP and non-SNAP?

Kasima Garst: Great question, and I believe the link also included on the slides for the Grants Policy Statement point to that as well. But effectively our Streamlined Noncompeting Award Process is some additional flexibilities and authorities that the recipients have in certain cases. Right? So, for example, your typical research-project grant is normally going to fall under SNAP or the Streamlined Noncompeting Award Process. This means that they do not need to necessarily provide a detailed budget as part of their annual RPPR and that they also typically will not need to submit annual FFRs as part of their progress reporting. So, it's the ability to provide a little bit more of a streamlined progress reporting as part of their terms and conditions of the award. More information on that is within the Grants Policy Statement. I'm going to try and dig up that citation for you and link it as well.

Brian Sass-Hurst: Well, while you look for that, I can answer another question or two from the Q and A box. Some folks are asking about the updated salary caps which we mentioned in our previous slide were passed and have been incorporated through a guide notice. The updated salary guides, I believe those are effective January 1st, even if the guide notice was published later. So correct me if I'm wrong, but applications submitted after January 1st would be able to take advantage of those revised salary caps. And then there's also several questions coming in asking about recordings and slides, and I believe the slides will be made available, and a recording should be put up on our YouTube page and linked through our various channels in the near future after it's ensured that it's fully accessible for everyone. Now, let's see. Let's fine some other additional questions that are coming in. We've received more than 300 questions in the last 1 hour, so bear with us while we search and see what can be handled real quick. Kasima, let's see a question about Forms I. When is that going to come out?

Kasima Garst: Yes, so Forms I will be effective for applications submitted for due dates on or after January 25th, 2025. Look for our formal communications and guide notice coming out early this spring. That'll have some more details for you, but the real driver is not only the adoption of the Common Forms for Other Support and Biosketch, but will also be critical for the implementation of our Simplified Review Framework. So again, more to come, but that is the effective date for Forms I.

Brian Sass-Hurst: And I also have a quick clarification. There is a question about the threshold for single audits being raised, and apparently the OMB has proposed raising that rate from $750,000 to $1 million, and so it does appear that that will likely be happening, and so it should be included in 2 CFR 200 in the upcoming revision in March or April which would then be incorporated into the NIH Grants Policy Statement. And just a reminder, the threshold is specifically in federal dollars expended, not awarded, within the recipient's fiscal year, and that's how it's determined whether or not an entity is required to go through the single-audit process and submit that to its funders.

Kasima Garst: And again, I do see some questions asking about the Common Form Implementation. Just a reminder to everybody: NIH will only accept the current NIH Other Support and Biosketch formats until that effective date. So please continue to use the current approved NIH Other Support and Biosketch formats until Forms I and the formal adoption. We'll, again, further outline this within the communications and resources that will be provided, but we do need folks to continue to use our OMB-cleared formats.

Brian Sass-Hurst: Thanks. I've seen a few questions coming in regarding the Final Invention Statement. People asking if their project did not have any inventions, are they still required to submit the Final Invention Statement. And the answer is yes. Even if there are no inventions, you are required to submit that, the Final Invention Statement, as part of your closeout package. See, and they are still coming in, so I'm glad to hear it. So, one question that I'm seeing is regarding specific information on NRSA stipends. Do we have any information yet on when the NRSA stipend updates will be coming?

Kasima Garst: I know that they'll be coming soon and will be communicated officially by an updated guide notice, so stay tuned. They tend to come not too far after the salary cap updates, but they are being finalized and will be coming soon.

Brian Sass-Hurst: All right. Thanks. Let's see. There's some other questions that I see. So, there is one question about, "How do people provide feedback to OPERA when it comes to updates to the Grants Policy Statement?" And, Kasima, correct me if I'm wrong, but I believe some policy updates are actually published through the Federal Register which has an ability to allow people to do public comments. Is that correct?

Kasima Garst: Yes. I believe that's correct. Our Division of Grants Policy works very closely with folks in getting that Federal Register Notice published and responding to any comments. But if you have any specific feedback regarding the Grants Policy Statement, you can also reach out to the Grants Policy inbox and the Division of Grants Policy within OPERA. And you can also follow up there because we know sometimes those things will pop up, whether it's questions or other things, even after the publication.

Brian Sass-Hurst: Great, thank you.

Kasima Garst: I think I see a couple of questions about some of the, I believe, the Parent T32 renewal and other Parent announcements. The main thing to keep in mind for folks is that anything that is listed on our Parent Funding Opportunities webpage are typically going to be renewed. On occasion they are extended as we are working towards other updates, and so the T32 will be renewed and reissued. The timing of that I believe is still under the works as it relates to Forms I and other things, but it will either be reissued or extended. If you do have any questions specifically about any of the training-funding opportunities, you can reach out to the NIH Training inbox. I'll grab that and put it in the chat as well, and that is monitored by OER's Division of Biomedical Research Workforce.

Brian Sass-Hurst: Thanks, and I saw a question from someone who was asking how did they get added to some of these NIH LISTSERVs. And really what I'd recommend is you just head over to our NIH website, and you can search for OER LISTSERVs, or you can use your favorite web-search product to search for NIH OER LISTSERVs, and there's a great page that contains all of the LISTSERVs and RSS feeds through the Office of Extramural Research at NIH. There's a LISTSERV about what's happening in eRA, in SEED for small businesses, the updates for our grants and contracts guides as well as information on upcoming NIH Grant events and laboratory animal welfare. So, lots of great resources there, so those link to our external blogs and other information, so I would encourage searching for that or going through our website and locating that on the News & Events page, the grants.nih.gov. Let's see what else we have. I've seen several people, I don't know if we will have an answer for it, Kasima, but several folks have asked about the $500,000 annual cap on common grants. This person says that the salary cap has been increasing, but not the overall cap, and it's a common question for faculty. Is there anything we can share?

Kasima Garst: I'm not specifically aware of any plans to change the current cap. I know the existing procedures do exist regarding requests and receiving prior approval to exceed that cap. So, please refer to those existing application instructions on the How to Apply webpage, but I'm not aware of any current efforts to change that.

Brian Sass-Hurst: Thanks, Kasima, and let's see. So, a few folks are asking about when the next virtual conference is. I don't know if that has been publicly posted yet. However, like I mentioned just a moment ago, there is a website where you can subscribe to our LISTSERV on NIH Events, and I'm sure that once the conference information is ready to be shared publicly, that would be a great place to be so you can be notified quickly.

Kasima Garst: I do see a question about the content requirements within the biosketch and current and other support documents. So, there will be content changes from the standpoint that we will be adopting those common forms and the associated definitions. There may be a little bit of clarifying instructions related to the NIH, how to complete those sections, but again, that is all being finalized and will be part of those communications. However, we will also still be collecting some NIH-specific information in another location. So that is all being finalized as part of the implementation details that will be communicated after we coordinate with OSTP regarding our implementation plan. So, stay tuned, but there will be some updates, but in general any NIH-specific information that we still need to collect will be collected through another avenue, so more to come. Please know that that will be forthcoming as well.

Brian Sass-Hurst: Yeah, and I have another question, Kasima. This person is asking who to reach out to. They're saying that there was an employee who was an AOR, and they retired last year, and their role was removed from eRA Commons, but some of the reminder e-mails are still being sent to that e-mail address, and who can they contact to get that looked at?

Kasima Garst: That is a great question. I would reach out recognize to the eRA Service Desk first. Some of the technology around the notifications can be a little bit complex depending on whether it's pulling from the institutional profile within the eRA Commons versus the individual grant record information because of those specific grant needs. So, it's possible that, that individual may have still been associated with the grant but not necessarily the IPF. We definitely always encourage institutions to make sure that their IPF sort of general notification updates are kept consistent to the greatest extent possible but definitely recommend reaching out to the eRA Service Desk first just to determine what might be causing it in the case of any particular notifications that you're referring to. It may require some reach out to the NIH Grants Management Specialist, but it may also be something that eRA can assist with.

Brian Sass-Hurst: Great, thank you, and, yeah, there have been a few other questions about, who should I contact about a problem? And I wonder if maybe sort of the slide we have in front of you right now. These different divisions can handle probably quite a bit of questions that come in, and if not, everyone that receives them would be more than happy to direct you to where your question should go. Grants Policy handles the grants policy statement and our notices. Grants Compliance & Oversight handles questions about compliance issues. Systems Policy branch, that's Kasima and anything involving systems. And then there's also Inventions, Technologies and FFRs, and all of those contacts are right there and just encourage those with questions to reach out to whoever looks best, and if it's not right, they will happily direct you to where you need to be.

Kasima Garst: Yeah, absolutely. And I did see somebody asking about the eRA Commons. I am going to put that in the response to that question as well so that folks have access to that help desk information.

Brian Sass-Hurst: Well.

Kasima Garst: We're just trying to go through as many as we can, sorry.

Brian Sass-Hurst: Yeah. I wondered if, so there's someone who is asking about biosketches, and will the new biosketches and other support. Will they be released at good timing before critical deadlines? Or is there going to be a grace period where we'll be accepting the new and the old formats?

Kasima Garst: No, so really to make sure that we are adopting those new common forms really within the spirit of all the efforts around the NSPM-33 and OSTP guidance as well as just the real desire to try and come up with those interagency fed-wide consistencies that we also adopt those as soon as possible. So, we are going to have that cut over, but that's also why we are implementing our communications and some of those resources as soon as possible to help ease that transition. And like I said, particularly around making sure that any institutions that might have internal systems that need to be updated will have the opportunity to do so. So, we're going to get that information out as soon as possible and be communicating, but we are going to require them effective the January 25th receipt dates and beyond. I want to pause for just a minute because we wanted to check on, we have some scheduling with our ASL interpreters. Cynthia, should we go ahead and plan on wrapping it up due to that? I know ... I'm sorry. I know you weren't originally planning on coming back on.

Cynthia Dwyer With the new platform that you're piloting, there's all ... And as you can see, it's complicated. I was trying to find how to get back on, so we have some scheduling issues, it looks like. Okay. So, what time is it now? It's 2:15. I would say let's go ahead, and I will leave it up to you, but we can go ahead and go on without our ASL interpreters, and we will have captioning. We will have the transcript available in 7 business days, so we have ... I was just typing in the chat. We have almost 400 questions have come in, so if I say let's just keep on answering questions for a little bit, is that okay with you two, Brian and Kasima? I know we're working you hard this hour and a half.

Kasima Garst: Yeah, I think we can go for a little bit more, but we'll just maybe answer one or two more questions, and then we'll go ahead and step away. We want to make sure that we have all the considerations for our interpreter, so.

Cynthia Dwyer Absolutely, let's do that. That's a great compromise.

Kasima Garst: Yeah, so I think there's one question about who to contact for permission to add an appropriate cost to an NIH award that's over 90 days. Just to make sure that I'm understanding this correctly from the user from Georgetown, I believe if there's any question about being able to associate a particular cost and attributing that to the NIH award, you should contact your NIH Grants Management Specialist regarding anything that might require the prior approval. So, if that's what you're getting at, I would recommend starting with your NIH Grants Management Specialist.

Brian Sass-Hurst: Great, and then I also saw a question on whether or not there's a delay in sending out notices of award. I would just recommend to the person who asked about expecting to receive these notices by now but hasn't. It might be a good idea to reach out to your grants manager and check in just to touch base and see if there's anything that they need.

Kasima Garst: Thank you so much, Brian. I definitely think we're ready to wrap up here. We want to thank you all so much for your time and your patience as we piloted this new platform. We hope that you found this helpful. We know we were not necessarily able to get to all of your questions today during this time, but that we are going to be taking them back and making sure that we can use them to update our resources and FAQs and other information as we move forward and thank you, everyone.

Brian Sass-Hurst: All right. Well, thank you, all. I appreciate the time and have a great rest of your day.